MONASH University

# Optimising Self-Management Interventions to improve Health-Related Quality of Life in patients with co-morbid Diabetes and Chronic Kidney Disease


**Edward Zimbudzi**

Bachelor of Nursing Science (Hons)

Master of International Health


A thesis submitted for the degree of

**Doctor of Philosophy**

at Monash University in 2019


Monash Centre for Health Research and Implementation

School of Public Health and Preventive Medicine

Faculty of Medicine, Nursing and Health Sciences

Monash University, Melbourne, Australia

## Copyright notices

© Edward Zimbudzi (*2019*).

Notice 1

Under the Copyright Act 1968, this thesis must be used only under the normal conditions of scholarly fair dealing. In particular, no results or conclusions should be extracted from it, nor should it be copied or closely paraphrased in whole or in part without the written consent of the author. Proper written acknowledgement should be made for any assistance obtained from this thesis.

Notice 2

I certify that I have made all reasonable efforts to secure copyright permissions for third-party content included in this thesis and have not knowingly added copyright content to my work without the owner's permission.

## ABSTRACT

**Background:** Type 2 diabetes is highly prevalent globally and it is the leading cause of chronic kidney disease (CKD). Together, co-morbid diabetes and CKD pose an ominous threat to global public health. First, patients with co-morbid diabetes and CKD have an increased risk of morbidity, mortality and low health-related quality of life (HRQOL). Second, co-morbid diabetes and CKD is associated with exponential costs, which increase as the disease progresses. A paradigm shift towards empowering patients to more effectively self-manage may improve the clinical and patient reported outcomes of those with co-morbid diabetes and CKD.

**Objective:** The overarching objective of this thesis was to determine whether optimising self-management ability could lead to improved HRQOL among patients with co-morbid diabetes and CKD.

**Methods:** The greater component of this research was guided by cross sectional and longitudinal data from the Diabetes Renal Project conducted from January 2015 to August 2018. Participants had a confirmed diagnosis of diabetes and estimated glomerular filtration rate less than 60 ml/min/1.73 $m^2$. Questionnaires utilised to answer several research questions examined in this thesis include the Patient Activation Measure, the Patient reported Barriers, the Summary of Diabetes Self-Care Activities and the Kidney Disease Quality of Life Questionnaires. Appropriate analytical methods were applied for each specific research question.

**Results:** The main novel results of this research are as follows;

1. Patients with co-morbid diabetes and CKD reported low levels of activation. Additionally, older age and worse self-reported health were associated with lower activation.
2. A high level of patient activation was positively associated with a higher overall level of self-management and patient age, gender, duration of diabetes and stage of CKD influenced patient self-management in co-morbid diabetes and CKD.

3. Younger age was associated with lower scores in all HRQOL subscales except the physical composite summary, and female gender, obese or normal weight and more advanced stages of CKD were associated with lower scores in one or more subscales.
4. Patient reported barriers to health care were associated with low physical and mental well-being. Additionally, a greater number of patient reported barriers was associated with lower mental health status.
5. Participation in diabetes self-management activities, particularly those focused on general diet, exercise and medication taking, was associated with higher HRQOL.
6. Self-management support interventions may improve the ability to self-manage, systolic blood pressure and glycated haemoglobin in patients with co-morbid diabetes and CKD. Interventions that utilised provider reminders, patient education and goal setting were associated with improved outcomes.
7. Patients with co-morbid diabetes and kidney disease have education gaps on the management of, and complications of diabetes and kidney disease.
8. Patients with comorbid diabetes and CKD attending a new co-designed, integrated diabetes and kidney disease model of care had maintained HRQOL over 12 months.

**Conclusions:** In patients with comorbid diabetes and CKD, the level of activation and ability to perform self-management activities are key factors for improving HRQOL. Sub-groups of this population who may benefit from tailored activation and self-management interventions were identified. This work demonstrated that an integrated, patient-centred diabetes and kidney disease model of care may prevent further deterioration of HRQOL among patients with comorbid diabetes and CKD. Disease-specific randomised interventions of longer duration are now needed to validate and extend these findings.

# ACKNOWLEDGEMENTS


## Professional

I would like to sincerely express my gratitude to my primary supervisor, Professor Sophia Zoungas. This thesis would not have been possible without your mentorship, support and patience. I am also most grateful to my secondary supervisor Professor Peter Kerr for financial and academic support during my candidature. To Dr Clement Lo, you were a supervisor, a mentor and above all a colleague who stood with me all the way. Thank you for your illustrious guidance and support. I would also like to acknowledge Professor Helena Teede for ensuring that I was well supported during my candidature. Mr Sanjeeva Ranasinha, you provided me with invaluable statistical advice, which shaped my research work. I would also like to acknowledge Stella Chaviaras, Dimitra Giannopoulos, Rachel McGrath and Sarah Coggan for their help in the conduct of this research.

I would especially like to thank all the participants of the Diabetes Renal Project (DRP). Your participation in this project did not only help me, but many generations to come.

I am grateful for all the support and resources I got from Monash Health, Monash Centre for Health Research and Implementation (MCHRI) and the Department of Epidemiology and Preventive Medicine, Monash University.

## Personal

I would not have completed this work without the sterling support from my wife Felani, my children Rufaro and Tafara. Their patience, support and understanding uplifted me.

Finally, I am so much indebted to my GOD who made this possible. (*Behold, I am the Lord, the God of all flesh. Is there anything too hard for me?* -Jeremiah 32:27).

# DEDICATION

This thesis is dedicated to my family who instilled in me the virtues of determination and commitment and relentlessly walked with me along this academic journey.

# TABLE OF CONTENTS

## LIST OF TABLES



## LIST OF FIGURES

# GENERAL DECLARATION

**Monash University**

**Declaration for the thesis based or partially based on conjointly published or unpublished work.**

In accordance with Monash University Doctorate Regulation 17.2 Doctor of Philosophy and Research Master's regulations, I declare that:

1. This thesis does not contain any material accepted for the award of any other qualifications (certificate, diploma or degree) at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person. Where such information is included, appropriate referencing is provided in the thesis.
2. This thesis is based on the Diabetes Renal Project (DRP), which is headed by my primary supervisor, Professor Sophia Zoungas. DRP is also driven by a steering committee (of which, I am a member) and patient advocate groups such as Diabetes Australia and Kidney Health Australia. All research included in this thesis was conducted at Monash Centre for Health Research Implementation (MCHRI) under the leadership of Professor Helena Teede.
3. This thesis contains eight original research papers; seven are published in reputable peer reviewed journals and one submitted. I also worked on four other published papers, which were part of the outputs from DRP.
4. There was a high level of rigor in all publications given that they involved multiple co-authors with expertise from different disciplines and underwent external peer review.

The Table below quantifies my level of contribution.

| **Thesis Chapter** | **Publication title** | **Publication status** (published, in press, accepted or returned for revision) | **Nature and extend (%) of student's contribution** | **Co-author name(s) Nature and % of Co-author's contribution** | **Co-author(s), Monash student Y/N** |
|---|---|---|---|---|---|
| 2.2 | Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross-sectional study. | Published | **65%.** Developed study questions, analysed data, wrote and revised first draft of the manuscript. | 1. Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Sanjeeva Ranasinha, data analysis 2%.<br>3. Gregory Fulcher, input into manuscript 2%.<br>4. Steven Jan, input into manuscript 2%.<br>5. Peter Kerr, input into manuscript 3%.<br>6. Kevan Polkinghorne, input into manuscript 2%.<br>7. Grant Russell, input into manuscript 2%.<br>8. Rowan Walker, input into manuscript 2%.<br>9. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N |
| 2.3 | The association between patient activation and self-care practices: a cross sectional study of an Australian population with co-morbid diabetes and chronic kidney disease. | Published | **60%.** Developed study questions, analysed data, wrote and revised first draft of the manuscript. | 1. Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Sanjeeva Ranasinha, data analysis 3%.<br>3. Peter Kerr, input into manuscript 5%.<br>4. Kevan Polkinghorne, input into manuscript 2%.<br>5. Helena Teede, input into manuscript 2%. | N<br>N<br>N<br>N<br>N |

| | | | | | |
|---|---|---|---|---|---|
| | | | | 6. Timothy Usherwood, input into manuscript 2%.<br>7. Rowan Walker, input into manuscript 2%.<br>8. Greg Johnson, input into manuscript 2%.<br>9. Gregory Fulcher, input into manuscript 2%.<br>10. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N<br>N<br>N |
| 3.2 | Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. | Published | **60%.** Developed study questions, analysed data, wrote and revised first draft of the manuscript. | 1. Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Sanjeeva Ranasinha, data analysis 2%.<br>3. Martin Gallagher, input into manuscript 2%.<br>4. Gregory Fulcher, input into manuscript 2%.<br>5. Peter Kerr, input into manuscript 6%.<br>6. Grant Russell, input into manuscript 2%.<br>7. Helena Teede, input into manuscript 2%.<br>8. Timothy Usherwood, input into manuscript 2%.<br>9. Rowan Walker, input into manuscript 2%.<br>10. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N |
| 3.3 | Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid | Published | **60%.** Primary responsibility for analysing data, writing and revising the | 1. Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Sanjeeva Ranasinha, data analysis 2%. | N<br>N |

| | | | | | |
|---|---|---|---|---|---|
| | diabetes and chronic kidney disease. | | first draft of the manuscript. | 3. Gregory Fulcher, input into manuscript 2%.<br>4. Martin Gallagher, input into manuscript 2%.<br>5. Steven Jan, input into manuscript 2%.<br>6. Peter Kerr, input into manuscript 4%.<br>7. Helena Teede, input into manuscript 2%.<br>8. Kevan Polkinghorne, input into manuscript 2%.<br>9. Grant Russell, input into manuscript 2%.<br>10. Rowan Walker, input into manuscript 2%.<br>11. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N |
| 4 | Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. | Published | **60%.** Developed study questions, analysed data, wrote and revised first draft of the manuscript. | 1**.** Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Sanjeeva Ranasinha, data analysis 4%.<br>3. Peter Kerr, input into manuscript 4%.<br>4. Timothy Usherwood, input into manuscript 4%.<br>5. Alan Cass, input into manuscript 4%.<br>6. Gregory Fulcher, input into manuscript 4%.<br>7. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N<br>N<br>N<br>N<br>N |
| 5 | Effectiveness of self-management support interventions for patients with co- | Published | **70%.** Primary responsibility for the concept, design, literature review, | 1**.** Clement Lo, conceptualisation of study, data analysis and manuscript revision 5%. | N |

| | | | | | |
|---|---|---|---|---|---|
| | morbid diabetes and chronic kidney disease -a systematic review and meta-analysis. | | development of methodology and writing the first draft of the manuscript. | 2. Marie Misso, search strategy development, data analysis and manuscript revision 10%.<br>3. Sanjeeva Ranasinha, data analysis 5%.<br>4. Sophia Zoungas, conceptualisation of study and manuscript revision 10%. | N<br>N<br>N |
| 6.0 | A needs-based approach to self-management education for adults with diabetes and renal disease. | Published | **80%.** Primary responsibility for the concept, design, literature review, development of methodology and writing the first draft of the manuscript. | 1**.** Clement Lo, conceptualisation of study, data analysis and manuscript revision 10%.<br>2. Peter Kerr, input into manuscript 5%.<br>3. Sophia Zoungas, conceptualisation of study and manuscript revision 5%. | N<br>N<br>N |
| 7.0 | Health-related quality of life among patients with comorbid diabetes and kidney disease attending a co-designed integrated model of care: a longitudinal study. | Submitted | **60%.** Developed study questions, analysed data, wrote and revised first draft of the manuscript. | 1**.** Clement Lo, conceptualisation of study, data analysis and manuscript revision 5%.<br>2. Sanjeeva Ranasinha, data analysis 2%.<br>3. Helena Teede, input into manuscript 2%.<br>4. Timothy Usherwood, input into manuscript 2%<br>5. Kevan Polkinghorne, input into manuscript 2%.<br>6. Peter Kerr, input into manuscript 5%.<br>7. Gregory Fulcher, input into manuscript 2%.<br>8. Martin Gallagher, input into manuscript 2%.<br>9. Stephen Jan, input into manuscript 2%.<br>10. Alan Cass, input into manuscript 2%. | N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N<br>N |

| | | | | | |
|---|---|---|---|---|---|
| | | | | 11. Rowan Walker, input into manuscript 2%.<br>12. Grant Russell, input into manuscript 2%.<br>13. Greg Johnson, input into manuscript 2%.<br>14. Sophia Zoungas, conceptualisation of study and manuscript revision 8%. | N<br>N<br>N<br>N |

I have renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

**Student signature**: [redacted] **Date**: 25 July 2019

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author, I have consulted with the responsible author to agree on the respective contributions of the authors.

**Main Supervisor's signature:** [redacted] **Date:** 25 July 2019

# ORGANISATION OF THESIS

The Chapters of the thesis are organised as follows:

**Chapter 1: Introduction**

Chapter 1 provides the background and overview of the thesis titled, 'Optimising self-management interventions to improve health-related quality of life in patients with co-morbid diabetes and chronic kidney disease'. This Chapter highlights the research gaps and introduces the research questions that guided the conduct of this project.

**Chapter 2: Determinants of self-management activity**

Patient activation defined as how skilled, knowledgeable and confident individuals are in performing self-care activities, is an important determinant of self-management ability. However, the levels of activation in patients with co-morbid diabetes and CKD is unknown. In this Chapter, patient activation in patients with diabetes and CKD is characterised. Following this, the relationship between patients' level of activation and how they self-manage is investigated. Chapter 2 is based on the following publications;

i) Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross sectional study published in *BMJ Open*.

ii) The association between patient activation and self-care practices: a cross sectional study of an Australian population with co-morbid diabetes and chronic kidney disease published in *Health Expectations*.

**Chapter 3: Determinants of health-related quality of life**

Chapter 3 ascertains the factors that may influence HRQOL in adults with co-morbid diabetes and CKD. Patient reported barriers to health care are also identified as potential determinants of HRQOL in patients with diabetes and CKD. To understand the influence of patient reported

barriers on HRQOL, their impact on physical and mental well-being is examined. The following publications are associated with Chapter 3;

i) Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease published in *PLoS One*.

ii) Patient reported barriers associated with poor physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease: A cross sectional study published in *Health and Quality of Life Outcomes*.

**Chapter 4: The relationship between self-management and health related quality of life**

There is insufficient and inconsistent data regarding the association between diabetes self-management, the process of facilitating the knowledge, skill, and ability necessary for diabetes self-management, and HRQOL in people with diabetes and moderate to severe CKD. Chapter 4 investigates whether there is a relationship between self-management and HRQOL among patients with diabetes and CKD. A paper published in *Diabetes and Its Complications* titled, 'Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL' forms the basis of this Chapter.

**Chapter 5: Review of self-management support interventions**

Self-management support interventions and the specific components and elements of such interventions, which are effective for patients with co-morbid diabetes and CKD, are investigated. Chapter 5 is based on a publication titled, 'Effectiveness of self-management support interventions for patients with diabetes and chronic kidney disease -a systematic review and meta-analysis' published in *Systematic Reviews*.

**Chapter 6: Educational needs for patients with diabetes and CKD**

This Chapter utilises a qualitative approach to assess the educational needs of patients with comorbid diabetes and CKD. An educational video was produced based on the identified

patient education needs. A paper titled, ‘A needs-based approach to self-management education for adults with diabetes and renal disease’ published in *BMC Nephrology* is associated with this Chapter.

**Chapter 7: Impact of a new model of care on patient reported outcomes**

This Chapter presents results of a before and after study which evaluates the impact of a new integrated model of care (the Diabetes Kidney Service) on HRQOL of patients with comorbid diabetes and CKD. The Chapter is based on a paper titled, “Health-related quality of life among patients with comorbid diabetes and kidney disease attending a co-designed integrated model of care: a longitudinal study” which is submitted in *Diabetic Medicine.*

**Chapter 8: Summary and Future Directions**

This Chapter provides a summary of the main findings and discusses how they relate to current clinical and research practice. Important directions for future research and specific recommendations are explored. The strengths and limitations of the research work presented in this thesis are also highlighted.

# GLOSSARY

| | |
|---|---|
| ADDQOL | Audit of Diabetes Dependent Quality of Life |
| CCM | Chronic Care Model |
| CI | Confidence Intervals |
| CINAHL | Cumulative Index to Nursing and Allied Health Literature |
| CKD | Chronic kidney disease |
| CVD | Cardiovascular disease |
| EBM | Evidence-Based Medicine |
| eGFR | Estimated Glomerular Filtration Rate |
| EMBASE | Excerpta Medica database |
| EQ5D | European Quality of Life-5 Dimensions questionnaire |
| ESKD | End-stage kidney disease |
| GRADE | Grading of Recommendations, Assessment, Development and Evaluations |
| HbA1c | Glycated Haemoglobin |
| HRQOL | Health-related quality of life |
| IDF | International Diabetes Federation |
| KDIGO | Kidney Disease Improving Global Outcomes |
| KDOQI | Kidney Disease Outcomes Quality Initiative |
| MCHRI | Monash Centre for Health Research and Implementation |
| MD | Mean Difference |
| PAM | Patient Activation Measure |
| PICO | Population, Intervention, Control/Comparator and Outcome |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analysis |
| PROMs | Patient Reported Outcome Measures |
| RCTs | Randomised Controlled Trials |
| SDSCA | Summary of Diabetes Self-Care Activities questionnaire |
| SMD | Standard Mean Difference |

# PUBLICATIONS

## PUBLICATIONS INCLUDED IN THIS THESIS

1. **Zimbudzi E.,** Lo C., Kerr PG., Zoungas S. A need-based approach to self-management education for adults with co-morbid diabetes and chronic kidney disease. BMC Nephrology 2019; 20:113. [Chapter 6.2].
2. **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G., Jan S., Kerr PG., Teede HJ., Polkinghorne KR., Russell G., Walker RG., Zoungas S. Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid diabetes and chronic kidney. Health and Quality of Life Outcomes 2018; 16:215 [Chapter 3.3].
3. **Zimbudzi E**., Lo, C., Misso M., Ranasinha S., Kerr PG., Teede H., Zoungas S. Effectiveness of self-management support interventions for patients with co-morbid diabetes and chronic kidney disease -a systematic review and meta-analysis. Systematic Reviews 2018; 7:84. [Chapter 5.3].
4. **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G. R., Jan S., Kerr PG., Polkinghorne K. R., Russell G., Walker R. G., Zoungas S. Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross-sectional study. BMJ Open 2017; 7 (10) [Chapter 2.2].
5. **Zimbudzi E**., Lo C., Ranasinha S., Kerr PG., Polkinghorne KR., Teede H., Usherwood T., Walker R., Johnson G., Fulcher G., Zoungas S. The association between patient activation and self-care practices in patients with co-morbid diabetes and chronic kidney disease. Health Expectations 2017; 20 (6): 1375–1384 [Chapter 2.3].
6. **Zimbudzi E**., Lo C., Ranasinha S., Kerr P., Usherwood T., Cass A., Fulcher GR., Zoungas S. (2016). Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. Journal of Diabetes and Its Complications 2017; 31:427-432 [Chapter 4.2].

7. **Zimbudzi E**., Lo C., Ranasinha S., Gallagher M., Fulcher F., Kerr PG., Russell G., Teede H., Usherwood T., Walker R., Zoungas S. (2016). Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. PLoS One 2016; 11 (12): e0168491 [Chapter 3.2].

## ADDITIONAL PUBLICATIONS OBTAINED DURING CANDIDATURE

1. Lo C., **Zimbudzi E**., Teede HJ., Kerr PG., Ranasinha S., Cass A., Fulcher G., Gallagher M., Polkinghorne KR., Russell G., Usherwood T., Walker R., Zoungas S. Patient-centred factors associated with poor glycaemic and blood pressure control in co-morbid diabetes and chronic kidney disease. Journal of Diabetes Complications 2019:33 (1):63-68. doi: 10.1016/j.jdiacomp.2018.09.020.
2. Lo C., **Zimbudzi E**., Teede H., Cass A., Fulcher G., Gallagher M., Kerr PG., Jan S., Johnson G., Mathew T., Polkinghorne K., Russell G., Usherwood T., Walker R. and Zoungas S. Review: An Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology 2018, doi:10.1111/nep.13232.
3. **Zimbudzi E**., Samlero R., Kerr P. G., Zoungas S. How much is enough? An investigation of the relationship between haemodialysis adequacy and quality of life of elderly patients. Nephrology 2016; 21: 314–320.

# CONFERENCE PRESENTATIONS

## PUBLISHED CONFERENCE ABSTRACTS DURING CANDIDATURE

1. **Zimbudzi E.,** Lo C., Kerr PG., Robinson T., Zoungas S. The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals: A qualitative study Kidney International Reports (2019) 4, S1–S437.
2. **Zimbudzi E.,** Lo C., Teede HJ., Usherwood T., Polkinghorne KR., Kerr PG., Fulcher G., Gallagher M., Jan S., Zoungas S. Health-related quality of life among patients with comorbid diabetes and kidney disease attending a co-designed integrated model of care: a longitudinal study. Kidney International Reports (2019) 4, S1–S437 [Chapter 7.2].
3. **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G., Jan S., Kerr PG., Teede HJ., Polkinghorne KR., Russell G., Walker RG., Zoungas S. Patient reported barriers associated with poor physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease: A cross sectional study. Hemodialysis International 2018 [Chapter 3.3].
4. Lo C., **Zimbudzi E**., Teede H., Kerr PG., Ranasinha S., Cass A., Fulcher G., Gallagher M., Polkinghorne K., Russell G., Usherwood T., Walker R., Zoungas S. Patient-centred factors associated with poor glycemic and blood pressure control in co-morbid diabetes and chronic kidney disease. Hemodialysis International 2018.
5. **Zimbudzi E**., Lo C., Ranasinha S., Kerr P., Polkinghorne K., Teede H., Walker R., Zoungas S. The association between patient activation and self-care practices in patients with co-morbid diabetes and chronic kidney disease. Hemodialysis International 2017; 21: A1–A54 [Chapter 2.3].
6. **Zimbudzi E**., Lo C., Misso M., Ranasinha S., Kerr PG., Teede H., Zoungas S. Effectiveness of self-management interventions for patients with diabetes and CKD -a systematic review. 2017 ADS-ADEA Annual Scientific Meeting [Chapter 4.3].

7. **Zimbudzi E**., Lo C., Ranasinha S., Teede H., Usherwood T., Kerr PG., Zoungas S. The association between patient activation and health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. Diabetes. June 2016; 65 (Suppl. 1) [Chapter 2.2].
8. **Zimbudzi E**., Lo C., Ranasinha S., Kerr P., Gallagher M., Russell G., Usherwood T., Zoungas S. Impact of chronic kidney disease stage and dialysis on different domains of quality of life in patients with co-morbid diabetes. Hemodialysis International 2016; 20 (1), 158-159 [Chapter 3.2].
9. **Zimbudzi E.**, Samlero R., Kerr PG., Zoungas S. How much is enough? An investigation of the relationship between hemodialysis adequacy and quality of life of elderly patients. Hemodialysis International 2015; 19 (2): S12-S73.

## CONFERENCE PRESENTATIONS ASSOCIATED WITH THIS THESIS

**Oral Presentations:**

1. **Zimbudzi E**., Lo C., Ranasinha S., Kerr P., Gallagher M., Russell G., Usherwood T., Zoungas S. Impact of chronic kidney disease stage and dialysis on different domains of quality of life in patients with co-morbid diabetes. Annual Dialysis Conference 2016 [Chapter 3.2].

**Poster Presentations:**

1. **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G., Jan S., Kerr PG., Teede HJ., Polkinghorne KR., Russell G., Walker RG., Zoungas S. Patient reported barriers associated with poor physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease: A cross sectional study. Annual Dialysis Conference 2018 [Chapter 3.3].
2. **Zimbudzi E**., Lo C., Ranasinha1 S., Kerr P., Polkinghorne K., Teede H., Walker R., Zoungas S. The association between patient activation and self-care practices in patients with co-morbid diabetes and chronic kidney disease. Annual Dialysis Conference 2017 [Chapter 2.3].
3. **Zimbudzi E**., Lo C., Misso M., Ranasinha S., Kerr PG., Teede H., Zoungas S. Effectiveness of self-management interventions for patients with diabetes and CKD -a systematic review. Australian Diabetes Society Scientific Meeting 2017 [Chapter 4.3].
4. **Zimbudzi E**., Lo C., Ranasinha S., Teede H., Usherwood T., Kerr PG., Zoungas S. The association between patient activation and health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. American Diabetes Association Scientific Meeting 2016 [Chapter 2.2].

**ADDITONAL CONFERENCE PRESENTATIONS**

1. Lo C., **Zimbudzi E**., Teede H., Kerr PG., Ranasinha S., Cass A., Fulcher G., Gallagher M., Polkinghorne K., Russell G., Usherwood T., Walker R., Zoungas S. Patient-centred factors associated with poor glycaemic and blood pressure control in co-morbid diabetes and chronic kidney disease. Annual Dialysis Conference 2018 [Poster].
2. **Zimbudzi E.**, Samlero R., Kerr PG., Zoungas S. How much is enough? An investigation of the relationship between hemodialysis adequacy and quality of life of elderly patients. International Congress of the International Society for Hemodialysis 2015 [Oral].
3. **Zimbudzi E.** Cost benefits of the Spectra Optia apheresis device compared to dialysis machines for therapeutic plasma exchange. International Congress of the International Society for Hemodialysis, Kuala Lumpar, Malaysia, 13-16th September 2015 [Poster].
4. **Zimbudzi E.,** Samlero R. How do hospitalization patterns of home hemodialysis patients compare with a reasonably well dialysis patient cohort? Home dialysis Conference, 2014 [Poster].

## AWARDS AND PRIZES DURING CANDIDATURE

1. Nurse of the Year Award, Monash Health 2017.
2. Innovation Scholarship, Monash Health Foundation, 2017.
3. Excellence in Nursing/Midwifery Award Monash Health, 2017.
4. Annual Dialysis Nursing Scholarship, Long Beach, United States, 2017.
5. Best Nursing research abstract, Annual Dialysis Conference, Seattle, United States, 2016.
6. Competitive Travel Grant for the Annual Dialysis Conference, Seattle, Washington, United States, 2016.
7. Young Investigator Award- International Congress of the International Society for Hemodialysis, Kuala Lumpur, Malaysia, 2015.

## COURSEWORK OR SHORT COURSES

| Year | Coursework or short course |
|---|---|
| 4-6 December 2017 | Qualitative Research Methods for Public Health Short Course, Monash University. |
| 01 November 2017 | Good Clinical Practices, NIDA Clinical Trial Network |
| Semester 1, 2015 | MPH 5040 Introductory Epidemiology, Monash University. |
| Semester 1, 2015 | MPH 5041, Introductory Biostatistics (High Distinction), Monash University. |
| 20 February 2015 | How to write a good journal article, Monash University. |
| 11 November 2014 | Thesis writing from the examiner's perspective, Monash University. |
| 24 September 2014 | Intellectual Property Induction, Monash University. |
| 09 September 2014 | Evaluate and maximise your research impact, Monash University. |
| 01 September 2014 | Introduction to Stata short course, Monash University. |
| 01 July 2014 | Finding your own voice in the literature review, Monash University. |

## PEER REVIEW

During my candidature, I actively participated in peer review for the following Journals;

1. Nephrology

2. Diabetes Research and Clinical Practice

3. The International Journal of Artificial Organs

4. Clinical Journal of the American Society of Nephrology

5. Journal of Renovascular Disease

6. BMC Nephrology

# STATEMENT OF OBJECTIVES

### Main Objective

The **primary objective** of this thesis is to determine whether optimising self-management ability can lead to improved health related quality of life among patients with co-morbid diabetes and chronic kidney disease.

### Chapter 2: Determinants of self-management activity

This Chapter explores the determinants of self-management activity in patients with diabetes and CKD. The Chapter has two sections.

The first section examines the factors associated with patient activation in an Australian population with co-morbid diabetes and CKD. The specific aim for this section is to:

- Examine to what degree patients with co-morbid diabetes and CKD are activated and to identify what modifiable risk factors are independently associated with activation levels in these patients.

The second section investigates the association between patient activation and self-care practices in patients with co-morbid diabetes and CKD. The specific aim of this section is to:

- Examine the association between performance of self-care activities and patient or disease factors as well as patient activation levels in patients with co-morbid diabetes and CKD.

### Chapter 3: Determinants of health-related quality of life

Chapter 3 focuses on identification of factors that influence health related quality of life. The Chapter comprises of two sections.

The first section examines the predictors of health-related quality of life. The specific aim of this section is to:

- Examine the factors associated with health-related quality of life in patients with co-morbid diabetes and CKD of varying severity who access specialist medical care from tertiary hospitals.

The second section investigates the possible patient reported barriers that may affect health-related quality of life of patients with co-morbid diabetes and CKD. The specific aim of this section is to:

- Explore the association between patient reported barriers to health care and the physical and mental health well-being of patients with co-morbid diabetes and CKD.

**Chapter 4: Relationship between self-management and health related quality of life**

The aim of this Chapter is to:

- Examine the relationship between self-management and HRQOL in the context of co-morbid diabetes and CKD and to establish whether there is a difference in this relationship by severity of CKD.

**Chapter 5: Review of self-management support interventions**

The aim of this Chapter is to:

- Determine which self-management support interventions, components and elements are effective in improving patient reported and clinical outcomes in adults with co-morbid diabetes and CKD.

**Chapter 6: Educational needs for patients with diabetes and chronic kidney disease**

The aim of this Chapter is to:

- Determine the self-management education needs for patients with co-morbid diabetes and CKD and co-develop an educational resource meeting the self-management education needs of patients with co-morbid diabetes and CKD.

**Chapter 7: The impact of a new model of care on patient reported outcomes**

The aim of this Chapter is to:

- Evaluate the impact of an integrated diabetes and kidney disease model of care on health-related quality of life of patients with co-morbid diabetes and CKD.

# CHAPTER 1

# INTRODUCTION

## 1.1 Preamble

This Chapter presents an overview of comorbid diabetes and chronic kidney disease (CKD) and highlights why this complex condition is an emerging global health threat. Additionally, opportunities for research addressing gaps in self-management among patients with comorbid diabetes and CKD are identified. Most importantly, evidence gaps and research needs relating to health related quality of life (HRQOL) of patients with comorbid diabetes and CKD are examined.

## 1.2 An overview of co-morbid diabetes and chronic kidney disease

The prevalence of diabetes continues to rise globally, driven primarily by the increasing incidence of type 2 diabetes in the setting of increasing overweight and obesity [1-3] (Figure 1). According to the International Diabetes Federation (IDF), 425 million adults (aged 20–79 years) were estimated to have diabetes in 2017, 4 million deaths were attributable to diabetes, and the total global health expenditure due to diabetes was 727 billion US dollars [4] (Table 1).

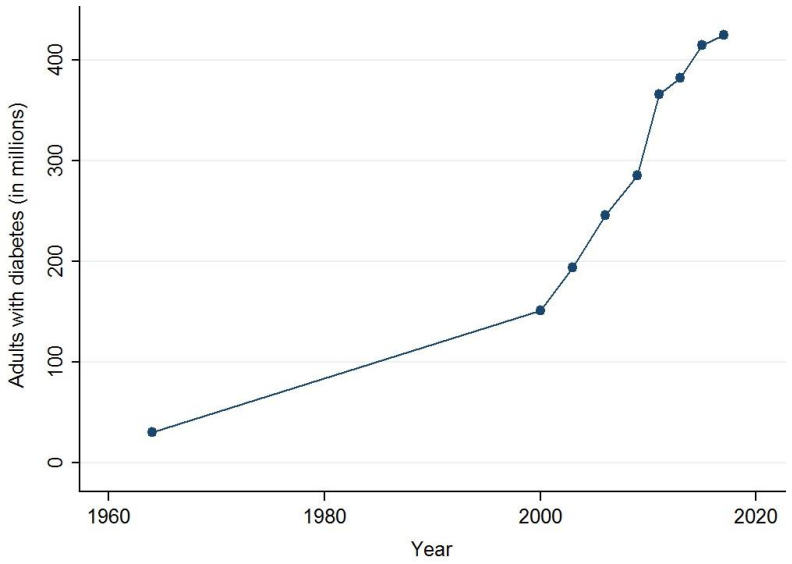



**Figure 1**. Estimates of the number of adults with diabetes from 1964 to 2017

By 2045, the number of adults with diabetes (aged 20–79 years) is expected to rise to 629 million with health expenditure expected to rise to 776 billion US dollars [4]. Diabetes is associated with a myriad of diabetes-related complications such as chronic kidney disease (CKD) and cardiovascular disease (CVD), which refers to a group of diseases that includes coronary artery disease, cerebrovascular disease (stroke), peripheral vascular disease, rheumatic heart disease, congenital heart disease, cardiac hypertension, arrhythmias and myopathy [5, 6].

**Table 1**. The International Diabetes Federation Diabetes Atlas estimates of global health expenditures on diabetes for adults aged 20-79 years

| Year | Estimated cost (USD billion) |
|---|---|
| 2010 | 376 |
| 2014 | 612 |
| 2015 | 673 |
| 2017 | 727 |
| 2040 | 802 |
| 2045 | 776 |

2010 and 2014 (Fernandes et al [7]; 2015 and 2040 (Ogurtsova et al [3]); 2017 and 2045 (Cho et al [8])

Chronic kidney disease is defined by the Kidney Disease Improving Global Outcomes (KDIGO) Work Group as functional or structural abnormalities of the kidneys persisting for at least 3 months as manifested by decreased estimated glomerular filtration rate (eGFR) (≤60 mL/min/1.73m$^2$) or by the presence of albuminuria (albumin excretion >30 mg/24 hr) [9]. End stage kidney disease (ESKD) includes patients treated by dialysis as well as [10] transplantation irrespective of their eGFR [9].

Similar to diabetes, CKD presents a challenging and rapidly growing public health problem [11, 12]. Worldwide, current estimates suggest that over 500 million patients have CKD, with the majority (80%) of these patients living in low and middle-income countries [13]. The increase in diabetes has resulted in significant growth in numbers of patients with co-morbid diabetes and CKD [14, 15]. The risk of ESKD is increased 12-fold in patients with diabetes [16] resulting in 30–40% of all cases of ESKD being attributable to diabetes [17]. Diabetes is already the leading cause of ESKD in most developed countries accounting for 50% of all cases of treated ESKD [18]. Indeed, the growth in the number of patients with ESKD around the world appears to have paralleled the increase in diabetes [19]. In Australia and New Zealand, a 60% increase in the number of people with type 2 diabetes starting dialysis from 2003 to 2013 has been observed (Figure 2). Over a similar period, the UK Prospective Diabetes Study (UKPDS) trial [20] estimated that from diagnosis to 15 year follow up, the proportion of patients with microalbuminuria snowballed from 12.8% to 39% and the proportion with proteinuria increased from 2.1% to 12.6% suggesting a further increase in the prevalence of CKD among those with diabetes.

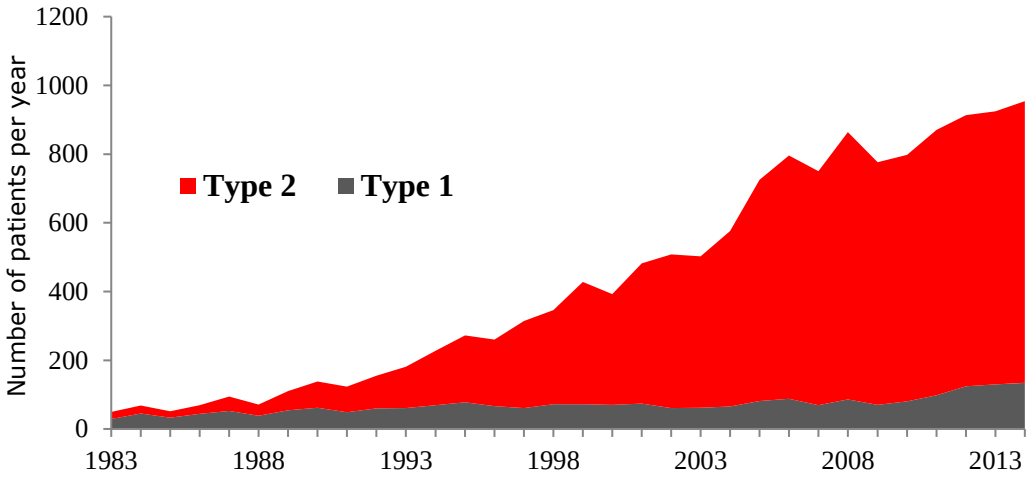



**Figure 2.** Diabetes progression to dialysis

(Reproduced from the Australia and New Zealand Dialysis and Transplant Registry, Annual Reports. Available at www.anzdata.org.au)

In terms of costs, an exponential increase by CKD stage has been described, with the greatest expenditure for patients on renal replacement therapy [21-23]. However, for patients who have co-morbid diabetes and CKD, the health care costs for those with stage 5 CKD (not yet on dialysis) is more than two-fold higher and those requiring dialysis more than six-fold higher than for those without diabetes [24]. Correspondingly, the health care costs for those with either an increase in albumin excretion rate in the range of ≥300 mg albumin/g creatinine or an eGFR <60 mL/min/1.73 $m^2$ are 50% higher than for those with diabetes without these complications [24].

Additionally, there is increasing evidence [25-27] to show an extraordinarily high risk of Cardiovascular Disease (CVD) in patients with CKD, with the risk of death over ten times higher than the risk of progression to ESKD for patients with CKD stage 3 (eGFR 40-60 mL/min/1.73$m^2$) [28]. Overall, for a significant proportion of patients with CKD, death usually precedes ESKD due to cardiovascular complications [29]. Among the relatively few patients who eventually reach ESKD, prognosis is poor with a five-year survival averaging less than 40% mainly due to CVD-associated morbidity and mortality [30]. In the presence of diabetes, the risk of cardiovascular morbidity and mortality increases sharply [31-33].

In view of the ominous threat to global public health posed by co-morbid diabetes and CKD, multipronged strategies have been adopted to reduce risk factors and complications. Chief among these strategies are interventions directed at managing risk factors such as hypertension, albuminuria, hyperglycaemia and dyslipidaemia. For instance, the most recent Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines have recommended intensive medical management that includes blood pressure [34] and lipid [10] control. There is also increasing recognition that strategies to improve outcomes cannot depend solely on the actions of health professionals but will also depend on the patient's own actions [35].

Consequently, self-management interventions that comprise life style changes have been introduced including reducing salt intake, following a diabetic diet [36], cessation of smoking [37] and blood pressure monitoring [38].

Self-management interventions have been widely assessed for single conditions (either diabetes or CKD) but evidence for their effectiveness in patients with co-morbid diabetes and CKD is limited [39, 40]. Given the competing treatment demands associated with managing complex conditions such as diabetes and CKD [41-43], when treatment recommendations for one condition conflict with or impede management of the other, or when patients prioritise one condition over another, it is important to characterise and streamline self-management interventions that can be utilised for patients with co-morbid diabetes and CKD.

### 1.3 Self-management in patients with co-morbid diabetes and chronic kidney disease

The terms 'self-management' and 'self-management support' are often used interchangeably [44]. Although the concepts of these two terms are related, self-management is defined as "the ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions" [45]. The identification of common patient-centric strategies to deal with challenges posed by chronic diseases is therefore the main focus of self-management. The Institute of Medicine [46] defines self-management support as "the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support". Recognizing the patient's central role in their care and the barriers they face in adopting health promoting behaviours and fostering a sense of responsibility for their own health is fundamental to self-management support [47].

The conceptual approach to self-management utilised in this thesis is shown in the logic model (Figure 3), which outlines the factors that may influence self-management (inputs) and the short, intermediate and long-term outcomes (outputs). Short-term outcomes measure the initial impact of an activity, for instance, improved self-efficacy described in Bandura's Social Cognitive Theory [48]. Self-efficacy is determined by a person's specific capabilities and other individual factors, as well as information sources such as education and access to health experts. Intermediate outcomes are often few and are common in individuals who continue to participate in self-management activities. They are the changes which are most likely associated with the project and they may not only impact individuals directly participating in the project's activities but may have an influence on those connected to them such as families, friends and community partners. Long-term outcomes may be achieved after a lengthy duration (7–10 years), and they represent the ultimate goal for the project [49]. Self-management is likely to be influenced by patient activation. Patient activation refers to the confidence, knowledge and skills a patient has in self-management [50].

Self-management plays a key role in the management of co-morbid diabetes and CKD. Patients with diabetes and CKD may spend more than 4 hours daily on self-management [51] performing up to 95% of their own diabetes care [52]. Several clinical guidelines among them the Kidney Disease Outcomes Quality Initiative (KDOQI), the National Institute for Health and Care Excellence (NICE), the Caring for Australasians with Renal Impairment (CARI) and the KDIGO guidelines, have emphasized that the success of strategies to promote glycaemic control, prevent cardiovascular disease (CVD) and development or progression of CKD, is dependent upon optimal patient self-management [19, 53-55]. It is also widely understood that a holistic approach to management including provision of information and education is a prerequisite to optimise the health of patients with diabetes and CKD.

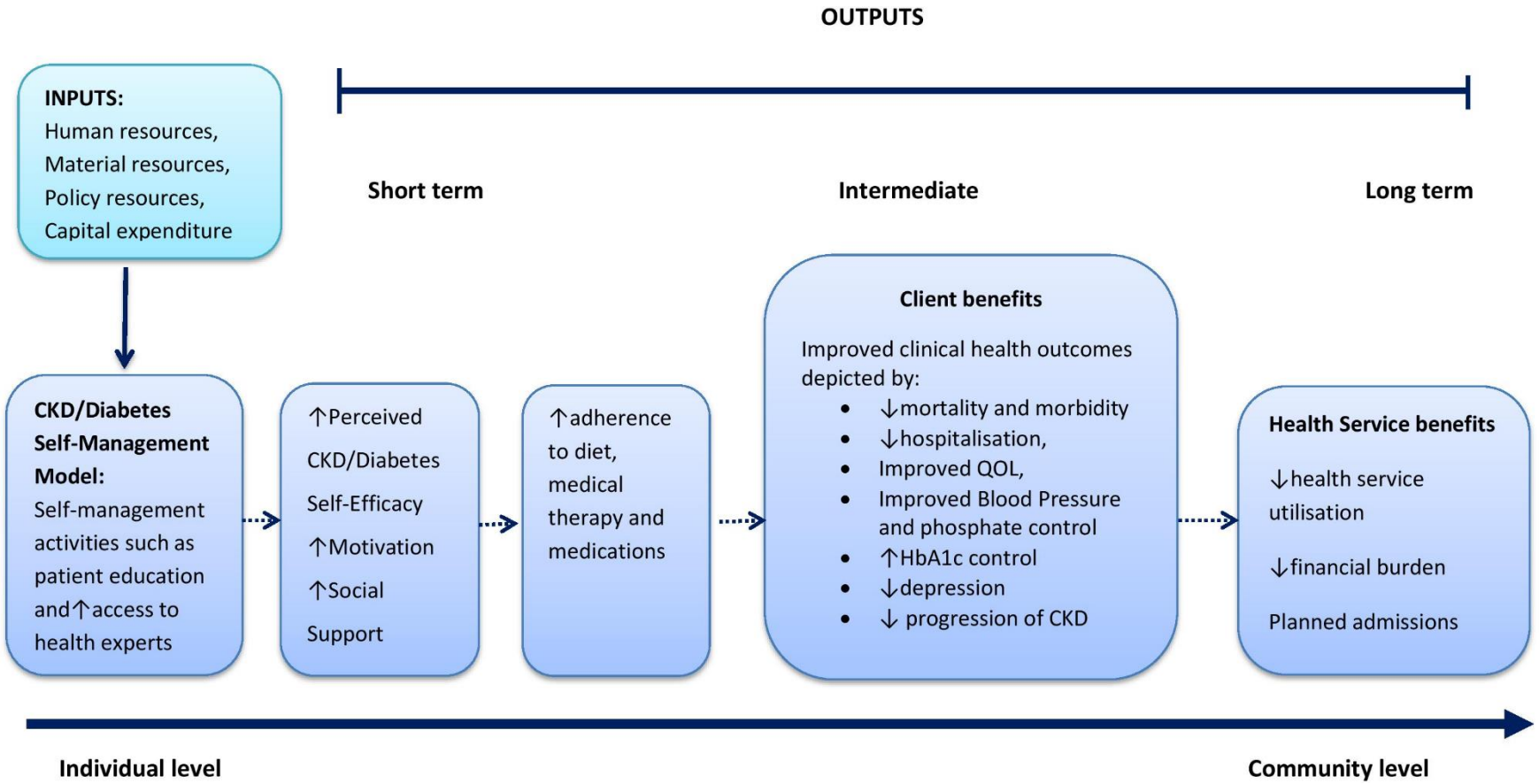



**Figure 3.** Program Logic Model for a chronic kidney disease/diabetes self-management program

(Adapted from **Zimbudzi E**., Lo, C., Misso M., Ranasinha S., Zoungas S. Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease. *Systematic Reviews* 2015; **4**:81)

Previous research in patients with diabetes has suggested that self-management is associated with improvements in HbA1c [56-60] although some studies have shown no differences between the control and intervention groups [61-65]. Improvements in blood pressure [66] , eGFR [67] and health related quality of life [60, 65, 68, 69] have also been reported among patients with either diabetes or CKD. Interestingly, most of the evidence on the impact of self-management tends to be limited to single diseases especially diabetes [70-72] suggesting that such evidence may not address the requirements of patients with more complex conditions such as diabetes and CKD.

While the importance of self-management in patients with co-morbid diabetes and CKD is recognized, various self-management initiatives have experienced challenges. These challenges include inadequate self-management knowledge by patients [38], limited health literacy [73], lack of support from family members [74], complicated self-management regimens [74], limited uptake by health care professionals and uncertainty of the benefits of self-management programs with limited evidence on the impact of such programs on patients' self-management abilities [75]. Additionally, lack of patient engagement in the design of self-management interventions as well as failure to consider the role of behavioural change theory have been documented as issues [39].

The risks that come with co-morbid diabetes and CKD call for pragmatic self-management strategies driven primarily by patients who should be active partners in the management of their care. However, the evidence base for self-management interventions for patients with co-morbid diabetes and CKD is underdeveloped [44]. Major gaps include lack of studies dedicated to evaluating interventions in patients with co-morbid diabetes and CKD with most of the evidence coming from patients with diabetes [76-78] or CKD [67, 79] . Furthermore, access to self-management and self-management support programs by patients with co-morbid diabetes

and CKD remains variable highlighting the need for prioritisation of activities designed to engage known hard-to-reach groups [18, 44].

There is an urgent need for research in patients with co-morbid diabetes and CKD to; 1) characterise patients' self-management ability, 2) identify the predictors of self-management activity, 3) determine the self-management interventions that are effective and 4) quantify the impact of self-management interventions on patient reported outcomes such as health-related quality of life.

### 1.4 Health-related quality of life in patients with co-morbid diabetes and chronic kidney disease

Health-related quality of life (HRQOL) is defined as a multidimensional concept, which describes the physical, role functioning, social, and psychological aspects of well-being and functioning [80]. In the last two decades, HRQOL has become an important measure of the outcome of care for patients with chronic diseases [81]. Health-related quality of life is being used in population surveys as well as for evaluating health care delivery systems. Some studies have suggested using HRQOL assessments to identify high risk patients in whom modifying factors associated with poorer HRQOL may be addressed to help these patients lead an active and healthy life particularly during the early stages of the disease [82, 83]. For patients with chronic diseases such as co-morbid diabetes and CKD, HRQOL remains one of the best predictors of morbidity and mortality and the main indicator of medical treatment effectiveness [84]. Reducing morbidity and mortality and improving quality of life for people with co-morbid diabetes and CKD is a key public health objective.

Research has shown a strong relationship between co-morbidity and the adjusted scores on all HRQOL indicators. Patients with a higher co-morbidity index have a lower quality of life [85, 86]. Moreover, progressively lower scores in all dimensions of HRQOL have been observed

with advancing stages of CKD [82, 87-89]. However, far less is known about the HRQOL of patients with earlier stages of CKD [90]. A reason for this is that most studies have been performed in nephrology clinics and as a result are small and include more patients with advanced stages of CKD, leading to a lack of generalizability [91]. Additionally, the impact of the 'labelling phenomenon' whereby patients with asymptomatic conditions who have been informed of their diagnosis experience a decrease in HRQOL, may have relevance in patients with earlier stages of CKD, but further work is required to confirm this finding [92].

Poorer quality of life has also been reported when CKD co-exists with diabetes [84, 85, 93-97]. However, most of this evidence is based on subgroup populations of patients with diabetes and CKD drawn from studies, which primarily had patients with CKD. The impact of earlier stages of CKD on HRQOL of patients with comorbid diabetes and CKD needs to be investigated. The majority of published HRQOL studies have been conducted among patients with diabetes and end stage kidney disease who are known to report the poorest quality of life [94, 98]. Knowing the impact of early stages of CKD on HRQOL of patients with comorbid diabetes and CKD will address the gaps in our knowledge about which interventions are appropriate, the optimal time to intervene, and what model of care to adopt across the disease continuum [99].

Understanding how HRQOL can be improved in patients with comorbid diabetes and CKD is particularly important given that quality of life can be more important to patients than longevity. Promoting patient self-management is an increasingly advocated approach to improve patient outcomes such as HRQOL. Among patients with either diabetes [100, 101] or CKD [68], improved self-management has been associated with better HRQOL. Whether HRQOL can be improved by increased uptake of self-management activities in people with comorbid diabetes and CKD remains unknown. Therefore, for patients with co-morbid diabetes and CKD, a clearer understanding of which, if any, interventions improve HRQOL is needed. To do this, it

is important to; 1) establish the levels of HRQOL in patients with co-morbid diabetes and CKD, 2) examine the determinants of HRQOL including demographic and disease factors as well as barriers to healthcare and 3) examine the independent relationship between self-management and HRQOL.

### 1.5 Summary

The management of comorbid diabetes and CKD is complex and often requires patients to be proficient in a number of self-management skills. However, the challenge is that the self-management ability, factors that influence self-management and the evidence on which self-management interventions are effective among patients with comorbid diabetes and CKD remain unknown. Additionally, the HRQOL of patients with comorbid diabetes and CKD and its determinants such as self-management, have not been characterised. These key evidence gaps are addressed by research in subsequent Chapters in this thesis.

### 1.6 Project layout

Figure 4 outlines the four phases of this PhD project. These are the pre-intervention, the intervention, evaluation and translation phase.

#### 1.6.1 Pre-intervention phase

The pre-intervention phase involved the assessment of demographic and clinical characteristics of patients with comorbid diabetes and CKD who were enrolled in the Diabetes Renal Project. This was followed by the characterisation of patient reported outcomes which include patient activation, self-management and HRQOL. Additionally, self-management education needs of patients with comorbid diabetes and CKD were determined in this phase. The work covered in this phase is reported in Chapters 2-5.

#### 1.6.2 Intervention phase

The intervention was delivered through the Diabetes Kidney Service, a patient centred and co-designed integrated model of care [102] (described in detail in a paper under other publications).

Patients with comorbid diabetes and CKD are referred into this service from hospitals and primary care. The service has a multidisciplinary team that comprises of a nephrologist, endocrinologist, renal and diabetes nurse practitioners, dietitian and a diabetes educator. The service provides streamlined access to healthcare services, improved communication between the specialist clinic and the General Practitioners and most importantly improved self-management support delivered by the multidisciplinary team. Self-management support is delivered through distribution of education resources produced by Diabetes Australia and Kidney Health Australia as well as tailored one-to-one education sessions for those in need.

### 1.6.3 Evaluation phase

The impact of the intervention on patient activation, self-management and HRQOL (reported in Chapter 7) was assessed. Feedback was also sought from patients, primary and specialist health professionals regarding their experience with the service [103].

### 1.6.4 Translation phase

In this phase, a targeted education resource in the form of a digital versatile disc (DVD) was produced [104]. The education resource produced in collaboration with patients, key stakeholders and the multidisciplinary team is already being used in the clinic. This resource may potentially address the self-management needs of patients with comorbid diabetes and CKD (Chapter 6).

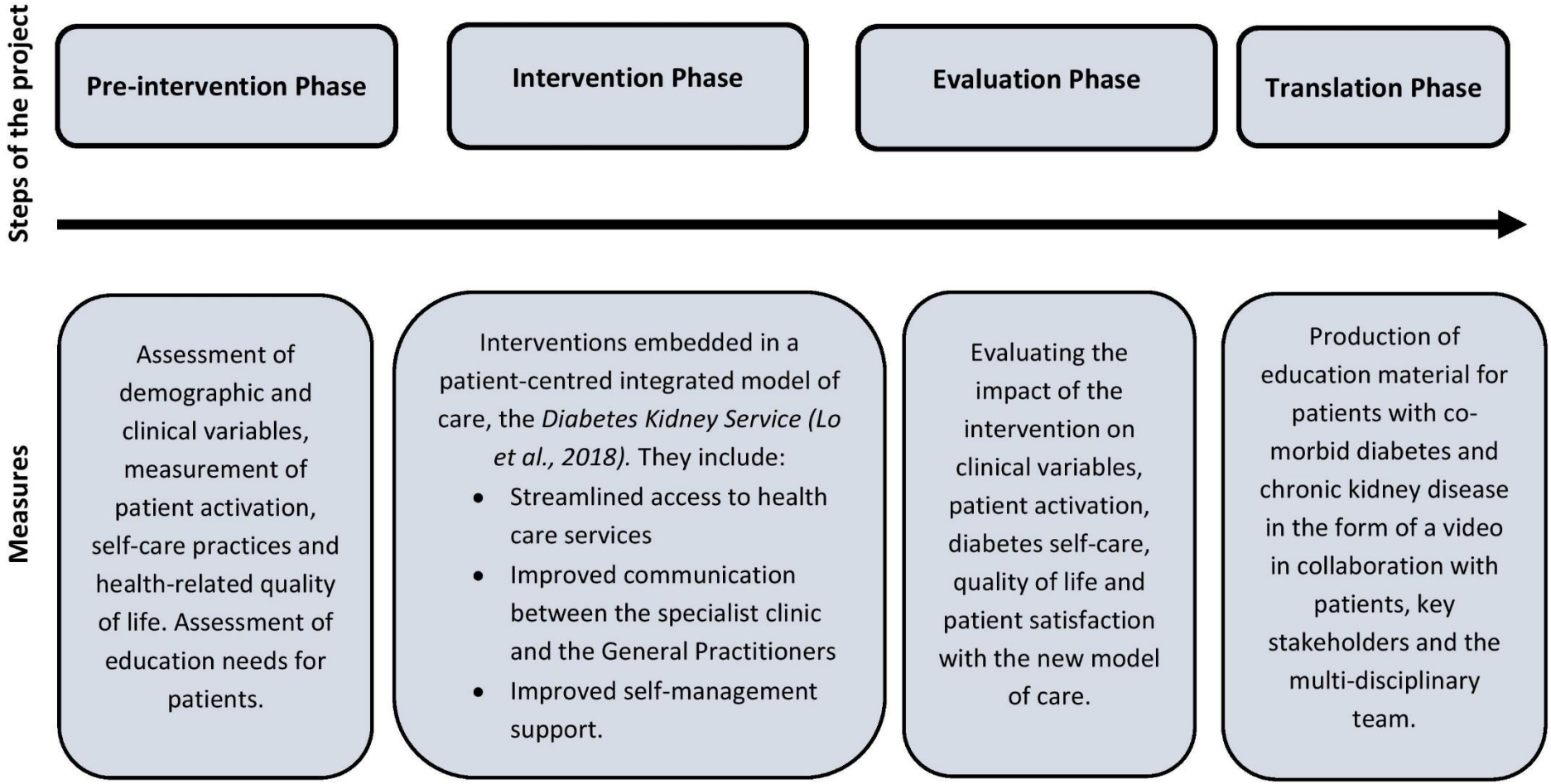



**Figure 4.** Project layout

# CHAPTER 2

# DETERMINANTS OF SELF-MANAGEMENT ACTIVITY

## 2.1 Introduction

Patient activation refers to the extent to which patients have the knowledge, motivation, belief, confidence and skills to manage chronic disease, access health-care and to collaborate with health-care providers for disease management [105]. It is widely believed that patient activation is a major determinant of self-management activity in people with chronic diseases [106-108]. However, the influence of patient activation on self-management activity among patients with co-morbid diabetes and CKD is largely unknown. In section 2.2 of Chapter 2, the degree of patient activation among patients with co-morbid diabetes and CKD is examined and modifiable risk factors that are independently associated with activation in these patients are highlighted. In section 2.3 the association between patient activation and self-management practices in patients with co-morbid diabetes and CKD is explored. The studies described in this Chapter were published in BMJ Open (Zimbudzi et al., 2017) and Health Expectations (Zimbudzi et al., 2017). The Chapter is presented as the published pdf versions of the manuscripts.

## 2.2 Published manuscript: Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross-sectional study

Citation: **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G. R., Jan S., Kerr PG., Polkinghorne K. R., Russell G., Walker R. G., Zoungas S. Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross-sectional study. BMJ Open 2017; 7 (10).

BMJ Open

# Factors associated with patient activation in an Australian population with comorbid diabetes and chronic kidney disease: a cross-sectional study

Edward Zimbudzi,[1,2] Clement Lo,[1,3] Sanjeeva Ranasinha,[1] Gregory R Fulcher,[4] Stephen Jan,[5,6] Peter G Kerr,[2] Kevan R Polkinghorne,[2] Grant Russell,[7] Rowan G Walker,[8] Sophia Zoungas[1,3,5]

**To cite:** Zimbudzi E, Lo C, Ranasinha S, *et al*. Factors associated with patient activation in an Australian population with comorbid diabetes and chronic kidney disease: a cross-sectional study. *BMJ Open* 2017;**7**:e017695. doi:10.1136/bmjopen-2017-017695

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2017-017695).

Received 11 May 2017
Revised 11 September 2017
Accepted 13 September 2017

For numbered affiliations see end of article.

**Correspondence to**
Professor Sophia Zoungas;
sophia.zoungas@monash.edu

## ABSTRACT

**Objective** To evaluate the extent of patient activation and factors associated with activation in adults with comorbid diabetes and chronic kidney disease (CKD).

**Design** A cross-sectional study.

**Setting** Renal/diabetes clinics of four tertiary hospitals across the two largest states of Australia.

**Study population** Adult patients (over 18 years) with comorbid diabetes and CKD (estimated glomerular filtration rate <60 mL/min/1.73 $m^2$).

**Main outcome measures** Patients completed the Patient Activation Measure, the Kidney Disease Quality of Life and demographic and clinical data survey from January to December 2014. Factors associated with patient activation were examined using $\chi^2$ or t-tests and linear regression.

**Results** Three hundred and five patients with median age of 68 (IQR 14.8) years were studied. They were evenly distributed across socioeconomic groups, stage of kidney disease and duration of diabetes but not gender. Approximately 46% reported low activation. In patients with low activation, the symptom/problem list, burden of kidney disease subscale and mental composite subscale scores were all significantly lower (all p<0.05). On multivariable analysis, factors associated with lower activation for all patients were older age, worse self-reported health in the burden of kidney disease subscale and lower self-care scores. Additionally, in men, worse self-reported health in the mental composite subscale was associated with lower activation and in women, worse self-reported health scores in the symptom problem list and greater renal impairment were associated with lower activation.

**Conclusion** Findings from this study suggest that levels of activation are low in patients with diabetes and CKD. Older age and worse self-reported health were associated with lower activation. This data may serve as the basis for the development of interventions needed to enhance activation and outcomes for patients with diabetes and CKD.

## Strengths and limitations of this study

- Several biological and non-biological patient variables were included as potential factors influencing patient activation since the factors are likely to be multifactorial.
- The study was conducted across multiple sites increasing the generalisability of the findings.
- The limitations include that our findings may not be generalised to culturally and linguistically diverse populations.
- The cross-sectional design of the study did not permit us to assess temporal effects or to rule out the potential for reverse causality with low activation causing poor health.

## INTRODUCTION

Patient activation may be defined as the ability and willingness of patients to take on the role of managing their own health and healthcare[1] and is related to the degree that a patient participates or engages in specific health behaviours.[2–4] Previous studies of patients with hypertension in primary care settings suggest that patient activation is associated with patient outcomes, where low activated patients are more likely to smoke,[5] have a higher body mass index (BMI) and less likely to achieve cholesterol and glycated haemoglobin targets.[6] In patients with diabetes, high activation has been associated with greater engagement in exercise,[7] fewer hospitalisations[8] and improved glycaemic control.[9] In patients with hypertension[5 10 11] and chronic kidney disease (CKD)[12] high activation is associated with better blood pressure control and in patients with end-stage kidney disease higher activation is likely to improve uptake of home dialysis.[13]

Low activation levels have been reported in 25%–40% of the general population[14] and in patients living with chronic diseases.[12 15 16] However, activation levels may vary considerably depending on the severity of the chronic disease.[17 18] Indeed, little is known about the

BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

activation levels of patients with multiple and complex chronic diseases, including comorbid diabetes and CKD. Among patients with diabetes and CKD, a sufficient degree of activation is required for patients to perform self-management behaviours such as blood glucose monitoring and medication self-management.[19] Moreover, as these patients face competing treatment demands especially when treatment recommendations for one condition conflict with or impede management of the other, or when patients prioritise one condition over another,[20–22] understanding the degree of patient activation becomes even more important.

Missed opportunities to enhance activation among patients with diabetes and CKD may result in more rapid progression of CKD and development of associated complications.[23] Additionally, activation levels may fluctuate as the disease progresses and complications arise necessitating matched changes in activation behaviour.[24]

Given the importance of patient activation for self-management in people with diabetes and CKD and ultimately patient outcomes, it is important to establish the level of activation in these patients and determine the patient and disease characteristics that influence activation. Consequently, the purpose of the present study was to (1) examine to what degree patients with comorbid diabetes and CKD are activated and (2) identify what modifiable risk factors are independently associated with activation levels in patients with comorbid diabetes and CKD.

## METHODS

### Study design and participants

A cross-sectional study was conducted (as previously described)[25] of patients attending diabetes and renal outpatient clinics of four public tertiary hospitals in Victoria and New South Wales (Monash Health, Alfred Health, Royal North Shore Hospital and Concord Hospital) from January to December 2014. Participants were eligible if they received their usual care at these hospitals and had a diagnosis of diabetes (either type 1 or type 2) and CKD stages 3–5 (estimated glomerular filtration rate (eGFR) <60 mL/min). The diagnosis of diabetes followed WHO definition[26] and was recorded from patients' prior inpatient or outpatient contacts. Patients were recruited prospectively from clinics and the following questionnaires were completed; the Diabetes Renal Project (Patient Survey), Diabetes Renal Project (Doctors Survey), the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire, the Kidney Disease Quality of Life short form (KDQoL-36) and the Patient Activation Measure (PAM-13) (online supplementary appendices 1-5). The Diabetes Renal Project (Patient Survey) (see online supplementary appendix 1) collected demographic information (age, gender, country of birth, language spoken at home) and clinical characteristics such as duration of diabetes and CKD. For each patient the site study staff or the clinician, using standardised procedures that included health assessment templates, also completed a corresponding clinical survey, the Diabetes Renal Project (Doctors Survey) (see online supplementary appendix 2). The questionnaire collected information on patients' medical history, clinical findings, access to medical care for diabetes and CKD, medications and investigations such as blood test results. All participants were provided with written informed consent and 317 agreed to participate. All local hospital and university human research ethics committees (Monash Health Human Research Ethics Committee, Alfred Health Research Ethics Committee, Monash University Human Research Ethics Committee, Northern Sydney Local Health District Human Research Ethics Committee, Sydney Local Health District Human Research Ethics Committee and the University of Sydney Human Research Ethics Committee) approved this study.

### Demographic and clinical variables

Age, gender, socioeconomic status (SES), stage of kidney disease, duration of kidney disease and duration of diabetes were all recorded as possible determinants of patient activation. SES was estimated using the Australian Bureau of Statistics data.[27] Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables, which include income, educational attainment and employment status. The IRSD scores for each postcode were then grouped into quintiles for analysis, where the highest quintile comprised 20% of postcodes with the highest IRSD scores (the most advantaged areas).

CKD stage as defined by the Kidney Disease: Improving Global Outcomes (KDIGO) was used to define severity of the disease.[28] Duration of CKD was analysed as a continuous variable. eGFR was calculated using the CKD Epidemiology Collaboration (EPI) formula $eGFR = 141 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-1.209} \times 0.993^{Age} \times 1.018 \times 1.159$, where Scr is serum creatinine (mg/dL), $\kappa$ is 0.7 for women and 0.9 for men, $\alpha$ is –0.329 for women and –0.411 for men, min indicates the minimum of Scr/$\kappa$ or 1 and max indicates the maximum of Scr/$\kappa$ or 1.[29] We used the CKD EPI formula because it is routinely reported in Australia[30] as the equation of choice and is recommended by the KDIGO guidelines.[31]

### Self-care

Self-care was assessed by the SDSCA questionnaire,[32] which is a self-report measure of how often participants performed diabetes self-care activities (see online supplementary appendix 3). The SDSCA measures several dimensions of diabetes self-management with adequate internal and test–retest reliability, and evidence of validity and sensitivity to change.[32] An overall Cronbach's $\alpha$ coefficient of 0.63 has been reported.[33] The SDSCA questionnaire has been used in several studies and settings[34–36] to evaluate self-care among adults with diabetes. This study used a version of the SDSCA questionnaire that included items assessing five domains of diabetes self-management: general diet (two items), specific diet (two items),

BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

exercise (two items), blood glucose testing (two items) and foot care (two items).[32] The medication self-management domain was excluded because of its ceiling effects and lack of variability among participants.[32] The smoking self-management domain was also excluded because smoking behaviour was relevant to smokers only.

### Health-related quality of life

Health-related quality of life (HRQoL) was assessed using the English version of the Kidney Disease and Quality of Life (KDQoL-36) questionnaire (see online supplementary appendix 4), which is a 36-item HRQoL survey with five subscales, namely the 12-item Short Form Health Survey measure of physical and mental functioning, burden of kidney disease, symptom/problems list and the effects of kidney disease subscales.[37] Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQoL.[29] The validity and reliability of the KDQoL-36 questionnaire has been reported previously.[38–40]

### Patient activation

A 13-item survey-based scale called the short form of the PAM-13 that groups patients along a four-point levelling scale based on how activated patients are was used to measure patient activation (see online supplementary appendix 5). It has similar reliability and validity to the 22-item version across different ages, genders and health condition status (Cronbach's alpha of 0.91 and a Rasch person statistic of 0.81 for the real and 0.85 for the model on which it was based).[3 41] The validity and reliability of the PAM-13 has also been tested in various regions and in patients with different conditions.[42–45] Each item of the form was scored on the five-point Likert response scale. The raw scores were transformed from the original metric to a 0–100 metric with higher scores indicating higher activation levels. Based on the patient activation score, patients were categorised into four levels: level 1 (score <47.0), level 2 (score 47.1–55.1), level 3 (score 55.2–67.0) and level 4 (score >67.0).[41] The activation levels were then dichotomised into low activation (levels 1 and 2) and high activation (levels 3 and 4) as reported in previous studies.[46 47]

### Data analysis

Normally distributed data are presented with mean and SD as the measures of central tendency and dispersion, respectively. Correspondingly, non-normally distributed continuous data are presented with median and IQR (thus 25th and 75th percentiles), respectively. All HRQoL subscales were treated as continuous variables. First, the four patient activation levels were dichotomised into low activation group (levels 1 and 2) and high activation group (levels 3 and 4). Second, $\chi^2$ or t-tests (as appropriate) were used to analyse differences or associations between patient and disease characteristics and patient activation. Third, using the PAM score as a continuous variable, univariable regression models were performed in which each covariate was controlled for separately to ascertain its potential importance. Covariates that reached a significance level of p<0.10 or were of clinical importance were included in stepwise backward multivariable linear regression models that investigated the factors associated with patient activation for the entire study population and stratified analyses according to gender.[48] Potential covariates were age, gender, subscales of HRQoL, eGFR, BMI, SES and the composite self-care score. CIs were reported at the 95% level and for all analyses, a p value<0.05 was considered statistically significant. Cases with missing values were not included in the analyses after checking for the amount of missing data which was minimal (less than 1%) for variables such as age, eGFR, SES and duration of diabetes and kidney disease. There was no pattern in the missing data on any variables. All analyses were performed with IBM SPSS V.22 or Stata V.12.1 (StataCorp).

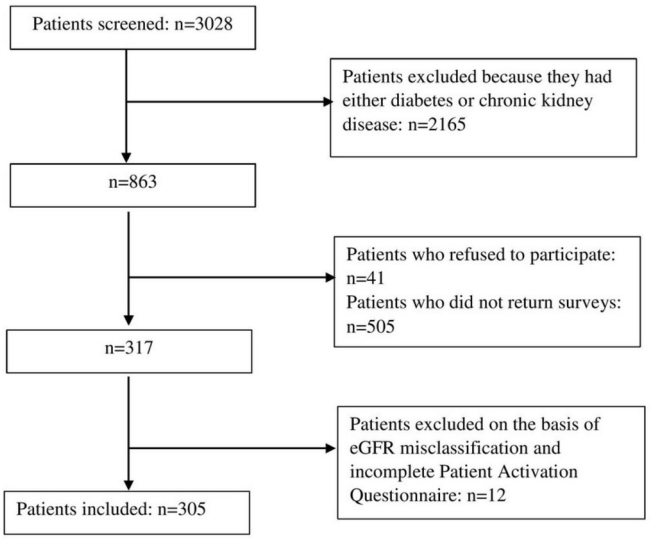



**Figure 1** Patient inclusion flow diagram. eGFR, estimated glomerular filtration rate.

## RESULTS

### Patient characteristics

A total of 3028 patients were screened, 317 studied and of those 305 included in the analyses after the exclusion of nine patients who had their eGFR misclassified (>60 mL/min/$m^2$) and three patients who had incomplete PAM data (figure 1). There were no differences in age, gender and stage of kidney disease (for one study site) between patients who participated and those who did not participate in the study (see online supplementary table S1). The baseline demographic and clinical characteristics of the study population are shown in table 1. The median age and IQR was 68 and 14.8 years, respectively, with 59% of the population being over 68 years old and 30% were women. The patients were evenly distributed across groups defined by SES and stage of kidney disease. Approximately 20% were receiving dialysis treatment.



BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

Table 1 Patient characteristics by activation status (N=305)

| | Patient activation status | | |
|---|---|---|---|
| | Low level, N (%) | High level, N (%) | p Value* |
| Age | | | |
| <68 years | 68 (49.3) | 88 (53.3) | 0.48 |
| ≥68 years | 70 (50.7) | 77 (46.7) | |
| Gender | | | |
| Female | 42 (30.4) | 51 (30.9) | 0.93 |
| Male | 96 (69.6) | 114 (69.1) | |
| Socioeconomic status,† n (%) | | | 0.86 |
| Upper | 24 (17.4) | 34 (20.6) | |
| Upper middle | 32 (23.2) | 31 (18.8) | |
| Lower middle | 27 (19.6) | 34 (20.6) | |
| Upper lower | 28 (20.3) | 31 (18.8) | |
| Lower | 27 (19.6) | 35 (21.2) | |
| CKD duration in years: mean (SD) | 8.8 (9.6) | 9.2 (11.6) | 0.74 |
| Stage of CKD‡ | | | 0.86 |
| 3a | 30 (21.7) | 42 (25.5) | |
| 3b | 35 (25.4) | 42 (25.5) | |
| 4 | 34 (24.6) | 40 (24.2) | |
| 5 | 39 (28.3) | 41 (24.8) | |
| Diabetes duration in years: mean (SD) | 17.1 (12.0) | 18.2 (11.8) | 0.40 |
| Body mass index: mean, n (%) | | | |
| Underweight | 1 (1.4) | 1 (1.2) | 0.60 |
| Healthy weight | 17 (24.3) | 15 (17.4) | |
| Overweight | 21 (30.0) | 23 (26.7) | |
| Obese | 47 (67.1) | 31 (36.0) | |
| Dialysis status | | | |
| Current | 29 (21.0) | 30 (18.2) | 0.54 |
| Predialysis | 109 (79.0) | 135 (81.8) | |
| HRQoL: mean (SD) | | | |
| Symptom/problem list | 72.0 (17.6) | 75.5 (17.4) | 0.08 |
| Effect of kidney disease | 71.0 (23.5) | 74.1 (23.6) | 0.27 |
| Burden of kidney disease | 55.9 (29.5) | 63.3 (31.9) | 0.04 |
| Physical composite summary | 34.4 (11.3) | 36.0 (11.0) | 0.26 |
| Mental composite summary | 45.5 (10.5) | 48.3 (11.0) | 0.03 |

Data are presented in N (%) unless otherwise indicated.
*T-test for mean differences and $X^2$ test for differences in proportions.
†Socioeconomic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage, a composite measure based on selected census variables, which include income, educational attainment and employment status.
‡Stage 5 CKD included patients on dialysis (n=59) and not on dialysis (n=21).
CKD, chronic kidney disease; HRQoL, health-related quality of life.

Patient activation scores were normally distributed across the study population (mean 57.6, SD 15.5); male (mean 57.4, SD 16.0) and female patients (mean 58.1, SD 14.4) (figure 2A,B). Twenty-two per cent self-reported PAM level 1, 23.6% level 2, 36.4% level 3 and 18% level 4 (indicating greatest activation) (figure 3). The proportions of the patients with low (levels 1 and 2) and high activation (levels 3 and 4) scores were 46% and 54%, respectively (figure 3).

Patients in the low activation group had significantly worse self-reported health in the burden of kidney disease and mental composite summary subscales than patients



BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

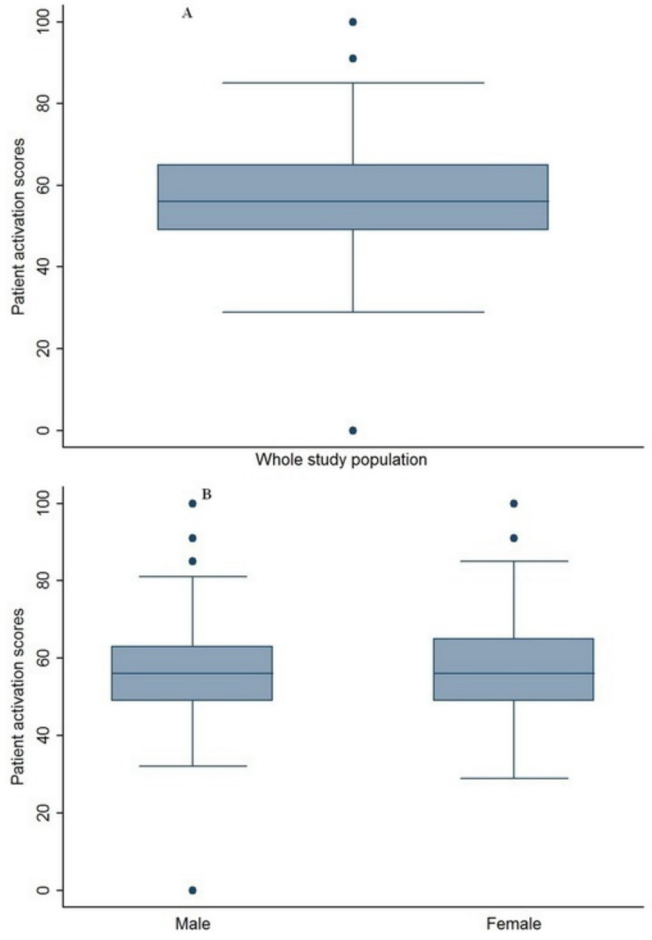



**Figure 2** Patient activation. Distribution of patient activation from (A) the study population (mean 57.6, SD 15.5) and (B) male (mean 57.4, SD 16.0) and female patients (mean 58.1, SD 14.4).

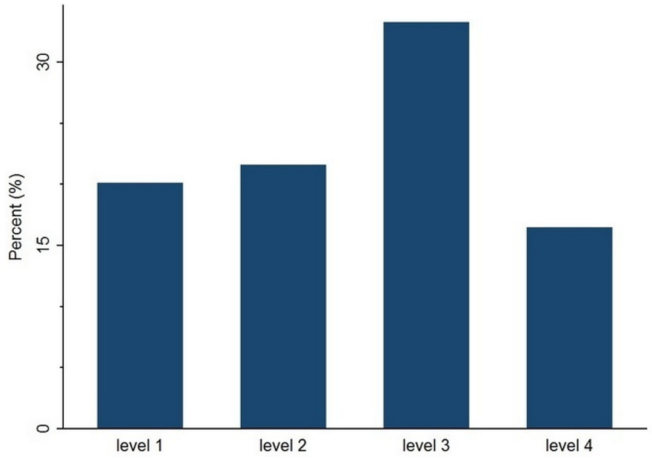



**Figure 3** Distribution of participants across the four levels of patient activation. Level 1 (score of 0.0–47.0) indicates that a person may not yet understand that their role as a patient is important. Level 2 (47.1–55.1) indicates that a person lacks the confidence and knowledge to take action. Level 3 (55.2–67) indicates that a person is beginning to take action and level 4 (67.1–100) indicates that a person is proactive about health and engages in many recommended health behaviours.

in the high activation group as shown in table 1 (all p<0.05). No other differences between low and high activation groups were found for demographic factors (age, gender and SES) and disease factors that included stage and duration of CKD, dialysis status, duration of diabetes and BMI (table 1).

### Factors associated with patient activation in the study population

On univariable analysis (table 2), factors associated with lower activation were worse self-reported health in all HRQoL subscales, greater renal impairment (lower eGFR) and lower self-care scores. On multivariable analysis, older age, worse self-reported health in the burden of kidney disease subscale and lower self-care scores were independently associated with lower activation (table 2).

### Factors associated with patient activation stratified by gender

Online supplementary tables S2 and S3 show stratified analyses according to gender. On univariable analysis, worse self-reported health in the symptom problems list, burden of kidney disease, mental composite summary subscales and lower self-care scores were associated with lower activation in men. Worse self-reported health in all HRQoL subscales and lower eGFR were associated with lower activation in women. On multivariable analysis, worse self-reported health in the mental composite subscale was independently associated with lower activation in men, and worse self-reported health in the symptom problem list and greater renal impairment (lower eGFR) were independently associated with lower activation in women.

## DISCUSSION

Among patients with comorbid diabetes and CKD, we document for the first time in this study that patient activation is low, and identify factors independently associated with lower patient activation. We report significantly worse self-reported health in the burden of kidney disease and mental composite subscales for patients in the low activation group compared with those in the high activation group. Lower activation was also independently associated with older age, having worse self-reported health in the burden of kidney disease subscale and lower self-care scores across the entire study population. In men, worse self-reported health in the mental composite subscale was associated with lower activation. In women, worse self-reported health in the symptom problem list (with symptoms including sore muscles, chest pain, cramps, itchy or dry skin and shortness of breath, faintness/dizziness and lack of appetite) and greater renal impairment were associated with lower patient activation.

The mean patient activation score was 57.6 on a theoretical scale of 0–100 and was comparable to the means cited in several studies across other regions and disease conditions.[15 42 49] Patient activation in patients with comorbid diabetes and CKD was generally low with close to 50% of

BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

Table 2 Univariable and multivariable regression model for factors associated with low activation in the study population

| Variables | Univariable B (95% CI) | Multivariable B (95% CI) |
|---|---|---|
| Age | −0.05 (−0.22 to 0.11) | −0.18 (−0.35 to 0.01)* |
| Gender | | |
| Men | Reference | Reference |
| Women | −0.79 (−4.59 to 3.02) | – |
| Health-related quality of life | | |
| Symptom problem list | 0.15 (0.05 to 0.25)** | – |
| Effects of kidney disease | 0.09 (0.02 to 0.17)* | – |
| Burden of kidney disease | 0.11 (0.05 to 0.16)*** | 0.11 (0.05 to 0.17)*** |
| Physical composite summary | 0.17 (0.01 to 0.33)* | – |
| Mental composite summary | 0.26 (0.09 to 0.42)** | – |
| Duration of diabetes | −0.02 (−0.17 to 0.13) | – |
| Duration of kidney disease | 0.07 (−0.11 to 0.25) | – |
| eGFR† | 0.11 (0.00 to 0.21)* | 0.01 (−0.12 to 0.15) |
| Body mass index | | |
| Healthy weight‡ | Reference | Reference |
| Overweight | −2.78 (−7.75 to 2.20) | – |
| Obese | 1.98 (−2.03 to 5.99) | – |
| Socioeconomic status§ | | |
| Lower | Reference | Reference |
| Lower middle | −0.31 (−4.75 to 4.12) | – |
| Upper lower | −1.42 (−5.80 to 2.95) | – |
| Upper middle | −0.95 (−5.27 to 3.38) | – |
| Upper | 3.17 (−1.28 to 7.62) | – |
| Self-care composite score | 0.21 (0.06 to 0.37)** | 0.18 (0.02 to 0.35)* |

*p<0.05.
**p<0.01.
***p<0.001.
-†Per 1 mL/min increase in eGFR.
‡Due to small numbers of underweight patients (n=2), the underweight group was combined with the healthy weight group for this analysis.
§-Socioeconomic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage , a composite measure based on selected census variables, which include income, educational attainment and employment status.
eGFR, estimated glomerular filtration rate.

our study population reporting low levels of activation. This is greater than that of the general population where 25%–40% have reported low activation[14] and in patients with diabetes where 20%–30% reported low activation.[48 50] Conversely in patients with CKD alone (eGFR <60 mL/min/1.73 m$^2$), patient activation has been observed to be even lower with over 65% of one study cohort[17] reporting low activation levels. Although we expected that diabetes and CKD in combination would lead to lower activation compared with either diabetes or CKD alone, our results suggest higher patient activation among patients with diabetes and CKD. This may be attributed to a focus on self-management of diabetes. More studies are required to confirm this observation.

We found that older age was independently associated with lower activation. Similar findings have been reported in people with diabetes[8 16 27] other chronic diseases[45 47 51–53] and in a national survey of US adults.[54] The reason for this could be a higher prevalence of depressive symptoms and functional difficulties impairing self-management in older patients.[51 52] In contrast, other studies in different populations found conflicting evidence, showing no direct relationship between patient activation and age.[2 55–57] These inconsistencies may be due to differences in clinical and demographic characteristics of the populations studied. For example, it has been previously reported that younger patients with CKD have poorer coping strategies compared with older patients,[58] which may lead to low activation or could possibly be due to low activation. Our results highlight a subgroup at risk of lower activation, which may benefit from targeted interventions to improve activation. These interventions may include encouraging patients to ask questions[59] when they attend medical appointments and training their peers to



BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

lead such interventions.[60] Additionally, the contradictions regarding the relationship between age and patient activation highlight that intervention strategies cannot exclusively be based on the knowledge of patients' demographics, but should include other modifiable factors as well.

In line with previous studies of patients with conditions other than comorbid diabetes and CKD,[15 51 54 61–63] patient activation was low in those with worse self-reported health status. Our study showed that lower mental health composite scores on KDQoL were independently associated with lower patient activation, particularly in men. This could be due to men with comorbid disease having less ability to cope with multiple conditions than women,[64] resulting in lower levels of activation. Men with chronic disease may also have less coping ability because they do not seek help as often as women do.[65] Given the high prevalence of mental disorders such as depression in patients with CKD,[66] addressing mental health issues may be very important for enhancing patient activation and outcomes.

Our data suggest that greater renal impairment in women may be associated with lower activation. The most likely explanation for this is that women tend to have lower physical functioning[67 68] which is associated with lower patient activation[63] even in the early stages of CKD.[17 54] Another plausible explanation is that women may receive less support from their caregivers compared with men due to caregiver stress and fatigue[69] associated with managing chronic diseases. The lack of support in managing chronic diseases may lead to lower activation among women. Additionally, due to the complexity of diabetes and CKD, there is limited time to address all patient needs resulting in lower quality medical care for discordant conditions.[70]

Interestingly, we did not find a significant association between SES and patient activation. This is in contrast to other studies that have reported patient activation to vary by SES with individuals from lower SES groups reported as less activated than those from higher SES groups.[6 14] These discordant findings could be attributable to our use of postcode as a surrogate for SES, which may not accurately represent SES.

### Strengths and limitations

Our findings should be interpreted in light of the strengths and limitations of our study design. The strengths include the inclusion of several biological and non-biological patient variables such as gender, age, SES, HRQoL, BMI and disease duration as potential factors influencing patient activation since the determinants are likely to be multifactorial. The study was conducted across multiple sites increasing the generalisability of the findings[71] and we also used validated and disease-specific instruments for measuring HRQoL (KDQoL-36) and patient activation (PAM-13). The limitations include that our findings may not be generalised to culturally and linguistically diverse populations. The cross-sectional design of the study did not permit assessment of temporal effects or the potential for reverse causality with low activation causing poor health. Longitudinal studies are needed to better understand the effects over time of factors influencing patient activation in this population.

## CONCLUSIONS

In conclusion, in patients with comorbid diabetes and CKD patient activation was low, with almost half of patients reporting low activation. Older age and worse self-reported health were associated with lower activation. This data may serve as the basis for the development of interventions needed to enhance activation and outcomes for patients with diabetes and CKD.

**Author affiliations**
[1]School of Public Health and Preventive Medicine, Monash Centre for Health Research and Implementation (MCHRI), Monash University, Melbourne, Victoria, Australia
[2]Department of Nephrology, Monash Health, Melbourne, Victoria, Australia
[3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Victoria, Australia
[4]Department of Diabetes and Endocrinology, Royal North Shore Hospital, St Leonards, New South Wales, Australia
[5]The George Institute for Global Health, University of Sydney, Sydney, New South Wales, Australia
[6]Sydney Medical School, Westmead, University of Sydney, Sydney, New South Wales, Australia
[7]Department of General Practice, School of Primary Health and Allied Health Care, Monash University, Melbourne, Victoria, Australia
[8]Department of Renal Medicine, Alfred Hospital, Melbourne, Victoria, Australia

**Acknowledgements** We acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

**Contributors** EZ, CL and SZ conceptualised the study. EZ, CL, SR and SZ performed data curation. EZ designed the analysis in consultation with CL, SR, GRF, SJ, PGK, KRP, GRF, RGW and SZ. EZ drafted the original draft and all authors reviewed and edited the final manuscript.

**Funding** This work was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups: Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; Kidney Health Australia. An Australian Postgraduate Award Scholarship supported CL.

**Competing interests** None declared.

**Ethics approval** Approval for the Diabetes Renal Project (DRP) was obtained from Monash University, Monash Health, Alfred Health, Royal North Shore Hospital and Concord Hospital.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Data for the DRP study can be shared for specific research questions that are available from the corresponding author on request.

**Open Access** This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

## REFERENCES


1. Hibbard JH, Greene J, Becker ER, *et al*. Racial/ethnic disparities and consumer activation in health. *Health Aff* 2008;27:1442–53.
2. Alegría M, Sribney W, Perez D, *et al*. The role of patient activation on patient-provider communication and quality of care for US and foreign born Latino patients. *J Gen Intern Med* 2009;24 Suppl 3:534–41.
3. Hibbard JH, Stockard J, Mahoney ER, *et al*. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;39(4 Pt 1):1005–26.
4. Donald M, Ware RS, Ozolins IZ, *et al*. The role of patient activation in frequent attendance at primary care: a population-based study of people with chronic disease. *Patient Educ Couns* 2011;83:217–21.
5. Kim JY, Wineinger NE, Steinhubl SR. The influence of wireless self-monitoring program on the relationship between patient activation and health behaviors, medication adherence, and blood pressure levels in hypertensive patients: a substudy of a randomized controlled trial. *J Med Internet Res* 2016;18:e116.
6. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *J Gen Intern Med* 2012;27:520–6.
7. Rask KJ, Ziemer DC, Kohler SA, *et al*. Patient activation is associated with healthy behaviors and ease in managing diabetes in an indigent population. *Diabetes Educ* 2009;35:622–30.
8. Begum N, Donald M, Ozolins IZ, *et al*. Hospital admissions, emergency department utilisation and patient activation for self-management among people with diabetes. *Diabetes Res Clin Pract* 2011;93:260–7.
9. Remmers C, Hibbard J, Mosen DM, *et al*. Is patient activation associated with future health outcomes and healthcare utilization among patients with diabetes? *J Ambul Care Manage* 2009;32:320–7.
10. Thiboutot J, Stuckey H, Binette A, *et al*. A web-based patient activation intervention to improve hypertension care: study design and baseline characteristics in the web hypertension study. *Contemp Clin Trials* 2010;31:634–46.
11. Olomu A, Khan NNS, Todem D, *et al*. Blood pressure control in hypertensive patients in federally qualified health centers: impact of shared decision making in the Office-GAP Program. *MDM Policy & Pract* 2016;1.
12. Johnson ML, Zimmerman L, Welch JL, *et al*. Patient activation with knowledge, self-management and confidence in chronic kidney disease. *J Ren Care* 2016;42:15–22.
13. Winterbottom A, Bekker H, Mooney A. Dialysis modality selection: physician guided or patient led? *Clin Kidney J* 2016;9:823–5.
14. Hibbard JH, Cunningham PJ. How engaged are consumers in their health and health care, and why does it matter? *Res Brief* 2008;8:1–9.
15. Skolasky RL, Green AF, Scharfstein D, *et al*. Psychometric properties of the patient activation measure among multimorbid older adults. *Health Serv Res* 2011;46:457–78.
16. Hendriks M, Rademakers J. Relationships between patient activation, disease-specific knowledge and health outcomes among people with diabetes; a survey study. *BMC Health Serv Res* 2014;14:393.
17. Bos-Touwen I, Schuurmans M, Monninkhof EM, *et al*. Patient and disease characteristics associated with activation for self-management in patients with diabetes, chronic obstructive pulmonary disease, chronic heart failure and chronic renal disease: a cross-sectional survey study. *PLoS One* 2015;10:e0126400.
18. The Canadian Diabetes Association. *clinical practice guidelines for the prevention and management of diabetes in Canada*, 2008.
19. Trisolini M, Roussel A, Zerhusen E, *et al*. Activating chronic kidney disease patients and family members through the Internet to promote integration of care. *Int J Integr Care* 2004;4:e17.
20. Al Shamsi S, Al Dhanhani A, Sheek-Hussein MM, *et al*. Provision of care for chronic kidney disease by non-nephrologists in a developing nation: a national survey. *BMJ Open* 2016;6:e010832.
21. Bower P, Harkness E, Macdonald W, *et al*. Illness representations in patients with multimorbid long-term conditions: qualitative study. *Psychol Health* 2012;27:1211–26.
22. Morris RL, Sanders C, Kennedy AP, *et al*. Shifting priorities in multimorbidity: a longitudinal qualitative study of patient's prioritization of multiple conditions. *Chronic Illn* 2011;7:147–61.
23. Fishbane S, Hazzan AD, Halinski C, *et al*. Challenges and opportunities in late-stage chronic kidney disease. *Clin Kidney J* 2015;8:54–60.
24. Holman H, Lorig K. Patients as partners in managing chronic disease. Partnership is a prerequisite for effective and efficient health care. *BMJ* 2000;320:526–7.
25. Lo C, Ilic D, Teede H, *et al*. The perspectives of patients on health-care for Co-Morbid Diabetes and Chronic Kidney Disease: a qualitative study. *PLoS One* 2016;11:e0146615.
26. World Health Organization. *Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF Consultation*. Geneva: World Health Organization, 2006.
27. Agrawal V, Jaar BG, Frisby XY, *et al*. Access to health care among adults evaluated for CKD: findings from the Kidney Early Evaluation Program (KEEP). *Am J Kidney Dis* 2012;59(Suppl 2):S5–15.
28. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int Suppl* 2012;3:1.
29. Resnick HE, Foster GL, Bardsley J, *et al*. Achievement of American Diabetes Association clinical practice recommendations among U.S. adults with diabetes, 1999-2002: the National Health and Nutrition Examination Survey. *Diabetes Care* 2006;29:531–7.
30. Johnson DW, Jones GR, Mathew TH, *et al*. Chronic kidney disease and automatic reporting of estimated glomerular filtration rate: new developments and revised recommendations. *Med J Aust* 2012;197:224–5.
31. Andrassy KM. Comments on 'KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease'. *Kidney Int* 2013;84:622–3.
32. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 2000;23:943–50.
33. Schmitt A, Gahr A, Hermanns N, *et al*. The Diabetes Self-Management Questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. *Health Qual Life Outcomes* 2013;11:138.
34. Freitas S, Freitas da Silva G, Neta D, *et al*. Analysis of the self-care of diabetics according to by the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA) Acta Scientiarum Health Sciences. *Health Science* 2014;36:73–81.
35. Jalaludin M, Fuziah M, Hong J, *et al*. Reliability and validity of the Revised Summary of Diabetes Self-Care Activities (SDSCA) for Malaysian children and adolescents. *Malays Fam Physician* 2012;7:10–20.
36. AlJohani KA, Kendall GE, Snider PD. Psychometric Evaluation of the Summary of Diabetes Self-Care Activities-Arabic (SDSCA-Arabic): Translation and Analysis Process. *J Transcult Nurs* 2016;27.
37. Hareri HA AM. Assessments of adherence to hypertension medications and associated factors among patients attending tikur anbessa specialized hospital renal unit, Addis Ababa, Ethiopia 2012. *Int J Nurs Sci* 2013;3:6.
38. Chow SK, Tam BM. Is the kidney Disease Quality of Life-36 (KDQOL-36) a valid instrument for Chinese dialysis patients? *BMC Nephrol* 2014;15:199.
39. Ricardo AC, Hacker E, Lora CM, *et al*. Validation of the Kidney Disease Quality of Life Short Form 36 (KDQOL-36) US Spanish and English versions in a cohort of Hispanics with chronic kidney disease. *Ethn Dis* 2013;23:202–9.
40. Chao S, Yen M, Lin TC, *et al*. Psychometric Properties of the Kidney Disease Quality of Life-36 Questionnaire (KDQOL-36™). *West J Nurs Res* 2016;38:1067–82.
41. Hibbard JH, Mahoney ER, Stockard J, *et al*. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;40(6 Pt 1):1918–30.
42. Rademakers J, Nijman J, van der Hoek L, *et al*. Measuring patient activation in The Netherlands: translation and validation of the American short form Patient Activation Measure (PAM13). *BMC Public Health* 2012;12:577.
43. Zill JM, Dwinger S, Kriston L, *et al*. Psychometric evaluation of the German version of the Patient Activation Measure (PAM13). *BMC Public Health* 2013;13:1027.
44. Prey JE, Qian M, Restaino S, *et al*. Reliability and validity of the patient activation measure in hospitalized patients. *Patient Educ Couns* 2016;99:2026–33.
45. Graffigna G, Barello S, Bonanomi A, *et al*. Measuring patient activation in Italy: translation, adaptation and validation of the Italian version of the patient activation measure 13 (PAM13-I). *BMC Med Inform Decis Mak* 2015;15:109.
46. Aung E, Donald M, Williams GM, *et al*. Joint influence of patient-assessed chronic illness care and patient activation on glycaemic control in type 2 diabetes. *Int J Qual Health Care* 2015;27:117–24.
47. Ahn YH, Kim BJ, Ham OK, *et al*. Factors associated with patient activation for self-management among community residents with Osteoarthritis in Korea. *J Korean Acad of Nurs* 2015;26:303–11.
48. Hendriks SH, Hartog LC, Groenier KH, *et al*. Patient activation in type 2 diabetes: does it differ between Men and Women? *J Diabetes Res* 2016;2016:1–8.


BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

49. Nijman J, Hendriks M, Brabers A, *et al*. Patient activation and health literacy as predictors of health information use in a general sample of Dutch health care consumers. *J Health Commun* 2014;19:955–69.
50. Aung E, Donald M, Coll JR, *et al*. Association between patient activation and patient-assessed quality of care in type 2 diabetes: results of a longitudinal study. *Health Expect* 2016;19:356–66.
51. Blakemore A, Hann M, Howells K, *et al*. Patient activation in older people with long-term conditions and multimorbidity: correlates and change in a cohort study in the United Kingdom. *BMC Health Serv Res* 2016;16:582.
52. Gleason KT, Tanner EK, Boyd CM, *et al*. Factors associated with patient activation in an older adult population with functional difficulties. *Patient Educ Couns* 2016;99:1421–6.
53. Ryvicker M, Feldman PH, Chiu YL, *et al*. The role of patient activation in improving blood pressure outcomes in Black patients receiving home care. *Med Care Res Rev* 2013;70:636–52.
54. Smith SG, Pandit A, Rush SR, *et al*. The role of patient activation in preferences for shared decision making: results from a National Survey of U.S. Adults. *J Health Commun* 2016;21:67–75.
55. Do V, Young L, Barnason S, *et al*. Relationships between activation level, knowledge, self-efficacy, and self-management behavior in heart failure patients discharged from rural hospitals. *F1000Res* 2015;4:150.
56. Fowles JB, Terry P, Xi M, *et al*. Measuring self-management of patients' and employees' health: further validation of the Patient Activation Measure (PAM) based on its relation to employee characteristics. *Patient Educ Couns* 2009;77:116–22.
57. Lubetkin EI, Lu WH, Gold MR. Levels and correlates of patient activation in health center settings: building strategies for improving health outcomes. *J Health Care Poor Underserved* 2010;21:796–808.
58. Abdel-Kader K, Myaskovsky L, Karpov I, *et al*. Individual quality of life in chronic kidney disease: influence of age and dialysis modality. *Clin J Am Soc Nephrol* 2009;4:711–8.
59. Deen D, Lu WH, Rothstein D, *et al*. Asking questions: the effect of a brief intervention in community health centers on patient activation. *Patient Educ Couns* 2011;84:257–60.
60. Druss BG, Zhao L, von Esenwein SA, *et al*. The Health and Recovery Peer (HARP) Program: a peer-led intervention to improve medical self-management for persons with serious mental illness. *Schizophr Res* 2010;118:264–70.
61. Magnezi R, Glasser S, Shalev H, *et al*. Patient activation, depression and quality of life. *Patient Educ Couns* 2014;94:432–7.
62. Hadgkiss EJ, Jelinek GA, Taylor KL, *et al*. Engagement in a program promoting lifestyle modification is associated with better patient-reported outcomes for people with MS. *Neurol Sci* 2015;36:845–52.
63. Mosen DM, Schmittdiel J, Hibbard J, *et al*. Is patient activation associated with outcomes of care for adults with chronic conditions? *J Ambul Care Manage* 2007;30:21–9.
64. Chamie K, Connor SE, Maliski SL, *et al*. Prostate cancer survivorship: lessons from caring for the uninsured. *Urol Oncol* 2012;30:102–8.
65. Cheshire A, Peters D, Ridge D. How do we improve men's mental health via primary care? An evaluation of the Atlas Men's Well-being Pilot Programme for stressed/distressed men. *BMC Fam Pract* 2016;17:13.
66. Hedayati SS, Minhajuddin AT, Toto RD, *et al*. Prevalence of major depressive episode in CKD. *Am J Kidney Dis* 2009;54:424–32.
67. Mujais SK, Story K, Brouillette J, *et al*. Health-related quality of life in CKD Patients: correlates and evolution over time. *Clin J Am Soc Nephrol* 2009;4:1293–301.
68. Zimbudzi E, Lo C, Ranasinha S, *et al*. Predictors of health-related quality of life in patients with co-morbid diabetes and Chronic Kidney Disease. *PLoS One* 2016;11:e0168491.
69. Pinquart M, Sörensen S. Correlates of physical health of informal caregivers: a meta-analysis. *J Gerontol B Psychol Sci Soc Sci* 2007;62:P126–37.
70. Piette JD, Kerr EA. The impact of comorbid chronic conditions on diabetes care. *Diabetes Care* 2006;29:725–31.
71. Gold JL, Dewa CS. Institutional review boards and multisite studies in health services research: is there a better way? *Health Serv Res* 2005;40:291–308.


BMJ Open: first published as 10.1136/bmjopen-2017-017695 on 22 October 2017. Downloaded from http://bmjopen.bmj.com/ on 9 June 2018 by guest. Protected by copyright.

**S1**: Characteristics of patients who did and did not participate in the study at one hospital site

| | **Responders** | **Non-responders** | **p-value** |
|---|---|---|---|
| Patient numbers (n) | 127 | 243 | |
| Age (SD) | 66.6 (10.8) | 68.9 (11.9) | 0.06 |
| Gender (Female) | 30.7 | 39.5 | 0.10 |
| CKD stage (KDOQI %) | | | |
| 3 | 34.2 | 40.9 | |
| 4 | 25.2 | 25.5 | |
| 5 | 33.9 | 40.3 | 0.37 |

KDOQI-Kidney Disease Outcomes Quality Initiative classification of stages of chronic kidney disease

**S2:** Univariable and multivariable regression model for factors associated with low activation in men with diabetes and chronic kidney disease

| Variables | Univariable<br>B (95% CI) | Multivariable<br>B (95% CI) |
|---|---|---|
| Age | -0.11 (-0.32 to 0.12) | - |
| *Health related quality of life* | | - |
| Symptom problem list | 0.12 (0.04 to 0.25)* | |
| Effects of kidney disease | 0.04 (-0.05 to 0.13) | - |
| Burden of kidney disease | 0.08 (0.01 to 0.15)* | - |
| Physical composite summary | 0.06 (-0.15 to 0.26) | - |
| Mental composite summary | 0.23 (0.03 to 0.43)* | 0.23 (0.02 to 0.44)* |
| Duration of diabetes | 0.01 (-0.17 to 0.20) | - |
| Duration of kidney disease | 0.10 (-0.12 to 0.16) | - |
| eGFR | 0.03 (-0.12 to 0.16) | - |
| *Body mass index* | | |
| Healthy weight [1] | Ref | Ref |
| Overweight | -5.08 (-10.96 to 0.80) | - |
| Obese | 2.87 (-2.08 to 7.81) | - |
| *Socioeconomic status* [2] | | |
| Lower | Ref | Ref |
| Lower middle | 0.41 (-5.04 to 5.85) | - |
| Upper lower | -0.63 (-5.98 to 4.73) | - |
| Upper middle | -2.23 (-7.37 to 2.92) | - |
| Upper | 4.65 (-1.04 to 10.33)* | - |
| Self-care composite score | 0.21 (0.01 to 0.40)* | - |

*p<0.05; **p<0.01, ***p<0.001; 1-due to small numbers of underweight patients (N=2), the underweight group was combined with the healthy weight group for this analysis; 2-Socioeconomic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage, a composite measure based on selected census variables, which include income, educational attainment and employment status.

**S3:** Univariable and multivariable regression model for factors associated with low activation in women with diabetes and chronic kidney disease

| Variables | Univariable<br>B (95% CI) | Multivariable<br>B (95% CI) |
|---|---|---|
| Age | 0.02 (-0.21 to 0.26) | - |
| *Health related quality of life* | | |
| Symptom problem list | 0.21 (0.06 to 0.36)** | 0.2 (0.05 to 0.35)** |
| Effects of kidney disease | 0.21 (0.09 to 0.33)** | - |
| Burden of kidney disease | 0.18 (0.09 to 0.27)*** | - |
| Physical composite summary | 0.45 (0.19 to 0.71)** | - |
| Mental composite summary | 0.33 (0.05 to 0.60)* | - |
| Duration of diabetes | -0.09 (-0.35 to 0.17) | - |
| Duration of kidney disease | 0.02 (-0.31 to 0.27) | - |
| eGFR | 0.27 (0.10 to 0.43)** | 0.27 (0.11 to 0.44)** |
| *Body mass index* | | |
| Healthy weight [1] | Ref | Ref |
| Overweight | 4.85 (-4.75 to 14.40) | - |
| Obese | -0.66 (-7.00 to 6.87) | - |
| *Socioeconomic status* [2] | | |
| Lower | Ref | Ref |
| Lower middle | -1.99 (-9.71 to 5.73) | - |
| Upper lower | -3.33 (-11.03 to 4.38) | - |
| Upper middle | -3.40 (-4.93 to 11.73) | - |
| Upper | 0.27 (-6.88 to 7.42) | - |
| Self-care composite score | 0.23 (-0.06 to 0.53 | - |

p<0.05; **p<0.01, ***p<0.001; 1-due to small numbers of underweight patients (N=2), the underweight group was combined with the healthy weight group for this analysis; 2-Socio-economic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage, a composite measure based on selected census variables, which include income, educational attainment and employment status.

## 2.3 Published manuscript: The association between patient activation and self-care practices in patients with co-morbid diabetes and chronic kidney disease

Citation: **Zimbudzi E**., Lo C., Ranasinha S., Kerr PG., Polkinghorne KR., Teede H., Usherwood T., Walker R., Johnson G., Fulcher G., Zoungas S. The association between patient activation and self-care practices in patients with co-morbid diabetes and chronic kidney disease. Health Expectations 2017; 20 (6): 1375–1384.

Accepted: 1 May 2017

DOI: 10.1111/hex.12577

ORIGINAL RESEARCH PAPER

WILEY

# The association between patient activation and self-care practices: A cross-sectional study of an Australian population with comorbid diabetes and chronic kidney disease

Edward Zimbudzi BSc (Hons) RN, MIH[1,2] | Clement Lo MBBS, PhD, FRACP[2,3] | Sanjeeva Ranasinha M Epi, MSc (Applied Stats)[2] | Peter G Kerr MBBS (Hons), PhD, FRACP[1] | Kevan R Polkinghorne BHB, MBChB, FRACP, MClinEpi, PhD[1] | Helena Teede MBBS, FRACP, PhD[2,3] | Timothy Usherwood BSc MD, MBBS, FRACGP, FRCP, FAICD[4,5] | Rowan G Walker MBBS, FRACP, MD, MPH[6] | Greg Johnson B Pharm, Dip Hosp Pharm, MBA[7] | Greg Fulcher MBBS, MD, FRACP[8] | Sophia Zoungas MBBS, PhD, FRACP[2,3,5]

[1]Department of Nephrology, Monash Health, Clayton, Vic, Australia

[2]Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, Clayton, Vic, Australia

[3]Diabetes and Vascular Medicine Unit, Monash Health, Clayton, Vic, Australia

[4]Department of General Practice, Sydney Medical School Westmead, University of Sydney, Sydney, NSW, Australia

[5]The George Institute for Global Health, Camperdown, NSW, Australia

[6]Department of Renal Medicine, Alfred Health, Prahran, Vic, Australia

[7]Diabetes Australia, Canberra, ACT, Australia

[8]Department of Diabetes and Endocrinology, Royal North Shore Hospital, St Leonards, NSW, Australia

**Correspondence**
Sophia Zoungas, Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, Clayton, Vic, Australia.
Email: sophia.zoungas@monash.edu

**Funding information**
This work was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups—Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. C Lo was supported by an Australian Postgraduate Award Scholarship. H Teede was supported by a National Health and Medical Research Council Practitioner Fellowship. S Zoungas was supported by a National Health and Medical Research Council Senior Fellowship.

## Abstract

**Objective:** This study aimed to examine the association between performance of self-care activities and patient or disease factors as well as patient activation levels in patients with diabetes and chronic kidney disease (CKD) in Australia.

**Methods:** A cross-sectional study was conducted among adults with diabetes and CKD (eGFR <60 mL/min/1.73m$^2$) who were recruited from renal and diabetes clinics of four tertiary hospitals in Australia. Demographic and clinical data were collected, as well as responses to the Patient Activation Measure (PAM) and the Summary of Diabetes Self-Care Activities (SDSCA) scale. Regression analyses were performed to determine the relationship between activation and performance of self-care activities.

**Results:** A total of 317 patients (70% men) with a mean age of 66.9 (SD=11.0) years participated. The mean (SD) PAM and composite SDSCA scores were 57.6 (15.5) % (range 0-100) and 37.3 (11.2) (range 0-70), respectively. Younger age, being male, advanced stages of CKD and shorter duration of diabetes were associated with lower scores in one or more self-care components. Patient activation was positively associated

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.
© 2017 The Authors Health Expectations Published by John Wiley & Sons Ltd

with the composite SDSCA score, and in particular the domains of general diet and blood sugar checking ($P<.05$), but not specific diet, exercising and foot checking.

**Conclusion:** In people with diabetes and CKD, a high level of patient activation was positively associated with a higher overall level of self-care. Our results identify subgroups of people who may benefit from tailored interventions to further improve their health outcomes. Further prospective studies are warranted to confirm present findings.

**KEYWORDS**

chronic kidney disease, diabetes, patient activation, self-care, self-management

## 1 | INTRODUCTION

Patient activation specifies the level of patients' involvement with their health care and refers to the extent to which they have the knowledge, motivation, belief, confidence and skills to manage chronic disease, access health care and to partner with health-care providers for disease management.[1-3] Patient activation is an important concept in chronic disease management driven by a person-centred approach and chronic care models.[1,4] Higher levels of patient activation are associated with better patient outcomes compared to lower levels of activation, in chronic diseases.[1,3,5-7] Individuals with low activation are more likely to be hospitalized,[8,9] have a longer length of stay in hospital,[10] have greater health-care costs,[11] are less likely to participate in self-management activities such as blood pressure monitoring[12] and have worst care experiences[13] compared to those with higher activation levels.

Patient self-management is a patient's ability to participate in the management of symptoms, treatment and the physical, psychological and lifestyle consequences associated with chronic disease.[14] There is growing evidence to suggest an association between patient activation levels and performance of self-care activities for single chronic diseases including human immunodeficiency virus,[15] congestive heart failure,[16] schizophrenia[17] and diabetes.[18,19] Patient activation predicts a variety of behaviours such as engaging in exercises, healthy diet and other disease-specific self-care and consumeristic behaviours.[6,12] However, studies are inconsistent in demonstrating an association between patient activation and self-management for patients with diabetes and other long-term diseases including chronic obstructive pulmonary disease (COPD), depression and musculoskeletal pain.[5,12,18,20]

The PAM has previously been used as a screening tool for tailoring self-management interventions or as a quality indicator for

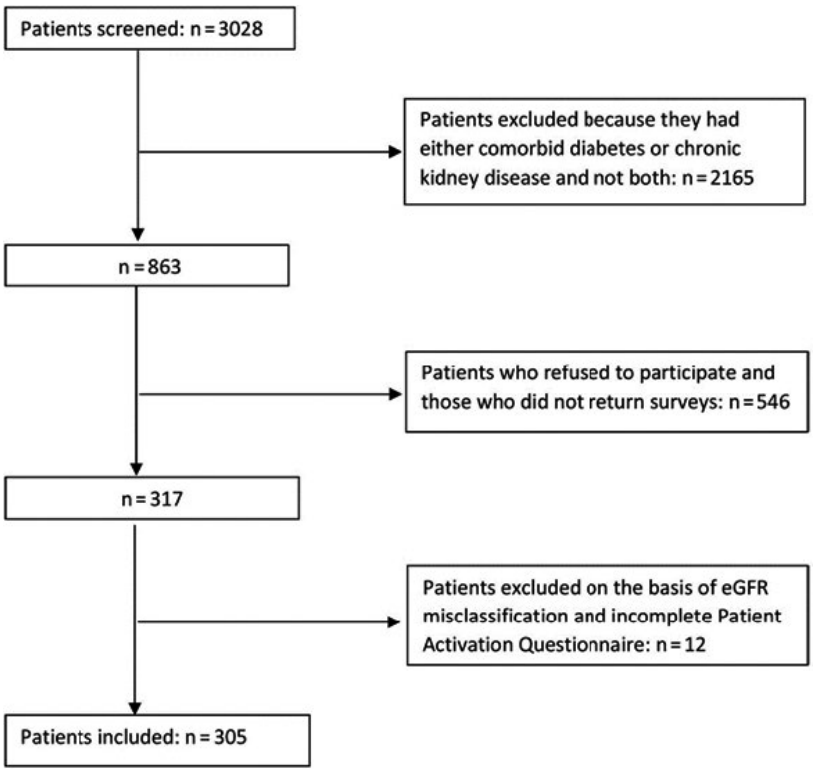



**FIGURE 1** Patient inclusion flow diagram

delivery of care.[21] In the UK, one health service has redesigned the diabetes review process according to the individual's level of activation.[22] Additionally, tailored coaching following activation assessment has resulted in improved clinical indicators and decreased health-care utilization in patients with asthma, coronary artery disease, congestive heart failure, COPD and diabetes.[23] Similarly, tailored care according to activation levels has been used to empower patients to ask questions during clinical reviews.[24]

There is a knowledge gap regarding the relationship between patient activation and self-management in instances of comorbidity and multimorbidity such as diabetes and chronic kidney disease (CKD). This gap is important given that multimorbidity is increasing globally[25,26] and CKD commonly coexists with diabetes[27] and is complex to manage. Moreover, greater understanding of how patient activation may influence performance of self-care activities will be important in the design of interventions to increase self-management.

The purpose of this study was to examine the association between performance of self-care activities and patient or disease factors as well as patient activation levels in patients with diabetes and CKD.

**TABLE 1** Demographic and clinical characteristics for all patients by mean activation and composite SDSCA scores

| | Total N (%) | Mean PAM scores (SD) Range (0-100) | Mean composite SDSCA scores (SD) Range (0-70) |
|---|---|---|---|
| Total | 305 (100) | 57.6 (15.5) | 37.3 (11.2) |
| Gender | | | |
| Male[a] | 212 (69.5) | 57.4 (15.9) | 36.7 (11.5) |
| Female[b] | 93 (30.5) | 58.1 (14.4) | 38.2 (10.3) |
| Age | | | |
| <68 y | 156 (51.1) | 57.2 (15.0) | 37.2 (11.3) |
| >68 y | 149 (48.9) | 58.0 (16.0) | 37.2 (11.3) |
| Socio-economic status | | | |
| Upper | 160 (53.2) | 58.0 (16.3) | 37.2 (11.4) |
| Upper middle | 40 (13.3) | 54.8 (17.2) | 37.3 (9.8) |
| Lower middle | 49 (16.3) | 58.0 (13.7) | 36.0 (11.1) |
| Upper lower | 21 (7.0) | 58.0 (15.6) | 36.0 (11.1) |
| Lower | 31 (10.3) | 56.3 (10.2) | 38.5 (10.3) |
| Smoking status | | | |
| Yes | 18 (5.9) | 58.5 (11.3) | 34.8 (12.7) |
| No | 287 (94.1) | 57.5 (15.7) | 37.3 (12.7) |
| Stage of CKD[c] | | | |
| 3a | 72 (23.6) | 59.2 (15.9) | 37.4 (11.3) |
| 3b | 79 (25.9) | 58.6 (17.8) | 39.5 (10.5) |
| 4 | 74 (24.3) | 57.5 (15.1) | 35.0 (11.0) |
| 5 | 80 (26.2) | 55.4 (12.7) | 36.9 (11.3) |
| Dialysis | | | |
| Yes | 59 (19.3) | 55.5 (13.0) | 38.4 (9.6) |
| No | 246 (80.7) | 58.1 (16.0) | 36.9 (11.5) |
| Diabetes duration | | | |
| 0-8 y | 81 (26.6) | 58.6 (16.1) | 34.5 (12.5)* |
| 9-18 y | 80 (26.2) | 54.6 (15.2) | 36.6 (11.9) |
| 19-25 y | 80 (26.2) | 59.8 (13.7) | 38.4 (9.5) |
| 26 y and over | 64 (21.0) | 57.3 (16.9) | 40.0 (9.3) |
| Kidney disease duration | | | |
| <5 y | 125 (41.0) | 58.1 (15.3) | 37.9 (11.6) |
| >5 y | 180 (59.0) | 57.3 (15.6) | 36.7 (10.7) |

[a]Missing PAM data for two male participants, not included in analysis; [b]Missing PAM data for one female participant, not included in analysis; [c]Kidney Disease Outcomes Quality Initiative staging of CKD based on GFR, 3a (45-59), 3b (30-44), 4 (15-29) 5 (less than 15 or on dialysis); age and CKD duration were stratified by median and diabetes duration by quartiles; *$P$<.05.

**TABLE 2** Summary of factors predicting self-management behaviours in patients with diabetes and chronic kidney disease

| | Composite self-management score | | General diet | | Specific diet | |
|---|---|---|---|---|---|---|
| | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable |
| Covariates | B (95% CI) | | B (95% CI) | | B (95% CI) | |
| Age | 0.05 (−0.02; 0.09) | - | 0.1 (0.02; 0.1)** | 0.06 (0.02; 0.09)** | −0.003 (−0.03; 0.03) | - |
| Gender | | | | | | |
| Male | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Female | 1.4 (−1.3; 4.2) | - | 0.4 (−0.5; 1.3) | - | −0.1 (−0.8; 0.7) | - |
| SES (quintiles) | | | | | | |
| Upper | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Upper middle | −1.4 (−5.4; −2.6) | - | −1.1 (−2.4; 0.2) | - | 0.5 (−1.6; 0.6) | - |
| Lower middle | −0.04 (−4.5; −3.7) | - | −0.04 (−1.4; 1.3) | - | 0.2 (−0.9; 1.3) | - |
| Upper lower | −1.7 (−5.7; −2.4) | - | −0.4 (−1.7; 1.0) | - | −0.4 (−1.5; 0.7) | - |
| Lower | −0.6 (−4.6; −3.5) | - | −0.6 (−2.0; 0.7) | - | 0.1 (−1.0; 1.2) | - |
| DM duration | 0.2 (0.1; 0.3)** | 0.2 (0.1; 0.3)** | 0.02 (−0.02;0.1) | - | 0.01 (−0.02; 0.04) | - |
| CKD duration | −0.03 (−0.2; 0.1) | - | −0.001 (−0.05; 0.04) | | −0.03 (−0.06; 0.01) | - |
| Stage of CKD | | | | | | |
| 3a | 1 (ref) | - | 1 (ref) | | 1 (ref) | |
| 3b | 2.5 (−1.1; 6.1) | - | 0.8 (−0.4; 2.0) | - | 0.5 (−0.5; 1.5) | - |
| 4 | −2.2 (−5.9; 1.4) | - | 0.6 (−0.7; 1.8) | - | −0.1 (−1.0; 0.9) | - |
| 5 | −0.5 (−4.1; 3.1) | - | 0.2 (−1.0; 1.4) | - | 0.9 (−0.1; 1.8) | - |
| PAM levels | | | | | | |
| 4 | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| 3 | −3.6 (−7.2; −0.1)* | −4.1 (−7.6; −0.6)* | −1.7 (−3.1; −0.4)* | −1.1 (−2.3; 0.1) | 0.4 (−0.6; 1.3) | - |
| 2 | −4.9 (−8.7; −0.1)* | −5.3 (−9.1; −1.8)** | −1.3 (−2.6; 0.003)* | −1.3 (−2.6; −0.01)* | 0.4 (−0.7; 1.4) | - |
| 1 | −5.8 (−9.7; −1.9)** | −5.6 (−9.5; −1.8)** | −1.2 (−2.4; 0.04) | −1.8 (−3.1; −0.5)** | −0.2 (−1.2; 0.9) | - |
| | Exercising | | Blood sugar checking | | Foot checking | |
| | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable |
| Covariates | B (95% CI) | | B (95% CI) | | B (95% CI) | |
| Age | −0.01 (−0.05; 0.03) | - | 0.01 (−0.04; 0.1) | - | 0.01 (−0.04; 0.1) | - |
| Gender | | | | | | |
| Male | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Female | −0.6 (−1.6; 0.3) | - | 1.4 (0.3; 2.5)* | 1.6 (0.5; 2.7)* | 0.7 (−0.5; 1.9) | - |
| SES (quintiles) | | | | | | |
| Upper | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Upper middle | 0.2 (−1.2; 1.6) | - | −0.2 (−1.8; 1.4) | - | 0.4 (−1.3; 2.1) | - |
| Lower middle | 0.2 (−1.2; 1.7) | - | −0.3 (−2.0; 1.3) | - | −1.4 (−3.2; 0.3) | - |
| Upper lower | −0.1 (−1.5; 1.3) | - | −0.1 (−1.8; 1.6) | - | −1.0 (−2.7; 0.7) | - |
| Lower | 0.3 (−1.1; 1.7) | - | −0.3 (−2.0; 1.3) | - | 0.02 (−1.7; 1.7) | - |
| DM duration | −0.01 (−0.05; 0.03) | - | 0.1 (0.06; 0.2)*** | 0.1 (0.07; 0.2)*** | 0.1 (0.01; 0.1)** | 0.1 (0.01; 0.1)* |
| CKD duration | −0.02 (−0.1; 0.03) | - | −0.01 (−0.1; 0.1) | - | 0.02 (−0.04; 0.1) | - |
| Stage of CKD | | | | | | |
| 3a | 1 (ref) | - | 1 (ref) | | 1 (ref) | |
| 3b | −0.1 (−1.4; 1.1) | - | 0.7 (−0.7; 2.2) | - | 0.1 (−1.5; 1.5) | - |

(Continues)

**TABLE 2** (Continued)

| | Exercising | | Blood sugar checking | | Foot checking | |
|---|---|---|---|---|---|---|
| | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable |
| Covariates | B (95% CI) | | B (95% CI) | | B (95% CI) | |
| 4 | −0.8 (−2.1; 0.4) | - | −0.6 (−2.1; 0.9) | - | −1.8 (−3.3; −0.2)** | −1.7 (−3.0; −0.5)** |
| 5 | −1.6 (−2.9; −0.4)* | −1.3 (−2.3; −0.3)* | −0.3 (−1.8; 1.1) | - | −0.1 (−1.6; 1.4) | - |
| PAM levels | | | | | | |
| 4 | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| 3 | −1.0 (−2.3; 0.2) | - | −1.1 (−2.6; 0.3) | −1.5 (−2.9; −0.1)* | −0.8 (−2.3; 0.8) | - |
| 2 | −1.5 (−2.8; −0.1)* | - | −1.9 (−3.5; −0.3)* | −2.1 (−3.7; −0.6)** | −0.9 (−2.6; 0.7) | - |
| 1 | −1.3 (−2.6; 0.1) | - | −2.0 (−3.7; −0.4)* | −1.9 (−3.5; −0.4)* | −0.9 (−2.6; 0.8) | - |

*$P$<.05; **$P$<.01; ***$P$<.001; SES—socio-economic status; DM—diabetes mellitus; CVD cardiovascular disease CKD—chronic kidney disease; PAM—patient activation measure; B (95% CI)—confidence intervals for beta coefficients, which represent the amount that the dependent variable (SDSCA domains) changes when the independent variable changes by 1 unit.

## 2 | METHODS

### 2.1 | Study design and participants

The design and recruitment of participants for this study have been described in great detail previously.[28] In short, patients attending diabetes and renal outpatient clinics of four public tertiary hospitals in the states of Victoria and New South Wales (Monash Health, Alfred Health, Royal North Shore Hospital and Concord Hospital) between 2013 and December 2014 were recruited.

Participants were included if they received their routine care at these hospitals and had a diagnosis of diabetes (either type 1 or type 2) and CKD stages 3-5 (estimated glomerular filtration rate <60 mL/min/1.73 $m^2$) including dialysis. Exclusion criteria included age less than 18 years of age, severe cognitive impairment and inability to communicate in English. Participants were identified as having diabetes if this was recorded from previous hospital records with the diagnosis of diabetes consistent with World Health Organization[29] criteria.

Participants were recruited prospectively from clinics and completed the Patient Activation Measure (PAM-13)[30] and the Summary of Diabetes Self-Care Activities (SDSCA)[31] questionnaires (Supplementary Appendices A and B). Additionally, for each patient, a corresponding clinical survey was also completed by the site study staff or the clinician, using standardized procedures. Information obtained from the clinical survey included demographic characteristics such as age and gender. Disease-specific characteristics such as diabetes duration, type of diabetes treatment, current HbA1c, CKD duration, CKD stage and current eGFR were also included (Supplementary Appendix C). The CKD EPI formula described by Levey and others[32] was used to estimate eGFR. The units of measurement for eGFR were millilitre per minute per 1.73 $m^2$.

Socio-economic measures were estimated using the Australian Bureau of Statistics data.[33] Postcodes were classified in accordance with the Index of Relative Social Disadvantage (IRSD), an index that provides a summary on a variety of data about the socio-economic conditions of people living in an area.[33] This was followed by categorizing the IRSD scores for each postcode into quintiles, where the lowest quintile represented 20% of postcodes with greatest socio-economic deprivation. Written informed consent was obtained from all participants. The study received ethics approval from Monash University and the respective health service ethics committees.

### 2.2 | Patient activation

The American version of the PAM-13[30] was used to evaluate the patients' level of involvement in their health care. The PAM scale examines participants' beliefs, knowledge and confidence in performing several self-management activities and then yields a score based on patients' answers to the 13 questions.[34] There are four alternative responses to each of the 13 items namely, "disagree strongly, disagree, agree and agree strongly" and fifth response option "not applicable" (N/A) was available for all items.

The authors used a standardized spreadsheet provided by Insignia Health® to calculate the PAM score.[35] We excluded participants who responded to less than 7 items or if all questions were answered with "disagree strongly" or "agree strongly." The mean PAM score was then calculated on all items leaving out the ones thought to be non-applicable by the participants. The raw mean score was converted into a standardized activation score ranging from 0 to 100 creating the PAM scores which were classified into the four levels of activation: level 1 (score <47.0), level 2 (score 47.1-55.1), level 3 (score 55.2-67.0) and level 4 (score >67.0) as per Insignia Health® scoring rules.[35]

### 2.3 | Outcomes

Self-management was evaluated by the SDSCA questionnaire,[31] a self-report measure of how often participants perform diabetes self-care activities. The SDSCA questionnaire has been utilized in several studies and settings and is deemed to be reliable, valid and sensitive[36–38] in evaluating diabetes self-management in adults. This

study used a version of the SDSCA questionnaire that comprised of items assessing five domains of diabetes self-management which are "general diet (2 items), specific diet (2 items), exercise (2 items), blood glucose testing (2 items) and foot care (2 items)".[31] The medication self-management component was excluded based on previous reports of its "ceiling effects and lack of variability among participants".[31] The smoking self-management component was also excluded because smoking behaviour was relevant to smokers only.

### 2.4 | Statistical analysis

Results are presented as mean and standard deviation (SD) and median and interquartile range (IQR) for normal and non-normally distributed data, respectively. Duration of diabetes was categorized into quartiles. First, chi-squared or t tests (as appropriate) examined differences in patient and disease characteristics by performance of self-care activities and levels of patient activation using PAM score as a continuous variable. Second, chi-squared tests for linear trend examined differences in performance of self-care activities across the four levels of patient activation (PAM score categories 1-4). Third, univariable and multivariable linear regression models assessed the relationship between the performance of self-care activities (composite SDSCA score) and the four levels of patient activation (PAM score categories 1-4), and any potential effect of patient or disease characteristics (any variable with a *P* value of <.1 in the univariable analysis). Similar models assessed the relationship between the individual self-care activities and the four levels of patient activation. A sensitivity analysis examined the effect of substitution of PAM score as a continuous variable into the models. All analyses were performed with Stata version 11 (Statacorp, College Station, TX). Statistical significance was indicated by a *P* value of <.05.

## 3 | RESULTS

### 3.1 | Patient characteristics

A total of 3028 patients were screened and 305 were included in the analyses after exclusion of nine patients who had their eGFR misclassified (>60 mL/min/$m^2$) and three patients who had incomplete PAM data (Figure 1). There were no differences in age, gender and stage of kidney disease between responders and non-responders (Table S1). Participants' age ranged from 32 to 90 years (median 68 years), with a predominance of men (70% of all participants). The mean (SD) PAM and composite SDSCA scores were 57.6 (15.5) % (range 0-100) and 37.3 (11.2) (range 0-70), respectively (Table 1). Approximately 50% of participants were of upper socio-economic status. Patient activation did not significantly differ by gender, age, socio-economic status, CKD stage, dialysis status, diabetes, and CKD duration (Table 1). Participation in self-care activities did not significantly differ by any demographic and clinical characteristics except for diabetes duration (*P*<.05).

### 3.2 | Association between self-care activities and patient or disease factors

Patient factors associated with self-care activities are shown in Table 2. On multivariable analysis, younger age was associated with lower scores in the general diet domain (all *P* value <.05). Male patients had lower scores in the blood sugar checking domain where they scored 1.6 points less than female patients. A shorter duration of diabetes was associated with lower composite scores, and with lower scores in the blood sugar checking and foot checking domains (all *P*<.05). (Figure 2). Patients with stage 5 kidney disease scored 1 point less than patients with stage 3a disease in the exercising domains. No association was found between socio-economic status and the composite score or any specific self-care domain.

### 3.3 | Association between self-care activities and patient activation

With decreasing patient activation level, the mean scores for the composite self-care score and the domains of general diet and blood sugar testing (all *P*<.05) decreased significantly, whereas the mean scores for the domains of specific diet, exercising and foot checking did not (Figure 3). Patients with level 1 activation scored 2-6 points lower than patients with level 4 activation (reference group) for the composite score, and the domains of general diet and blood sugar testing (Table 2).

In univariable and multivariable analyses, the level of patient activation was positively associated with the composite self-care score and the domains of general diet and blood sugar checking (all *P*<.05) but not the domains of specific diet, exercising and foot checking (Table 2). When patient activation was included in the models as a continuous variable, the results remained similar (data not shown).

## 4 | DISCUSSION

In our study, among patients with comorbid diabetes and CKD, we have demonstrated an association between patient activation and diabetes self-care activities. A higher patient activation level was associated with a higher overall self-care score. However, this association was not observed for all specific self-care domains; only for general diet and blood sugar checking. Additionally, different patient and disease characteristics were associated with diabetes self-care: younger age and male gender were associated with less home blood glucose monitoring, more severe CKD was associated with less foot checking and exercising, and a shorter duration of diabetes was associated with lower overall self-care score as well as less blood sugar checking and foot checking.

In patients with comorbid diabetes and CKD, higher patient activation levels were associated with higher composite self-care scores. Previous studies have only examined this association for single chronic diseases, such as diabetes.[18] In patients with diabetes, the relationship

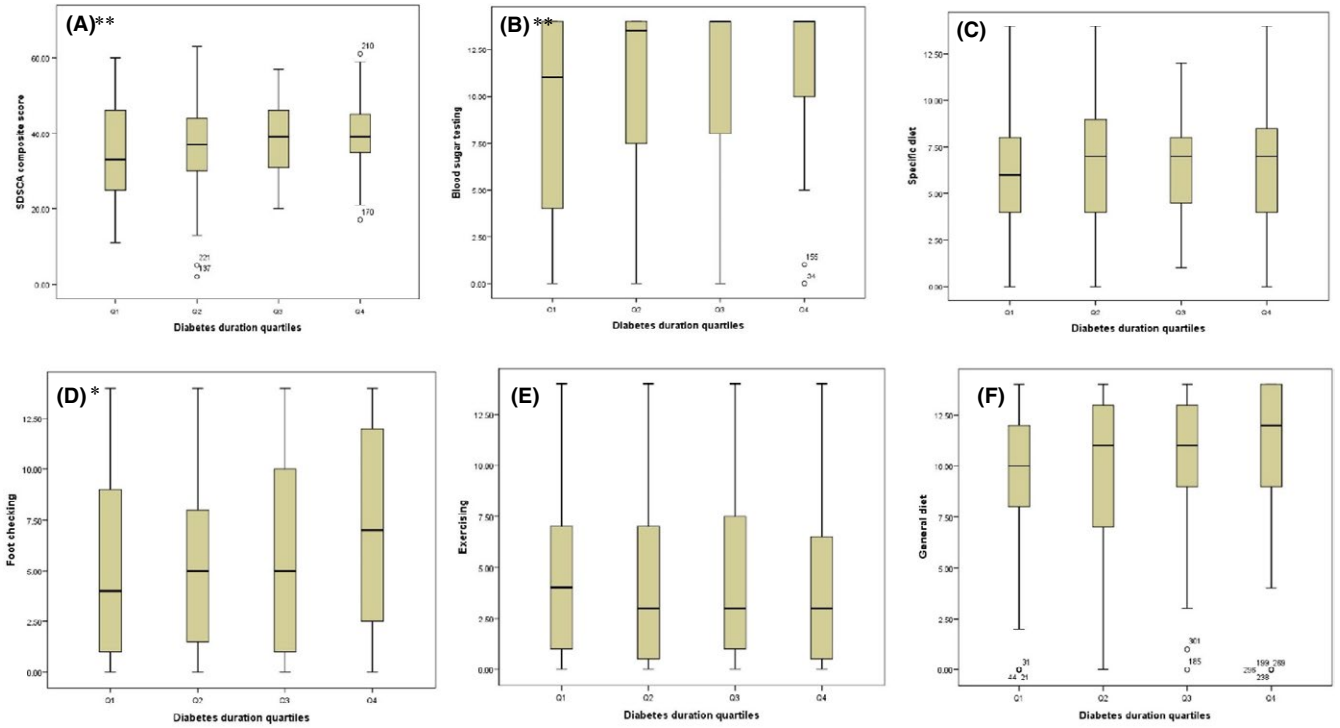



**FIGURE 2** A-F, Nonparametric test for trend assessing differences in self-management practices across diabetes duration quartiles. ***P*<.01 and **P*<.05

is inconsistent, with some studies showing a positive association between patient activation and self-care activities[5,39] and others showing no association.[18] In patients with CKD, this association has not been explored. Our study adds to the literature by showing that in the setting of multimorbidity, the association is positive and independent of certain potential confounding patient or disease factors such as age, gender and disease duration.

Interestingly, the association between patient activation levels and diabetes self-care was not observed for all specific self-care domains. While there was a positive association between general diet and blood sugar checking, there was no association between patient activation levels and specific diet, exercising and foot checking domains. This suggests that an activated patient may not necessarily or automatically participate in all self-care activities—they not only need to have knowledge, motivation and skills to self-manage, but they also need to have the physical and financial ability to self-manage across all domains of diabetes self-management. A possible reason for the lack of association between PAM and exercise and foot checking is that both these activities require a certain degree of physical fitness and ability, which is compromised in patients with diabetes and CKD due to comorbidity.[40,41] Similarly, a lack of association between PAM and a specific diet could be that the specific diabetes diet may be financially prohibitive.[42,43] These results highlight the importance of addressing all self-care domains to improve self-management for patients with comorbid diabetes and CKD across all spectrums of activation.

We found an association between younger ages and lower self-care scores in the domain of general diet independent of patient activation. The explanation is likely to be multifactorial, but we hypothesize that younger patients may be less motivated to self-manage compared to older patients, as risk perception is altered in younger populations, especially in males[44,45] and they have competitive priorities that take precedence such as socializing and work commitments.[46] Lack of knowledge may also contribute but less so than other factors given that younger patients are reported to have greater diabetes knowledge than older patients.[47]

Additionally, we found that a shorter duration of diabetes was associated with lower self-care scores. Previous studies among patients with diabetes have not been consistent with some reporting an association between lower self-care scores with a shorter duration of diabetes,[48,49] while others reported an association between lower self-care scores and longer duration of diabetes.[50,51] In patients with comorbid diabetes and CKD, we found a shorter duration of diabetes to be associated with lower self-care scores. This suggests that patients with a shorter duration of diabetes may not be exposed to sufficient diabetes education or have not yet mastered self-management skills, and should be targeted by interventions to improve self-management such as tailored Diabetes Self-Management Education and support[52]. Alternatively, participants with a longer duration of diabetes are likely to be older and may have some physical limitations such that they receive more attention and social support to improve their ability to self-manage.[53]

More advanced CKD was associated with lower scores in the self-care domains of exercising and foot checking. Exercising and foot checking require a certain level of mobility and physical fitness such

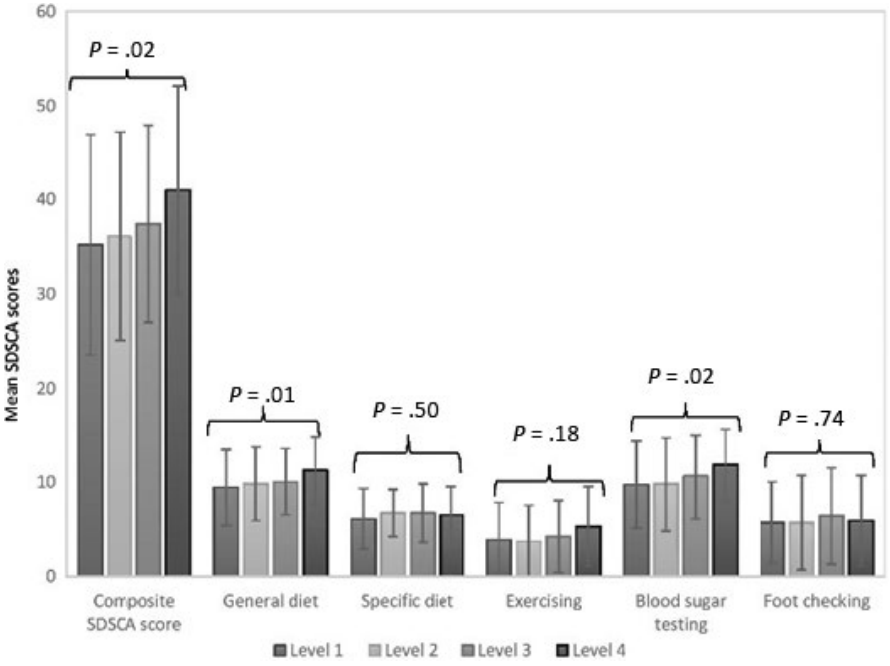



**FIGURE 3** Mean scores of the composite SDSCA scale and the five individual SDSCA domains across ordered levels of patient activation. Statistical significance values are for trend across patient activation levels 1 to 4

that patients with advanced CKD with lower exercise tolerance, and functional capacity, and more muscle wasting cannot as easily complete self-care activities without assistance.[54,55] This emphasizes the importance of the actual physical fitness of an individual in performing self-care activities and is an important factor to consider when individualizing management of a patient with advanced diabetes and CKD.

Our findings should be interpreted in the light of the strengths and limitations of our study. The strengths include that our study provides insight into the level of activation and utility of the PAM in patients with diabetes and moderate to severe CKD, a group of patients who may have a greater need for support to engage in their health-care needs. Our data are consistent with and extends the findings of previous longitudinal studies by assessing patients across different stages of CKD. This informs the provision of targeted interventions to improve the activation levels of patients with more advanced renal disease. The other strengths include the inclusion of several demographic and clinical variables as potential predictors for diabetes self-management behaviour, and the use of valid and reliable tools to measure patient activation[30] and diabetes self-management.[31] Additionally, the study population was drawn from multiple hospitals across Australia, increasing generalizability of our findings. Potential limitations are due to the cross-sectional nature of the study design, which did not allow us to track patient activation patterns over time. Assessment of patient activation over time permits an early identification of patients in whom a change in activation levels may flag a change in health status. Moreover, longitudinal PAM data can be used to develop risk prediction models that predict adverse patient outcomes.[56] Another apparent limitation was the modest response rate of 38.5%, which is, however, comparable to other studies in people with diabetes.[18,57] We did not collect data on some factors such as depression and health literacy, which have been found to be associated with patient activation in different population groups.[58,59] In addition, our sample of participants who attend hospital may be a biased group from the aspect of utilizers of the service.

Our findings have important implications for practice and future research. First, targeted multifactorial risk reduction interventions focusing on subgroups of patients identified in this study, who are likely to perform poorly in self-care activities, may improve health outcomes. There is evidence that such interventions could be delivered optimally through collaborative care,[60] a key feature of combined diabetes kidney specialist clinics, which often have a multidisciplinary team.[61] Second, we have shown that highly activated patients are more likely to participate in self-care activities than those with low activation levels. Additionally, assessment of patient activation in this patient group, which is already suffering a double burden of chronic disease,[62,63] ensures that resources are directed to those who need them most, thereby improving on resource utilization and reduction in health inequalities. Our study, being of an exploratory nature, opens up opportunities for future research, which should include well-designed and disease-specific longitudinal studies to validate and extend our findings.

In patients with comorbid diabetes and CKD, although a high level of patient activation in self-care is associated with a high level of patient self-management in general, this is not the case across all individual domains of diabetes self-care. Patient age, gender, duration of diabetes and stage of CKD may also influence patient self-management in comorbid diabetes and CKD.

## ACKNOWLEDGEMENT

We acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

## CONFLICTS OF INTEREST

The authors declare no conflicts of interest in relation to this work.

## REFERENCES

1. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;1:1005-1026.
2. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *Journal of General Internal Medicine*. 2012;27:520-526. doi:10.1007/s11606-011-1931-2.
3. Remmers C, Hibbard JF, Mosen DM, Wagenfield M, Hoye RE, Jones C. Is patient activation associated with future health outcomes and healthcare utilization among patients with diabetes? *Journal of Ambulatory Care Management*. 2009; 32: 320–327. doi: 10.1097/JAC.0b013e3181ba6e77.
4. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. *Milbank Q*. 1996;74:511-544.
5. Mayberry R, Willock RJ, Boone L, Lopez P, Qin H, Nicewander D. A High Level of Patient Activation Is Observed But Unrelated to Glycemic Control Among Adults With Type 2 Diabetes. *Diabetes Spectr*. 2010;23:171-176.
6. Mosen DM, Schmittdiel J, Hibbard J, Sobel D, Remmers C, Bellows J. Is patient activation associated with outcomes of care for adults with chronic conditions? *J Ambul Care Manage*. 2007;30:21-29.
7. Salyers MP, Matthias MS, Spann CL, Lydick JM, Rollins AL, Frankel RM. The role of patient activation in psychiatric visits. *Psychiatr Serv* 2009;60:1535-1539.
8. Begum N, Donald M, Ozolins IZ, Dower J. Hospital admissions, emergency department utilisation and patient activation for self-management among people with diabetes. *Diabetes Res Clin Pract* 2011;93:260-267.
9. Hibbard JH, Cunningham PJ. How engaged are consumers in their health and health care, and why does it matter? *Res Brief*. 2008;8:1-9.
10. Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Aff (Millwood)*. 2013;32:207-214.
11. Greene J, Hibbard JH, Sacks R, Overton V, Parrotta CD. When patient activation levels change, health outcomes and costs change, too. *Health Aff (Millwood)*. 2015;34:431-437.
12. Hibbard JH, Mahoney ER, Stock R, Tusler M. Do increases in patient activation result in improved self-management behaviors? *Health Serv Res* 2007;42:1443-1463.
13. Greene J, Hibbard JH, Sacks R, Overton V. When seeing the same physician, highly activated patients have better care experiences than less activated patients. *Health Aff* 2013;32:1299-1305.
14. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. *Patient Education and Counseling* 2002; 48:177-187.
15. Marshall R, Beach MC, Saha S, et al. Patient activation and improved outcomes in HIV-infected patients. *J Gen Intern Med* 2013;28:668-674.
16. Shively MJ, Gardetto NJ, Kodiath MF, et al. Effect of patient activation on self-management in patients with heart failure. *J Cardiovasc Nurs* 2013;28:20-34.
17. Kukla M, Salyers MP, Lysaker PH. Levels of patient activation among adults with schizophrenia: associations with hope, symptoms, medication adherence, and recovery attitudes. *J Nerv Ment Dis* 2013;201:339-344.
18. Hendriks M, Rademakers J. Relationships between patient activation, disease-specific knowledge and health outcomes among people with diabetes; a survey study. *BMC Health Serv Res*. 2014;14:393.
19. Rask KJ, Ziemer DC, Kohler SA, Hawley JN, Arinde FJ, Barnes CS. Patient Activation Is Associated With Healthy Behaviors and Ease in Managing Diabetes in an Indigent Population. *Diabetes Educ*. 2009;35:622-630.
20. Turner A, Anderson JK, Wallace LM, Bourne C. An evaluation of a self-management program for patients with long-term conditions. *Patient Educ Couns* 2015;98:213-219.
21. Roberts NJ, Kidd L, Dougall N, Patel IS, McNarry S, Nixon C. Measuring patient activation: The utility of the Patient Activation Measure within a UK context-Results from four exemplar studies and potential future applications. *Patient Educ Couns* 2016;99:1739-1746.
22. National Health Service. Independent evaluation of the feasibility of using the patient activation measure in the NHS in England: early findings. 2015.
23. Hibbard JH, Greene J, Tusler M. Improving the outcomes of disease management by tailoring care to the patient's level of activation. *Am J Manag Care*. 2009;15:353-360.
24. Deen D, Lu WH, Rothstein D, Santana L, Gold MR. Asking questions: the effect of a brief intervention in community health centers on patient activation. *Patient Educ Couns* 2011;84:257-260.
25. Fortin M, Soubhi H, Hudon C, Bayliss EA, van den Akker M. Multimorbidity's many challenges. *BMJ* 2007;334:1016-1017.
26. Vos T, Barber RM, Bell B, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;386:743-800.
27. Ceramidas DM, Glasgow NJ. Multi-morbidity: a system design challenge in delivering patient-centred care. *Aust Health Rev* 2013;37:309-311.
28. Zimbudzi E, Lo C, Ranasinha S, et al. Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. *J Diabetes Complications* 2017;31:427-432.
29. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF Consultation. Geneva: 2006.
30. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. *Health Serv Res* 2005;1:1918-1930.
31. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*. 2000;23:943-950.
32. Levey AS, Stevens LA, Schmid CH, et al. A new equation to estimate glomerular filtration rate. *Ann Intern Med* 2009;150:604-612.
33. Australian Bureau of Statistics. Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2011. Canberra: Australian Bureau of Statistics, 2013 Contract No.: 2033.0.55.001.
34. Lopez JS, Snyder CR, Maddux JE. Self-Efficacy: The Power of Believing You Can. 'Oxford University Press'; 2009.
35. Insignia Health. *Patient Activation Measure (PAM) 13TM License Materials*. Portland USA: Insignia Health; 2010.
36. AlJohani KA, Kendall GE, Snider PD. Psychometric Evaluation of the Summary of Diabetes Self-Care Activities-Arabic (SDSCA-Arabic): Translation and Analysis Process. *J Transcult Nurs* 2016;27:65-72.
37. Freitas S, Freitas da Silva G, Neta D, Vilarouca da Silva A. Analysis of the self-care of diabetics according to by the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA). *Acta Scientiarum Health Sciences*. 2014;36:73-81.
38. Jalaludin M, Fuziah M, Hong J, Mohamad Adam B, Jamaiyah H. Reliability and Validity of the Revised Summary of Diabetes Self-Care Activities (SDSCA) for Malaysian Children and Adolescents. *Malays Fam Physician*. 2012;7:10-20.
39. Rask KJ, Ziemer DC, Kohler SA, Hawley JN, Arinde FJ, Barnes CS. Patient activation is associated with healthy behaviors and ease in managing diabetes in an indigent population. 2009; 35:622-630.

40. Fortin M, Lapointe L, Hudon C, Vanasse A, Ntetu AL, Maltais D. Multimorbidity and quality of life in primary care: a systematic review. *Health Qual Life Outcomes* 2004;2:51.
41. Heyworth IT, Hazell ML, Linehan MF, Frank TL. How do common chronic conditions affect health-related quality of life? *Br J Gen Pract* 2009;59:e353-e358.
42. Ebrahim Z, De Villiers A, Ahmed T. Factors influencing adherence to dietary guidelines: a qualitative study on the experiences of patients with type 2 diabetes attending a clinic in Cape Town. *J Endocrinol Metab Diabetes South Africa*. 2014;19:76-84. https://doi.org/10.1080/16089677.2014.11073604.
43. Houle J, Lauzier-Jobin F, Beaulieu MD, et al. Socioeconomic status and glycemic control in adult patients with type 2 diabetes: a mediation analysis. *BMJ Open Diabetes Res Care*. 2016;4:e000184.
44. Reyes-Velázquez W, Sealey-Potts C. Unrealistic Optimism, Sex, and Risk Perception of Type 2 Diabetes Onset: Implications for Education Programs. *Diabetes Spectr*. 2015;28:5.
45. Diaz VA, Mainous 3rd AG, Williamson D, Johnson SP, Knoll ME. Cardiovascular and diabetes risk perception in a Hispanic community sample. *Ethn Dis* 2012;22:5-11.
46. Wu YF, Xie GQ, Li Y, Zhao LC, Zhou BF. [The current status on the prevalence, awareness, treatment and control of diabetes mellitus in several Chinese subpopulations]. *Zhonghua Liu Xing Bing Xue Za Zhi*. 2005;26:564-568.
47. Firestone DN, Jimenez-Briceno L, Reimann JO, Talavera GA, Polonsky WH, Edelman SV. Predictors of diabetes-specific knowledge and treatment satisfaction among Costa Ricans. *Diabetes Educ*. 2004;30:281-292.
48. Chang HY, Chiou CJ, Lin MC, Lin SH, Tai TY. A population study of the self-care behaviors and their associated factors of diabetes in Taiwan: results from the 2001 National Health Interview Survey in Taiwan. *Prev Med* 2005;40:344-348.
49. Rothman RL, Malone R, Bryant B, et al. The Spoken Knowledge in Low Literacy in Diabetes scale: a diabetes knowledge scale for vulnerable patients. *Diabetes Educ*. 2005;31:215-224.
50. Adwan MA, Najjar YW. The relationship between demographic variables and diabetes self-management in diabetic patients in Amman city/Jordan. *Glob J Health Sci*. 2013;5:213-220.
51. Huang M, Zhao R, Li S, Jiang X. Self-Management Behavior in Patients with Type 2 Diabetes: A Cross-Sectional Survey in Western Urban China. *PLoS ONE*. 2014;9:e95138.
52. Powers MA, Bardsley J, Cypress M, et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *Diabetes Care* 2015;38:1372-1382.
53. Ahmad Sharoni SK, Shdaifat EA, Mohd Abd Majid HA, Shohor NA, Ahmad F, Zakaria Z. Social support and self-care activities among the elderly patients with diabetes in Kelantan. *Malays Fam Physician*. 2015;10:34-43.
54. Chin HJ, Ahn SY, Ryu J, et al. Renal function and decline in functional capacity in older adults. *Age Ageing* 2014;43:833-838.
55. Intiso D. The rehabilitation role in chronic kidney and end stage renal disease. *Kidney Blood Press Res* 2014;39:180-188.
56. Hibbard JH, Greene J, Sacks R, Overton V, Parrotta CD. Adding A Measure Of Patient Self-Management Capability To Risk Assessment Can Improve Prediction Of High Costs. *Health Aff* 2016;35:489-494.
57. Adams KF, Sperl-Hillen JM, Davis H, et al. Factors Influencing Patient Completion of Diabetes Self-Management Education. *Diabetes Spectrum*. 2013;26:40-45.
58. Schmaderer MS, Zimmerman L, Hertzog M, Pozehl B, Paulman A. Correlates of Patient Activation and Acute Care Utilization Among Multimorbid Patients. *West J Nurs Res* 2016;38:1335-1353.
59. Magnezi R, Glasser S, Shalev H, Sheiber A, Reuveni H. Patient activation, depression and quality of life. *Patient Educ Couns*. 2014;94:432-437.
60. Dennis SM, Zwar N, Griffiths R, et al. Chronic disease management in primary care: from evidence to policy. *Med J Aust*. 2008;188(8 Suppl):S53-S56.
61. Patel M, Shilliday IR, McKay GA. A combined diabetes renal clinic improves risk factor management, progression of renal disease in a district general hospital. *J Eval Clin Pract*. 2009;15:832-835.
62. Foley RN, Collins AJ. The growing economic burden of diabetic kidney disease. *Curr DiabRep*. 2009;9:460-465.
63. McQueen RB, Farahbakhshian S, Bell KF, Nair KV, Saseen JJ. Economic burden of comorbid chronic kidney disease and diabetes. *J Med Econ*. 2017;14:1-7.


**How to cite this article:** Zimbudzi E, Lo C, Ranasinha S, et al. The association between patient activation and self-care practices: A cross-sectional study of an Australian population with comorbid diabetes and chronic kidney disease. *Health Expect*. 2017;20:1375–1384. https://doi.org/10.1111/hex.12577

## 2.4 Conclusion

Patients with co-morbid diabetes and CKD reported low levels of activation. Factors associated with lower activation were older age and lower quality of life scores. A high level of patient activation was positively associated with a higher overall level of self-management. Patient age, gender, duration of diabetes and stage of CKD influenced patient self-management among patients with co-morbid diabetes and CKD. Longitudinal studies are needed to better understand the effects over time of factors influencing patient activation and self-management in this population.

# CHAPTER 3

# DETERMINANTS OF HEALTH-RELATED QUALITY OF LIFE

## 3.1 Introduction

Evidence regarding the determinants of health-related quality of life (HRQOL) in patients with co-morbid diabetes and chronic kidney disease (CKD) is limited. However, understanding factors that may improve the HRQOL of this group of patients is critical for optimising the patient experience and outcomes. Chapter 3 has two sections. Section 3.2 examines the factors that influence HRQOL in adults with co-morbid diabetes and CKD. Section 3.3 explores the patient reported barriers to health care that influence HRQOL in patients with co-morbid diabetes and CKD. The studies described in this Chapter were published in PLoS One (Zimbudzi et al., 2016) and Health and Quality of Life Outcomes (Zimbudzi et al., 2018). The Chapter is presented as the published pdf versions of the manuscripts.

## 3.2 Published manuscript: Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease

Citation: **Zimbudzi E**., Lo C., Ranasinha S., Gallagher M., Fulcher F., Kerr PG., Russell G., Teede H., Usherwood T., Walker R., Zoungas S. (2016). Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. PLoS One 2016; 11 (12): e0168491.

PLOS ONE

RESEARCH ARTICLE

# Predictors of Health-Related Quality of Life in Patients with Co-Morbid Diabetes and Chronic Kidney Disease

**Edward Zimbudzi[1,2], Clement Lo[2,3], Sanjeeva Ranasinha[2], Martin Gallagher[4,5], Gregory Fulcher[6,7], Peter G. Kerr[1], Grant Russell[8], Helena Teede[2,3], Tim Usherwood[9,10], Rowan Walker[11], Sophia Zoungas[2,3,9]***

**1** Department of Nephrology, Monash Health, Melbourne, Australia, **2** Monash Centre for Health Research and Implementation (MCHRI), School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia, **3** Diabetes and Vascular Medicine Unit, Monash Health, Clayton, Melbourne, Australia, **4** Concord Clinical School, University of Sydney, Sydney, Australia, **5** The George Institute for Global Health, Sydney, Australia, **6** Department of Diabetes, Endocrinology & Metabolism, Royal North Shore Hospital, Sydney, Australia, **7** Northern Clinical School, University of Sydney, Royal North Shore Hospital, Sydney, Australia, **8** Southern Academic Primary Care Research Unit. School of Primary Health Care, Monash University, Melbourne, Australia, **9** The George Institute for Global Health, University of Sydney, Sydney, Australia, **10** Department of General Practice, Sydney Medical School Westmead, Sydney, Australia, **11** Department of Renal Medicine, the Alfred Hospital, Melbourne, Australia

* sophia.zoungas@monash.edu

CrossMark
click for updates

OPEN ACCESS

**Citation:** Zimbudzi E, Lo C, Ranasinha S, Gallagher M, Fulcher G, Kerr PG, et al. (2016) Predictors of Health-Related Quality of Life in Patients with Co-Morbid Diabetes and Chronic Kidney Disease. PLoS ONE 11(12): e0168491. doi:10.1371/journal.pone.0168491

**Editor:** Pasqual Barretti, Universidade Estadual Paulista Julio de Mesquita Filho, BRAZIL

**Received:** July 5, 2016

**Accepted:** December 1, 2016

**Published:** December 19, 2016

**Copyright:** © 2016 Zimbudzi et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

**Data Availability Statement:** All relevant data are within the paper and its Supporting Information files.

**Funding:** This study was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University

## Abstract

### Background

People living with diabetes and chronic kidney disease (CKD) experience compromised quality of life. Consequently, it is critical to identify and understand factors influencing their health-related quality of life (HRQoL). This study examined factors associated with HRQoL among patients with diabetes and CKD.

### Methods

A cross sectional study among adults with comorbid diabetes and CKD (eGFR <60 mL/min/1.73m$^2$) recruited from renal and diabetes clinics of four large tertiary referral hospitals in Australia was performed. Each participant completed the Kidney Disease Quality of Life (KDQoL ™ -36) questionnaire, which is comprised of two composite measures of physical and mental health and 3 kidney disease specific subscales with possible scores ranging from 0 to 100 with higher values indicating better HRQoL. Demographic and clinical data were also collected. Regression analyses were performed to determine the relationship between HRQoL and potential predictor factors.

### Results

A total of 308 patients were studied with a mean age of 66.9 (SD = 11.0) years and 70% were males. Mean scores for the physical composite summary, mental composite summary, symptom/problem list, effects of kidney disease and burden of kidney disease scales were 35.2, 47.0, 73.8, 72.5 and 59.8 respectively. Younger age was associated with lower scores

of Sydney; Diabetes Australia; and Kidney Health Australia. CL was supported by an Australian Postgraduate Award Scholarship. HT was supported by a NHMRC, Australia Fellowship. SZ was supported by a National Heart Foundation of Australia Fellowship. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing Interests:** The authors have declared that no competing interests exist.

in all subscales except for the physical composite summary. Female gender, obese or normal weight rather than overweight, and smoking were all associated with lower scores in one or more subscales. Scores were progressively lower with more advanced stage of CKD ($p<0.05$) in all subscales except for the mental composite summary.

## Conclusion

In patients with diabetes and CKD, younger age was associated with lower scores in all HRQoL subscales except the physical composite summary and female gender, obese or normal weight and more advanced stages of CKD were associated with lower scores in one or more subscales. Identifying these factors will inform the timely implementation of interventions to improve the quality of life of these patients.

## Introduction

People are living longer, but with an increased burden of chronic disease [1]. This is partly due to advances in medical treatment of chronic diseases such as diabetes and chronic kidney disease (CKD) [2]. Diabetes is increasing in prevalence with 382 million people worldwide, or 8.3% of adults, estimated to have diabetes and by 2035, some 592 million people, or one adult in 10, will have diabetes [3]. Given that CKD is a common complication of diabetes, the number of patients with diabetes requiring dialysis is also likely to increase. Contributing factors include an ageing population, increase in prevalence of obesity and improved survival rates after cardiovascular events [4].

HRQoL is an indicator of the impact of a condition on a patient's life and well-being [5]. Patients with diabetes and CKD have significantly impaired HRQoL [6–9] which may worsen as the disease progresses [5]. Lower HRQoL scores are strongly associated with higher risk of death and hospitalisation [2, 4, 10–12] and poorer glycaemic control in patients with diabetes [13]. Assessment of HRQoL allows for identification of factors that may be targeted to improve patient well-being. Effective interventional strategies to enhance HRQoL may then be implemented [5].

Previous studies have assessed HRQoL in people with either diabetes or CKD but not people with diabetes and CKD [14]. As people with these two chronic diseases are known to have competing physical and psychological needs when compared to people with the single condition, there is a need to understand how their complex needs translate into impact on HRQoL and its specific subscales as well as the impact of increasing disease severity. Within this context there is a need for studies across the continuum from early stages of diabetes and CKD through to late stages [8] that seek to identify factors associated with HRQoL particularly those that can be modified [15]. To do this we examined factors associated with HRQoL in patients with co-morbid diabetes and CKD of varying severity who access specialist medical care from tertiary hospitals.

## Methods

### Study design and participants

This was a cross sectional study of patients attending diabetes and renal outpatient clinics of four public and tertiary hospitals in Victoria and New South Wales (Monash Health, Alfred Health, Royal North Shore Hospital and Concord Hospital) between 2013 and December

2014. Participants were eligible if they received their usual care at one of these hospitals, were fluent in English and had a diagnosis of diabetes (either type 1 or type 2) and CKD stages 3 to 5 (eGFR<60 mL/min/1.73 $m^2$) including dialysis. As patients with CKD stages 1 to 2 were excluded from the study albuminuria or proteinuria was not used in the staging of CKD. The diagnosis of diabetes followed the World Health Organisation definition [16] and was recorded from patients' prior inpatient or outpatient contacts. Patients were recruited prospectively from clinics and asked to complete the Kidney Disease Quality of Life short form (KDQoL ™ -36) (S1 Appendix). The questionnaire was self-administered. For each patient a clinical survey was also completed by the site study staff or the clinician. Using standardised procedures, information was extracted from the patient's medical record. The data included demographic and disease-specific characteristics such as gender, age, body mass index, diabetes type, diabetes duration, estimated glomerular filtration rate (eGFR), treatments including dialysis requirement and type, complications/comorbidities, and glycated hemoglobin (HbA1c) (S2 Appendix). All participants provided written informed consent. The study was approved by Monash University and the respective health service human research ethics committees.

## Demographic and clinical variables

Age, gender, socio-economic status, smoking, body mass index (BMI), stage of kidney disease, duration of kidney disease, duration of diabetes, cardiovascular risk factors (hypertension and dislipidemia) and diabetes complications (retinopathy, peripheral vascular disease and nephropathy) were all recorded as possible determinants of HRQoL.

Socio-economic measures were estimated using the Australian Bureau of Statistics data [17]. Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables which include income, educational attainment and employment status. The IRSD scores for each postcode were then grouped into quintiles for analysis, where the highest quintile comprised 20% of postcodes with the highest IRSD scores (the most advantaged areas).

BMI (kg/$m^2$) was calculated by dividing participants' weight (in kilograms) by the square of their height (in meters). BMI was categorized into four groups which are underweight ($\leq$18.5 kg/$m^2$), normal weight (18.5–24.9 kg/$m^2$), overweight (25.0–29.9 kg/$m^2$) and obese ($\geq$30.0 kg/$m^2$) according to the World Health Organization (WHO) classification [18].

CKD stage as defined by the Kidney Disease Outcomes Quality Initiative (KDOQI) was used to define severity of the disease [19]. Duration of CKD was analysed as a continuous variable and also dichotomised by median duration (to less than 5 years or greater or equal to 5 years). eGFR was calculated using the CKD Epi formula GFR = 141 X min (Scr/κ, 1) $^{\alpha}$ X max (Scr/κ, 1)$^{-1.209}$ X $0.993^{Age}$ X 1.018 X 1.159 where Scr is serum creatinine (mg/dL), κ is 0.7 for females and 0.9 for males, α is –0.329 for females and –0.411 for males, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1 [20].

## Outcomes

Health related quality of life was assessed using the English version of the Kidney Disease and Quality of Life (KDQoL™-36) questionnaire. This is a 36-item HRQoL survey with five subscales namely the SF-12 measure of physical and mental functioning, burden of kidney disease, symptom/problems list and the effects of kidney disease subscales [21]. Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQoL [21]. The scores of the two summary measures and the total SF-36 are based on the average of the respective scale components.

### Statistical analysis

To determine the factors associated with HRQoL, crude and adjusted analyses of the 5 HRQoL subscales were performed using univariate and multiple linear regression methods. The HRQoL subscales were considered as dependent variables and the socio-demographic and clinical variables were considered as independent variables. Variables included in the multivariable model had a significance level of $p<0.10$. Parameter estimates were examined by backward elimination after every iteration to derive a parsimonious model. Differences in HRQoL across stages of kidney disease were assessed by the chi-squared test for linear trend. Finally, subgroup analysis by dialysis status as well as gender, were tested using two-sample t-test or ANOVA for continuous variables. Results were considered significant at conventional $p<0.05$ level. All analyses were performed with IBM SPSS version 22 (Armonk, NY: IBM Corp.) or Stata version 12.1 (Statacorp, College Station, TX). All $p$ values were calculated using two-tailed tests.

## Results

### Patient characteristics

Of the 317 patients who participated in the study, 9 were excluded from the analysis due to misclassification of the severity of their kidney disease (eGFR>60 mL/min/1.73 $m^2$). The demographic and clinical characteristics of the study population are shown in Table 1. The mean (±SD) age of the cohort was 66.9 ±11 years and 70% were male. The majority of participants were born in Australia (44%) and 78% spoke English as their first language. The median duration of CKD and diabetes were 5 years and 18 years respectively. The means (±SD) for HbA1c and eGFR were 6.8±2.5% (51 mmol/mol) and 29.1±16.7 mL/min/1.73$m^2$ respectively. The mean scores for the physical composite summary, mental composite summary, symptom/problem list, effects of kidney disease and burden of kidney disease scales were 35.2 ± 11, 47.0 ± 10.9, 73.8 ± 17.8, 72.5 ± 23.7 and 59.8 ± 31.0 respectively (Fig 1 and Table 2).

### Association between patient characteristics and HRQoL

Patient factors associated with HRQoL subscales are shown in Fig 2A and 2B. In multivariable analysis, younger age was associated with lower HRQoL scores in the mental composite summary, effect of kidney disease and burden of kidney disease subscales (all $p$ values $<0.05$). Female patients had lower scores in all subscales compared to male patients but the difference was only significant for the physical composite scale, with female patients scoring on average 3 points lower than their male counterparts (Fig 1). Patients with a BMI in the obese range scored lower on the symptom/problem list and effect of kidney disease subscales than patients with a BMI in the normal range but patients with a BMI in the normal range scored lower on the physical composite summary subscale than patients with a BMI in the overweight range (all $p$ values in adjusted analyses $<0.05$). Smokers scored on average 11 points lower than non-smokers in the symptom/problem list subscale. No associations between socio-economic status and any HRQoL subscales were observed.

### Association between disease severity, duration and HRQoL

With increasing severity of CKD, the mean HRQoL subscales scores decreased significantly except for the mental composite summary subscale (Fig 3). For the physical composite summary, effects of kidney disease, and burden of kidney disease subscales patients in stages 3b, 4 and 5 scored 4–38 points lower than patients in stage 3a (reference group). When the HRQoL scores of dialysis and non-dialysis patients were compared, all the HRQoL subscale scores

**Table 1. Demographic and clinical characteristics of participants (n = 308).**

| Characteristic | Value N (SD/%) |
|---|---|
| N | 308 |
| Age (in years) | 66.9±11.0 |
| Male | 214 (69.5) |
| **Ethnicity** | |
| Australian | 136 (44.2) |
| Sri Lanka | 16 (5.2) |
| Greece | 13 (4.2) |
| Italy | 12 (3.9) |
| England | 12 (3.9) |
| Others | 119 (38.6) |
| **Language** | |
| English | 239 (77.6) |
| Greek | 13 (4.2) |
| Italian | 7 (2.3) |
| Cantonese | 5 (1.6) |
| Mandarin | 5 (1.6) |
| Others | 39 (12.7) |
| **Clinical characteristics** | |
| HbA1c | 6.8±2.5 |
| eGFR | 29.1±16.6 |
| Diabetes duration (years), median (IQR) | 18 (17) |
| CKD duration (years), median (IQR) | 5 (8) |
| Body Mass Index (kg/m$^2$), median (IQR) | 29.9 (8.3) |
| Smoking status (Yes) | 18 (5.8) |
| Stages of chronic kidney disease | |
| 3a | 72 (22.9) |
| B | 79 (25.8) |
| 4 | 76 (23.5) |
| 5 (on dialysis) | 59 (19.2) |
| 5 (not on dialysis) | 22 (7.1) |

Data are means ± SD or *n* (%); SD-Standard deviation; %- Percentage; HbA1c-glycated haemoglobin; eGFR-estimated Glomerular Filtration Rate.

doi:10.1371/journal.pone.0168491.t001

were lower for dialysis patients but only significantly so for the effect of kidney disease and burden of kidney disease subscales (Table 2).

A shorter duration of CKD was associated with lower scores for mental composite summary, symptom/problem list and burden of kidney disease subscale (all $p$ values for adjusted analyses $<0.05$) (Fig 2A). There was no interaction between the effects of duration of CKD and CKD stages on HRQoL ($p$ for interaction $>0.05$). No associations between diabetes duration or diabetes and cardiovascular complications and any HRQoL subscales were observed (Fig 2B).

## Discussion

The data presented here from a large sample of people with diabetes and CKD attending outpatient specialist diabetes and renal clinics report impaired HRQoL in this population. Younger age was associated with lower scores in the mental composite summary, effect of kidney

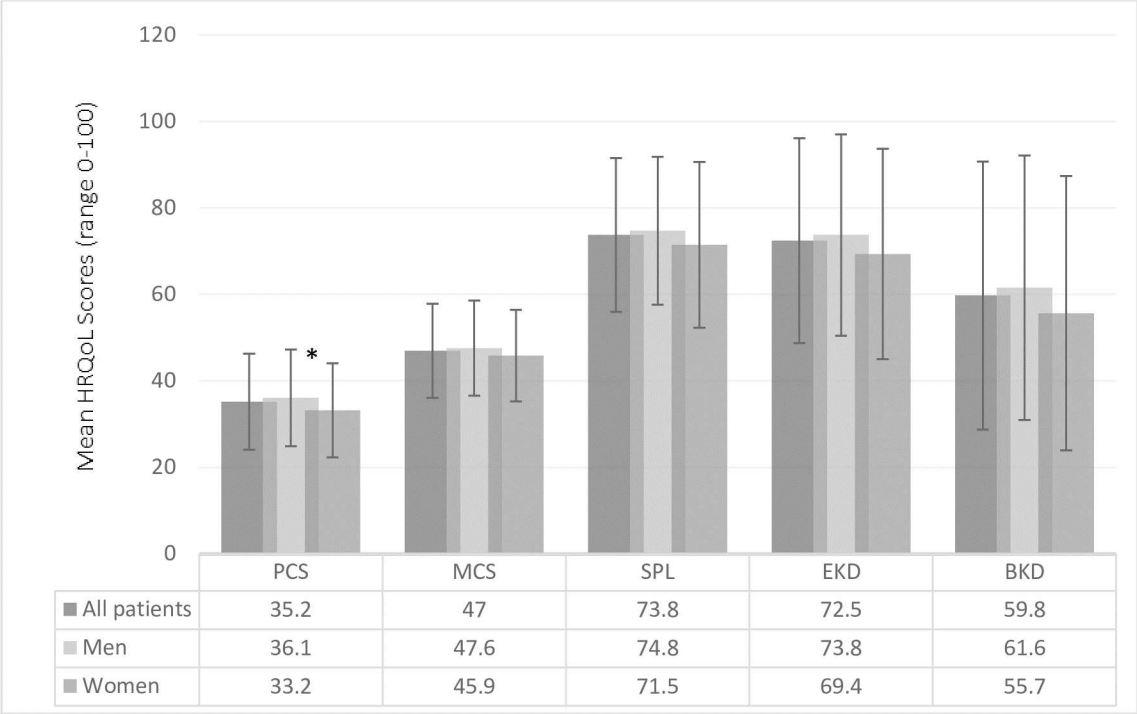



**Fig 1. Mean scores for the physical composite summary (PCS), mental composite summary (MCS), symptom/problem list (SPL), effects of kidney disease (EKD) and burden of kidney disease (BKD) subscales.** *- Scores significantly different between men and women ($p<0.05$)

doi:10.1371/journal.pone.0168491.g001

disease and burden of kidney disease subscales. Female gender was associated with lower physical composite summary scores and BMI in the normal or obese range (compared with overweight range) was associated with lower physical composite summary and lower symptom/problem list and effect of kidney disease scores respectively. In addition, more advanced stages of CKD (stage 3b to 5) were associated with lower physical composite summary, effect of kidney disease and burden of kidney disease scores whilst a shorter duration of CKD was associated with lower mental composite summary, symptom/problem list and burden of kidney disease scores.

Our findings build upon previous research in patients with diabetes [22] or CKD [6] by providing a detailed exploration of factors independently associated with HRQoL across each of the HRQoL subscales and CKD stages in patients with both diabetes and CKD.

**Table 2. Mean health-related quality of life scores of diabetes and chronic kidney disease patients by dialysis status.**

| SF-36 subscales | All patients | Dialysis | Not on dialysis | *p*-value |
|---|---|---|---|---|
| | | Mean (SD) | Mean (SD) | |
| Physical composite | 35.2±11.1 | 33.0 (10.3) | 35.7 (11.3) | 0.10 |
| Mental composite | 47.0±10.9 | 46.4 (10.1) | 47.2 (11.1) | 0.61 |
| Symptom/Problem List | 73.8±17.8 | 70.8 (16.0) | 74.5 (18.1) | 0.15 |
| Effects of Kidney Disease | 72.5±23.7 | 58.1 (22.3) | 76.0 (22.7) | 0.000* |
| Burden of Kidney Disease | 59.8±31.0 | 33.8 (24.7) | 66.3 (28.9) | 0.000* |

**p*-values were significant at 0.05; SD-standard deviation

doi:10.1371/journal.pone.0168491.t002

**A.**

| Covariates | Physical Composite Summary | | Mental Composite Summary | | Symptom/Problem List | | Effect of Kidney Disease | | Burden of Kidney Disease | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable |
| | B (95% CI) | | B (95% CI) | | B (95% CI) | | B (95% CI) | | B (95% CI) | |
| Age[i] | -0.05 (-0.2; 0.1) | - | 0.2(0.1;0.3)** | 0.1(0.02;0.3)* | 0.2 (0;0.4) * | - | 0.5 (0.3;0.8)*** | 0.3 (0.1, 0.6)*** | 0.7 (0.4;1.0)*** | .4 (0.07;0.7)* |
| *Gender* | | | | | | | | | | |
| Male | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Female | -2.8 (-5.6,-0.02)* | -2.8 (-5.5;-0.01)* | -1.7 (-4.5;1.1) | - | -3.3(-7.7;.01) | - | -4.4 (-10.4;1.5) | - | -5.9 (-13.7;1.9) | - |
| *SES (quintiles)* | | | | | | | | | | |
| Upper | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Upper middle | 1.2(-2.9;5.3) | - | -2.7(-6.7;1.3) | - | 0.2(-6.2;6.6) | - | 0.4(-8.4;9.1) | - | 6.5(-5.0;18.0) | - |
| Lower middle | -0.4(-4.7;3.8) | - | -1.3(-5.4;2.9) | - | -2.9(-9.5;3.5) | - | 3.6(-5.3;12.4) | - | 2.2(-9.4;13.9) | - |
| Upper lower | -0.3(-4.5;3.8) | - | 2.9(-6.9;1.2) | - | -2.8(-9.2;3.7) | - | 3.1(-5.8;12.0) | - | 0.8(-10.8;12.5) | - |
| Lower | 0.2(-3.9, 4.3) | - | -2.8(-6.9;1.2) | - | -1.5(-7.9;4.9) | - | 4.0(-4.7;12.8) | - | 2.9(-8.6;14.4) | - |
| DM duration | -0.04(-0.2;0.05) | - | -0.3(-0.1; 0.1) | - | -0.02(-0.2;0.2) | - | -0.1(-0.3;0.2) | - | -0.1 (-0.4;0.2) | - |
| CKD duration | -0.1(-0.2,.05) | - | 0.2(0.1;0.3)** | 0.2(0.04;0.3)* | 0.2 (0;0.5 * | 0.3(0.03;0.5)* | 0.2(-0.1;0.5) | - | 0.4(0.05;0.8)* | 0.4(0.08;0.7)* |
| *Smoking* | | | | | | | | | | |
| No | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Yes | -4.2(9.8;1.4) | - | -6.1(-11.6;0.6)* | - | -9.9(-18.5;-1.2)* | -11.3(-21.2;-1.4)* | -6.3 (-18.3;5.7) | - | -12.5(-28.7;3.6) | - |

**B.**

| Covariates | Physical Composite Summary | | Mental Composite Summary | | Symptom/Problem List | | Effect of Kidney Disease | | Burden of Kidney Disease | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable | Univariable | Multivariable |
| | B (95% CI) | | B (95% CI) | | B (95% CI) | | B (95% CI) | | B (95% CI) | |
| *CKD stages* | | | | | | | | | | |
| 3a | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| b | -4.1(-7.7;-0.5)* | -4.2(-7.9;-0.6)* | -0.1(-3.8;3.5) | - | -3.0 (-8.8;2.8) | - | -2.9(-10.5,4.6) | - | -9.1(-18.2;1.0)* | - |
| 4 | -7.7(-11.3;-4.0)*** | -7.7(-11.4;-4.1)*** | 0.05(-3.6;3.7) | - | -6.2(-12.0, -0.4)* | - | -9.5(-17.0;-1.9) * | -7.7(-13.9;-1.9)* | -17.5(-26.6;-8.4)*** | -16.8(-27.8;-5.9)*** |
| 5 | -5.9 (-9.5, -2.3)** | -5.9 (-9.5;-2.4)** | 0.8(-4.5;2.8) | - | -6.7(-12.4, -1.0)* | - | -20.7(-28.1;-13.3)*** | -16.9(-23.1;-10.8)*** | -41.7(-50.7;32.7)*** | -38.4(-49.1,-27.7)*** |
| *BMI* | | | | | | | | | | |
| Normal weight | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Underweight | 3.5 (-0.3;7.2) | | 13.2(-2.0;28.4)* * | | 9.1 (-15.6;33.9) | | -6.7(39.3;26.0) | | -24.7(-68.0;18.7) | |
| Overweight | -0.9 (-16.4;14.7) | 3.6 (0.1;7.1)* | -1.7 (5.3;2.0) | | 3.9 (-2.0;9.7) | | 5.7 (-2.1;13.5) | | | |
| Obese | -0.8 (-3.8;2.2) | - | -1.9(-4.9;1.0) | - | -4.0(-8.7;0.8) | -5.4(-10.5;-0.3)* | -8.3(-14.6;-2.0)** | -7.9(-13.6;-2.2)** | -6.9(-15.3;1.5) | - |
| DM complications | | | | | | | | | -2.4(-12.9;8.1) | |
| No | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | |
| Yes | 3.0(-1.0;7.1) | - | -0.8 (-4.8;3.2) | - | 0.9(-5.5;7.3) | - | 2.5(-6.0;11.0) | - | -0.9(-12.1;10.2) | - |
| CVD complications | | | | | | | | | | |
| No | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | | 1 (ref) | - |
| Yes | -0.2 (-6.7;6.3) | - | -0.5 (-6.9;5.8) | - | -2.7(-7.6;13.0) | - | 7.1 ( -6.6;20.8) | - | 8.2(-9.7;26.2) | - |

**Fig 2. Summary of factors predicting health-related quality of life in patients with diabetes and chronic kidney disease.** [i]The regression coefficient is for a one year increase in age; * p<0.05; **p<0.01; ***p<0.001; SES-Socio Economic Status; DM-Diabetes Mellitus; CKD-Chronic Kidney Disease; CVD-Cardiovascular Disease; BMI-Body Mass Index.

doi:10.1371/journal.pone.0168491.g002

We show that people with diabetes and CKD have lower scores in physical and mental composite summary subscales compared to the general population [6]. The mean scores for the HRQoL subscales were comparable to findings from previous studies in patients with kidney disease alone [23, 24] (see S1 Fig) except for the effect of kidney disease and burden of kidney disease subscales where our participants appeared to have scored higher than participants in the ADEMEX [23] and DOPPS [24] studies. This may be explained by the fact that the majority of patients in our study did not have end stage kidney disease compared to patients in the ADEMEX and DOPPS studies who were receiving renal replacement therapy but who did not have diabetes. Despite expecting the physical composite, mental composite and symptom problem list scores to be less impaired in our population with less advanced CKD and diabetes, these subscales were impaired to a similar level to those of patients on dialysis without diabetes. This suggests that the addition of diabetes adds to the burden of disease impacting HRQoL thus physical composite, mental composite and symptom problem list scores to a similar extent as that of dialysis.

Patients with diabetes and more advanced CKD had significantly lower HRQoL mean scores across physical composite summary, symptoms of kidney disease, effect of kidney

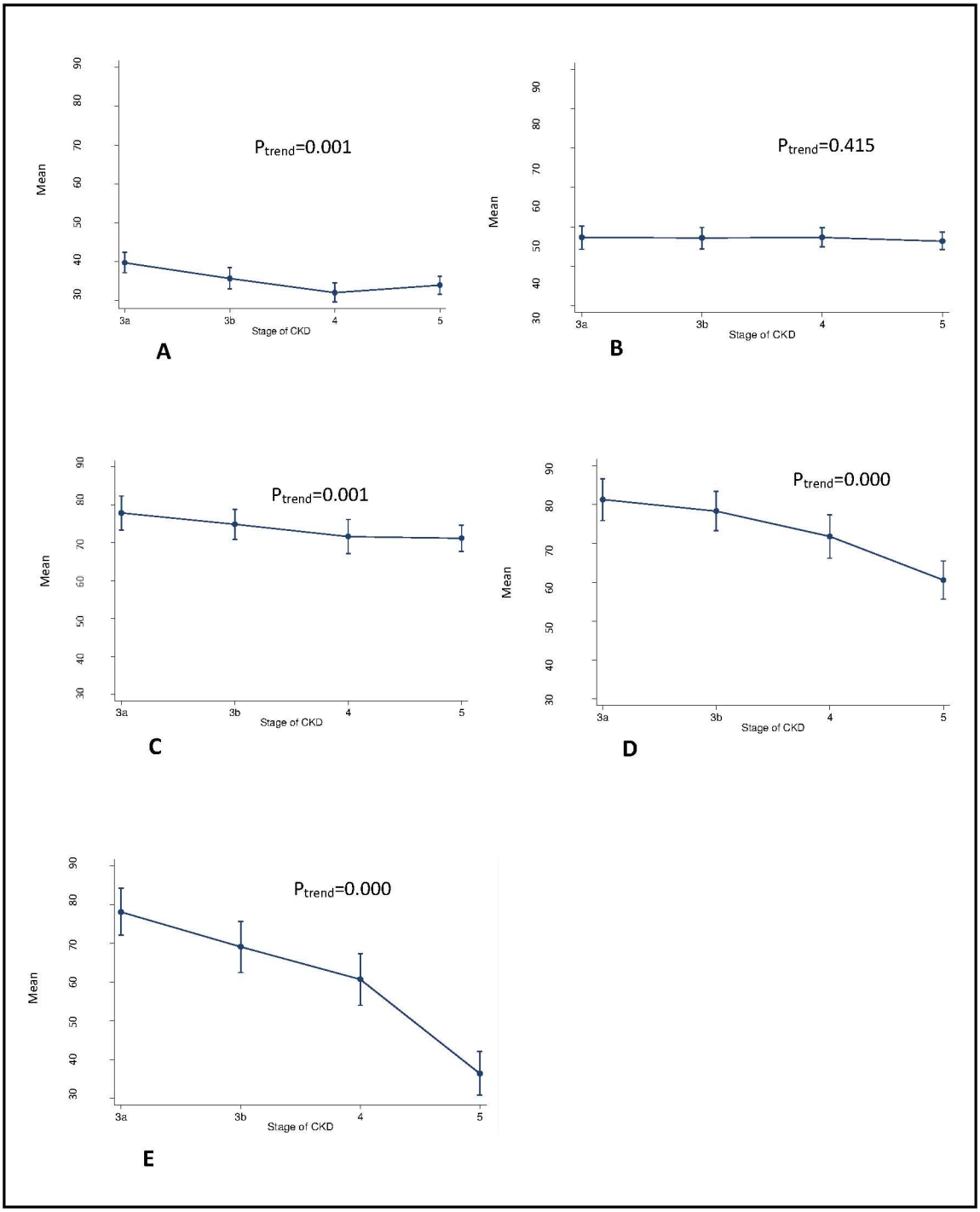



**Fig 3. The mean for the health related quality of life subscales.** (A) physical composite summary, (B) mental composite summary, (C) symptom problem list, (D) effect of kidney disease and (E) burden of kidney disease scores by stage of kidney disease. Error bars are 95% CI.

doi:10.1371/journal.pone.0168491.g003

disease, and burden of kidney disease scores compared to less advanced CKD. It is of interest to note that the decline in HRQoL is apparent well before dialysis has commenced and increases with progression of disease suggesting the need for support for patients at earlier as well as later stages of CKD. In addition, shorter rather than longer duration of CKD was

associated with lower mental composite summary, symptom/problem list and burden of kidney disease scores. One explanation may be that as patients become accustomed to their disease over time, they cope better mentally.

In contrast to widely held views and previous reports in patients with CKD alone, [25–27] our data suggest a positive association between age and HRQoL subscales in those with diabetes and CKD. A possible explanation for this relationship, especially for the mental composite summary subscale is that older patients may have better emotional well-being [6]. We speculate that the reason younger patients had lower scores in the burden of kidney disease subscale is that they experience a larger gap between their expected and actual HRQoL and may therefore score lower on HRQoL assessments than older patients, whose experiences are more aligned with their expectations as highlighted by one previous study [28]. This highlights the need to consider and address HRQoL issues in younger people with CKD.

In our study, women scored lower in all HRQoL subscales, but significantly so only for the physical composite summary. Although data for the diabetes and CKD population has not been previously reported, our results are consistent with those of previous studies of populations with advanced CKD [5, 12, 29–31] and may be explained by the fact that women appear to suffer more from chronic illnesses as has also been suggested by studies of populations with vascular diseases [32–34]. Another explanation could be that women, who are also more likely to be care givers than men, may suffer from additional care giver stress [35]. Our failure to demonstrate an association between gender and other HRQoL subscales could be attributed to the smaller number of women surveyed (only 30% of our study population were female).

Patients with a BMI in the normal range scored lower on the physical composite summary subscale than patients with a BMI in the overweight range (BMI of 25–29.9 $kg/m^2$). A possible explanation is that being overweight is now more common such that normal weight in patients with diabetes and CKD may reflect more severe disease or the presence of other illnesses. Although seemingly counter-intuitive, wide-ranging benefits of overweight but not obese status among patients with CKD have previously been reported [36, 37]. In contrast, others [5] have reported significantly lower physical composite summary scores among patients who were overweight in CKD stages 2–5, with a GFR ranging from 69 down to 2 ml/min/1.73 $m^2$. Of note, patients with a BMI in the obese range also scored lower for symptom/problem list and effect of kidney disease subscales. Further research seeking to determine the ideal BMI for improved survival and HRQoL in this patient population is needed if the reverse epidemiology of being overweight in patients with CKD and diabetes is to be understood.

Our findings should be interpreted in light of design strengths and limitations. The strengths include the inclusion of several biologic and non-biological patient factors as potential predictors for HRQoL in the study population since the likely factors are multifactorial and an even distribution of patients across each KDOQI stage of CKD [19]. We also used a valid and reliable tool (KDQoL™-36) for measuring HRQoL. The limitations include a skewed gender distribution with a majority of participants being males, but this is consistent with previously reported gender distribution of studies of patients with CKD [38]. The cross sectional design of the study did not permit us to assess temporal effects. Longitudinal studies need to be conducted to seek a better understanding of factors associated with HRQoL in patients with diabetes and CKD. Additionally, because only participants speaking English were included, our findings cannot be generalised to culturally and linguistically diverse (CALD) populations who may benefit from targeted interventions.

In patients with diabetes and CKD, younger age was associated with lower scores in all HRQoL subscales except the physical composite summary. Additionally, female gender, obese or normal weight, shorter duration of CKD and increasing severity of CKD were associated

with lower HRQoL scores in various HRQoL subscales. Identification of these factors informs interventions to improve the quality of life of these patients.

## Supporting Information

**S1 Fig. Mean HRQoL scores for the physical composite summary (PCS), mental composite summary (MCS), symptom/problem list (SPL), effects of kidney disease (EKD) and burden of kidney disease (BKD) in the ADEMEX study [23], the Dialysis Outcomes and Practice Patterns Study (DOPPS) divided by region [24] and the present study (*Diabetes Renal Project).**
(TIF)

**S1 Appendix. Kidney Disease and Quality of Life (KDQOL™-36) questionnaire.** Measures participants' health related quality of life.
(PDF)

**S2 Appendix. Diabetes Renal Project questionnaire.** Asks questions about participants' health indicators.
(PDF)

## Acknowledgments

We would like to acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

## Author Contributions

**Conceptualization:** EZ CL SZ HT.

**Data curation:** EZ CL SR SZ.

**Formal analysis:** EZ CL SR MG GF PK GR HT TU RW SZ.

**Funding acquisition:** CL HT SZ.

**Investigation:** EZ CL HT SZ.

**Methodology:** EZ CL SR MG GF PK GR HT TU RW SZ.

**Project administration:** EZ CL HT SZ.

**Resources:** EZ CL HT SZ.

**Supervision:** CL HT PK SZ.

**Validation:** EZ CL SR MG GF PK GR HT TU RW SZ.

**Visualization:** EZ CL SR MG GF PK GR HT TU RW SZ.

**Writing – original draft:** EZ.

**Writing – review & editing:** EZ CL SR MG GF PK GR HT TU RW SZ.

## References

1. Vos T, Barber RM, Bell B, Bertozzi-Villa A, Biryukov S, Bolliger I, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. The Lancet. 386(9995):743–800. http://dx.doi.org/10.1016/S0140-6736(15)60692-4.

2. Karner-Hutuleac A. Health related quality of life of diabetic and chronic renal failure patients. Procedia —Social and Behavioral Sciences. 2012; 33(0):85–9. http://dx.doi.org/10.1016/j.sbspro.2012.01.088.
3. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes research and clinical practice. 2014; 103 (2):137–49. Epub 2014/03/19. doi: 10.1016/j.diabres.2013.11.002 PMID: 24630390
4. Osthus TB, von der Lippe N, Ribu L, Rustoen T, Leivestad T, Dammen T, et al. Health-related quality of life and all-cause mortality in patients with diabetes on dialysis. BMC nephrology. 2012; 13:78. Epub 2012/08/07. doi: 10.1186/1471-2369-13-78 PMID: 22863310
5. Pagels AA, Soderkvist BK, Medin C, Hylander B, Heiwe S. Health-related quality of life in different stages of chronic kidney disease and at initiation of dialysis treatment. Health and quality of life outcomes. 2012; 10:71. Epub 2012/06/20. doi: 10.1186/1477-7525-10-71 PMID: 22710013
6. Mujais SK, Story K, Brouillette J, Takano T, Soroka S, Franek C, et al. Health-related quality of life in CKD Patients: correlates and evolution over time. Clinical journal of the American Society of Nephrology: CJASN. 2009; 4(8):1293–301. Epub 2009/08/01. doi: 10.2215/CJN.05541008 PMID: 19643926
7. Hayashino Y, Fukuhara S, Akiba T, Akizawa T, Asano Y, Saito S, et al. Low health-related quality of life is associated with all-cause mortality in patients with diabetes on haemodialysis: the Japan Dialysis Outcomes and Practice Pattern Study. Diabet Med. 2009; 26(9):921–7. Epub 2009/09/02. doi: 10.1111/j.1464-5491.2009.02800.x PMID: 19719714
8. Madhan K. The CARI guidelines. Quality of life. Nephrology (Carlton, Vic). 2010; 15 Suppl 1:S32–4. Epub 2010/04/01.
9. Soni RK, Weisbord SD, Unruh ML. Health-related quality of life outcomes in chronic kidney disease. Current opinion in nephrology and hypertension. 2010; 19(2):153–9. Epub 2010/01/07. doi: 10.1097/MNH.0b013e328335f939 PMID: 20051850
10. Mapes DL, Lopes AA, Satayathum S, McCullough KP, Goodkin DA, Locatelli F, et al. Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Int. 2003; 64(1):339–49. Epub 2003/06/06. doi: 10.1046/j.1523-1755.2003.00072.x PMID: 12787427
11. Merkus MP, Jager KJ, Dekker FW, de Haan RJ, Boeschoten EW, Krediet RT. Predictors of poor outcome in chronic dialysis patients: The Netherlands Cooperative Study on the Adequacy of Dialysis. The NECOSAD Study Group. American journal of kidney diseases: the official journal of the National Kidney Foundation. 2000; 35(1):69–79. Epub 2000/01/06.
12. Porter AC, Lash JP, Xie D, Pan Q, DeLuca J, Kanthety R, et al. Predictors and Outcomes of Health-Related Quality of Life in Adults with CKD. Clinical journal of the American Society of Nephrology: CJASN. 2016; 11(7):1154–62. Epub 2016/06/02. doi: 10.2215/CJN.09990915 PMID: 27246012
13. Kamarul Imran M, Ismail AA, Naing L, Wan Mohamad WB. Type 2 diabetes mellitus patients with poor glycaemic control have lower quality of life scores as measured by the Short Form-36. Singapore Med J. 2010; 51(2):157–62. Epub 2010/04/02. PMID: 20358156
14. Griva K, Mooppil N, Khoo E, Lee VYW, Kang AWC, Newman SP. Improving outcomes in patients with coexisting multimorbid conditions—the development and evaluation of the combined diabetes and renal control trial (C-DIRECT): study protocol. BMJ Open. 2015; 5(2).
15. Moura A, Madureira J, Alija P, Fernandes JC, Oliveira JG, Lopez M, et al. Predictors of health-related quality of life perceived by end-stage renal disease patients under online hemodiafiltration. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2015; 24(6):1327–35. Epub 2014/11/09.
16. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF Consultation. Geneva: 2006.
17. Australian Bureau of Statistics. Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2011. Canberra: Australian Bureau of Statistics, 2013 Contract No.: 2033.0.55.001.
18. World Health Organisation (WHO). Global Database on Body Mass Index: BMI Classification. 2006.
19. Hallan SI, Orth SR. The KDOQI 2002 classification of chronic kidney disease: for whom the bell tolls. Nephrol Dial Transplant. 2010; 25(9):2832–6. Epub 2010/07/06. doi: 10.1093/ndt/gfq370 PMID: 20601368
20. Liu X, Wang Y, Wang C, Shi C, Cheng C, Chen J, et al. A new equation to estimate glomerular filtration rate in Chinese elderly population. PloS one. 2013; 8(11):e79675. Epub 2013/11/19. doi: 10.1371/journal.pone.0079675 PMID: 24244543
21. Kidney Disease Quality of Life Working Group. The KDQOL-36™ Survey. [Accessed 05 May 2016]; http://www.rand.org/health/surveys_tools/kdqol.html.

22. Lung TW, Hayes AJ, Hayen A, Farmer A, Clarke PM. A meta-analysis of health state valuations for people with diabetes: explaining the variation across methods and implications for economic evaluation. Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation. 2011; 20(10):1669–78. Epub 2011/04/08.

23. Paniagua R, Amato D, Vonesh E, Guo A, Mujais S. Health-related quality of life predicts outcomes but is not affected by peritoneal clearance: The ADEMEX trial. Kidney international. 2005; 67(3):1093–104. Epub 2005/02/09. doi: 10.1111/j.1523-1755.2005.00175.x PMID: 15698450

24. Mapes DL, Bragg-Gresham JL, Bommer J, Fukuhara S, McKevitt P, Wikstrom B, et al. Health-related quality of life in the Dialysis Outcomes and Practice Patterns Study (DOPPS). American journal of kidney diseases: the official journal of the National Kidney Foundation. 2004; 44(5 Suppl 2):54–60. Epub 2004/10/16.

25. Cruz MC, Andrade C, Urrutia M, Draibe S, Nogueira-Martins LA, Sesso Rde C. Quality of life in patients with chronic kidney disease. Clinics (Sao Paulo, Brazil). 2011; 66(6):991–5. Epub 2011/08/03.

26. Barotfi S, Molnar MZ, Almasi C, Kovacs AZ, Remport A, Szeifert L, et al. Validation of the Kidney Disease Quality of Life-Short Form questionnaire in kidney transplant patients. Journal of psychosomatic research. 2006; 60(5):495–504. Epub 2006/05/03. doi: 10.1016/j.jpsychores.2005.09.009 PMID: 16650590

27. Kimmel PL, Peterson RA, Weihs KL, Simmens SJ, Boyle DH, Cruz I, et al. Aspects of quality of life in hemodialysis patients. J Am Soc Nephrol. 1995; 6(5):1418–26. Epub 1995/11/01. PMID: 8589317

28. Ortega F, Rebollo P. Health related quality of life (HRQOL) in the elderly on renal replacement therapy. J Nephrol. 2002; 15(3):220–4. Epub 2002/07/13. PMID: 12113590

29. Ayoub AM, Hijjazi KH. Quality of life in dialysis patients from the United Arab Emirates. J Family Community Med. 2013; 20(2):106–12. Epub 2013/08/29. doi: 10.4103/2230-8229.114772 PMID: 23983562

30. MahboobLessan P, Zohreh R. Contributing factors in health-related quality of life assessment of ESRD patients: a single center study. Nephro-Urology Monthly. 2009;(IJNU, Volume 1, Issue 2, Autumn):129–36.

31. Seica A, Segall L, Verzan C, Vaduva N, Madincea M, Rusoiu S, et al. Factors affecting the quality of life of haemodialysis patients from Romania: a multicentric study. Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association—European Renal Association. 2009; 24(2):626–9. Epub 2008/09/18.

32. Norris CM, Spertus JA, Jensen L, Johnson J, Hegadoren KM, Ghali WA. Sex and gender discrepancies in health-related quality of life outcomes among patients with established coronary artery disease. Circulation Cardiovascular quality and outcomes. 2008; 1(2):123–30. Epub 2009/12/25. doi: 10.1161/CIRCOUTCOMES.108.793448 PMID: 20031799

33. Shaw LJ, Bugiardini R, Merz CN. Women and ischemic heart disease: evolving knowledge. Journal of the American College of Cardiology. 2009; 54(17):1561–75. Epub 2009/10/17. doi: 10.1016/j.jacc.2009.04.098 PMID: 19833255

34. Niewada M, Kobayashi A, Sandercock PA, Kaminski B, Czlonkowska A. Influence of gender on baseline features and clinical outcomes among 17,370 patients with confirmed ischaemic stroke in the international stroke trial. Neuroepidemiology. 2005; 24(3):123–8. Epub 2005/01/08. doi: 10.1159/000082999 PMID: 15637449

35. Schulz R, Sherwood PR. Physical and mental health effects of family caregiving. The American journal of nursing. 2008; 108(9 Suppl):23–7; quiz 7. Epub 2008/09/23. doi: 10.1097/01.NAJ.0000336406.45248.4c PMID: 18797217

36. Lu JL, Kalantar-Zadeh K, Ma JZ, Quarles LD, Kovesdy CP. Association of body mass index with outcomes in patients with CKD. Journal of the American Society of Nephrology: JASN. 2014; 25(9):2088–96. Epub 2014/03/22. doi: 10.1681/ASN.2013070754 PMID: 24652789

37. Kalantar-Zadeh K, Block G, Humphreys MH, Kopple JD. Reverse epidemiology of cardiovascular risk factors in maintenance dialysis patients. Kidney international. 2003; 63(3):793–808. Epub 2003/03/13. doi: 10.1046/j.1523-1755.2003.00803.x PMID: 12631061

38. Rajapurkar MM, John GT, Kirpalani AL, Abraham G, Agarwal SK, Almeida AF, et al. What do we know about chronic kidney disease in India: first report of the Indian CKD registry. BMC Nephrol. 2012; 13:10. Epub 2012/03/07. doi: 10.1186/1471-2369-13-10 PMID: 22390203

## 3.2 Published manuscript: Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease

Citation: **Zimbudzi E**., Lo C., Ranasinha S., Fulcher G., Jan S., Kerr PG., Teede HJ., Polkinghorne KR., Russell G., Walker RG., Zoungas S. Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid diabetes and chronic kidney. Health and Quality of Life Outcomes 2018; 16:215.

Health and Quality of Life Outcomes

RESEARCH Open Access

# Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease

Edward Zimbudzi[1,2], Clement Lo[1,3], Sanjeeva Ranasinha[1], Gregory Fulcher[4,5], Martin Gallagher[6,7], Stephen Jan[6,8], Peter G. Kerr[2,9], Helena J. Teede[1,3], Kevan R. Polkinghorne[2,9], Grant Russell[10], Rowan G. Walker[11] and Sophia Zoungas[1,3,6*]

## Abstract

**Background:** Little is known about how patient reported barriers to health care impact the quality of life (HRQoL) of patients with comorbid disease. We investigated patient reported barriers to health care and low physical and mental well-being among people with diabetes and chronic kidney disease (CKD).

**Methods:** Adults with diabetes and CKD (estimated Glomerular Filtration Rate < 60 ml/min/1.73m$^2$) were recruited and completed a questionnaire on barriers to health care, the 12-Item HRQoL Short Form Survey and clinical assessment. Low physical and mental health status were defined as mean scores < 50. Logistic regression models were used.

**Results:** Three hundred eight participants (mean age 66.9 ± 11 years) were studied. Patient reported 'impact of the disease on family and friends' (OR 2.07; 95% CI 1.14 to 3.78), 'feeling unwell' (OR 4.23; 95% CI 1.45 to 12.3) and 'having other life stressors that make self-care a low priority' (OR 2.59; 95% CI 1.20 to 5.61), were all associated with higher odds of low physical health status. Patient reported 'feeling unwell' (OR 2.92; 95% CI 1.07 to 8.01), 'low mood' (OR 2.82; 95% CI 1.64 to 4.87) and 'unavailability of home help' (OR 1.91; 95% CI 1.57 to 2.33) were all associated with higher odds of low mental health status. The greater the number of patient reported barriers the higher the odds of low mental health but not physical health status.

**Conclusions:** Patient reported barriers to health care were associated with lower physical and mental well-being. Interventions addressing these barriers may improve HRQoL among people with comorbid diabetes and CKD.

**Keywords:** Chronic kidney disease, Diabetes, Health related quality of life, Mental well-being, Patient reported barriers, Physical well-being

## Background

Health-related quality of life (HRQOL) is a multi-dimensional concept commonly used to examine the impact of health status on quality of life [1] and is widely regarded as the best assessment of the impact of disease on a patient's well-being [2]. Among patients with comorbid diabetes and chronic kidney disease (CKD), low HRQoL [3, 4] as well as its association with several demographic [3, 5] and disease factors has been reported [4, 6], but little is known about its association with patient reported barriers to health care. Examining the patient reported barriers associated with HRQoL offers an excellent opportunity for addressing the provision of patient-centred care, which is largely considered the gold standard for health care across the world [7].

* Correspondence: sophia.zoungas@monash.edu
[1]School of Public Health and Preventive Medicine, Monash University, Melbourne, VIC, Australia
[3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, VIC, Australia
Full list of author information is available at the end of the article

© The Author(s). 2018 **Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

Among patients with diabetes, those who have reported barriers such as cost, transportation difficulties, competing demands, low self-efficacy and psychosocial barriers have also reported lower physical and mental well-being [8, 9]. In contrast, among patients with CKD, the impact of patient reported barriers such as communication, physical health, socioeconomic status, psychosocial and access to health services on physical and mental well-being has not been reported [10]. While patient reported barriers to health care for patients with comorbid diabetes and CKD have been characterised [11], their association with optimal physical or mental well-being is largely unknown.

A comprehensive understanding of key modifiable patient reported barriers to health care may thus inform the development of contextually tailored interventions to improve the physical and mental well-being of patients with comorbid diabetes and CKD. The objective of this study was to explore the association between patient reported barriers to health care and the physical and mental health well-being of patients with diabetes and CKD. We hypothesized that patients with comorbid diabetes and CKD who experience barriers to health care will report lower mental and physical well-being. We also hypothesized that mental and physical well-being would vary depending on the number patient-reported barriers.

## Methods

### Study design, setting and participants

This multi-centre cross-sectional study was conducted across four large tertiary hospitals in Australia's two most populous cities, (Alfred and Monash Health in Melbourne and the Royal North Shore and Concord Hospitals in Sydney). The study also involved collaboration with research institutes, national consumer stakeholder groups (Diabetes Australia and Kidney Health Australia) and primary care groups.

Adult patients (over 18 years) who were fluent in English and had diabetes and CKD (eGFR < 60 ml/min/1.73m$^2$) were drawn from ambulatory diabetes or renal clinics of each participating tertiary hospital between January to September 2014. The diagnosis of diabetes was noted on medical records and/or confirmed by laboratory results as per World Health Organisation (WHO) criteria [12, 13]. Patients were considered to have CKD if they had a sustained estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m$^2$ calculated using the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation [14] (i.e. two or more eGFR readings) over a 3 month period.

The reporting in this study followed the STROBE (Strengthening The Reporting of Observational Studies in Epidemiology) guidelines [15]. Ethics approval was obtained from Monash University and respective health service ethics committees.

### Demographic and clinical variables

Age, gender, language spoken at home, socio-economic status (SES), stage of kidney disease, duration of kidney disease and duration of diabetes were obtained from the first questionnaire (see Additional file 1) which was prospectively completed by site study staff or the clinician, using standardised procedures from the doctor's notes and laboratory results from clinic. We estimated socio-economic status using the Australian Bureau of Statistics data [16]. Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables, which include income, educational attainment and employment status. The IRSD scores for each postcode were then grouped into quintiles for analysis, where the highest quintile comprised 20% of postcodes with the highest IRSD scores (the most advantaged areas).

### Patient reported barriers

Patients completed the second questionnaire, which examined patient reported barriers to health care (see Additional file 2). The barriers were identified from the content analysis of 12 focus groups of 58 participants with co-morbid diabetes and CKD and 8 semi-structured interviews of carers from a previous multi-centre qualitative study performed by the authors [11]. Patient reported barriers were organised into three categories namely personal, clinician and health system-related barriers.

### Health-related quality of life

The Kidney Disease and Quality of Life (KDQoL™-36) questionnaire [17] (see Additional file 3) measured the physical and mental well-being of patients. The KDQoL-36™ is a is a 36-item survey that includes the SF-12 as generic core plus 24 items on quality of life related to kidney disease (the burden of kidney disease, symptoms/problems of kidney disease, and effects of kidney disease scales). Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQoL. This study utilised the SF-12 physical and mental composite measures, which both have a general population mean of 50 and standard deviation of 10. Scores less than 50 were categorised as low health status. The validity and reliability of the KDQoL-36 questionnaire has been reported previously [18–20].

### Statistical analysis

Distributions of demographic and clinical characteristics are presented as descriptive statistics (continuous variables are reported as means and standard deviations or

medians with interquartile ranges if distributions are skewed and categorical variables are reported as frequencies and percentages). First, a sub-analysis according to low and high physical and mental well-being was performed for age, gender, stage of kidney disease, diabetes duration and all the patient reported barriers. Continuous data were analysed with t-tests and categorical data were analysed with chi squared test and Fisher's exact tests, as appropriate. To analyse barriers, Likert scales were collapsed into 2 categories (disagree and agree). Second, univariable and multivariable logistic regression were performed to identify factors associated with lower physical and mental health well-being. Potential factors included demographic and patient reported barriers to health care. The multivariable model included variables identified a priori to be of importance (age and gender) and factors significant on univariable analyses. Predictor variables with $p < 0.05$ in univariable analyses were included in multivariable models to reduce the likelihood of type 2 error. Statistical significance was indicated by a $p$ value of $< 0.05$ in multivariable analyses. All analyses were performed with Stata version 11 (Statacorp, College Station, TX).

## Results

### Patient characteristics

Of the 3028 patients identified with diabetes or CKD, 863 met the inclusion criteria and were invited to participate and of these, 308 agreed to participate (Fig. 1). The final inclusion rate based on eligible participants was 36%. Characteristics of respondents and non-respondents are reported in Additional file 4: Table S1. Responders were younger and predominantly male. There were no differences with respect to type of diabetes and stage of kidney disease. The demographic and clinical characteristics of respondents are described in Table 1.

The mean age of participants was 66.9 ± 11.0 years, 70% were male and most were English speaking (78%) and evenly distributed across the socio-economic quintiles (lower-20.3%, upper lower-19.3%, lower middle-20.0%, upper middle-21.0% and upper-19.3%). Most had type 2 diabetes (88.0%) with 23.4, 25.7, 24.6 and 26.3% having CKD stage 3a, 3b, 4 and 5 respectively.

### Health related quality of life

The mean ± SD for the physical and mental composite scores were 35.2 ± 11.1 and 47.1 ± 10.9 respectively. The proportions of patients who scored below the general population mean (μ = 50 and SD = 10) for the physical and mental composite scores were 86 and 51% respectively (Table 2).

Patients with low physical health status differed by stage of CKD ($p = 0.03$) and language spoken ($p = 0.02$), and patients with low mental health status differed by age (p = 0.02) and smoking status ($p = 0.04$) but not

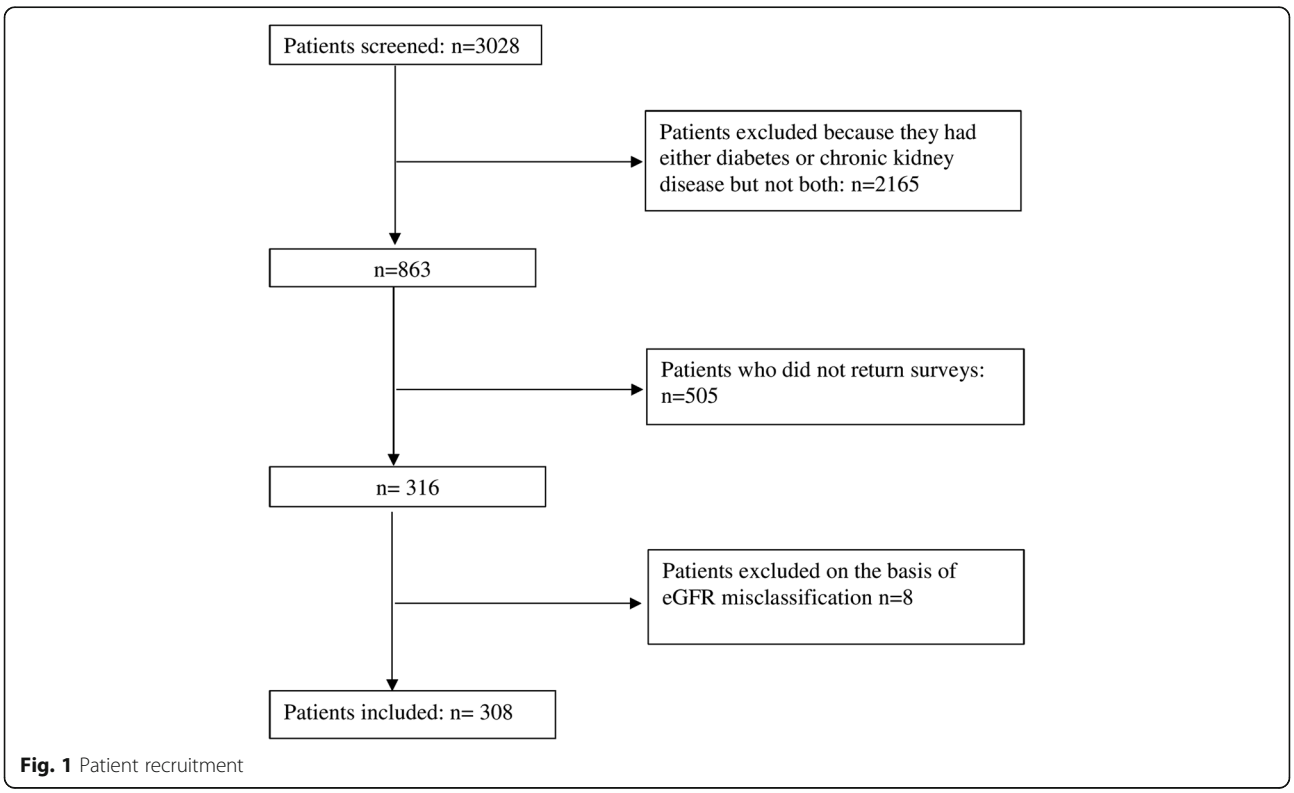



**Fig. 1** Patient recruitment

**Table 1** Baseline characteristics

| Variable | Mean ± SD/% | Range |
|---|---|---|
| Age (years) | 66.9 ± 11.0 | 32–90 |
| Male (%) | 69.5 | |
| Socio-economic status (in quintiles) * | | |
| Lower | 20.3 | |
| Upper lower | 19.3 | |
| Lower middle | 20.0 | |
| Upper middle | 21.0 | |
| Upper | 19.3 | |
| English speaking (%) | 78.0 | |
| Currently smoking (%) | 7.8 | |
| Diabetes type (%) | | |
| Type 1 | 9.1 | |
| Type 2 | 88.0 | |
| Other | 2.9 | |
| Diabetes duration (median, IQR♦) years | 17 (13) | 1–57 |
| CKD stages | | |
| 3a | 23.4 | |
| b | 25.7 | |
| 4 | 24.6 | |
| 5 (including dialysis) | 26.3 | |
| Health Related Quality of Life | | |
| SF-12 Physical Composite Summary | 35.2 ± 11.1 | 12–64 |
| SF-12 Mental Composite Summary | 47.1 ± 10.9 | 10–68 |

* Socio-economic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables, which include income, educational attainment and employment status.
♦IQR-Interquartile range.

gender, socio-economic status, type of diabetes and duration of diabetes (all $p > 0.05$) (Table 2).

### Patient reported barriers associated with lower physical and mental well-being

Patient reported barriers associated with higher odds of low physical health status included the personal barriers of 'impact of the disease on family and friends' (OR 2.07; 95% CI 1.14 to 3.78), 'feeling unwell' (OR 4.23; 95% CI 1.45 to 12.3) and 'having other life stressors that make self-care a low priority' (OR 2.59; 95% CI 1.20 to 5.61) (Fig. 2 and Additional file 4: Table S2). Patient reported barriers associated with lower odds of low physical health status included the clinician and health system barriers of 'being seen by a different doctor' (OR 0.47; 95% CI 0.27 to 0.80) and 'inadequate diabetes education' (OR 0.40; 95% CI 0.22 to 0.72) (Fig. 2 and Additional file 4: Table S2).

Patient reported barriers associated with higher odds of low mental health status included the personal barriers of 'feeling unwell' (OR 2.92; 95% CI 1.07 to 8.01), low mood (OR 2.82; 95% CI 1.64 to 4.87) and 'unavailability of home help' (OR 1.91; 95% CI 1.57 to 2.33) (Fig. 3 and Additional file 4: Table S3).

Patient reported personal barriers such as socio-economic status and language spoken as well as patient reported clinician and health system barriers such as communication and cost were not associated with lower physical or mental health status (see Additional file 4: Tables S2 and S3).

The greater the total number of patient reported barriers the greater the odds of low mental health status but not physical health status (see Additional file 4: Table S5).

## Discussion

In this multi-site cross sectional study of patients with both diabetes and CKD, patient reported barriers to health care were associated with poorer quality of life. Particularly, the disease having an impact on family and friends, feeling unwell and having other life stressors that make self-care a low priority increased the odds of low physical health status. Additionally, feeling unwell, low mood and difficulty obtaining home help, increased the odds of low mental health status. A greater total number of patient reported barriers was also associated with increased odds of low mental health status.

In our study, the impact of the disease on family and friends was strongly associated with increased odds of low physical health status. This has not been extensively explored in the literature. A qualitative study among patients with comorbid diabetes and CKD has suggested that patients' tiredness, feeling unwell, increased disability and loss of independence negatively affected their families, marriages and social circles [21]. Consequently, we hypothesise that it is the low physical health status, which has a negative impact on relationships with family and friends, rather than the inverse. This needs to be confirmed in a longitudinal study. Additionally, carer burden and depression has been described especially for those providing care to patients with advanced kidney disease [22–24]. Since there appears to be a direct relationship between family caregivers' quality of life and that of the patients they care for, it may also be important for the health care system to address the quality of life needs of care givers.

Patients reporting the presence of other life stressors (any other life stressors unrelated to the patients' illness, family situation and jobs) that made self-care of diabetes and CKD a lower priority was associated with low physical health status. Although not previously studied in patients with both diabetes and CKD, in patients with diabetes alone, lack of engagement in self-care is associated with poorer overall HRQoL [25–28]. Moreover, in patients with CKD alone, self-management programs have been reported to improve

**Table 2** Differences between low and high groups on demographic and clinical characteristics

| Measure | Physical health status | | | Mental health status | | |
|---|---|---|---|---|---|---|
| | *Low scores (*N* = 158) | High Scores (*N* = 26) | *P*-value | *Low scores (*N* = 94) | High Scores (*N* = 90) | *P*-value |
| Age (years), mean (SD) | 66.9 (11.2) | 66.3 (9.5) | 0.79 | 65.5 (11.5) | 68.5 (10.2) | 0.02 |
| Gender | | | | | | |
| Male, n (%) | 172 (68.3) | 28 (69.6) | 0.05 | 110 (69.2) | 90 (71.4) | 0.68 |
| Female, n (%) | 80 (31.7) | 5 (30.4) | | 49 (30.8) | 36 (28.6) | |
| Socioeconomic status, n (%) | | | | | | |
| Lower | 51 (20.2) | 8 (24.2) | 0.97 | 37 (23.3) | 22 (17.4) | 0.65 |
| Upper lower | 51 (20.2) | 7 (21.2) | | 33 (20.8) | 25 (19.8) | |
| Lower middle | 47 (18.7) | 6 (18.2) | | 29 (18.2) | 24 (19.0) | |
| Upper middle | 54 (21.4) | 7 (21.2) | | 34 (21.4) | 27 (21.4) | |
| Upper | 49 (19.4) | 5 (15.2) | | 26 (16.4) | 28 (22.2) | |
| Language, n (%) | | | | | | |
| English speaking | 189 (75.9) | 31 (94.0) | 0.02 | 117 (74.1) | 103 (83.1) | 0.08 |
| Non-English speaking | 60 (24.1) | 2 (6.0) | | 41 (25.9) | 21 (16.9) | |
| Smoking status, n (%) | | | | | | |
| Yes | 15 (8.1) | 1 (3.8) | 0.70 | 13 (11.3) | 3 (3.1) | 0.04 |
| No | 170 (91.9) | 25 (96.2) | | 102 (88.7) | 93 (96.9) | |
| Diabetes type, n (%) | | | | | | |
| Type 1 | 25 (9.9) | 3 (9.1) | 1.00 | 17 (10.7) | 11 (8.7) | 0.71 |
| Type 2 | 219 (86.9) | 29 (87.9) | | 136 (85.5) | 112 (88.9) | |
| Other | 8 (3.2) | 1 (3.0) | | 6 (3.8) | 3 (2.4) | |
| Diabetes duration (years), median (IQR) | 17 (0–57) | 19 (1–34) | 0.68 | 16 (0–53) | 20 (1–57) | 0.13 |
| CKD stages, n (%) | | | | | | |
| 3a | 52 (20.6) | 12 (36.4) | 0.03 | 33 (20.8) | 31 (24.6) | 0.27 |
| 3b | 62 (24.6) | 11 (33.3) | | 37 (23.3) | 36 (28.6) | |
| 4 | 68 (27.0) | 3 (9.1) | | 39 (24.5) | 32 (25.4) | |
| 5 | 70 (27.8) | 7 (21.1) | | 50 (31.4) | 27 (21.4) | |

*Scores were defined as low for both physical and mental well-being if they were lower than the general population mean (μ = 50 and SD)

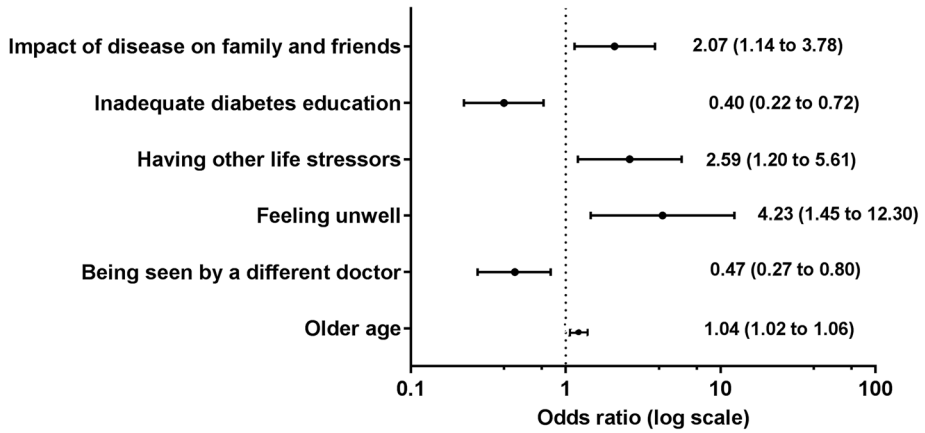



**Fig. 2** Patient reported barriers associated with low physical health status

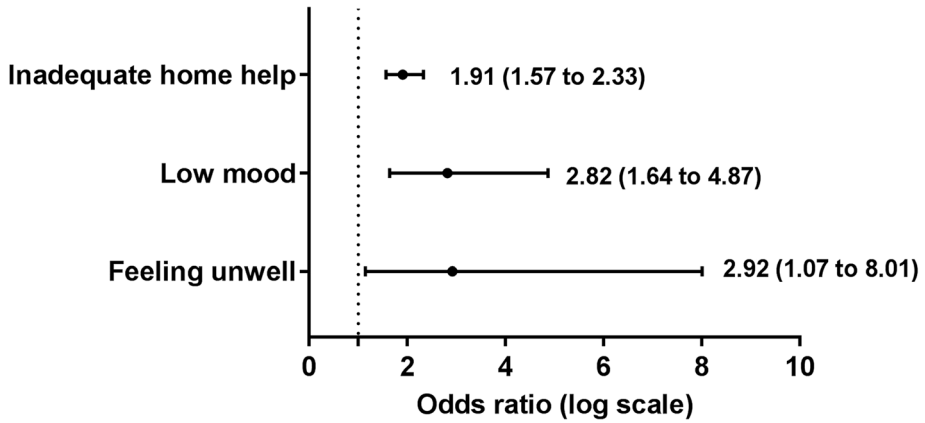



**Fig. 3** Patient reported barriers associated with low mental health status

mental quality of life measures but not physical quality of life measures [29]. Taken together, these data and our findings suggest that helping patients deal with life stressors so they can better self-care will improve their mental and physical well-being.

Seeing a different doctor in outpatient specialist clinics was associated with lower odds of low physical health status. A possible reason for this is that patients who see a different doctor receive additional opinions or information which may reinforce the information they are provided and improve their perceived health status. In contrast, a study among patients with diabetes showed that consultation by different doctors increased patients' social vulnerability and directly affected their quality of life [30]. Our findings suggest that different specialists may be used in multidisciplinary clinics such as combined diabetes and kidney clinics without affecting patients' physical health status.

Additionally, patient reported inadequate diabetes education was associated with lower odds of low physical health status. This was an unexpected finding as patients who have received diabetes education are reported to be more likely to have higher HRQoL [31–33]. An explanation may be that maintaining the impact of diabetes education over time is especially challenging due to competing interests of managing more than one complex disease. Additionally, having inadequate education may mean that patients become less worried or anxious about their health.

Self-reported low mood, which has an impact on motivation to engage in self-management activities [34] was, as expected, associated with lower mental health status. Studies in both CKD and diabetes show an association between low mood and lower scores on quality of life domains of psychological health [35–37]. Here we show that an association similarly exists in patients with both diabetes and CKD. Interventions that screen for and target low mood may result in improved quality of life in this population.

Patients who reported feeling unwell had lower scores for both physical and mental health status in patients with both diabetes and CKD. These associations are intuitive and predictable given the nature of the physical and mental health status scores and serve to validate the rest of our results.

Patient reported difficulty receiving home help was also associated with low mental health status in patients with both diabetes and CKD. As far as we know, this has not been previously reported. This association emphasises the importance of supporting patients with physical disabilities with home help services. Improving access to, and the process of receiving home help, may improve patient quality of life in this group with complex needs.

Finally, we found that a greater number of patient reported barriers was associated with increased odds of low mental health status. This highlights the importance of involving patients in co-designing improvements to health care. This approach makes health services more patient-centred and provides a platform for addressing issues that are important to patients. It also emphasises the importance of addressing these patient reported barriers in health care improvement interventions, as this may lead to improved HRQoL particularly in the mental health domain.

Our findings carry important practice, policy and research implications. First, the approach taken by health services providing care to patients with comorbid diabetes and CKD should consider the barriers to health care for this patient group if physical and mental well-being are to be maintained or even improved. Second, well-being measures may be used to provide information on areas that are less often addressed such as the impact of the disease on family and friends. Additionally, we found that it was possible to assess the patient's well-being directly in order to tailor interventions appropriately rather than relying on reports from relatives or caregivers. Well designed and disease-specific

longitudinal studies are required to determine the impact of patient-reported barriers on patients' well-being.

Interpretation of our results should be based on the strengths and limitations of the study. Strengths include the multi-site patient recruitment from geographically distinct large metropolitan areas, and the use of a valid and reliable tool to measure HRQoL (SF-12). Limitations include the cross-sectional study design negating our ability to make definitive causal inferences. Thus, the potential for reverse causality cannot be ruled out where low physical and mental well-being may predispose patients to some barriers such as the impact of the disease on family, low mood and feeling unwell. Even though our study excluded non-English speaking patients, we do not think that this would substantially change our findings based on previous studies among patients with diabetes [38, 39]. In addition, we acknowledge that a test–retest reliability was not performed for the patient-reported barriers questionnaire, but partnering with patients in developing this survey ensured a form of reliability in the study. Another limitation is that responders were generally younger and predominantly male with lower eGFR. This finding is in keeping with that of other studies of patients with CKD [40–42].

## Conclusions

Patient reported barriers to health care are associated with both lower physical and mental health status. Additionally, a greater number of patient reported barriers was associated with lower mental health status. Interventions addressing these barriers may improve HRQoL among people with diabetes and CKD.

## Additional files

**Additional file 1:** DRP: Diabetes Renal Project (Doctors Survey - Health Indicators). (PDF 69 kb)

**Additional file 2:** Supplementary Appendix S2-Barriers to Health-care Questionnaire. (DOCX 19 kb)

**Additional file 3:** Kidney Disease and Quality of Life (KDQOL™-36). (PDF 25 kb)

**Additional file 4:** **Table S1.** Characteristics of patients who did and did not participate in the study. **Table S2.** Univariable and multivariable logistic regression for factors associated with low physical health status (SF Physical Composite Summary <50). **Table S3.** Univariable and multivariable logistic regression for factors associated with low mental health status (SF Mental Composite Summary <50). **Table S4.** Odds of low physical and mental health status by number of patient reported barriers. (DOCX 23 kb)

### Abbreviations

CI: Confidence interval; CKD: Chronic kidney disease; DRP: Diabetes Renal Project; eGFR: Estimated glomerular filtration rate; HRQoL: Health-related quality of life; IRSD: Index of Relative Social Disadvantage; KDQoL: Kidney Disease Quality of life; OR: Odds ratio; PROM: Patient reported outcome measure; SES: Socio economic status; WHO: World Health Organisation

### Acknowledgements

We want to acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

### Funding

The study was funded by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. An Australian Postgraduate Award Scholarship supported C Lo. H Teede was supported by a NHMRC, Practitioner Fellowship. A NHMRC Senior Research Fellowship supported S Zoungas. The funding organisations had no role in design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

### Availability of data and materials

The datasets used can be shared for specific research questions that are available from the corresponding author on request.

### Authors' contributions

EZ, CL and SZ conceptualised the study. EZ, CL, SR and SZ performed data curation. EZ designed the analysis in consultation with CL, SR, GF, SJ, MG, PK, HT, KP, GR, RW, and SZ. EZ, CL and SZ drafted the original draft and all authors reviewed and edited the final manuscript. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

Approval for the Diabetes Renal Project was obtained from Monash University (CF12/4030–2,012,001,924), Monash Health (12,340 L), Alfred Health (526/12), Royal North Shore Hospital (1212-431 M), University of Sydney (2013/672) and Concord Hospital (LNRSSA/13/CRGH/139).

### Consent for publication

All eligible patients provided a written informed consent after receiving an explanation of study procedures and aims and after having an opportunity to ask questions.

### Competing interests

The authors declare that they have no competing interests.

## Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

### Author details

[1]School of Public Health and Preventive Medicine, Monash University, Melbourne, VIC, Australia. [2]Department of Nephrology, Monash Health, Melbourne, VIC, Australia. [3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, VIC, Australia. [4]Department of Diabetes and Endocrinology, Royal North Shore Hospital, Sydney, NSW, Australia. [5]Northern Clinical School, University of Sydney, Royal North Shore Hospital, Sydney, NSW, Australia. [6]The George Institute for Global Health, University of NSW, Sydney, NSW, Australia. [7]Concord Clinical School, University of Sydney, Sydney, NSW, Australia. [8]Sydney Medical School, University of Sydney, Sydney, NSW, Australia. [9]Department of Medicine, School of Clinical Sciences at Monash Health, Monash University, Melbourne, VIC, Australia. [10]School of Primary Health and Allied Health Care, Monash University, Melbourne, VIC, Australia. [11]Department of Renal Medicine, Alfred Hospital, Melbourne, VIC, Australia.

Received: 12 May 2018 Accepted: 4 November 2018
Published online: 19 November 2018

### References

1. Baig MK, Tonsi A, Sajid MS. Health-related quality of life measurement. Int J Health Care Qual Assur. 2008;21(4):365–73.
2. Spertus J. Barriers to the use of patient-reported outcomes in clinical care. Circ Cardiovasc Qual Outcomes. 2014;7(1):2–4.

3. Zimbudzi E, Lo C, Ranasinha S, et al. Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. PLoS One. 2016;11(12):e0168491.
4. Aggarwal HK, Jain D, Pawar S, Yadav RK. Health-related quality of life in different stages of chronic kidney disease. QJM. 2016;109(11):711–6.
5. Soni RK, Weisbord SD, Unruh ML. Health-related quality of life outcomes in chronic kidney disease. Curr Opin Nephrol Hypertens. 2010;19(2):153–9.
6. Pagels AA, Soderkvist BK, Medin C, Hylander B, Heiwe S. Health-related quality of life in different stages of chronic kidney disease and at initiation of dialysis treatment. Health Qual Life Outcomes. 2012;10:71.
7. Li J, Porock D. Resident outcomes of person-centered care in long-term care: a narrative review of interventional research. Int J Nurs Stud. 2014; 51(10):1395–415.
8. Jepson R, Harris FM, Bowes A, Robertson R, Avan G, Sheikh A. Physical activity in south Asians: an in-depth qualitative study to explore motivations and facilitators. PLoS One. 2012;7(10):e45333.
9. Glasgow RE, Toobert DJ, Gillette CD. Psychosocial barriers to diabetes self-management and quality of life. Diab Spectrum. 2001;14(1):33.
10. Lockwood MB, Saunders MR, Nass R, et al. Patient-reported barriers to the Prekidney transplant evaluation in an at-risk population in the United States. Prog Transplant. 2017;27(2):131–8.
11. Lo C, Teede H, Fulcher G, et al. Gaps and barriers in health-care provision for co-morbid diabetes and chronic kidney disease: a cross-sectional study. BMC Nephrol. 2017;18(1):80.
12. WHO. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia. Geneva: World Health Organisation; 2006.
13. WHO. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus. Geneva: World Health Organisation; 2011.
14. Levey AS, Stevens LA, Schmid CH, et al. A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009;150(9):604–12.
15. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007;370(9596):1453–7.
16. Australian Bureau of Statistics. Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA). Canberra: Australian Bureau of Statistics; 2011(2033.0.55.001).
17. Hays RD, Kallich JD, Mapes DL, Coons SJ, Carter WB. Development of the kidney disease quality of life (KDQOL) instrument. Qual Life Res. 1994;3(5):329–38.
18. Chow SKY, Tam BML. Is the kidney disease quality of life-36 (KDQOL-36) a valid instrument for Chinese dialysis patients? BMC Nephrol. 2014;15(1):199.
19. Ricardo AC, Hacker E, Lora CM, et al. Validation of the kidney disease quality of life short form 36 (KDQOL-36) US Spanish and English versions in a cohort of Hispanics with chronic kidney disease. Ethn Dis. 2013;23(2):202–9.
20. Chao S, Yen M, Lin TC, Sung JM, Wang MC, Hung SY. Psychometric properties of the kidney disease quality of Life-36 questionnaire (KDQOL-36). West J Nurs Res. 2016;38(8):1067–82.
21. Lo C, Ilic D, Teede H, et al. The perspectives of patients on health-Care for co-Morbid Diabetes and Chronic Kidney Disease: a qualitative study. PLoS One. 2016;11(1):e0146615.
22. Avsar U, Avsar UZ, Cansever Z, et al. Caregiver burden, anxiety, depression, and sleep quality differences in caregivers of hemodialysis patients compared with renal transplant patients. Transplant Proc. 2015; 47(5):1388–91.
23. Arechabala MC, Catoni MI, Palma E, Barrios S. Depression and self-perceived burden of care by hemodialysis patients and their caregivers. Revista Panamericana De Salud Publica. 2011;30(1):74–9.
24. Sajadi SAM, Ebadi AP, Moradian STP. Quality of life among family caregivers of patients on hemodialysis and its relevant factors: a systematic review. Int J community Based Nurs Midwifery. 2017;5(3):206–18.
25. Jannoo Z, Wah YB, Lazim AM, Hassali MA. Examining diabetes distress, medication adherence, diabetes self-care activities, diabetes-specific quality of life and health-related quality of life among type 2 diabetes mellitus patients. J Clin Transl Endocrinol. 2017;9:48–54.
26. Saleh F, Mumu SJ, Ara F, Hafez MA, Ali L. Non-adherence to self-care practices & medication and health related quality of life among patients with type 2 diabetes: a cross-sectional study. BMC Public Health. 2014;14:431.
27. Lee S, Kim H. Structural equation modeling on self-care behavior and quality of life in older adults with diabetes using citizen health promotion centers. J Korean Acad Nurs. 2017;47(4):514–25.
28. Ausili DA-Ohoo, Bulgheroni M, Ballatore P, et al. Self-care, quality of life and clinical outcomes of type 2 diabetes patients: an observational cross-sectional study. Acta Diabetol. 2017;54(11):1001–8.
29. Lee MC, Wu SV, Hsieh NC, Tsai JM. Self-Management Programs on eGFR, Depression, and Quality of Life among Patients with Chronic Kidney Disease: A Meta-Analysis. Asian Nurs Res (Korean Soc Nurs Sci). 2016;10(4):255–62.
30. Pera PI. Living with diabetes: quality of care and quality of life. Patient Prefer Adherence. 2011;5:65–72.
31. Cooke D, Bond R, Lawton J, et al. Structured type 1 diabetes education delivered within routine care: impact on glycemic control and diabetes-specific quality of life. Diabetes Care. 2013;36(2):270–2.
32. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. Diabetes Educ. 2008;34(5):815–23.
33. Trento M, Passera P, Borgo E, et al. A 5-year randomized controlled study of learning, problem solving ability, and quality of life modifications in people with type 2 diabetes managed by group care. Diabetes Care. 2004;27(3):670–5.
34. Maneze D, Everett B, Astorga C, Yogendran D, Salamonson Y. The influence of health literacy and depression on diabetes self-management: a cross-sectional study. J Diab Res. 2016;2016:3458969.
35. Rebollo Rubio A, Morales Asencio JM, Eugenia Pons Raventos M. Depression, anxiety and health-related quality of life amongst patients who are starting dialysis treatment. (1755–6686 (Electronic)).
36. Bujang MA, Musa R, Liu WJ, Chew TF, Lim CT, Morad Z. Depression, anxiety and stress among patients with dialysis and the association with quality of life. (1876–2026 (Electronic)).
37. Paschalides C, Wearden AJ, Dunkerly R, Bundy C, Davies R, Dickens CM. The associations of anxiety, depression and personal illness representations with glycaemic control and health-related quality of life in patients with type 2 diabetes mellitus. J Psychosomat Res. 2004;57:557–64.
38. Glasgow RE, Ruggiero L, Eakin EG, Dryfoos J, Chobanian L. Quality of life and associated characteristics in a large national sample of adults with diabetes. Diabetes Care. 1997;20(4):562–7.
39. Cheah W, Lee P, Lim P, Fatin Nabila A, Luk K, Nur Iwana A. Perception of quality of life among people with diabetes. Malays Fam Physician. 2012;7(2–3):21.
40. Rajapurkar MM, John GT, Kirpalani AL, et al. What do we know about chronic kidney disease in India: first report of the Indian CKD registry. BMC Nephrol. 2012;13:10.
41. Berg UB. Differences in decline in GFR with age between males and females. Reference data on clearances of inulin and PAH in potential kidney donors. Nephrol Dial Transplant. 2006;21(9):2577–82.
42. Lin C-M, Yang M-C, Hwang S-J, Sung J-M. Progression of stages 3b–5 chronic kidney disease—preliminary results of Taiwan National pre-ESRD disease management program in Southern Taiwan. J Formos Med Assoc. 2013;112(12):773–82.



**Ready to submit your research? Choose BMC and benefit from:**

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

**At BMC, research is always in progress.**

**Learn more** biomedcentral.com/submissions

### 3.3 Conclusion

Younger age was associated with lower scores in all HRQOL subscales except the physical composite summary and female gender, obese or normal weight and more advanced stages of CKD were associated with lower scores in one or more subscales. Additionally, patient reported barriers to health care were associated with low physical and mental well-being. Well designed and disease-specific longitudinal studies are required to determine the impact of these factors on patients' well-being. While some important patient and health system characteristics have been shown to influence HRQOL in this Chapter, the focus of the next Chapter is to examine the relationship between self-management and HRQOL.

**Additional file 1:** Diabetes Renal Project (Doctors Survey - Health Indicators) in appendices under research instruments.

**Additional file 2**: Supplementary Appendix S2-Barriers to Health-care Questionnaire.

Sometimes people have difficulty looking after their diabetes and kidney disease due to a variety of barriers or obstacles. Listed below are several barriers that may influence your ability to look after your diabetes and kidney disease. To what extent do you agree or disagree with the following factors being a current barrier for you? (Please tick the appropriate box in the table below).

| | Disagree | Somewhat Disagree | Somewhat Agree | Agree |
|---|---|---|---|---|
| My diabetes and kidney specialist does not spend enough time with me | ☐ | ☐ | ☐ | ☐ |
| My diabetes and kidney specialist does not provide me with enough information/education about my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I am often seen by a different doctor each time I attend my diabetes or kidney disease appointment. | ☐ | ☐ | ☐ | ☐ |
| My specialists give me conflicting advice | ☐ | ☐ | ☐ | ☐ |
| I do not have a good relationship with my specialist or other specialist health service staff. | ☐ | ☐ | ☐ | ☐ |
| Specialist health service staff are not caring, polite and helpful | ☐ | ☐ | ☐ | ☐ |
| My specialists do not communicate well with my GP | ☐ | ☐ | ☐ | ☐ |
| My specialists don't communicate well with each other | ☐ | ☐ | ☐ | ☐ |
| I do not have a good GP | ☐ | ☐ | ☐ | ☐ |
| I need more education and understanding of my diabetes | ☐ | ☐ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| I need more education and understanding of my kidney disease | ☐ | ☐ | ☐ | ☐ |
| The information provided by my doctors or health professionals is hard to understand because English is not my first language, or the information is not culturally relevant | ☐ | ☐ | ☐ | ☐ |
| The information provided by my doctors or health professionals is too complicated | ☐ | ☐ | ☐ | ☐ |
| It is difficult to obtain medical support and advice for my diabetes when I need it | ☐ | ☐ | ☐ | ☐ |
| It is difficult to obtain medical support and advice for my kidney disease when I need it | ☐ | ☐ | ☐ | ☐ |
| I have had an unsatisfactory prior experience with a diabetes or kidney health service/specialist | ☐ | ☐ | ☐ | ☐ |
| I am unable to afford the cost of attending appointments or buying medication for my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I have trouble adjusting to the impact that diabetes and kidney disease has made on my life and/or that of my family and friends | ☐ | ☐ | ☐ | ☐ |
| My diabetes and kidney disease make me feel very unwell | ☐ | ☐ | ☐ | ☐ |
| My other illnesses affect my ability to look after my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I have many other stressors in my life, and taking care of my diabetes and kidney disease is not a high priority | ☐ | ☐ | ☐ | ☐ |
| My job makes it difficult to take care of my diabetes and kidney disease well. | ☐ | ☐ | ☐ | ☐ |
| My mood (e.g. feeling down, worried, frustrated) gets in the way of me looking after my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I do not feel motivated enough to look after my diabetes and kidney disease well | ☐ | ☐ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| I have trouble maintaining the right diet or fluid restriction for my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I have difficulty knowing what I can eat/drink, for my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| I experience unpleasant side-effects from my medication | ☐ | ☐ | ☐ | ☐ |
| I do not receive support from my family | ☐ | ☐ | ☐ | ☐ |
| I do not receive support from my friends | ☐ | ☐ | ☐ | ☐ |
| I find it difficult to get services for home-help | ☐ | ☐ | ☐ | ☐ |

Do you have difficulty accessing a diabetes service?

□ Yes □ No

Do you have difficulty accessing a kidney service?

□ Yes □ No

**Additional file 3:** Kidney Disease and Quality of Life (KDQOL™-36) in appendices under research instruments.

## Additional file 4

**S1**: Characteristics of patients who did and did not participate in this study

| | **Responders** | **Non-responders** | **p-value** |
|---|---|---|---|
| Patient numbers (n) | 308 | 120* | - |
| Age (SD) | 66.9 (11.0) | 71.5 (9.6) | 0.0001 |
| Gender (Female, %) | 30.5 | 40.8 | 0.04 |
| Type of diabetes (Type 2, %) | 88.0 | 94.2 | 0.06 |
| eGFR, mean (SD) | 29.0 (16.7) | 36.3 (10.0) | 0.0001 |

* Non-responders from one sampling site; eGFR was calculated using the Chronic Kidney Disease Epidemiology Collaboration equation and expressed in mL/min/1.73 $m^2$

**S2**: Univariable and multivariable logistic regression for factors associated with low physical health status (SF Physical Composite Summary <50)

| | **Univariable** | | **Multivariable** | |
|---|---|---|---|---|
| Factor | OR (95% CI) | p-value | OR (95% CI) | p-value |
| Age | 1.00 (0.98 to 1.03) | 0.72 | 1.04 (1.02 to 1.06) | 0.001 |
| Gender (Ref: male) | 2.60 (1.74 to 3.89) | 0.001 | 1.44 (0.69 to 3.00) | 0.33 |
| Socioeconomic status | 1.00 (0.99 to 1.01) | 0.40 | - | - |
| Language (Ref: English) | 4.9 (1.25 to 19.39) | 0.02 | 3.05 (0.75 to 12.40) | 0.12 |
| Inadequate time spent with specialist | 0.92 (0.49 to 1.72) | 0.79 | - | - |
| Inadequate information provided by specialist | 1.20 (0.43 to 3.34) | 0.72 | - | - |
| Being seen by a different doctor | 0.71 (0.48 to 1.04) | 0.08 | 0.47 (0.27 to 0.80) | 0.01 |
| Poor relationship with health staff | 3.80 (0.24 to 60.13) | 0.34 | - | - |
| Staff not caring, polite and helpful | 2.23 (0.19 to 26.64) | 0.53 | - | - |
| Poor communication from specialists to GPs | 1.62 (0.41 to 6.35) | 0.49 | - | - |
| Poor communication between specialists | 1.34 (1.06 to 1.69) | 0.01 | 1.44 (0.71 to 2.92) | 0.32 |
| Not having a good GP | 1.37 (0.46 to 4.05) | 0.57 | - | - |
| Inadequate diabetes education | 0.68 (0.58 to 0.79) | 0.001 | 0.40 (0.22 to 0.72) | 0.002 |
| Inadequate kidney disease education | 0.95 (0.23 to 3.99) | 0.95 | - | - |
| Complicated education material | 1.15 (0.61 to 2.14) | 0.67 | - | - |
| Inadequate advice regarding diabetes | 1.82 (0.63 to 5.25) | 0.27 | - | - |
| Inadequate advice regarding kidney disease | 1.09 (0.29 to 4.07) | 0.90 | - | - |
| Unsatisfactory previous experience | 0.64 (0.36 to 1.14) | 0.13 | - | - |
| Costs (transport and buying medications) | 1.42 (0.46 to 4.36) | 0.54 | - | - |
| Impact of disease on family and friends | 3.48 (1.71 to 7.07) | 0.001 | 2.07 (1.14 to 3.78) | 0.02 |
| Feeling unwell due to illness | 3.83 (1.25 to 11.8) | 0.02 | 4.23 (1.45 to 12.30) | 0.01 |
| Other illness | 5.51 (0.62 to 49.0) | 0.13 | - | - |
| Having other life stressors | 3.59 (1.97 to 6.54) | 0.001 | 2.59 (1.20 to 5.61) | 0.02 |
| Mood affects self-management | 2.71 (1.06 to 6.95) | 0.04 | 0.98 (0.57 to 1.66) | 0.93 |
| Feels unmotivated to self-manage | 1.51 (0.36 to 6.35) | 0.57 | - | - |
| Maintaining dietary and fluid restrictions | 1.67 (0.81 to 3.46) | 0.17 | - | - |
| Not knowing what is allowed to eat/drink | 1.47 (0.46 to 4.74) | 0.52 | - | - |
| Experience of medication side effects | 3.60 (2.08 to 6.25) | 0.001 | 1.73 (0.53 to 5.62) | 0.36 |
| Inadequate support from family | 2.63 (0.97 to 7.13) | 0.06 | - | - |
| Inadequate support from friends | 3.89 (1.12 to 13.58) | 0.03 | 2.84 (0.5 to 15.67) | 0.23 |
| Difficulties getting home help | 2.87 (1.27 to 6.50) | 0.01 | 1.40 (0.92 to 2.12) | 0.12 |

Variable with a P<0.05 were included in the logistic multivariable model. Variables with P<0.05 in logistic multivariable were significant. GP-General Practitioner; OR-Odds ratio; CI-Confidence interval.

**S3**: Univariable and multivariable logistic regression for factors associated with low mental health status (SF Mental Composite Summary <50)

| | **Univariable** | | **Multivariable** | |
|---|---|---|---|---|
| Factor | OR (95% CI) | p-value | OR (95% CI) | p-value |
| Age | 0.97 (0.96 to 0.98) | 0.001 | 0.99 (0.98 to 1.00) | 0.20 |
| Gender (Ref: male) | 1.11 (1.01 to 1.22) | 0.03 | 1.15 (0.65 to 2.05) | 0.62 |
| Socioeconomic status | 1.00 (0.99 to 1.01) | 0.04 | 1.00 (0.99 to 1.01) | 0.26 |
| Language (Ref: English) | 1.72 (0.95 to 3.11) | 0.07 | - | - |
| Inadequate time spend with specialist | 2.17 (1.17 to 4.04) | 0.01 | 1.67 (0.53 to 5.27) | 0.39 |
| Specialist provides inadequate information | 2.23 (0.96 to 5.14) | 0.06 | - | - |
| Being seen by different specialists | 1.50 (1.40 to 1.66) | 0.001 | 1.02 (0.48 to 2.17) | 0.95 |
| Poor relationship with health staff | 3.00 (1.46 to 6.18) | 0.001 | 2.37 (0.80 to 7.04) | 0.12 |
| Staff not caring, polite and helpful | 1.94 (1.46 to 2.56) | 0.001 | 0.52 (0.25 to 1.10) | 0.09 |
| Poor communication from specialists to GPs | 1.44 (0.85 to 2.46) | 0.18 | - | - |
| Poor communication between specialists | 2.02 (1.16 to 3.52) | 0.01 | 1.12 (0.46 to 2.73) | 0.80 |
| Not having a good GP | 3.85 (1.19 to 12.51) | 0.03 | 2.18 (0.68 to 7.03) | 0.19 |
| Inadequate diabetes education | 0.81 (0.45 to 1.48) | 0.50 | - | - |
| Inadequate kidney disease education | 0.98 (0.64 to 1.52) | 0.94 | - | - |
| Complicated education material | 1.24 (0.83 to 1.84) | 0.29 | - | - |
| Inadequate advice regarding diabetes | 1.23 (0.31 to 4.89) | 0.77 | - | - |
| Inadequate advice regarding kidney disease | 1.74 (0.52 to 5.84) | 0.37 | - | - |
| Unsatisfactory previous experience | 1.53 (0.62 to 3.80) | 0.36 | - | - |
| Costs (transport and buying medications) | 1.48 (1.04 to 2.10) | 0.03 | 0.59 (0.32 to 1.07) | 0.08 |
| Disease affecting family and friends | 3.36 (1.96 to 5.76) | 0.001 | 1.16 (0.90 to 1.49) | 0.25 |
| Feeling unwell due to illness | 3.82 (1.85 to 7.92) | 0.001 | 2.92 (1.07 to 8.01) | 0.04 |
| Other illness | 4.39 (1.47 to 13.16) | 0.01 | 1.47 (0.29 to 7.32) | 0.64 |
| Having other life stressors | 2.50 (1.67 to 3.73) | 0.001 | 1.16 (0.45 to 3.00) | 0.76 |
| Mood affects self-management | 7.29 (3.66 to 14.51) | 0.001 | 2.82 (1.64 to 4.87) | 0.001 |
| Feels unmotivated to self-manage | 4.19 (1.47 to 11.94) | 0.01 | 1.54 (0.43 to 5.57) | 0.51 |
| Maintaining dietary and fluid restrictions | 1.97 (1.20 to 3.24) | 0.01 | 0.78 (0.41 to 1.50) | 0.46 |
| Not knowing what is allowed to eat/drink | 1.27 (0.73 to 2.23) | 0.40 | - | - |
| Experience of medication side effects | 2.53 (1.85 to 3.46) | 0.001 | 0.96 (0.48 to 1.93) | 0.91 |
| Inadequate support from friends | 3.18 (1.89 to 5.34) | 0.001 | 1.66 (0.24 to 11.67) | 0.61 |
| Inadequate support from family | 3.36 (1.22 to 9.26) | 0.02 | 1.95 (0.84 to 4.55) | 0.12 |
| Difficulties getting home help | 3.44 (2.11 to 5.61) | 0.001 | 1.91 (1.57 to 2.33) | 0.001 |

Variable with a P<0.05 were included in the logistic multivariable model. Variables with P<0.05 in logistic multivariable were significant. GP-General Practitioner; OR-Odds ratio; CI-Confidence interval.

**Table S4:** Odds of low physical and mental health status by number of patient reported barriers

| **Number of barriers∗** | **Low physical health scores** | | **Low mental health scores** | |
|---|---|---|---|---|
| | OR (95% CI) | P-value | OR (95% CI | P-value |
| 0-3 (reference) | | | | |
| 4-8 | 1.67 (0.64 to 4.36) | 0.29 | 2.03 (1.52 to 2.69) | 0.001 |
| 9-29 | 1.87 (0.61 to 5.75) | 0.28 | 4.08 (1.43 to 11.61) | 0.01 |

∗ The total number of barriers identified by each patient were categorised into tertiles. The first tertile (patient reported 0-3 barriers) was the reference group; OR-Odd ratio; CI-Confidence interval

# CHAPTER 4

# RELATIONSHIP BETWEEN SELF-MANAGEMENT AND HEALTH-RELATED QUALITY OF LIFE

## 4.1 Introduction

The association between self-management and health-related quality of life has been described in patients with heart failure, chronic obstructive pulmonary disease and diabetes [101, 109-113], but not in those with co-morbid diabetes and CKD. Among some studies that have evaluated the effects of diabetes self-management on health related quality of life (HRQOL) in patients with diabetes only [101], HRQOL was not treated as a primary outcome [114]. Even so, improvements in HRQOL have been reported following diabetes self-management training that was not specifically designed to improve HRQOL [101]. To close this gap in the literature, the relationship between self-management and HRQOL in patients with co-morbid diabetes and CKD was evaluated. Chapter 4 examines the relationship between self-management and HRQOL in the context of co-morbid diabetes and CKD and establishes whether there is a difference in this relationship by severity of CKD. The study described in this Chapter was published in the Journal of Diabetes and Its Complications (Zimbudzi et al., 2016). The Chapter is presented as the published pdf version of the manuscript.

## 4.2 Published manuscript: Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in health-related quality of life

Citation: **Zimbudzi E**., Lo C., Ranasinha S., Kerr P., Usherwood T., Cass A., Fulcher GR., Zoungas S. (2016). Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. Journal of Diabetes and Its Complications 2017; 31:427-432.

Journal of Diabetes and Its Complications 31 (2017) 427–432

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

# Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL

Edward Zimbudzi [a,b], Clement Lo [b,c], Sanjeeva Ranasinha [b], Peter G. Kerr [a], Timothy Usherwood [d,e], Alan Cass [f], Gregory R. Fulcher [g], Sophia Zoungas [b,c,d,*]

[a] Department of Nephrology, Monash Health, Melbourne, Australia
[b] Monash Centre for Health Research and Implementation (MCHRI), School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia
[c] Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Australia
[d] The George Institute for Global Health, University of Sydney, Sydney, Australia
[e] Department of General Practice, Sydney Medical School Westmead, Sydney, Australia
[f] Menzies School of Health Research, Darwin, Australia
[g] Department of Endocrinology, University of Sydney, Sydney, Australia

ARTICLE INFO

*Article history:*
Received 18 August 2016
Received in revised form 3 October 2016
Accepted 26 October 2016
Available online 29 October 2016

*Keywords:*
Self-management behavior
Health-related quality of life
Diabetes
Chronic kidney disease
Self-care

ABSTRACT

*Aims:* There is insufficient and inconsistent data regarding the association between diabetes self-management, the process of facilitating the knowledge, skill, and ability necessary for diabetes self-care, and health-related quality of life (HRQOL) in people with diabetes and moderate to severe chronic kidney disease (CKD).

*Methods:* In a cross sectional study, participation in diabetes self-management assessed by the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire and HRQOL was examined in 308 patients with diabetes and CKD (stages 3 to 5) recruited from outpatient diabetes and renal clinics of 4 public tertiary hospitals. Associations were examined by Pearson correlation coefficients and hierarchical multiple regression after controlling for potential confounders. An examination of trend across the levels of patient participation in self-management was assessed using a non-parametric test for trend.

*Results:* The median age and interquartile range (IQR) of patients were 68 and 14.8 years, respectively with 59% of the population being over 65 years old and 69.5% male. The median durations of diabetes and CKD were 18 years (IQR-17) and 5 years (IQR-8) respectively. General diet, exercise and medication taking were positively associated with at least one HRQOL subscale (all $p < 0.05$) but diabetes specific diet, blood sugar testing and foot checking were not. As levels of participation in self-management activities increased there was a graded increase in mean HRQOL scores across all subscales ($p$ for trend $<0.05$).

*Conclusions:* In people with diabetes and moderate to severe CKD, participation in diabetes self-management activities, particularly those focused on general diet, exercise and medication taking, was associated with higher HRQOL.

© 2017 Elsevier Inc. All rights reserved.

## 1. Introduction

Chronic kidney disease (CKD) and diabetes share common risk factors which when experienced together enhance the risk of progressive disease and adverse outcomes. Approximately 50% of patients with type 2 diabetes globally are affected by CKD (Thomas, Cooper, & Zimmet, 2016; Tuttle et al., 2014) and over 35% of patients commencing renal replacement therapy have diabetes (Centre for Disease Control, 2010; Collins et al., 2005; Grace, Clayton, & McDonald, 2012; Icks et al., 2011; Wakasugi, Kazama, & Narita, 2016). Both diabetes and CKD are associated with substantially higher lifetime financial costs and reduced life expectancy (Zhuo et al., 2014). Low cost, but effective diabetes self-management interventions can potentially reduce complications and progression of diabetes and CKD.

Diabetes self-management programs seek to change behavior leading to better disease control that should, in turn, result in better patient outcomes. So far, several diabetes self-management interventions have been reported in the literature, albeit with inconsistent outcomes with some short to medium term studies reporting improved outcomes and others not. These interventions have been associated with improved clinical outcomes (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Curtin et al., 2008; Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001) and reduced costs (Ahn et al., 2013) in some short to medium term studies (Glasgow, Fisher, Skaff, Mullan, &

Conflicts of interest: The authors declare no conflict of interest.

* Corresponding author at: Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, 43-51 Kanooka Grove, Clayton, VIC, 3168, Australia. Tel.: +61 3 9594 7500; fax: +61 3 9594 7554.
*E-mail address:* sophia.zoungas@monash.edu (S. Zoungas).

http://dx.doi.org/10.1016/j.jdiacomp.2016.10.027
1056-8727/© 2017 Elsevier Inc. All rights reserved.

Toobert, 2007; Norris, Engelgau, & Narayan, 2001; Norris et al., 2002; Warsi, Wang, LaValley, Avorn, & Solomon, 2004) but not others (Khunti et al., 2012).

Very few studies have evaluated the effects of diabetes self-management on health related quality of life (HRQOL) (Cochran & Conn, 2008) and available evidence fails to portray HRQOL as a priority target outcome (Magwood, Zapka, & Jenkins, 2008). Among adults with diabetes, improvements in HRQOL following diabetes self-management training have been reported even though the interventions were not designed to improve HRQOL (Cochran & Conn, 2008). Among people with diabetes and moderate to severe CKD, poorer self-management decisions due to the additional health care burden imposed by the development of kidney disease, have been proposed to result in lower HRQOL but no studies have examined this relationship (Griva et al., 2015). The present study thus aimed to examine the relationship between self-management and HRQOL in the context of complex multisystem disease and whether there was a difference in this relationship by severity of CKD.

## 2. Subjects, materials and methods

A cross-sectional study (as part of a large health care improvement study) of patients attending diabetes and renal outpatient clinics of four public and tertiary hospitals in Victoria and New South Wales (Monash Health, Alfred Health, Royal North Shore Hospital and Concord Hospital) between 2013 and December 2014 was conducted. Participants were eligible if they received their usual care at these hospitals and had a diagnosis of diabetes (either type 1 or type 2) and CKD stages 3 to 5 (estimated glomerular filtration rate <60 ml/min/1.73m$^2$). The diagnosis of diabetes followed the World Health Organization (World Health Organization, 2006) definition and was recorded from patients' prior inpatient or outpatient contacts. Patients were recruited prospectively from clinics and asked to complete the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire and the Kidney Disease Quality of Life short form (KDQOL™-36) (Supplementary Appendices A and B). The questionnaires were self-administered. For each patient a clinical survey was also completed by the site study staff or the clinician, using standardized procedures. Information was extracted from the patient's medical record and included demographic and disease-specific characteristics such as gender, age, body mass index, diabetes type, diabetes duration, type of diabetes treatment, late complication status, and current HbA1c (Supplementary Appendix C). Socio-economic measures were estimated using the Australian Bureau of Statistics data (Australian Bureau of Statistics, 2013). Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables which include income, educational attainment and employment status. The IRSD scores for each postcode were then grouped into quintiles for analysis, where the highest quintile comprised 20% of postcodes with the highest IRSD scores (the most advantaged areas). All participants provided written informed consent. The study was approved by Monash University and respective health service ethics committees.

### 2.1. Self-management

Self-management was assessed using the revised version of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (Toobert, Hampson, & Glasgow, 2000) which is a self-report measure of the frequency of performing diabetes self-care activities. The SDSCA scale has been evaluated in numerous studies and settings and is deemed to be reliable, valid, and sensitive in evaluating diabetes self-care in adults (AlJohani, Kendall, & Snider, 2014; Freitas, Freitas da Silva, Neta, & Vilarouca da Silva, 2014; Jalaludin, Fuziah, Hong, Mohamad Adam, & Jamaiyah, 2012). The scale consists of 11 core items comprising of five sub-scales namely diet, consisting of general diet (item 1–2) and diabetes specific diet (3–4), exercise (item 5–6), blood-glucose testing (item 7–8), foot-care (item 9–10) and smoking (item 11) (Du & Yuan, 2010; Song, Ratcliffe, Tkacs, & Riegel, 2012; Tol et al., 2012). For all the items except item 11, scoring was done on an 8 point Likert scale from 0 to 7. For each subscale, the mean number of days the specific self-care activities were performed over the past 7 days was calculated, with reverse scoring on item 4 (dietary fat); higher scores indicating better self-care practice. A medication subscale was also added to the SDSCA to have a comprehensive understanding of the adherence levels of respondents to their diabetes medication (pills and/or insulins).

### 2.2. Health related quality of life

HRQOL was assessed using the English version of the Kidney Disease and Quality of Life (KDQOL™-36) which is a 36-item survey with five subscales namely the SF-12 measure of physical and mental functioning, burden of kidney disease, symptom/problems list and the effects of kidney disease subscales (Agrawal et al., 2012). Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQOL (Agrawal et al., 2012).

### 2.3. Statistical analysis

Normally distributed data were presented with mean and standard deviation (SD) as the measures of central tendency and dispersion, respectively. Correspondingly, non-normally distributed continuous data were presented with medians and interquartile ranges (IQR, thus 25th and 75th percentiles), respectively. Differences of continuous variables between groups and categorical variables were compared by using the t-test and the $\chi^2$ test respectively.

First, linear regression models were used to evaluate the bivariate associations of diabetes self-care activities and HRQOL subscales. Diabetes self-care subscales were selected as independent variables in the regression analyses based on both clinical experience and findings from previous studies (Heisler, Smith, Hayward, Krein, & Kerr, 2003; Hendriks & Rademakers, 2014; Skolasky et al., 2011; Taru, Tsutou, Nakawatase, Usami, & Miyawaki, 2008). Second, independent associations of diabetes self-care subscales and the 5 HRQOL subscales were examined by using a 7 step hierarchical multiple linear regression. Age, eGFR, diabetes and kidney disease duration were identified a priori as important potential confounders based on previous studies (Kim et al., 2013; Lee et al., 2012) and these were entered into the model first. Diabetes self-care scales were then entered into the model individually (step 2 to step 7). The $R^2$ and F change between the first and second steps of the hierarchical model determined the magnitude to which diabetes self-care subscales were predictors of HRQOL beyond the predictive capacity of variables included in the first step. Third, the mean composite SDSCA was transformed into a categorical variable with three categories that defined the average number of days diabetes self-care activities were undertaken and these were 0–2 days, 3–4 days and 5–7 days. To assess the primary study purpose, a non-parametric test for trend for the ranks across the ordered three categories was performed. Confidence intervals (CIs) were reported at the 95% level and results were considered significant at conventional $p < 0.05$ level. All analyses were performed with IBM SPSS version 22 (IBM Corp., Armonk, NY) or Stata version 12.1 (Statacorp, College Station, TX).

## 3. Results

The baseline demographic and clinical characteristics of the study population are shown in Table 1. Overall, the median age and interquartile range (IQR) were 68 and 14.8 years respectively with 59% of the population being over 65 years old. There was an even distribution of participants across the five socioeconomic strata. The

**Table 1**
Baseline demographic and clinical characteristics of the study population.

| Characteristic | N (%) | SDSCA mean score | *p* value[a] |
|---|---|---|---|
| Age (years), median (IQR) | 68 (14.8) | | |
| ≤65 | 129 (41.9) | 3.9 ± 1.1 | |
| >65 | 179 (59.1) | 4.0 ± 1.1 | 0.60 |
| Gender | | | |
| Male | 214 (69.5) | 3.9 ± 1.1 | |
| Female | 94 (30.5) | 4.1 ± 1.0 | 0.14 |
| [b]Socioeconomic status (by quintiles) | | | |
| Lower | 63 (20.5) | 4.0 ± 1.0 | |
| Upper lower | 60 (19.5) | 3.8 ± 1.1 | |
| Lower middle | 61 (19.8) | 3.8 ± 1.3 | |
| Upper middle | 64 (20.8) | 4.0 ± 1.1 | |
| Upper | 60 (19.5) | 4.0 ± 0.9 | 0.65 |
| Diabetes | | | |
| Type of diabetes | | | |
| Type 1 | 45 (14.6) | 4.0 ± 1.2 | |
| Type 2 | 249 (80.8) | 3.9 ± 1.2 | |
| Unsure | 14 (4.6) | 3.9 ± 1.0 | 0.94 |
| Glycemic control | | | |
| Glycated hemoglobin (%), μ ± SD | 6.8 ± 7.1 | | |
| Suboptimal (HbA1c >7) | 155 (50.3) | 4.2 ± 0.9 | |
| Optimal (HbA1c ≤7) | 153 (49.7) | 3.7 ± 1.2 | <0.001 |
| Diabetes duration (years), median (IQR) | 18 (17) | | |
| Kidney disease | | | |
| Stages of chronic kidney disease | | | |
| 3a | 72 (23.4) | 4.1 ± 1.0 | |
| 3b | 79 (25.6) | 4.2 ± 1.0 | |
| 4 | 76 (24.7) | 3.7 ± 1.2 | |
| 5 | 81 (26.3) | 3.8 ± 1.2 | 0.02 |
| eGFR (mL/min/1.73 $m^2$), μ ± SD | 29.1 ± 16.6 | | |
| CKD duration (years), median (IQR) | 5 (8) | | |
| Quality of life (score of 0–100), μ ± SD | | | |
| Physical composite summary | 35.2 ± 11.1 | | |
| Mental composite summary | 47.0 ± 10.9 | | |
| Symptom problem/list | 73.8 ± 17.8 | | |
| Effect of kidney disease | 72.5 ± 23.7 | | |
| Burden of kidney disease | 59.8 ± 31.0 | | |
| Body mass index (kg/$m^2$), median (IQR) | 29.9 (8.3) | | |
| [c]Participation in self-care activities | | | |
| 0–2 days | 13 (4.3) | | |
| 3–4 days | 145 (48.5) | | |
| 5–7 days | 142 (47.2) | | |

[a] t Test for mean differences and chi-square test for differences in proportions.
[b] Lower quintile representing the areas of greatest socioeconomic disadvantage.
[c] Average number of days self-management activities were undertaken.

median duration of diabetes was 18 years (IQR-17) with 14.6% and 80.8% of the participants reporting to have type 1 and type 2 diabetes respectively and 4.6% unsure of their diabetes type. The mean (±SD) HbA1c was 6.8 ± 7.1% and 49.7% of the participants had HbA1c less than 7%. The median duration for CKD was 5 years (IQR-8) and participants were evenly distributed across CKD stages 3a to 5.

The mean (±SD) scores for the SDSCA subscales (i.e. the mean number of days per week that self-care activities were performed) ranged from 2.1 ± 2.0 (exercising) to 5.2 ± 2.3 (sugar testing) with a composite mean score of 3.9 ± 1.1 as shown in Table 2. Just over half of patients reported participating in self-care activities on 4 or less days per week (Table 1). The mean (±SD) HRQOL scores for the physical composite summary, mental composite summary, symptom/problem list, effect of kidney disease and burden of kidney disease were 35.2 ± 11.1, 47.0 ± 10.9, 73.8 ± 17.8, 72.5 ± 23.7 and 59.8 ± 31.0 respectively.

### *3.1. Relationship between diabetes self-management and HRQOL*

The mean composite SDSCA score was positively associated with all the HRQOL subscales ($p < 0.01$) (Table 2). As levels of participation in self-management increased from 0 - 2 days, 3–4 days to 5–7 days there was a graded increase in mean HRQOL scores across all subscales (all $p$ for trend <0.05) (Fig. 1). Moreover, the greatest increments in HRQOL scores were found when patients increased from the middle to highest level of participation in self-management (i.e. 3–4 days to 5–7 days per week).

When the self-care activities were considered separately, there was a significant positive association between exercise and all HRQOL subscales, general diet and all HRQOL subscales apart from the physical composite summary subscale, and medication taking and the mental composite summary and burden of kidney disease subscales (Table 2). Diabetes specific diet, blood sugar testing and foot checking were not significantly associated with any HRQOL subscale.

In models adjusting for participants' age, eGFR, diabetes and CKD duration, exercise remained significantly associated with all HRQOL subscales, general diet remained significantly associated with the mental composite summary, symptom problem/list and the burden of kidney disease subscales, and medication taking remained significantly associated with only the mental composite summary subscale (all $p < 0.05$) (Table 3).

## 4. Discussion

In people with diabetes and moderate to severe CKD, there was a positive linear relationship between level of participation in diabetes self-management (as a composite score of the SDSCA scale) and scores in all HRQOL subscales. This relationship remained after

**Table 2**
Association between self-management and HRQOL.

| Self-care activities | Mean ± SD[a] (range 0–7 days) | Health-related quality of life | | | | |
|---|---|---|---|---|---|---|
| | | Physical composite summary B (95% CI) | Mental composite summary B (95% CI) | Symptom/problem list B (95% CI) | Effects of kidney disease B (95% CI) | Burden of kidney disease B (95% CI) |
| General diet | 5.0 ± 1.9 | 0.29 (−0.06–0.63) | 0.73 (0.40–1.06)** | 0.99 (0.46–1.52)** | 0.87 (0.14–1.39)* | 1.37 (0.42–2.32)** |
| Diabetes specific diet | 3.2 ± 1.5 | 0.07 (−0.37–0.51) | −0.31 (−0.73–0.11) | −0.07 (−0.76–0.61) | −0.35 (−1.30–0.58) | −1.24 (−2.46–0.02) |
| Exercise | 2.1 ± 2.0 | 0.94 (0.63–1.25)** | 0.46 (0.14–0.78)** | 1.07 (0.56–1.57)** | 1.37 (0.69–2.06)** | 1.9 (1.01–2.80)** |
| Sugar testing | 5.2 ± 2.3 | 0.03 (−0.25–0.32) | 0.07 (−0.21–0.35) | 0.15 (−0.29–0.59) | 0.06 (−0.53–0.65) | 0.47 (−0.31–1.24) |
| Foot check | 3.0 ± 2.4 | 0.17 (−0.10–0.44) | 0.15 (−0.12–0.41) | 0.23 (−0.19–0.66) | 0.25 (−0.32–0.83) | 0.51 (−0.24–1.27) |
| Medication | 4.7 ± 1.9 | -0.18 (−0.74–0.38) | 0.74 (0.20–1.30)** | 0.63 (−0.25–1.50) | 0.45 (−0.70–1.60) | 1.86 (0.34–3.40) |
| Mean composite score | 3.9 ± 1.1 | 0.19 (0.07–0.30)** | 0.15 (0.04–0.27)** | 0.31 (0.13–0.49)** | 0.29 (0.05–0.54)** | 0.48 (0.16–0.80)** |

B – unstandardized beta coefficient; 95% CI – 95% confidence interval.
[a] The mean of number of days self-care activities were performed.
* $p < 0.05$.
** $p < 0.01$ (2-tailed).

controlling for potential confounding covariates such as age, eGFR, duration of CKD and diabetes. In particular, increased diabetes self-care activities in the domains of general diet, exercising and medication taking were positively associated with at least one HRQOL subscale but the domains of diabetes specific diet, blood sugar testing and foot checking were not.

Our results extend findings from other studies reporting on HRQOL outcomes in patients with diabetes (Cochran & Conn, 2008; Kueh, Morris, & Ismail, 2016; Sugiyama, Steers, Wenger, Duru, & Mangione, 2015; Toobert et al., 2011) by examining the relationship between self-management and HRQOL in patients with diabetes and moderate to severe CKD; a group of patients who may have a greater need for support to engage in self-care activities. Additionally, we demonstrate that in this group of patients, the different self-care activities are independent of one another in their relationship with HRQOL and the different domains of HRQOL. For instance, while the self-care composite score and the specific components of exercise and general diet were positively associated with most if not all HRQOL domains, diabetes specific diet, blood sugar testing and foot checking were not associated with any HRQOL domains. This highlights the importance of addressing particular self-care activities rather than others in order to achieve optimal outcomes across all HRQOL domains in people with moderate to severe CKD.

There was no relationship between the SDSCA domains of diabetes specific diet, blood sugar testing and foot checking and HRQOL. This was despite the fact that participants scored reasonably well in these respective self-care activities. The likely explanation may be the prohibitive cost associated with diabetes diet (Ebrahim, De Villiers, & Ahmed, 2014; Houle et al., 2016) and the effect of unmeasured confounders such as underlying depression (Wagner, Tennen, & Osborn, 2010) or social support (Rosland et al., 2014) which have been shown to influence adherence to blood sugar testing and foot checking respectively. Another reason is that the burden of an individual undertaking self-care activities may result in poorer HRQOL. Well-designed clinical trials of models of care incorporating self-care activities that assess HRQOL as an outcome are warranted to clarify this.

HRQOL scores across all domains significantly improved with an increase in the number of days participants were engaged in self-care activities. These data suggest that multi-component self-management interventions may be important for improving quality of life in patients with co-morbid diabetes and moderate to severe CKD and this is consistent with findings from previous studies (Barrera et al.,

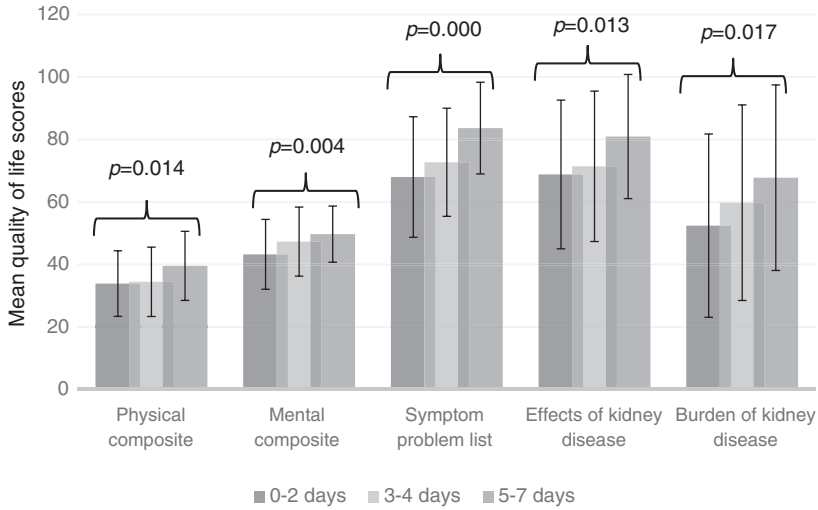



**Fig. 1.** Non-parametric test for trend assessing differences in health-related quality of scores across the levels of participation in self-management (0–2 days, 3–4 days and 5–7 days).

**Table 3**
Adjusted model[a] for the relationship between self-management and HRQOL.

| | Physical composite summary | | Mental composite summary | | Symptom/Problem list | | Effects of kidney disease | | Burden of kidney disease | |
|---|---|---|---|---|---|---|---|---|---|---|
| | B | $R^2$ | B | $R^2$ | B | $R^2$ | B | $R^2$ | B | $R^2$ |
| Step 1 | | | | | | | | | | |
| Potential confounders | | | | | | | | | | |
| Age | −0.01 | 6.5** | 0.2 | 5.9** | 0.2 | 5.7** | 0.39 | 16.4*** | 0.4 | 29.6*** |
| eGFR | 0.2 | | 0.01 | | 0.2 | | 0.46 | | 0.9 | |
| Diabetes duration | −0.03 | | 0.04 | | −0.04 | | −0.11 | | −0.2 | |
| CKD duration | −0.07 | | 0.2 | | 0.2 | | 0.18 | | 0.4 | |
| Step 2 | | | | | | | | | | |
| General diet | 0.7 | 7.8 | 1.4 | 11.3** | 1.9 | 9.7** | 1.5 | 17.7 | 2.3 | 31.6** |
| Step 3 | | | | | | | | | | |
| Diabetes specific diet | 0.2 | 7.8 | −0.5 | 11.8 | −0.04 | 9.7 | −0.2 | 17.7 | −1.7 | 32.3 |
| Step 4 | | | | | | | | | | |
| Exercising | 1.6 | 15.5*** | 0.8 | 14.0* | 1.8 | 13.5** | 2.1 | 20.5** | 2.6 | 34.8** |
| Step 5 | | | | | | | | | | |
| Blood sugar testing | −0.2 | 15.6 | −0.02 | 14.0 | −0.03 | 13.5 | −0.3 | 20.6 | 0.4 | 34.9 |
| Step 6 | | | | | | | | | | |
| Foot checking | 0.1 | 15.7 | 0.1 | 14.0 | 0.08 | 13.5 | 0.13 | 20.6 | 0.5 | 35.0 |
| Step 7 | | | | | | | | | | |
| Medication | −0.3 | 15.8 | 0.9 | 16.0* | 0.7 | 13.9 | −0.3 | 20.7 | 0.9 | 35.3 |

*p* value (significant at <0.05) for the change in predictive power added to the model by the addition of each predictor variable in the six steps of the hierarchical regression.
B – unstandardized beta coefficient.
[a] Model adjusted for potentially confounding variables (age, estimated glomerular filtration rate, diabetes duration and kidney disease duration).
* $p < 0.05$.
** $p < 0.01$.
*** $p < 0.001$.

2011; Heinrich, Schaper, & de Vries, 2010). The main challenge of employing multi-component self-management strategies is that they are often complex to teach; require engagement and collaboration between people with diabetes and health service providers; and require investment of considerable time and effort on the part of the patient.

We report an association between medication adherence and the mental health composite summary. This is consistent with previous reports (DiBonaventura, Wintfeld, Huang, & Goren, 2014; Kulkarni, Alexander, Lytle, Heiss, & Peterson, 2006) although the mechanism of this association remains unclear. A possible explanation may be the mental empowerment garnered from proactive disease management despite the burden of more complex medication regimens (Lau, Qureshi, & Scott, 2004). Others have reported that the improvement in mental HRQOL achieved by the diabetes self-management education was not likely mediated by glycemic control (Sugiyama et al., 2015).

It is possible that the relationship between diabetes self-management and quality of life is reversed and that patients with better quality of life are more likely to participate in self-care activities as they may feel more motivated and empowered (Kueh, Morris, Borkoles, & Shee, 2015). One study examining factors influencing patient completion of Diabetes Self-Management Education (DSME) (Adams et al., 2013) found that SF-12 scores indicating poorer physical and mental health were responsible for non-completion of individual DSME. Another study which identified factors that influence ability to self-care for adults living with diabetes types 1 or 2 reports that low HRQOL scores may result in inability to perform self-care tasks (Wilkinson, Whitehead, & Ritchie, 2014). Further longitudinal studies may help clarify the impact of reverse causality on this relationship.

Our findings should be interpreted in light of a number of limitations some of which may offer opportunities for future research. First, we cannot infer causal relationships in this study due to its cross sectional design. Second, there was a skewed gender distribution with only a third of participants being women. This is consistent with the gender distribution of populations with CKD in other studies (Rajapurkar et al., 2012). The study's strengths include the use of validated tools for measuring self-management and HRQOL. Second, the study examined the complex relationships of individual SDSCA scales with different domains of HRQOL and lastly, this was a multi-site study allowing for generalization of our findings.

In conclusion, there is a positive association between diabetes self-management and health related quality of life particularly in the domains of exercise, general diet and medication in people with co-morbid diabetes and moderate to severe CKD. Further longitudinal studies are required to determine if optimizing individual self-care activities may improve HRQOL.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.jdiacomp.2016.10.027.

## Acknowledgment

This study was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. C Lo was supported by an Australian Postgraduate Award Scholarship. H Teede was supported by a NHMRC, Australia Fellowship. S Zoungas was supported by a National Heart Foundation of Australia Fellowship. We also acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

## References

Adams, K. F., Sperl-Hillen, J. M., Davis, H., Spain, C. V., Hanson, A. M., Fernandes, O. D., ... Beaton, S. (2013). Factors influencing patient completion of diabetes self-management education. *Diabetes Spectrum*, *26*(1), 40–45. http://dx.doi.org/10.2337/diaspect.26.1.40.

Agrawal, V., Jaar, B. G., Frisby, X. Y., Chen, S. C., Qiu, Y., Li, S., ... Bomback, A. S. (2012). Access to health care among adults evaluated for CKD: Findings from the Kidney Early Evaluation Program (KEEP). *American Journal of Kidney Diseases*, *59*(3 Suppl 2), S5–15. http://dx.doi.org/10.1053/j.ajkd.2011.10.043.

Ahn, S., Basu, R., Smith, M. L., Jiang, L., Lorig, K., Whitelaw, N., & Ory, M. G. (2013). The impact of chronic disease self-management programs: Healthcare savings through

a community-based intervention. *BMC Public Health*, *13*, 1141. http://dx.doi.org/10.1186/1471-2458-13-1141.
AlJohani, K. A., Kendall, G. E., & Snider, P. D. (2014). Psychometric evaluation of the Summary of Diabetes Self-Care Activities-Arabic (SDSCA-Arabic): Translation and analysis process. *Journal of transcultural nursing : official journal of the Transcultural Nursing Society / Transcultural Nursing Society*. http://dx.doi.org/10.1177/1043659614526255.
Australian Bureau of Statistics (2013). *Census of population and housing: Socio-economic indexes for areas (SEIFA), Australia, 2011*. Canberra: Australian Bureau of Statistics.
Barrera, M., Toobert, D. J., Strycker, L. A., Osuna, D., King, D. K., & Glasgow, R. E. (2011). Multiple-behavior–change interventions for women with type 2 diabetes. *Diabetes Spectrum*, *24*(2), 75–80. http://dx.doi.org/10.2337/diaspect.24.2.75.
Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *JAMA*, *288*(19), 2469–2475.
Centre for Disease Control (2010). Incidence of end-stage renal disease attributed to diabetes among persons with diagnosed diabetes – United States and Puerto Rico, 1996–2007. *MMWR. Morbidity and Mortality Weekly Report*, *59*(42), 1361–1366.
Cochran, J., & Conn, V. S. (2008). Meta-analysis of quality of life outcomes following diabetes self-management training. *The Diabetes Educator*, *34*(5), 815–823. http://dx.doi.org/10.1177/0145721708323640.
Collins, A. J., Kasiske, B., Herzog, C., Chavers, B., Foley, R., Gilbertson, D., ... Agodoa, L. (2005). Excerpts from the United States Renal Data System 2004 annual data report: Atlas of end-stage renal disease in the United States. *American Journal of Kidney Diseases*, *45*(1 Suppl 1), A5–A7 (s1-280).
Curtin, R. B., Walters, B. A., Schatell, D., Pennell, P., Wise, M., & Klicko, K. (2008). Self-efficacy and self-management behaviors in patients with chronic kidney disease. *Advances in Chronic Kidney Disease*, *15*(2), 191–205. http://dx.doi.org/10.1053/j.ackd.2008.01.006.
DiBonaventura, M., Wintfeld, N., Huang, J., & Goren, A. (2014). The association between nonadherence and glycated hemoglobin among type 2 diabetes patients using basal insulin analogs. *Patient Prefer Adherence*, *8*, 873–882. http://dx.doi.org/10.2147/ppa.s55550.
Du, S., & Yuan, C. (2010). Evaluation of patient self-management outcomes in health care: A systematic review. *International Nursing Review*, *57*(2), 159–167. http://dx.doi.org/10.1111/j.1466-7657.2009.00794.x.
Ebrahim, Z., De Villiers, A., & Ahmed, T. (2014). Factors influencing adherence to dietary guidelines: A qualitative study on the experiences of patients with type 2 diabetes attending a clinic in Cape Town. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*, *19*(2). http://dx.doi.org/10.1080/16089677.2014.11073604.
Freitas, S., Freitas da Silva, G., Neta, D., & Vilarouca da Silva, A. (2014). Analysis of the self-care of diabetics according to by the Summary of Diabetes Self-Care Activities Questionnaire (SDSCA) *Acta Scientiarum. Health Sciences*, *36*(1), 73–81.
Glasgow, R. E., Fisher, L., Skaff, M., Mullan, J., & Toobert, D. J. (2007). Problem solving and diabetes self-management: Investigation in a large, multiracial sample. *Diabetes Care*, *30*(1), 33–37. http://dx.doi.org/10.2337/dc06-1390.
Grace, B. S., Clayton, P., & McDonald, S. P. (2012). Increases in renal replacement therapy in Australia and New Zealand: Understanding trends in diabetic nephropathy. *Nephrology (Carlton)*, *17*(1), 76–84. http://dx.doi.org/10.1111/j.1440-1797.2011.01512.x.
Griva, K., Mooppil, N., Khoo, E., Lee, V. Y. W., Kang, A. W. C., & Newman, S. P. (2015). Improving outcomes in patients with coexisting multimorbid conditions – the development and evaluation of the combined diabetes and renal control trial (C-DIRECT): Study protocol. *BMJ Open*, *5*(2). http://dx.doi.org/10.1136/bmjopen-2014-007253.
Heinrich, E., Schaper, N. C., & de Vries, N. K. (2010). Self-management interventions for type 2 diabetes: A systematic review. *European Diabetes Nursing*, *7*(2), 71–76. http://dx.doi.org/10.1002/edn.160.
Heisler, M., Smith, D. M., Hayward, R. A., Krein, S. L., & Kerr, E. A. (2003). How well do patients' assessments of their diabetes self-management correlate with actual glycemic control and receipt of recommended diabetes services? *Diabetes Care*, *26*(3), 738–743.
Hendriks, M., & Rademakers, J. (2014). Relationships between patient activation, disease-specific knowledge and health outcomes among people with diabetes; a survey study. *BMC Health Services Research*, *14*, 393. http://dx.doi.org/10.1186/1472-6963-14-393.
Houle, J., Lauzier-Jobin, F., Beaulieu, M. D., Meunier, S., Coulombe, S., Cote, J., ... Lambert, J. (2016). Socioeconomic status and glycemic control in adult patients with type 2 diabetes: A mediation analysis. *BMJ Open Diabetes Research & Care*, *4*(1), e000184. http://dx.doi.org/10.1136/bmjdrc-2015-000184.
Icks, A., Haastert, B., Genz, J., Giani, G., Hoffmann, F., Trapp, R., & Koch, M. (2011). Incidence of renal replacement therapy (RRT) in the diabetic compared with the non-diabetic population in a German region, 2002–08. *Nephrology, Dialysis, Transplantation*, *26*(1), 264–269. http://dx.doi.org/10.1093/ndt/gfq398.
Jalaludin, M., Fuziah, M., Hong, J., Mohamad Adam, B., & Jamaiyah, H. (2012). Reliability and validity of the revised Summary of Diabetes Self-Care Activities (SDSCA) for Malaysian children and adolescents. *Malaysian Family Physician*, *7*(2&3), 10–20.
Khunti, K., Gray, L. J., Skinner, T., Carey, M. E., Realf, K., Dallosso, H., ... Davies, M. J. (2012). Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *BMJ*, *344*. http://dx.doi.org/10.1136/bmj.e2333.
Kim, J. Y., Kim, B., Park, K. S., Choi, J. Y., Seo, J. J., Park, S. H., ... Kim, Y. L. (2013). Health-related quality of life with KDQOL-36 and its association with self-efficacy and treatment satisfaction in Korean dialysis patients. *Quality of Life Research*, *22*(4), 753–758. http://dx.doi.org/10.1007/s11136-012-0203-x.
Kueh, Y. C., Morris, T., Borkoles, E., & Shee, H. (2015). Modelling of diabetes knowledge, attitudes, self-management, and quality of life: A cross-sectional study with an Australian sample. *Health and Quality of Life Outcomes*, *13*, 129. http://dx.doi.org/10.1186/s12955-015-0303-8.
Kueh, Y. C., Morris, T., & Ismail, A. A. (2016). The effect of diabetes knowledge and attitudes on self-management and quality of life among people with type 2 diabetes. *Psychology, Health & Medicine*, 1–7. http://dx.doi.org/10.1080/13548506.2016.1147055.
Kulkarni, S. P., Alexander, K. P., Lytle, B., Heiss, G., & Peterson, E. D. (2006). Long-term adherence with cardiovascular drug regimens. *American Heart Journal*, *151*(1), 185–191. http://dx.doi.org/10.1016/j.ahj.2005.02.038.
Lau, C. Y., Qureshi, A. K., & Scott, S. G. (2004). Association between glycaemic control and quality of life in diabetes mellitus. *Journal of Postgraduate Medicine*, *50*(3), 189–193 (discussion 194).
Lee, H., Oh, Y. J., Kim, M., Kim, H., Lee, J. P., Kim, S., ... Kim, D. K. (2012). The association of moderate renal dysfunction with impaired preference-based health-related quality of life: 3rd Korean National Health And Nutritional Examination Survey. *BMC Nephrology*, *13*(1), 1–11. http://dx.doi.org/10.1186/1471-2369-13-19.
Lorig, K. R., Sobel, D. S., Ritter, P. L., Laurent, D., & Hobbs, M. (2001). Effect of a self-management program on patients with chronic disease. *Effective Clinical Practice*, *4*(6), 256–262.
Magwood, G. S., Zapka, J., & Jenkins, C. (2008). A review of systematic reviews evaluating diabetes interventions: Focus on quality of life and disparities. *The Diabetes Educator*, *34*(2), 242–265. http://dx.doi.org/10.1177/0145721708316551.
Norris, S. L., Engelgau, M. M., & Narayan, K. M. (2001). Effectiveness of self-management training in type 2 diabetes: A systematic review of randomized controlled trials. *Diabetes Care*, *24*(3), 561–587.
Norris, S. L., Nichols, P. J., Caspersen, C. J., Glasgow, R. E., Engelgau, M. M., Jack, L., ... McCulloch, D. (2002). Increasing diabetes self-management education in community settings. A systematic review. *American Journal of Preventive Medicine*, *22*(4 Suppl), 39–66.
Rajapurkar, M. M., John, G. T., Kirpalani, A. L., Abraham, G., Agarwal, S. K., Almeida, A. F., ... Jha, V. (2012). What do we know about chronic kidney disease in India: First report of the Indian CKD registry. *BMC Nephrology*, *13*, 10. http://dx.doi.org/10.1186/1471-2369-13-10.
Rosland, A. -M., Piette, J. D., Lyles, C. R., Parker, M. M., Moffet, H. H., Adler, N. E., ... Karter, A. J. (2014). Social support and lifestyle vs. medical diabetes self-management in the diabetes study of northern California (DISTANCE). *Annals of behavioral medicine : A publication of the Society of Behavioral Medicine*, *48*(3), 438–447. http://dx.doi.org/10.1007/s12160-014-9623-x.
Skolasky, R. L., Green, A. F., Scharfstein, D., Boult, C., Reider, L., & Wegener, S. T. (2011). Psychometric properties of the patient activation measure among multimorbid older adults. *Health Services Research*, *46*(2), 457–478. http://dx.doi.org/10.1111/j.1475-6773.2010.01210.x.
Song, M., Ratcliffe, S. J., Tkacs, N. C., & Riegel, B. (2012). Self-care and health outcomes of diabetes mellitus. *Clinical Nursing Research*, *21*(3), 309–326. http://dx.doi.org/10.1177/1054773811422604.
Sugiyama, T., Steers, W. N., Wenger, N. S., Duru, O. K., & Mangione, C. M. (2015). Effect of a community-based diabetes self-management empowerment program on mental health-related quality of life: A causal mediation analysis from a randomized controlled trial. *BMC Health Services Research*, *15*(1), 1–9. http://dx.doi.org/10.1186/s12913-015-0779-2.
Taru, C., Tsutou, A., Nakawatase, Y., Usami, M., & Miyawaki, I. (2008). Gender differences of dietary self-management behavior affecting control indices in type II diabetes. *The Kobe Journal of Medical Sciences*, *54*(2), E82–E96.
Thomas, M. C., Cooper, M. E., & Zimmet, P. (2016). Changing epidemiology of type 2 diabetes mellitus and associated chronic kidney disease. *Nature Reviews. Nephrology*, *12*(2), 73–81. http://dx.doi.org/10.1038/nrneph.2015.173.
Tol, A., Shojaeezadeh, D., Eslami, A., Alhani, F., Mohajeritehrani, M., Baghbanian, A., & Sharifirad, G. (2012). Evaluation of self-care practices and relative components among type 2 diabetic patients. *Journal of Education and Health Promotion*, *1*, 19. http://dx.doi.org/10.4103/2277-9531.99219.
Toobert, D. J., Hampson, S. E., & Glasgow, R. E. (2000). The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care*, *23*(7), 943–950.
Toobert, D. J., Strycker, L. A., King, D. K., Barrera, M., Jr., Osuna, D., & Glasgow, R. E. (2011). Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: Inverted exclamation markViva Bien! *Translational Behavioral Medicine*, *1*(3), 416–426. http://dx.doi.org/10.1007/s13142-010-0011-1.
Tuttle, K. R., Bakris, G. L., Bilous, R. W., Chiang, J. L., de Boer, I. H., Goldstein-Fuchs, J., ... Molitch, M. E. (2014). Diabetic kidney disease: a report from an ADA Consensus Conference. *American Journal of Kidney Diseases*, *64*(4), 510–533. http://dx.doi.org/10.1053/j.ajkd.2014.08.001.
Wagner, J. A., Tennen, H., & Osborn, C. Y. (2010). Lifetime depression and diabetes self-management in women with type 2 diabetes: A case control study. *Diabetic Medicine : A Journal of the British Diabetic Association*, *27*(6), 713–717. http://dx.doi.org/10.1111/j.1464-5491.2010.02996.x.
Wakasugi, M., Kazama, J. J., & Narita, I. (2016). Age- and gender-specific incidence rates of renal replacement therapy in Japan: An international comparison. *Renal Replacement Therapy*, *2*(1), 1–7. http://dx.doi.org/10.1186/s41100-016-0017-3.
Warsi, A., Wang, P. S., LaValley, M. P., Avorn, J., & Solomon, D. H. (2004). Self-management education programs in chronic disease: A systematic review and methodological critique of the literature. *Archives of Internal Medicine*, *164*(15), 1641–1649. http://dx.doi.org/10.1001/archinte.164.15.1641.
Wilkinson, A., Whitehead, L., & Ritchie, L. (2014). Factors influencing the ability to self-manage diabetes for adults living with type 1 or 2 diabetes. *International Journal of Nursing Studies*, *51*(1), 111–122. http://dx.doi.org/10.1016/j.ijnurstu.2013.01.006.
World Health Organization (2006). *Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF consultation.* , 69 (Geneva).
Zhuo, X., Zhang, P., Barker, L., Albright, A., Thompson, T. J., & Gregg, E. (2014). The lifetime cost of diabetes and its implications for diabetes prevention. *Diabetes Care*, *37*(9), 2557–2564. http://dx.doi.org/10.2337/dc13-2484.

### 4.3 Conclusion

In people with diabetes and moderate to severe CKD, participation in diabetes self-management activities, particularly those focused on general diet, exercise and medication taking was associated with higher HRQOL. However, this finding needs to be confirmed in longitudinal studies designed to determine if optimizing individual self-management activities may improve HRQOL. It is also important to identify the elements and components of self-management interventions associated with improved HRQOL, which is the focus of the next Chapter.

# CHAPTER 5

# REVIEW OF SELF-MANAGEMENT SUPPORT INTERVENTIONS

## 5.1 Introduction

The previous Chapter has shown that there is a positive relationship between self-management and HRQOL. Currently a plethora of self-management support interventions exist for managing patients with single diseases only, making it difficult for health care providers to select the most pragmatic and effective interventions for use in patients with complex diseases such as co-morbid diabetes and CKD. Given self-management support interventions may be particularly important for people with co-morbid diabetes and CKD, a systematic review of intervention studies was undertaken to determine which interventions and which components can be applied in daily practice.

This Chapter investigates the self-management support interventions that improve patient reported and clinical outcomes in adults with co-morbid diabetes and CKD. Chapter 5.2 consists of a systematic review and meta-analysis protocol registered in the International Prospective Register of Systematic Reviews (PROSPERO 2015 CRD42015017316). The protocol is available from https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=17316 and is published in Systematic Reviews (Zimbudzi et al., 2015). The systematic review and meta-analysis is presented in Chapter 5.3 and is published in Systematic Reviews (Zimbudzi et al., 2018). The Chapter is presented as the published pdf version of both the protocol and the manuscript.

## 5.2 Published manuscript: Effectiveness of management models for facilitating self-management and patient outcomes in people with diabetes and chronic kidney disease (PROTOCOL)

**Citation: Zimbudzi E**., Lo C., Misso M., Ranasinha S., Zoungas S. Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease. *Systematic reviews* 2015; *4*: 81. Doi: 10.1186/s13643-015-0072-9.

Zimbudzi et al. Systematic Reviews (2015) 4:81
DOI 10.1186/s13643-015-0072-9

SYSTEMATIC REVIEWS

PROTOCOL Open Access

# Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease

Edward Zimbudzi[1,2*], Clement Lo[2,3], Marie Misso[2], Sanjeeva Ranasinha[2] and Sophia Zoungas[2,3,4]

## Abstract

**Background:** Self-management models can be a very powerful resource in the health system provided they are well tailored to a particular disease and setting. Patient outcomes have been demonstrated to improve when self-management practices are embedded in the care of people with certain diseases. However, it remains unclear whether self-management models and specific components of these programmes can be implemented in order to effectively improve the care of people with diabetes and/or chronic kidney disease.

**Methods/Design:** Medline (including Medline in-process), Excerpta medica database (EMBASE), Cumulative Index to Nursing and Allied Health (CINAHL) and all evidence-based medicine (EBM) will be systematically searched for randomised controlled studies comparing self-management models with usual care in patients with diabetes or chronic kidney disease. Two reviewers will independently assess articles for eligibility: extract data, evaluate risk of bias and complete quality assessment of included studies. The data will be tabulated and narratively synthesised. Meta-analyses will be performed if there is sufficient homogenous data.

**Discussion:** This protocol utilises rigorous methodology as well as pre-specified eligibility criteria to comprehensively search for diabetes and kidney disease self-management models which have been compared with usual care in randomised controlled trials. The review is likely to provide insight into the effectiveness of current models for improving patient self-management, and this may address the key translational issue of how to integrate and tailor these self-management practices for patients with diabetes and chronic kidney disease.

**Systematic review registration:** PROSPERO CRD42015017316.

**Keywords:** Diabetes, Chronic kidney disease, Self-management practices, Self-management models, Systematic review

* Correspondence: edward.zimbudzi@monash.edu
[1]Department of Nephrology, Monash Health, Clayton, Melbourne, VIC, Australia
[2]Monash Centre for Health Research and Implementation—MCHRI, School of Public Health and Preventive Medicine, Monash University, Clayton, Melbourne, VIC, Australia
Full list of author information is available at the end of the article

BioMed Central

© 2015 Zimbudzi et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly credited. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

## Background

Chronic diseases are defined as illnesses that are prolonged in duration, do not often resolve spontaneously and are rarely cured completely [1]. They are the largest cause of death globally [2]. Among these diseases are diabetes and chronic kidney disease. The incidence and prevalence of diabetes mellitus has soared throughout the world, mainly due to the increase in type 2 diabetes, which in turn is largely related to the increase in overweight and obesity [3, 4]. It is projected that by 2025, there will be 380 million people with type 2 diabetes and 418 million people with impaired glucose tolerance [5]. Direct medical costs of treating diabetes and its complications during a lifetime are estimated to be $85,000 in the United States. In this regard, diabetes presents a huge financial challenge to the health system and the economy at large.

Chronic kidney disease can occur as a sequela of or independent of diabetes. Worldwide, CKD affects over 200 million people [6] and diabetes contributes 30–40 % of all end stage kidney disease (ESKD) cases [7]. In developed countries, diabetes-related kidney damage is the leading cause of treated end stage kidney disease accounting for approximately 50 % of cases [8]. Given the incidence of diabetes is increasing, a concurrent rising tide of people with kidney disease is anticipated.

Due to the complex nature of diabetes and CKD, it is not only important to prevent but to improve the entire continuum of care from prevention to treatment and self-management. Several self-management strategies have therefore been implemented to manage illnesses and minimise the impact on patients, families and the health system [9]. These strategies have been organised into models, which have produced some favourable outcomes including improvement of the physiological measures of disease, adherence to treatment, health service and self-reported health measures such as health-related quality of life [10]. However, the approach to self-management in these various chronic disease models has differed substantively. While some are centred on patient education, motivational interviewing and health coaching, others follow a much broader approach of the way the patient relates to health providers and the community.

Given the wide array of chronic disease health care models and self-management practices promulgated, it is possible to apply a model which poorly fits the particular chronic disease and setting of implementation. For example, often a "mismatch" between the needs of the patients and health care available exists due to the traditional acute care orientation of existing health systems [11–13]. Several studies have compared the outcomes of usual care (for various diseases in different settings) with one or other chronic disease health care models in order to identify the most effective means by which to provide care [13–15]. However, the effectiveness of these models in the management of people with diabetes and CKD has not been established.

A systematic review of the evidence is required to provide insight as to the most effective self-management models and the specific components of chronic disease health care models that can be implemented in order to improve the outcomes of people with diabetes and chronic kidney disease (CKD) [16, 17].

### Objectives of the systematic review

The objectives of this study are to investigate:

- The effectiveness of current diabetes and CKD management models in improving clinical outcomes of patients with diabetes and CKD,
- The common elements of a model of care that improves patient outcomes for diabetes and CKD and
- The effectiveness of current models of care in improving self-management in diabetes and CKD patients.

### Conceptual framework

As depicted in Fig. 1, a CKD/diabetes self-management model needs to have activities or interventions which are applied to the target population in addition to their usual care. These activities include patient education, patient reminders, motivational interviewing, health coaching, increased access to health experts and incentives. The impact of these interventions can be classified as short-term outcomes, intermediate outcomes and long-term outcomes.

Short-term outcomes measure the initial impact of an activity, for instance, improved self-efficacy. They capture the "potential" for continued change created through activities and their outputs. Intermediate outcomes are often few and are seen in individuals who continue to participate in self-management activities. They are the changes believed to be created by the project and not only impact individuals directly participating in the project's activities but impact those connected to them such as families, friends and community partners. Long-term outcomes may be achieved after a lengthy duration (7–10 years), and they represent the ultimate goal for the project.

## Methods

### Systemic review design

A systematic review and meta-analysis which adopts methods outlined in the Cochrane Handbook for Systematic Reviews of Interventions guidelines [18] and conforms to the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols (PRISMA-P) statement recommendations [19] will

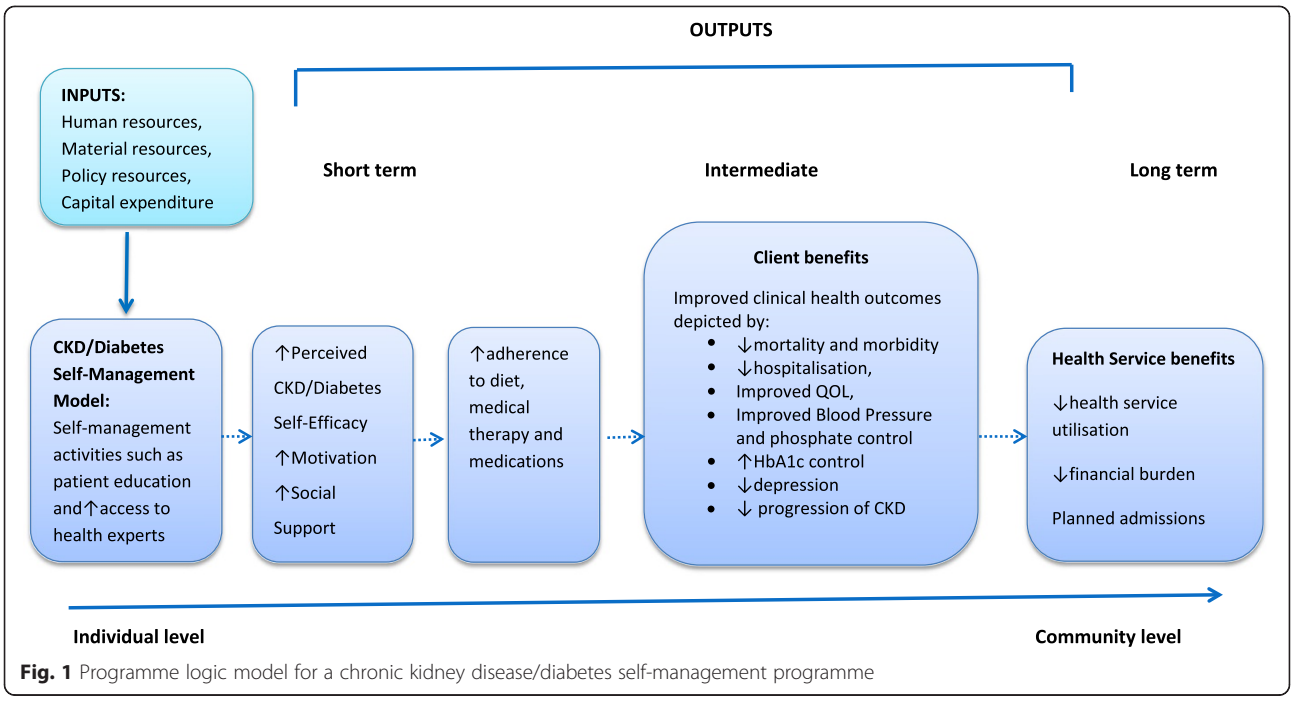



**Fig. 1** Programme logic model for a chronic kidney disease/diabetes self-management programme

be conducted. The methodology of this review will be guided by the PICOS format.

### *Population/participants*

Adult patients (above 18 years) with diabetes and CKD in any healthcare setting (acute care, primary health care, family medical practice, general medical practice, clinics, outpatient departments, rehabilitation or community settings) in all countries.

### *Interventions*

Chronic disease management models focusing on the healthcare provider or the patient will be considered. As a typical chronic disease management model has multiple interventions, relevant interventions will be classified into five groups [12]:

- Use of evidence-based planned care
- Reorganisation of practice systems and provider roles
- Improved patient self-management support
- Increased access to expertise
- Availability of clinical information

Relevant intervention components include [20]:

- Provider education—includes education materials or instructions given to the healthcare provider to aid with the management of a given chronic disease.
- Provider feedback—information given to healthcare providers regarding the care or results of care experienced by their patient.
- Provider reminders—prompts given to providers to perform specific patient care tasks.
- Patient education—materials and instructions given to patients to enhance the management of their chronic disease condition.
- Patient reminders—prompts given to patients to remind them to perform specific tasks related to the management of their disease condition.
- Patient financial incentives—payments (direct or indirect) to patients for achieving certain disease management goals.

Only studies whose chronic disease management models have included one or more of the above components will be eligible for inclusion.

### *Comparator*

Usual or standard care must be clearly defined to be eligible for inclusion in this systematic review. This may be the chronic disease management programme that is already in place before a new model of care is introduced. Usual care will potentially present some challenges in this study since this may differ depending on setting.

### *Outcomes*

**Primary** Clinical indicators (*blood pressure*, eGFR and HbA1C): non-invasive measures of blood pressure performed by an automated machine or manually by a health practitioner will be accepted.

**Secondary** Adherence to medical treatment: adherence to medication, diet, lifestyle changes or appointment keeping. All validated adherence measurement tools will be considered, including but not limited to direct observable behaviour, subjective self-reports (patient-reported outcome), objective monitoring of medication usage, objective physiological/biomedical measures, health outcomes or combined adherence measurements. Examples of some of the validated tools are the Medication Event Monitoring System (MEMS) [21], medication adherence report scale (MARS-5) [22], Morisky medication taking adherence scale (MMAS) [23] and the brief medication questionnaire (BMQ) [24].

Self-management behaviour: self-management (SM) can be defined as the "active management by individuals of their treatment, symptoms and lifestyle, physical and psychological consequences inherent with living with a chronic condition" [25]. To achieve adequate SM skills, individuals may require a series of SM interventions addressing their area of need. Effectiveness of SM models will be determined by evaluation of at least two key areas, such as, but not limited to whether people developed the skills to manage their own health and secondly, whether this has resulted in better health. Measures of impact of SM may include the patient activation measure (PAM) indicators such as patient knowledge, skill and confidence for SM and prediction of a range of behaviours including healthy behaviours, disease specific management behaviours and consumeristic type of behaviours [26]. The method of measurement of SM behaviour must be reported to be eligible for inclusion in this systematic review.

Health service utilisation: measures of the population's use of the health care services available to them, incorporating economic indicators which are based on volume such as number of hospitalisations and number of visits per year. Ideally, chronic disease management models would aim for fewer hospitalisations due to the financial connotations associated with health service utilisation. It is very important to note that health service utilisation may be a long-term outcome and therefore may only be properly ascertained by studies with a reasonably longer follow-up period.

Health-related quality of life: only validated tools will be considered including EuroQol 5D [27], quality of life scale (QoLS) [28] and the kidney disease quality of life instrument (KDQOL) [29].

Adverse outcomes: adverse events such as hospitalisation and deaths will be considered in this review.

#### *Study design/setting*

Randomised controlled trials: For the purpose of this review, only randomised controlled studies and systematic reviews of randomised controlled studies, reporting adequate information to allow for estimation of at least one relevant outcome of the chronic disease management model as outlined above, will be considered.

The following *publication types will be excluded*: articles reporting non-randomised studies, narrative reviews, letters, editorials, commentaries, unpublished manuscripts, dissertations, government reports, books and book chapters, conference proceedings, meeting abstracts, lectures and addresses, and consensus development statements and guidelines.

Language: Studies published in English language will be included.

### Search methods

The following electronic databases will be used to identify relevant literature using a systematic search developed according to the selection criteria (Additional file 1):

- Medline
- Medline in-process and other non-indexed citations
- EMBASE
- CINAHL
- All Evidence-Based Medicine (EBM) Reviews incorporating The Cochrane Library, Cochrane Database of Systematic Reviews (Cochrane reviews), Database of Abstracts of Reviews of Effects (other reviews), Cochrane Central Register of Controlled Trials (clinical trials), Cochrane Database of Methodology Reviews (methods reviews), The Cochrane Methodology Register (methods studies), Health Technology Assessment Database (technology assessments), NHS Economic Evaluation Database (economic evaluations) and ACP Journal Club.

We will also search the bibliographies of relevant studies identified by the search strategy for identification of additional studies. The National Institute of Health Clinical Trials Register (https://clinicaltrials.gov/) and the Australian and New Zealand Clinical Trials Registry (https://www.anzctr.org.au/) will also be searched.

### Inclusion of studies

To determine the literature to be assessed further, two reviewers (EZ and CL) will scan the titles, abstract sections and keywords of every record retrieved by the search strategy (Fig. 2). Full articles will be retrieved for further assessment if the information given suggests that the study meets the inclusion criteria. If there is any doubt regarding these criteria from the information given in the title and abstract, the full article will be retrieved for clarification. During the full text review, if the two reviewers are in doubt about the inclusion of any particular study, there will be an option of involving the third reviewer (MM).

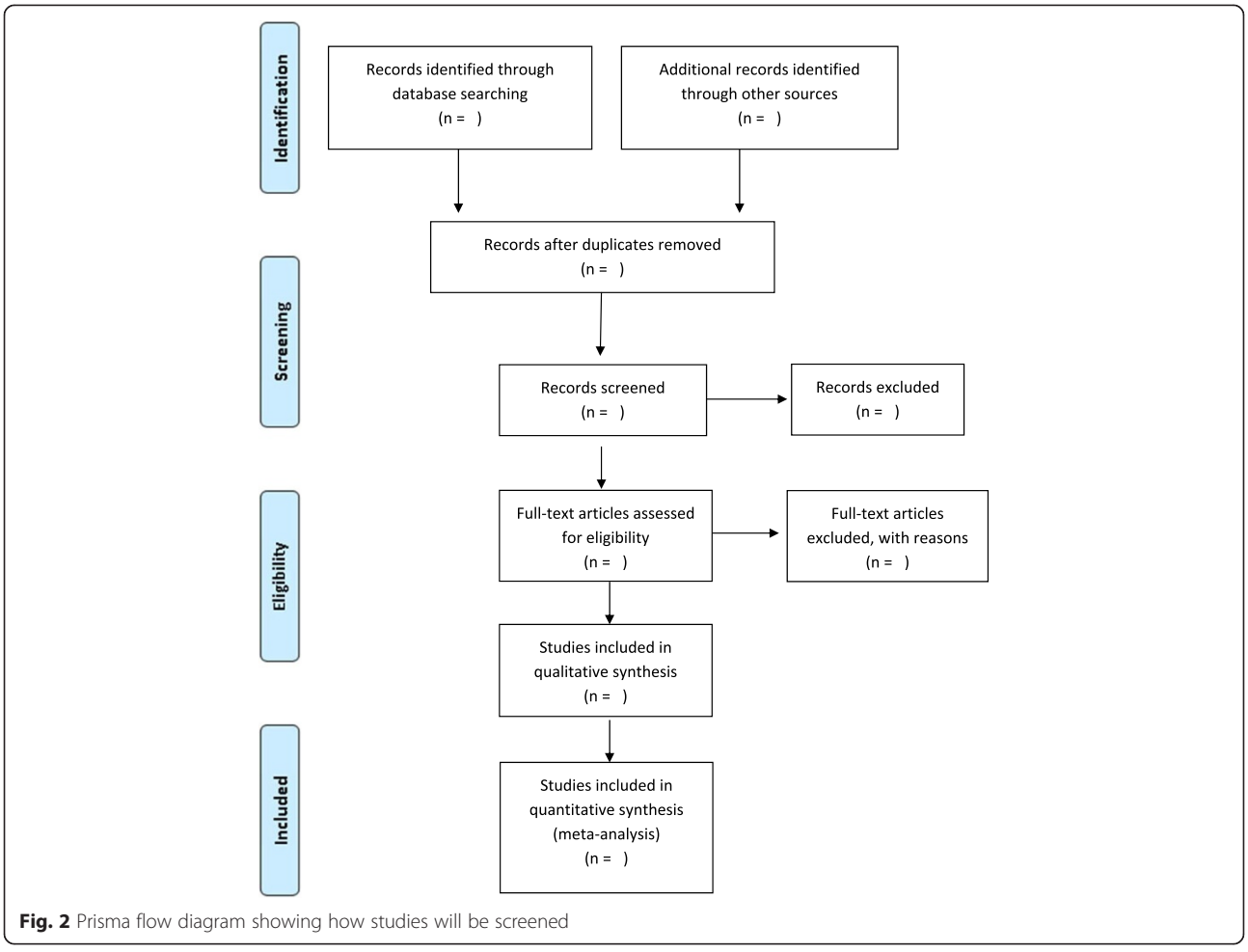



**Fig. 2** Prisma flow diagram showing how studies will be screened

Level of agreement on study eligibility will be tested using the kappa statistic and 95 % confidence interval.

### Assessment of methodological quality

Methodological quality of the included studies will be assessed by two reviewers (EZ and CL) using the Monash Centre for Health Research and Implementation (MCHRI) template for appraisal of methodological quality of a randomised controlled trial (Additional file 2) [30]. This template uses a descriptive component approach to assess risk of bias as well as outline internal and external validity. Any disagreement will be resolved by discussion with MM to reach a consensus.

### Quality of evidence

The grading technique recommended by Guyatt and associates [28] will be used to assess the quality of the body of evidence for each outcome of interest. The effect estimate will be assessed for direction and size of the effect. In considering the quality of evidence for the effect, the following five factors will be considered: indirectness, risk of bias, imprecision, inconsistency and publication bias.

Overall quality will be classified as high, moderate, low and very low. Randomised controlled trials will start with high quality rating with each consideration being downgraded by 1 or 2 points as necessary. The final quality score will be interpreted as shown in Table 1.

### Data extraction

Data will be extracted from included studies using a specially developed data extraction form according to the selection criteria. Information will be collected on general details (title, authors, reference/source, country, year of publication, setting), participants (age, sex, inclusion/exclusion criteria, withdrawals/losses to follow-up, subgroups), results (point estimates and measures of variability, frequency counts for dichotomous variables, number of participants, intention-to-treat analysis) and validity results.

**Table 1** Grading the evidence (adapted from Guyatt et al. 2011[28])

| Strength of evidence | Interpretation |
|---|---|
| High quality | Very confident that the true effect lies close to the estimate of the effect and therefore further research very unlikely to change our confidence in the estimate of effect |
| Moderate quality | Moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Further research likely to have an important impact on our confidence and may change the estimate |
| Low quality | Confident that the effect estimate is limited. The true effect may be substantially different from the estimate of the effect. Further research very likely to have an important impact on our confidence and is likely to change the estimate |
| Low | Very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect |

### Data analysis and synthesis of evidence

Data will be presented in summary form and descriptively, in tables or narratively for each clinical question. Where appropriate, meta-analyses will be conducted.

Data will be summarised statistically if they are available, sufficiently similar and of sufficient quality. The Review Manager 5.3.5 software will be used for statistical analysis. Results will be expressed as relative risks (RR) with 95 % confidence interval (CI) for dichotomous outcomes and weighted mean differences (WMD) with 95 % CI for continuous outcomes. Results of clinically and statistically homogenous trials will be pooled to provide estimates of the effectiveness of the interventions. Clinical homogeneity will be satisfied when participants, interventions, outcome measures and timing of outcome measurement are considered to be similar. For trials that are clinically heterogeneous or present insufficient information for pooling, a descriptive analysis will be performed. Statistical homogeneity will be assessed using the $I^2$ test where $I^2$ values over 50 % indicate moderate to high heterogeneity [31]. Pooled results will be analysed using a random-effects model, assuming a degree of heterogeneity among self-management trials being sought here. Statistical significance will be set up at $P \sim 0.05$ for primary and secondary outcome measures.

#### *Subgroup analysis*

Subgroup analysis will be conducted according to age, gender and duration of intervention since these factors may cause variations in outcomes. The duration and type of self-management training will also be considered carefully.

A sensitivity analysis will be done according to risk of bias. For meta-analyses containing more than ten studies, funnel plots will be employed in order to investigate small study effects as well as publication bias [32]. Publication bias will be determined where a symmetrical inverted funnel plot indicates the absence of bias and an asymmetrical funnel plot indicates the presence of bias.

**Narrative** A narrative synthesis will be performed using a framework that consists of the following four elements as highlighted by several authors [33–36]:

1. Developing a preliminary synthesis of findings of included studies.
2. Assessing the robustness of the synthesis which will involve performing a critical reflection with special emphasis to the methodology of the synthesis (focusing on the limitations and their possible impact on the results), evidence used (quality, reliability, validity and generalizability), assumptions made, discrepancies and uncertainties identified and how discrepancies were dealt with, areas where the evidence is weak or non-existent, possible areas for future research and, finally, a discussion of the evidence presented that will consider the "thick" and "thin" evidence and comment on similarities and/or differences between evidences.
3. Exploring relationships within and between studies will be done in three ways namely;
   i. *Moderator variables and subgroup analysis*—study characteristics that vary between studies or sample (subgroup) characteristics which might help explain differences in findings will be identified.
   ii. *Idea webbing and concept mapping*—idea webbing conceptualises and explores connections among the findings reported in the review studies and often take the form of a spider diagram.
   iii. *Qualitative case descriptions*—descriptions of outliers or exemplars of why particular results were found in the outcome studies.
4. Developing a theory of how the intervention works, why and for whom.

## Discussion

Our review utilises rigorous methodology as well as pre-specified eligibility criteria to comprehensively search for diabetes and CKD health care models and self-management practices which have been compared with usual care in randomised controlled trials. The search strategy for this review was developed in consultation with a methodological expert (MM). Furthermore, eligibility and risk of bias and extraction of data will be independently assessed by a team of two reviewers while a third reviewer will be available to adjudicate discrepancies.

This review may have some limitations. The study relies on published data so publication bias cannot be ruled out. We may also miss some relevant studies as we have limited the search to publication date and English language due to funding and time constraints.

Our review will provide insight into the effectiveness of current chronic disease health care models for improving patient self-management, and this may address the key translational issue of how to integrate and tailor these self-management practices to patients with diabetes and CKD. If the existing models are found to be less efficient, this review may flag avenues for further research.

## Additional files

**Additional file 1: Search without RCT filter.** Search terms used to develop a comprehensive systematic search.

**Additional file 2: Template for critical appraisal of RCT.** Template for critical appraisal of randomised controlled trials.

#### Abbreviations

CKD: chronic kidney disease; ESKD: end stage kidney disease; RRT: renal replacement therapy; CORE: The Centre for Outcomes Research Diabetes Model; HbA1c: glycated haemoglobin; eGFR: estimated glomerular filtration rate; MEMS: Medication Event Monitoring System; MARS-5: medication adherence report scale; MMAS: Morisky medication taking adherence scale; BMQ: brief medication questionnaire; SM: self-management; PAM: patient activation measure; QoLS: quality of life scale; KDQOL: kidney disease quality of life instrument; EuroQol: European quality of life scale; EMBASE: Excerpta medica database; CINAHL: Cumulative Index to Nursing and Allied Health; EBM: evidence-based medicine; MCHRI: Monash Centre for Health Research Innovation; WMD: weighted mean difference; CI: confidence interval.

#### Competing interests

The authors declare that they have no competing interests.

#### Authors' contributions

EZ conceived the study, developed the methodology, and led the write-up. CL refined the review methodology and revised the manuscript. MM contributed to the design of the search strategy and statistical methods and also revised the manuscript. SR reviewed statistical methods and revised the manuscript. SZ determined the scope of the review, refined the search strategy and review methodology, and revised the manuscript. All authors read and approved the final version of the manuscript.

#### Acknowledgement

There are no funding sources to disclose.

#### Author details

[1]Department of Nephrology, Monash Health, Clayton, Melbourne, VIC, Australia. [2]Monash Centre for Health Research and Implementation—MCHRI, School of Public Health and Preventive Medicine, Monash University, Clayton, Melbourne, VIC, Australia. [3]Diabetes and Vascular Medicine Unit, Monash Health, Clayton, Melbourne, VIC, Australia. [4]The George Institute for Global Health, University of Sydney, Sydney, NSW, Australia. [5]Level 1, 43-51 Kanooka Grove, Clayton, Melbourne, VIC 3168, Australia.

Received: 17 March 2015 Accepted: 2 June 2015
Published online: 10 June 2015

#### References

1. Australian Institute of Health and Welfare (AIHW). Chronic diseases and associated risk factors in Australia 2001. Cat. no. PHE 33. Canberra: AIHW; 2002.
2. Yach D et al. The global burden of chronic diseases: overcoming impediments to prevention and control. JAMA. 2004;291(21):2616–22.
3. Molitch ME et al. Diabetic kidney disease: a clinical update from kidney disease: improving global outcomes. Kidney Int. 2015;87(1):20–30.
4. Guariguata L et al. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137–49.
5. van Dieren S et al. The global burden of diabetes and its complications: an emerging pandemic. Eur J Cardiovasc Prev Rehabil. 2010;17 Suppl 1:S3–8.
6. Ojo A. Addressing the global burden of chronic kidney disease through clinical and translational research. Trans Am Clin Climatol Assoc. 2014;125:229–43. discussion 243–6.
7. Schernthaner G. Kidney disease in diabetology. Nephrol Dial Transplant. 2007;22(3):703–7.
8. Tuttle KR et al. Diabetic kidney disease: a report from an ADA Consensus Conference. Am J Kidney Dis. 2014;64(4):510–33.
9. Katterl R, Kalucy E. Chronic disease self-management. Prim Health Care Res Inf Serv. 2009;7:2.
10. Lorig KR et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care. 1999;37(1):5–14.
11. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002;288(14):1775–9.
12. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. Milbank Q. 1996;74(4):511–44.
13. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. Health Aff (Millwood). 2001;20(6):64–78.
14. Battersby M, Harvey P, Mills PD, Kalucy E, Pols RG, Frith PA, et al. SA HealthPlus: a controlled trial of a statewide application of a generic model of chronic illness care. Milbank Q. 2007;85(1):37–67.
15. Soria R, Legido A, Escolano C, Lopez Yeste A, Montoya J. A randomised controlled trial of motivational interviewing for smoking cessation. Br J Gen Pract. 2006;56(531):768–74.
16. Hisashige A. The effectiveness and efficiency of disease management programs for patients with chronic diseases. Glob J Health Sci. 2013;5(2):27–48.
17. Sevick MA et al. Patients with complex chronic diseases: perspectives on supporting self-management. J Gen Intern Med. 2007;22 Suppl 3:438–44.
18. Higgins J, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions, volume version 5.1.0. 2011. The Cochrane Collaboration.
19. Moher D et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA-P statement. PLoS Med. 2009;6(7):e1000097.
20. Weingarten SR, Henning JM, Badamgarav E, Knight K, Hasselblad V, Gano Jr A, et al. Interventions used in disease management programmes for patients with chronic illness—which ones work? Meta-analysis of published reports. BMJ. 2002;325(7370):925.
21. Farmer KC. Methods for measuring and monitoring medication regimen adherence in clinical trials and clinical practice. Clin Ther. 1999;21(6):1074–90.
22. Thompson K, Kulkarni J, Sergejew AA. Reliability and validity of a new Medication Adherence Rating Scale (MARS) for the psychoses. Schizophr Res. 2000;42(3):241–7.
23. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24:7.
24. Svarstad BL et al. The brief medication questionnaire: a tool for screening patient adherence and barriers to adherence. Patient Educ Couns. 1999;37(2):113–24.
25. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med. 2003;26(1):1–7.
26. Hibbard JH et al. Do increases in patient activation result in improved self-management behaviors? Health Serv Res. 2007;42(4):1443–63.
27. Rabin R, Charro FD. EQ-SD: a measure of health status from the EuroQol Group. Ann Med. 2001;33(5):337–43.
28. Guyatt GH, Oxman AD, Schünemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol. 2011;64(4):380–2.
29. Hays RD et al. Development of the kidney disease quality of life (KDQOL) instrument. Qual Life Res. 1994;3(5):329–38.
30. Monash Centre for Health Research and Implementation (MCHRI). Evidence Synthesis Program templates for critical appraisal and risk of bias (adapted from Critical Appraisal Templates, Centre for Clinical Effectiveness, Southern Health, Melbourne, 2010). Melbourne: MCHRI—Monash University and Monash Health; 2013.
31. Higgins JP et al. Measuring inconsistency in meta-analyses. BMJ. 2003;327(7414):557–60.

32. Sterne JA et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. BMJ. 2011;343:d4002.
33. Higginbottom GM et al. Immigrant women's experiences of postpartum depression in Canada: a protocol for systematic review using a narrative synthesis. Syst Rev. 2013;2:65.
34. Ryan R, Cochrane Consumers and Communication Review Group. Cochrane Consumers and Communication Review Group: data synthesis and analysis. 2013 [cited 2013 06 December 2014].
35. Snilstveit B, Oliver S, Vojtkova M. Narrative approaches to systematic review and synthesis of evidence for international development policy and practice. J Dev Effectiveness. 2012;4(3):409–29.
36. Popay J et al. Guidance on the conduct of narrative synthesis in systematic reviews. In: Results of an ESRC funded research project. UK: University of Lancaster; 2006.

**Submit your next manuscript to BioMed Central and take full advantage of:**

- **Convenient online submission**
- **Thorough peer review**
- **No space constraints or color figure charges**
- **Immediate publication on acceptance**
- **Inclusion in PubMed, CAS, Scopus and Google Scholar**
- **Research which is freely available for redistribution**

Submit your manuscript at
www.biomedcentral.com/submit

BioMed Central

## Online resources

**Additional file 1:** Search terms used to develop a comprehensive systematic search**.**

| | **Search without RCT filter** |
|---|---|
| 1 | exp Chronic Disease/ |
| 2 | (chronic adj3 (illness* or disease* or condition*)).mp. |
| 3 | chronic disease therapy.mp. |
| 4 | or/1-3 |
| 5 | kidney diseases/ or anuria/ or diabetic nephropathies/ or hypertension, renal/ or hypertension, renovascular/ or renal insufficiency, chronic/ |
| 6 | chronic kidney disease.mp. |
| 7 | (chronic kidney or chronic renal).mp. |
| 8 | (CKD or CRD).mp. |
| 9 | diabetes mellitus/ or diabetes mellitus, type 1/ or wolfram syndrome/ or diabetes mellitus, type 2/ or diabetes mellitus, lipoatrophic/ or diabetic ketoacidosis/ or donohue syndrome/ |
| 10 | (MODY or NIDDM or T2DM or T2D).mp. |
| 11 | (non insulin* depend* or noninsulin* depend* or noninsulin?depend* or non insulin?depend*).mp. |
| 12 | ((typ? 2 or typ? II or typ?2 or typ?II) adj3 diabet*).mp. |
| 13 | (((late or adult* or matur* or slow or stabl*) adj3 onset) and diabet*).mp. |
| 14 | (IDDM or T1DM or T1D).mp. |
| 15 | (insulin* depend* or insulin?depend*).mp. |
| 16 | ((typ? 1 or typ? I or typ?1 or typ?I) adj3 diabet*).mp. |
| 17 | (insulin* defic* adj2 absolut*).mp. |
| 18 | or/5-17 |
| 19 | exp Consumer Participation/ |
| 20 | exp Self Care/ |
| 21 | exp Self Concept/ |
| 22 | ((self or self directed or self-directed or self monitor* or self-monitor* or symptom*) adj (care or help or manag* or efficacy or admin* or concept)).mp. |
| 23 | patient financial incentives.mp. |
| 24 | health education/ or consumer health information/ or health literacy/ or patient education as topic/ |
| 25 | Health Communication/ |
| 26 | interdisciplinary communication/ |

| | |
|---|---|
| 27 | ((consumer or patient*) adj2 (educat* or information or particip* or behavio?r*)).mp. |
| 28 | ((health educat* or health information) adj2 (program* or intervention* or meeting* or session* or strategy* or workshop* or visit* or method* or material* orcampaign*)).mp. |
| 29 | access to expertise.mp. |
| 30 | availability of clinical information.mp. |
| 31 | Reminder Systems/ |
| 32 | patient reminders.mp. |
| 33 | Pamphlets/ |
| 34 | (leaflet* or booklet* or poster* or pamphlet*).mp. |
| 35 | ((written or printed or oral) adj information).mp. |
| 36 | (provider adj2 (educat* or feedback or remind* or behavio?r)).mp. |
| 37 | Health Care Reform/ |
| 38 | health care reform.mp. |
| 39 | exp Patient Care Management/ |
| 40 | (care co-ordinat* or care coordinat*).mp. |
| 41 | chronic disease management model.mp. |
| 42 | exp "Continuity of Patient Care"/ |
| 43 | continuity of patient care.mp. |
| 44 | behavio?r change.mp. |
| 45 | models, nursing/ or models, organizational/ |
| 46 | or/19-45 |
| 47 | (model* or strateg* or intervention* or program*).mp. |
| 48 | 22 or 27 or 28 or 36 or 40 or 43 or 44 |
| 49 | 47 and 48 |
| 50 | 46 or 49 |
| 51 | 4 and 18 and 50 |

Note: Validated filters for identifying randomised controlled trials and systematic reviews will be used. Search will be used in Ovid for all databases except for Cinahl for which this string will be translated. The search will be limited to articles from 1994 as it is deemed that relevant studies could have been reported in the past 20 years.

**Additional file 2:** Template for critical appraisal of a randomised controlled trial

Document evidence from the article in quotation marks.

| | | |
|---|---|---|
| **Study ID** | | |
| **Study citation** | | |
| **EXTERNAL VALIDITY – IS THIS STUDY AND ITS RESULTS GENERALIZABLE TO MY SYSTEMATIC REVIEW QUESTION?** | | |
| **Patient/population/ participants** | Describe whether they were gender specific, had a particular condition or the general population, age and any other relevant characteristics (e.g. BMI) | |
| **N** | Where possible, list the number of participants that were:<br>• Screened<br>• Enrolled<br>• Allocated/randomised<br>• Assessed<br>• Followed up | |
| **Setting** | List where the intervention was conducted and assessed i.e. hospital, clinic, community and/or university setting. | |
| **Intervention/indicator** | Describe the intervention in as much detail as possible e.g. medication type, dose, duration, intervals. | |
| **Comparison/control** | Describe the comparison in as much detail as possible e.g. medication type, dose, duration, intervals. | |
| **Outcomes** | List what the study measured (e.g. weight, BMI, HbA1c) as primary outcomes and secondary outcomes. If the outcomes are not relevant to your systematic review, list these as measured but not relevant to your systematic review. | |
| **Inclusion Criteria** | Yes<br>No<br>Not reported | |
| **Exclusion Criteria** | Yes<br>No<br>Not reported | |
| **Does the study have a clearly focused question and/or PICO?** | Yes<br>Partial<br>No<br>Not reported | Consider if the question is 'focused' in terms of:<br>– the population studied<br>– the intervention given or exposure<br>- the comparison(s)<br>– the outcomes considered |

| | | | |
|---|---|---|---|
| **Does the study have specified inclusion/exclusion criteria?** | | Yes<br>Partial<br>No | Consider if the inclusion or exclusion of patients was clearly defined a priori. |
| **If there were specified inclusion/ exclusion criteria, were these appropriate?** | | Yes<br>Partial<br>No<br>N/A | Consider if:<br>- The eligibility criteria used to specify the patients, interventions/ exposures and outcomes of interest. |
| **Were the outcomes measured appropriate?** | | Yes<br>Partial<br>No<br>Not reported | Consider if the outcomes measured are appropriate and important outcome. |
| **Was there sufficient duration of follow-up?** | | Yes<br>Partial<br>No<br>Not reported | May need to check with clinicians regarding what is sufficient duration for important events to occur. |
| **INTERNAL VALIDITY – HAS THIS STUDY BEEN CONDUCTED RIGOROUSLY IN ORDER TO REDUCE BIAS?** | | | |
| **SELECTION BIAS** | **Did the study have an adequate method of randomisation?** | Yes<br>No<br>Not reported | Method of randomisation is considered adequate when patient's allocation is entirely due to chance.<br>Adequate methods include:<br>- computer-generated random numbers<br>- table of random numbers<br>- coin tossing<br>Inadequate methods include:<br>- systematic methods (DOB, case record number, day of the week presenting)<br>- sequence may be related to confounding variable<br>- allows foreknowledge of assignment. (These studies should therefore be classed as Controlled Clinical Trials rather than RCTs.) |
| | **Was allocation to intervention group concealed?** | Yes<br>No<br>Not reported | Concealment of allocation is considered adequate when the person responsible for allocation cannot influence which group a patient is randomised to.<br>Adequate methods of concealment of randomisation include:<br>- Centralised or pharmacy-controlled randomisation<br>- On-site computer-based system with a randomisation sequence that is not readable until allocation |

| | | | |
|---|---|---|---|
| | | | - Other approaches with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients<br>Inadequate approaches to concealment of randomisation<br>- Open random numbers lists<br>- Serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation) |
| **PERFORMANCE BIAS** | **Were patients blind to intervention group?** | Yes<br>No<br>Not reported | Consider:<br>- how the study has attempted to maintain blinding<br>- if there is any indication that patients were aware of intervention group<br>- the fact that blinding is not always possible<br>- if every effort was made to achieve blinding |
| | **Were investigators and care providers blind to intervention group?** | Yes<br>Partial<br>No<br>Not reported | Consider:<br>- how the study has attempted to maintain blinding<br>- if there is any indication that investigators or care providers were aware of intervention group<br>- the fact that blinding is not always possible<br>- if every effort was made to achieve blinding |
| | **Aside from the experimental intervention, were the groups treated the same?** | Yes<br>Partial<br>No<br>Not reported | To be sure it's the intervention which is responsible for the effect. |
| **DETECTION BIAS** | **Were outcome assessors blind to intervention group?** | Yes<br>Partial<br>No<br>Not reported | Consider:<br>- If the outcome is objective (e.g. death) then blinding is less critical.<br>- If the outcome is subjective (e.g. symptoms or function) then blinding of the outcome assessor is critical. |
| | **Were all outcomes measured in a standard, valid and reliable way?** | Yes<br>Partial<br>No<br>Not reported | Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study. |

| | | | |
|---|---|---|---|
| | **Were outcomes assessed objectively and independently?** | Yes<br>Partial<br>No<br>Not reported | Independence of assessment is important where the result of one outcome may affect the interpretation of another.<br>When outcomes are objectively assessed, their independence from each other is less important. |
| **ATTRITION BIAS** | **What percentage of the individuals recruited into each arm of the study dropped out?** | X% treatment<br>X% control/ comparison | Consider:<br>- If all patients who entered the trial were properly accounted for and attributed at its conclusion.<br>- Why patients dropped out, as well as how many.<br>- the dropout rate may be expected to be higher in studies conducted over a long period of time. |
| | **Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?** | Yes<br>No<br>Not reported | Consider:<br>- if analysis was as per protocol or intention to treat<br>- number of crossovers<br>- reason for crossover |
| **REPORT BIAS** | **Is the paper free of selective outcome reporting?** | Yes<br>Partial<br>No<br>Not reported | Consider:<br>- if all the planned outcomes were measured<br>- if all the measured outcomes were reported<br>- if any additional or composite outcomes were measured.<br>This is difficult to determine if there isn't a protocol. |
| **CONFOUNDING** | **Were the groups similar at baseline with regards to key prognostic variables?** | Yes<br>Partial<br>No<br>Not reported | Key prognostic variable include age, sex, disease severity. If the randomisation process worked (that is, achieved comparable groups) the groups should be similar, however particularly in small studies, some variations are very likely.<br>There should be some indication of whether differences between groups are clinically important. May need to check with clinician for this information. |
| | **If confounding was present, was it controlled for?** | Yes<br>Partial<br>No<br>Not reported | Consider if any effort was made to control for confounding – whether the participants were exposed to other factors that may lead to an effect similar to that expected as a result of the intervention ie. for an exercise study, was one group more motivated than the other? Which may lead to higher intervention effect. Look for comments about stratifying for ages etc. |

| | | | |
|---|---|---|---|
| OTHER INTERNAL VALIDITY/BIAS | **Were there any conflicts of interest in the writing or funding of this study?** | Yes<br>No<br>Not reported | Consider:<br>- if any of the authors are/were employed, sponsored etc. by pharmaceutical companies, or have other financial/other ties<br>- if any commercial companies were involved in funding, writing, editing, data analysis or manuscript approval |
| | **Was the study sufficiently powered to detect any differences between the groups?** | Yes<br>Partial<br>No<br>Not reported | Consider:<br>- if an adequate sample size calculation was undertaken<br>- if the required sample size recruited and retained<br>- for which outcomes the study was powered<br>- if confidence intervals include a clinically important difference, the study was underpowered<br>NB this is less important if significant differences were found. |
| | **For cross over studies - was the washout period adequate?** | Yes<br>No<br>Not reported<br>NA | Consider:<br>- The likely duration of action of the treatment being tested. |
| | **If statistical analysis was undertaken, was this appropriate?** | Yes<br>Partial<br>No<br>Not reported<br>N/A | Consider:<br>- whether the authors performed any statistical tests or just presented figures<br>- if the statistical analysis was planned a priori<br>- if the data were analysed accordingly to the study protocol.<br>- the type of data and the statistical tests used. (Please refer to the CCE workbook as required)<br>- use of parametric versus non-parametric tests; whether the data has been checked for normality<br>- if the tests used are obscure, why did the authors used them, and have they included a reference.<br>- if point estimates and measures of variability were presented for the primary outcome<br>- if subgroups were analysed appropriately<br>- if potential confounders were identified and taken into account in the analysis |

| | | | |
|---|---|---|---|
| | | | - if there was any adjustment made for multiple testing<br>- if missing data was handled appropriately |
| **Comments** | | *Add any other relevant comments, including if this is likely to influence the results of the study* | |
| **What is the overall risk of bias?** | | Low<br>Moderate<br>High<br>Insufficient information | *Low - All of the criteria have been fulfilled or where criteria have not been fulfilled it is very unlikely the conclusions of the study would be affected.*<br>*Moderate - Some of the criteria have been fulfilled and those criteria that have not been fulfilled may affect the conclusions of the study.*<br>*High - Few or no criteria fulfilled, or the conclusions of the study are likely or very likely to be affected.*<br>*Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias.* |

**Cited in full as:** Monash Centre for Health Research and Implementation (MCHRI) Evidence Synthesis Program template for critical appraisal of a randomised controlled trial (2013), MCHRI – Monash University and Monash Health, Melbourne, Australia (*adapted from* Critical Appraisal Templates (2010) Centre for Clinical Effectiveness, Southern Health, Melbourne, Australia).

## 5.3 Published manuscript: Effectiveness of self-management support interventions for patients with co-morbid diabetes and chronic kidney disease -a systematic review and meta-analysis

Citation: **Zimbudzi E**., Lo, C., Misso M., Ranasinha S., Kerr PG., Teede H., Zoungas S. Effectiveness of self-management support interventions for patients with co-morbid diabetes and chronic kidney disease -a systematic review and meta-analysis. Systematic Reviews 2018; 7:84.

Zimbudzi et al. Systematic Reviews (2018) 7:84
https://doi.org/10.1186/s13643-018-0748-z

Systematic Reviews

RESEARCH Open Access

# Effectiveness of self-management support interventions for people with comorbid diabetes and chronic kidney disease: a systematic review and meta-analysis

Edward Zimbudzi[1,2], Clement Lo[1,3], Marie L. Misso[1], Sanjeeva Ranasinha[1], Peter G. Kerr[2,4], Helena J. Teede[1,3] and Sophia Zoungas[1,3,5*]

## Abstract

**Background:** Self-management support interventions may potentially delay kidney function decline and associated complications in patients with comorbid diabetes and chronic kidney disease. However, the effectiveness of these interventions remains unclear. We investigated the effectiveness of current self-management support interventions and their specific components and elements in improving patient outcomes.

**Methods:** Electronic databases were systematically searched from January 1, 1994, to December 19, 2017. Eligible studies were randomized controlled trials on self-management support interventions for adults with comorbid diabetes and chronic kidney disease. Primary outcomes were systolic blood pressure, diastolic blood pressure, estimated glomerular filtration rate, and glycated hemoglobin. Secondary outcomes included self-management activity, health service utilization, health-related quality of life, medication adherence, and death.

**Results:** Of the 48 trials identified, eight studies (835 patients) were eligible. There was moderate-quality evidence that self-management support interventions improved self-management activity (standard mean difference 0.56, 95% CI 0.15 to 0.97, $p < 0.007$) compared to usual care. There was low-quality evidence that self-management support interventions reduced systolic blood pressure (mean difference − 4.26 mmHg, 95% CI − 7.81 to − 0.70, $p = 0.02$) and glycated hemoglobin (mean difference − 0.5%, 95% CI − 0.8 to − 0.1, $p = 0.01$) compared to usual care.

**Conclusions:** Self-management support interventions may improve self-care activities, systolic blood pressure, and glycated hemoglobin in patients with comorbid diabetes and chronic kidney disease. It was not possible to determine which self-management components and elements were more effective, but interventions that utilized provider reminders, patient education, and goal setting were associated with improved outcomes. More evidence from high-quality studies is required to support future self-management programs.

**Systematic review registration:** PROSPERO CRD42015017316.

**Keywords:** Chronic kidney disease, Diabetes, Interventions, Self-management, Systematic review, Meta-analyses

* Correspondence: sophia.zoungas@monash.edu
[1]Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, 43-51 Kanooka Grove, Clayton, Melbourne, Victoria, Australia
[3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Victoria, Australia
Full list of author information is available at the end of the article

© The Author(s). 2018 **Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

## Background

The prevalence of diabetes is on the rise globally, driven primarily by the increasing incidence of type 2 diabetes in the setting of increasing overweight and obesity [1]. The International Diabetes Federation estimated that 415 million adults (aged 20–79 years) had diabetes in 2015 and 5 million deaths were attributable to diabetes and the total global health expenditure due to diabetes was 673 billion US dollars [2]. By 2040, the number of adults with diabetes (aged 20–79 years) is expected to rise to 642 million [2]. The dramatic increase in diabetes is associated with a myriad of diabetes-related complications such as cardiovascular disease, renal failure, blindness, and lower limb amputation [3].

Chronic kidney disease (CKD) is one of the commonest diabetes-related complications. Worldwide, current estimates suggests that over 500 million people have CKD, with the majority (80%) of those people living in low- and middle-income countries [4] and diabetes contributes to 30–40% of all cases of end-stage renal disease (ESRD) [5]. In developed countries, diabetes accounts for 50% of cases of treated ESRD [6]. As the prevalence of diabetes increases, the incidence of CKD is expected to increase.

Co-morbid diabetes and CKD is associated with an increased risk of a range of adverse outcomes including increased mortality [7], low health-related quality of life [8], and increased health service utilization [9]. Self-management support interventions have generated considerable interest in the management of CKD as a means of helping to improve risk factors and slow disease progression [10]. However, the effects of self-management strategies for those with co-morbid diabetes and CKD are largely unknown [11]. Many current approaches to self-management for patients with both diabetes and CKD are based on interventions for single conditions rather than for patients with complex multimorbidity [11]. Additionally, there is a huge diversity of potential self-management support interventions which have been trialed making it difficult for health care providers to select the most pragmatic and effective interventions. To date, there has been no systematic review of the literature examining the effectiveness of self-management support interventions in people with both diabetes (type 1 or type 2) and CKD.

To address this, we undertook a systematic review, which sought to answer the following questions:

1. How effective are self-management support interventions in improving patient-reported and clinical outcomes in adults with comorbid diabetes and CKD?
2. Which specific self-management components and elements are associated with improved outcomes for patients with comorbid diabetes and CKD?

## Methods

The conduct of this review was guided by the Cochrane Handbook for Systematic Reviews of Interventions [12] and conforms to the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement recommendations [13]. The protocol of this systematic review was registered on PROSPERO 2015 (registration number CRD42015017316) [14] and published [15].

### Selection criteria

Table 1 presents the Population, Intervention, Comparison, and Outcome (PICO) framework established a priori to include and exclude studies for this systematic review.

### Participants

This review considered studies of people with both diabetes (type 1 or type 2) and CKD. CKD was defined as a sustained decrease in estimated glomerular filtration rate (eGFR) to levels less than 60 mL/min/1.73 $m^2$ for a period of 3 months or longer [16]. In studies where the inclusion criteria were not clear, we sought clarification from the corresponding authors and such studies were excluded if we could not get verification.

### Interventions

For the purpose of this review, self-management support was defined as "the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support" [17]. The core components of the interventions were provider education, provider feedback, provider reminders, patient education, patient reminders, and patient financial incentives with elements that included standardized training, multidisciplinary team, peer contact, keeping logs, goal setting skills, problem solving skills, and seeking support.

### Outcomes

Primary outcomes included clinical indicators such as blood pressure, eGFR, and $HbA_{1c}$, and secondary outcomes included self-management activity, health service utilization, health-related quality of life (HRQOL), adherence to medications, and death.

### Study design

Randomized controlled studies (including cluster randomized controlled trials) and systematic reviews of randomized controlled studies were considered. We included English-language peer-reviewed journal articles. We excluded articles reporting non-randomized studies, narrative reviews, letters, editorials, commentaries,

**Table 1** Selection criteria

| | Inclusion | Exclusion |
|---|---|---|
| Participants | Adult patients (above 18 years) with diabetes[a] and CKD in any health care setting | Participants without the diagnosis of diabetes and CKD |
| Interventions | Self-management models including at least one of the following intervention components: Provider education, provider feedback, provider reminders, patient education, patient reminders, and patient financial incentives | No intervention or any intervention other than those prespecified in the inclusion criteria |
| Control | Clearly defined usual or standard care. This may be the chronic disease management programme that is already in place before a new model of care is introduced | Any intervention except those listed in the inclusion criteria |
| Outcomes | Must include at least one of the following outcomes:<br>Primary:<br>1. Clinical indicators (blood pressure, eGFR, and $HbA_{1c}$)<br>Secondary:<br>1. Medication adherence<br>2. Self-management activity<br>3. Health service utilization including hospitalization<br>4. Health-related quality of life<br>5. Adverse events such as deaths | Lack of at least one relevant prespecified outcome |
| Study design | Randomized controlled trials and systematic reviews of randomized controlled trials | Studies reporting non-randomized studies |

[a]Participants with either type 1 or type 2 diabetes were included
*CKD* chronic kidney disease which was defined as a sustained decrease in eGFR to levels less than 60 mL/min/1.73 $m^2$ for a period of 3 months or longer, *eGFR* estimated glomerular filtration rate, $HbA_{1c}$ glycated hemoglobin

unpublished manuscripts, dissertations, government reports, books and book chapters, conference proceedings, meeting abstracts, lectures and addresses, and consensus development statements and guidelines.

### Literature search

We conducted a comprehensive search of literature, which has been described in detail elsewhere [15]. In brief, we identified RCTs through Medline, Medline in-process and other non-indexed citations, EMBASE, CINAHL, and all evidence-based medicine (EBM) reviews. We also searched the bibliographies of relevant studies identified by the search strategy for identification of additional studies. The databases were searched from January 1, 1994, to December 19, 2017. A detailed description of search limits is provided elsewhere (Additional file 1: Table S1). To ensure reliability, two reviewers (EZ and CL) independently scanned the titles, abstract sections, and keywords of every article obtained by the search strategy. The two reviewers retrieved full texts of potentially relevant studies and screened them independently for inclusion. During the full-text review, if the two reviewers were in doubt about the inclusion of any particular study, the third reviewer (MM) was involved. Investigators of all eligible studies were also contacted by email to request unpublished data relevant to the review.

### Data extraction and critical appraisal

Two reviewers (EZ and CL) independently extracted data relevant to the PICO framework using a specially designed data abstraction form. Information was collected on general details (title, authors, reference/source, country, year of publication, setting), participants (age, sex, inclusion/exclusion criteria, withdrawals/losses to follow-up, subgroups), results (point estimates and measures of variability, frequency counts for dichotomous variables, number of participants, intention-to-treat analysis), and validity results.

The methodological quality of each of the included studies was independently appraised by two reviewers (EZ and CL) using the Monash Centre for Health Research and Implementation (MCHRI) template [18] (Additional file 2: Table S2) and the quality of evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [19]. Any disagreement was resolved by discussion with the third reviewer (MM) to reach a consensus. We contacted authors of included trials when clarification surrounding study conduct or missing data was required.

### Data synthesis and meta-analysis

Analyses of data from included trials were performed with Review Manager (RevMan version 5.3.5, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). For meta-analysis, all outcomes were continuous and results are presented as mean differences (MDs) or standard mean difference (SMD) if different scales were used [12] with 95% confidence interval (CI). A positive SMD value indicated the intervention group was superior to the control group on a positively oriented outcome measure. Data from eligible studies were pooled using the random effects model to

account for heterogeneity [20]. Statistical heterogeneity was quantified using the inconsistency index-$I^2$ statistic with "low" heterogeneity set at ≤ 25%, "moderate" 50%, and "high" ≥ 75%. To assess clinical heterogeneity, we performed a sensitivity analysis excluding a study of people with end-stage renal disease from the analysis. A subgroup analysis of pooled data based on the different self-management components was also carried out. Publication bias was not statistically assessed due to the small number of RCTs included. Statistical significance was set at $p < 0.05$ for primary and secondary outcome measures. A descriptive analysis was performed to summarize data narratively for outcomes that had unexplained heterogeneity and missing data such as means and SDs and when there was a small number of studies reporting an outcome (less than 2 studies).

## Results

### Literature search and study characteristics

The results of the systematic search are shown in Fig. 1. Two thousand and eighty references were identified by the search including 11 obtained from hand-searching of reference lists of seven systematic reviews [21–27] obtained from the search. After removal of duplicates and screening of titles and abstracts, 48 full-text articles were reviewed for further assessment. Following the full-text review, 40 articles were excluded based on reasons outlined in Fig. 1 and Additional file 3: Table S3. Eight studies [28–34] remained and were included in the systematic review. One of the studies (the SURE study) [30] had a duplicate publication [9], which reported on cost implication of the intervention. We treated the two publications as one study.

Characteristics of the eight included studies are presented in Table 2. Three studies were performed in the UK [28, 31, 34] and one each in Canada [29], China [30], USA [32], Netherlands [33], and Australia [35]. Four studies [28, 29, 31, 33] were conducted in a primary care setting, two in hospital-based outpatient clinics [34, 35], one in hospital [30], and one in hemodialysis or peritoneal dialysis units [32]. Three studies [30, 33, 34] included patients with type 2 diabetes only; two studies [29, 32] specified

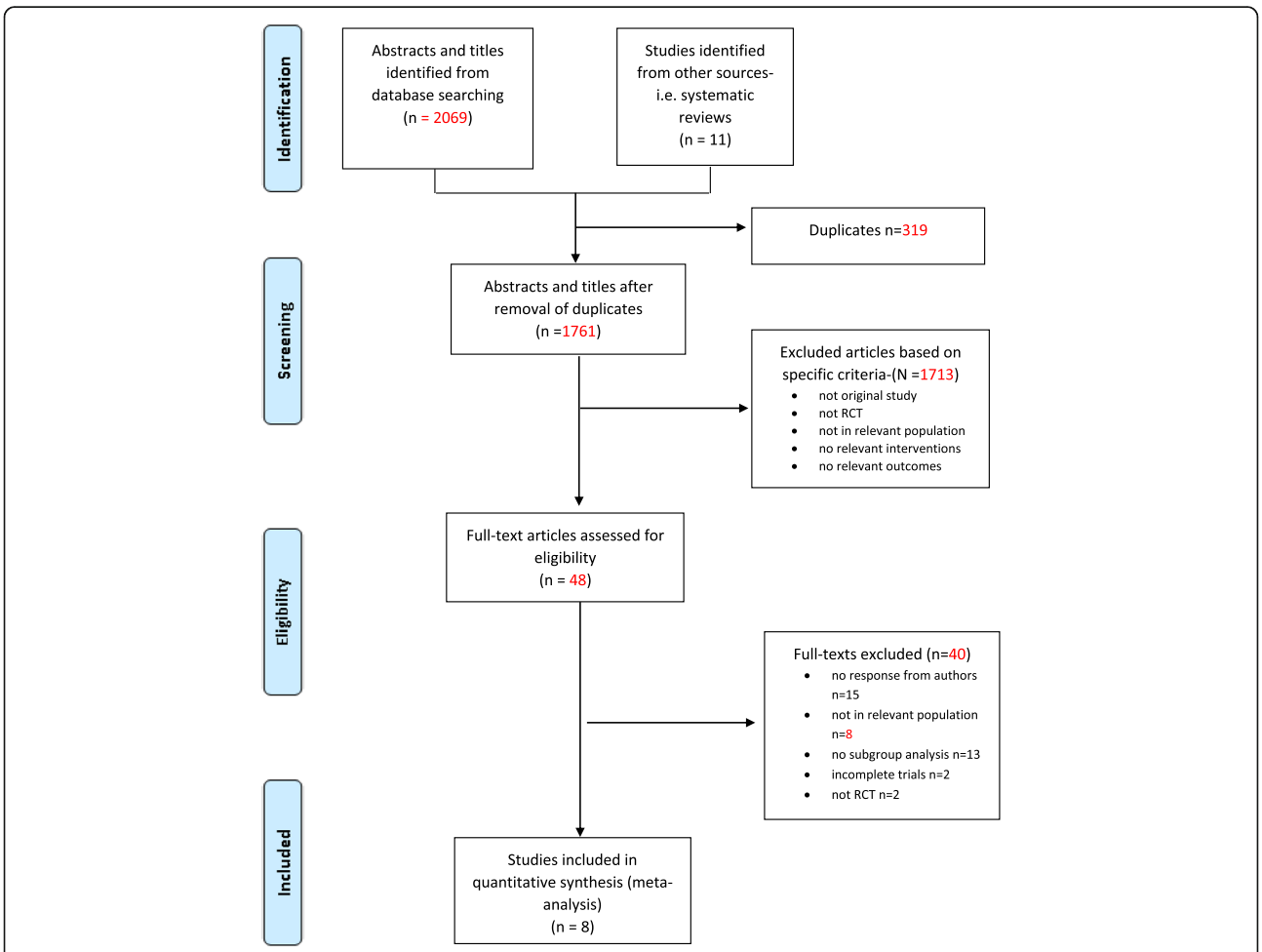



**Fig. 1** PRISMA flow diagram showing how studies were screened [13]

**Table 2** Characteristics of included studies

| Study/setting | N[a] | Population | Intervention (content, delivery and duration characteristics) | Control | Outcomes[b] | Follow-up/dropouts/ sample size analyzed | Risk of bias |
|---|---|---|---|---|---|---|---|
| Blakeman et al. 2014[a][28] Primary care, 24 general practices in UK | *N* = 101 IG—49 CG—52 ND by gender | Adult patients who had a diagnosis of stage 3 CKD. Type of diabetes not specified. | Information and telephone-guided access to community support. The intervention entailed provision of: 1. A kidney information guidebook. 2. A PLANS booklet and access to an interactive website with tailored access to local resources. 3. Telephone support from a peer support worker. The intervention was delivered for 4 weeks. | Patients were provided with the guidebook and website link at the end of the trial. | Self-management, blood pressure control, and HRQOL | Follow-up: 6 months Dropouts: ND Sample size analyzed: *n* = 101 IG: *n* = 49 CG: *n* = 52 | Moderate |
| Barrett et al. 2011[a] [29] Primary care, 5 urban centers in Canada | *N* = 149 IG—73 CG—76 ND by gender | 40–75 years with CKD, eGFR between 25 and 60 mL/min per 1.73m$^2$ Type 1 and 2 diabetes | Nurse-coordinated care focused on risk factor modification. Intervention group participants had additional clinical care delivered by the study nurse and nephrologist guided by protocols aimed at achieving the prespecified targets but focused on the needs of the individual. Study visits occurred every 4 months for the duration of the study. | Patients received usual care that their health care providers felt indicated. | $HbA_{1c}$, blood pressure, and eGFR | Follow-up: 24 months Dropouts: ND Sample size analyzed: *n* = 149 IG: *n* = 73 CG: *n* = 76 | Moderate |
| Chan et al. 2009 [30] Hospitals, 9 public hospitals in China | *N* = 205 Male: IG—66 CG—67 Female: IG—38 CG—34 | Type 2 diabetic patients with renal insufficiency | Structured care managed by a diabetes team. A dietitian saw the intervention group after randomization. ACE inhibitor or ARB therapy was started in treatment-naive patients with monitoring of renal function at week 2, then every 4 weeks for 12 weeks and subsequently every 8–12 weeks, throughout the study period. A doctor-nurse team saw patients every 3 months and more often if indicated. | Patients were managed according to the usual clinic practice as defined by the respective hospital with no modification. | Blood pressure, $HbA_{1c}$, eGFR, and death | Follow-up: 24 months Dropout: *n* = 38 IG: *n* = 20 CG: *n* = 18 Sample size analyzed: *n* = 167 IG: *n* = 84 CG: *n* = 83 | Low |
| McManus et al. 2014[a] [31] Primary care practices in UK | *N* = 28 I—10 C—18 ND by gender | > 35 years with stroke, CHD, diabetes, or CKD and hypertension Type of diabetes not specified. | Self-monitoring of blood pressure and individualized self-titration algorithm. Patients in the intervention group were trained to self-monitor blood pressure in 2 or 3 sessions, each lasting approximately an hour. Following training, intervention patients went to their family physician to agree with the individualized 3-step plan to increase or add antihypertensive medications. The intervention occurred for the duration of the study. | Patients had routine blood pressure check and medication review with the participating family physician. | Blood pressure | Follow-up: 6 and 12 months Dropout: ND Sample size analyzed: *n* = 28 IG: *n* = 10 CG: *n* = 18 | Moderate |
| McMurray et al. 2002 [32] Hemodialysis or peritoneal dialysis units in USA | *N* = 83 Male: IG—24 CG—21 Female: IG—21 CG—17 | ESRD on either HD or PD with a diagnosis of a type 1 or type 2 diabetes mellitus | Diabetes education and care management program. The diabetes care manager delivered self-management education, diabetes care monitoring and management, and motivational coaching to the intervention group. The renal dietitian performed initial nutritional counseling. Follow-up was performed at hemodialysis sessions or monthly for peritoneal dialysis patients. | Patients received standard diabetes care prevalent at the dialysis facility as directed by their physician. | $HbA_{1c}$, HRQOL, self-management behavior, and hospitalization | Follow-up: 12 months Dropout: *n* = 0 Sample size analyzed: *n* = 83 IG: *n* = 45 CG: *n* = 38 | High |
| Scherpbier-de Haan et al. 2013[a] [33] | *N* = 65 Male: IG—17 CG—16 Female: | > 18 years, hypertension or type 2 diabetes mellitus, and eGFR of < 60 mL/min/ 1.73m$^2$ | Shared care. The nurse practitioner saw patients every 3 months for a 20-min consultation, in which blood pressure treatment was the main aim. Patients and nurse practitioners decided together which other treatment goals were to | No intervention other than routine review. | Blood pressure, eGFR, and $HbA_{1c}$ | Follow-up: 12 months Dropout: ND Sample size analyzed: *n* = 65 | High |

**Table 2** Characteristics of included studies *(Continued)*

| Study/setting | N[a] | Population | Intervention (content, delivery and duration characteristics) | Control | Outcomes[b] | Follow-up/dropouts/ sample size analyzed | Risk of bias |
|---|---|---|---|---|---|---|---|
| Primary care, 9 general practices in Netherlands | IG—22<br>CG—10 | | be prioritized. GPs supervised the consultation afterwards. GPs and nurse practitioners could, if necessary, consult a nephrology team in a protected digital environment. | | | IG: $n = 39$<br>CG: $n = 26$ | |
| Steed et al. 2005 [34] Outpatient clinics at two inner city hospitals in UK | $N = 124$<br>Male:<br>IG—44<br>CG—44<br>Female:<br>IG—21<br>CG—15 | Type 2 diabetes, with renal insufficiency | The University College London-Diabetes Self-management Programme (UCL-DSMP) The intervention was a group-based program consisting of five 2.5-h sessions held weekly for 5 weeks, plus one booster session of 2.5 h held 3 months after the end of the intervention. Facilitators were diabetes specialist nurses and dieticians. | No intervention other than completion of assessments. | $HbA_{1c}$, self-management practices, and HRQOL | Follow-up: 3 months<br>Dropout: $n = 10$<br>IG: $n = 10$<br>CG: $n =$ ND<br>Sample size analyzed: $n = 114$<br>IG: $n = 55$<br>CG: $n = 59$ | High |
| Williams et al. 2012[a] [35] Outpatient clinics in Australia | $N = 80$<br>Male:<br>IG—22<br>CG—23<br>Female:<br>IG—17<br>CG—18 | Aged > 18 years with diabetes, CKD, and systolic hypertension Type of diabetes not specified. | Multifactorial Medication Self-Management Intervention (MESMI)<br>1. Self-monitoring of blood pressure.<br>2. An individualized medication review.<br>3. A 20-min digital versatile disc (DVD)<br>4. Fortnightly motivational interviewing follow-up telephone contact for 12 weeks to support blood pressure control and optimal medication self-management.<br>A renal nurse trained in motivational interviewing delivered all components of the intervention. | No intervention | Blood pressure, $HbA_{1c}$, eGFR | Follow-up: 3, 6, and 12 months<br>Dropout: $n = 5$<br>IG: $n = 3$<br>CG: $n = 2$<br>Sample size analyzed: $n = 75$<br>IG: $n = 36$<br>CG: $n = 39$ | Low |

[a]These are participants who had diabetes and chronic kidney disease from the included studies. Additional data obtained from corresponding authors
[b]Outcomes relevant to this systematic review; total $N = 835$
*CKD* chronic kidney disease, *CHD* coronary heart disease, *HRQOL* health-related quality of life, *eGFR* estimated glomerular filtration rate, $HbA_{1c}$ glycated hemoglobin, *ESRD* end-stage renal disease, *HD* hemodialysis, *PD* peritoneal dialysis, *IG* intervention group, *CG* control group, *ND* no data available, *ACE* angiotensin-converting enzyme inhibitors, *ARB* angiotensin II receptor blockers, *PLANS* patient-led assessment for network support

having patients with both type 1 and type 2, and three studies [28, 31, 35] did not specify the type of diabetes. There was a substantial variation in the study sample sizes ($n$ = 28 to 205), interventions, and follow-up period (3 to 24 months). Most of the studies were excluded due to inadequate data reported and no responses from authors ($N$ = 15) and lack of evidence demonstrating that they included the correct population relevant to this review ($N$ = 13) (Additional file 3: Table S3).

### Elements and components of self-management support interventions

All the included studies had a theoretical underpinning for their self-management elements. Key elements of these interventions were derived from the Chronic Care Model [36], the Stanford Model [37], the Expert Patient Programme [38], and the Flinders Model [39] (Table 3). These elements include standardized training, multidisciplinary team, peer contact, keeping logs, goal setting and problem solving skills, and seeking support. There was a marked variation in the elements of interventions in terms of both content and delivery (Tables 2 and 3). Seven studies [28–34] described interventions underpinned by care coordination and a team based-approach with a focus on patient self-management and working collaboratively. The intervention components reported were patient education [28, 30–32, 34, 35], provider reminders [29, 30], and provider education [28, 33] (Fig. 2).

### Delivery characteristics

The delivery characteristics for the interventions are shown in Table 2. The study duration ranged from 3 to 24 months, with two studies having a duration of less than 12 months. The potential influence of follow-up duration on the estimates was explored by plotting the effect size against follow-up time, and there was no relationship between the two. Most of the studies had more than one delivery element. Five studies utilized face-to-face delivery [30–32, 34, 35], three had the self-management component delivered by telephone [28, 30, 35], and four used written information, websites, and protocols [28, 29, 31, 33] to guide the delivery of the interventions. All studies apart from one [35] had members of the multidisciplinary team facilitating the delivery of self-management support interventions. The members included nurses, dietitians, social workers, general practitioners, diabetologists, endocrine trainees, and nephrologists.

### Risk of bias in included studies

Additional file 4: Figure S1 and Additional file 5: Figure S2 present an overview of the risk of bias for the included studies assessed against six risk-of-bias criteria which included selection (randomization and allocation), performance, detection, attrition, and reporting bias. Five studies [28–31, 35] reported random sequence generation, and four studies [28–30, 35] demonstrated adequate allocation concealment. The majority of studies had high risk of performance bias [28, 29, 31, 32, 34] and detection bias [28, 29, 31, 32, 34]. Only one study had a low risk of performance bias [33] and one study a low risk of detection bias [35]. Seven studies [28, 30–35] had a low risk of attrition bias, and all included studies had a low risk of reporting bias.

### Effects of interventions

Table 4 provides the main comparison between groups, which had self-management support interventions, and controls. The study interventions were of varying intensity levels. Meta-analyses were only performed for systolic blood pressure, diastolic blood pressure, eGFR, $HbA_{1c}$, diabetes self-management activity, and HRQOL.

### Primary outcomes

#### *Systolic blood pressure*

Treatment effects for systolic blood pressure were reported by six studies [28–31, 33, 35] with mean systolic blood pressures ranging from 127 to 144 mmHg for the

**Table 3** Key elements to effective planned self-management support interventions

| Study | Standardized training | Multidisciplinary team | Peer contact | Keeping logs | Goal setting skills | Problem solving skills | Seeking support |
|---|---|---|---|---|---|---|---|
| Blakeman et al. [28] | * | * | * | | * | | * |
| Barrett et al. [29] | | * | | | | | |
| Chan et al. [30] | * | * | | | | | |
| McManus et al. [31] | * | * | | * | * | * | * |
| McMurray et al. [32] | * | * | | | * | * | |
| Scherpbier-de Haan et al. [33] | * | * | | | * | | * |
| Steed et al. [34] | * | * | * | | * | | |
| Williams et al. [35] | * | | | * | * | | * |

The studies utilized elements derived from the following self-management models: (a) the Chronic Care Model, (b) the Stanford Model, (c) the Expert Patient Programme, and (d) the Flinders Models
*means respective self-management element was used by the study

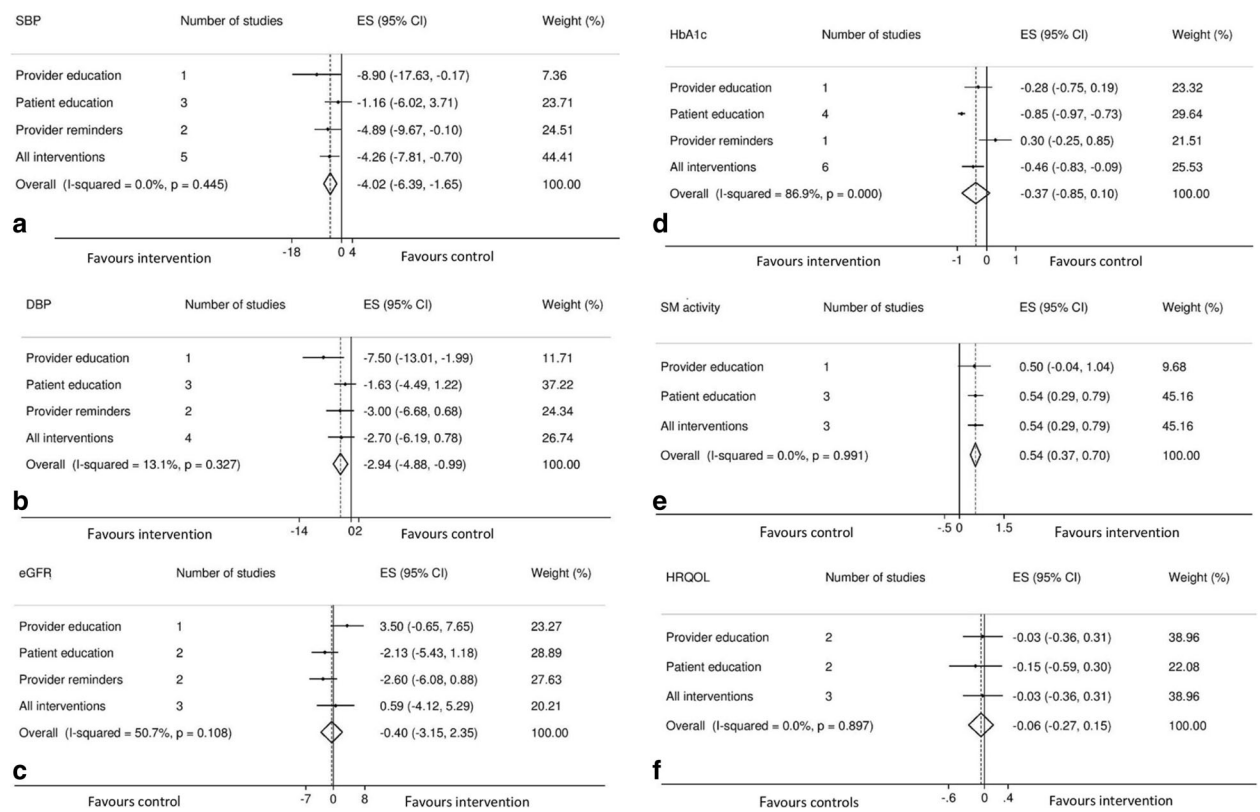



**Fig. 2** Meta-analyses showing effect of the different intervention components on **a** systolic blood pressure, **b** diastolic blood pressure, **c** estimated glomerular filtration rate, **d** glycated hemoglobin (%), **e** self-management activity, and **f** health-related quality of life. Intervention components with one trial are not based on meta-analysis (individual trial result is presented)

intervention groups and 134 to 146 mmHg for the control groups. Two of the six studies [29, 33] utilizing structured care and shared care as interventions reported significant improvements in blood pressure in the intervention groups compared to the control groups. Barrett et al. [29] reported a mean difference (MD) of − 7.20 mmHg (95% CI − 13.69 to 0.71, $p < 0.05$) between the intervention and control groups, while the study by Scherpbier-de Haan et al. [33] showed a MD of − 8.90 mmHg (17.63 to − 0.17, $p < 0.05$) (Fig. 3a). Data was pooled from five studies [29–31, 33, 35], which were deemed sufficiently homogenous to conduct a meta-analysis. The intervention group had a significantly lower systolic blood pressure than the control group [Fig. 3a; MD − 4.26 mmHg (95% CI − 7.81 to − 0.70) $p = 0.02$].

### *Diastolic blood pressure*

Four studies [30, 31, 33, 35] reported mean diastolic blood pressures ranging from 68 to 74 mmHg for the intervention groups and 71 to 80 mmHg for the control groups. Significantly lower diastolic blood pressures were reported in two studies by Chan et al. [30] and Scherpbier-de Haan et al. [33]: MDs in diastolic blood pressure of − 3 mmHg (95% CI − 6.68 to 0.68) and − 7.5 mmHg (95% CI − 13.01 to − 1.99) respectively (Fig. 3b). Data from four studies was available for a meta-analysis. There was no significant difference in the diastolic blood pressure of the intervention and control groups [Fig. 3b; MD − 2.70 (95% CI − 6.19 to 0.78) $p = 0.13$].

### *Estimated glomerular filtration rate*

Estimated glomerular filtration rate was evaluated by four studies [29, 30, 33, 35]. Data from three [30, 33, 35] studies were available for a meta-analysis. The mean differences for eGFR among the three studies ranged from − 2.6 to 3.5 mL/min/1.73 $m^2$. There was no significant difference in the eGFR of the intervention and control groups [Fig. 3c; MD − 0.59 (95% CI − 4.12 to 5.29) $p = 0.81$]. However, a moderate degree of heterogeneity was detected ($I^2 = 60\%$).

### *Hemoglobin $A_{1c}$*

Six studies [29, 30, 32–35] reported mean $HbA_{1c}$ levels ranging from 6.3 to 8.1% for the intervention groups and 7.1 to 8.5% for the control groups. Three studies [30, 32, 35] which included structured care managed by a diabetes team, diabetes education and care management program, and multifactorial medication self-management reported lower $HbA_{1c}$ levels in the intervention groups (MDs

**Table 4** Summary of findings for the main comparison

Self-management compared with control for participants with diabetes and chronic kidney disease

Patient or population: patients with diabetes and chronic kidney disease
Settings: community, primary care, hospital outpatient
Intervention: self-management
Comparison: standard care

| Outcomes | Impact | Relative effect estimate (95% CI) | No. of studies (participants) | Quality of evidence (GRADE)[a] |
|---|---|---|---|---|
| Systolic blood pressure<br>Follow-up:<br>6 to 24 months<br>[28–31, 33, 35] | SBP MDs ranged from − 8.90 to 3.60 mmHg. One study* [28] was excluded from the meta-analysis due to insufficient data. | MD − 4.26<br>(− 7.81, − 0.71) | 6 (577) | Low[1] |
| Diastolic blood pressure<br>Follow-up:<br>12 to 24 months<br>[30, 31, 33, 35] | DBP MDs − 7.50 to 2.30 mmHg | MD − 2.70<br>(− 6.19, 0.78) | 4 (336) | Low[1] |
| eGFR<br>Follow-up:<br>12 to 24 months<br>[29, 30, 33, 35] | Estimated GFR MDs ranged from -2.60 to 3.50 mL/min/1.73 $m^2$. One study* [29] was excluded from the meta-analysis due to insufficient data. | MD 0.59<br>(− 4.12, 5.29) | 4 (499) | Very low[1, 2, 3] |
| $HbA_{1c}$<br>Follow-up:<br>3–24 months<br>[29, 30, 32–35] | $HbA_{1c}$ MDs ranged from − 0.90 to 0.30%. | MD − 0.46%<br>(− 0.83, − 0.09) | 6 (595) | Low[1, 3] |
| Adherence to medications<br>Follow-up: 12 months<br>[35] | One study [35] identified no difference in medication adherence between the control and intervention groups using the Morisky scale. | Not estimable | 1 (80) | Moderate[4] |
| Self-management activity<br>Follow-up:<br>3–12 months<br>[28, 32, 34] | The self-management SMDs for the three studies ranged from 0.31 to 0.99. | SMD 0.56<br>(0.15, 0.97) | 3 (308) | Moderate[5] |
| Health service utilization<br>Follow-up: 6–24 months<br>[28, 30, 32] | Two studies [28, 30] showed no differences in hospitalization between the intervention and control groups and one study [32] reported that the study group had lower hospitalization rates. | Not estimable | 3 (389) | Low[1] |
| Health-related quality of life<br>Follow-up: 3–12 months<br>[28, 32–34] | Two studies [28, 33] showed no difference in quality of life between the intervention and control groups, and in the other two studies [32, 34], the intervention group showed a statistically significant improvement in the quality of life assessment. | SMD − 0.03<br>(− 0.36, 0.31) | 4 (373) | Moderate[1] |
| Death<br>Follow-up:<br>12 to 24 months<br>[30–32] | The three studies showed no differences in mortality between the intervention and control groups. | Not estimable | 3 (354) | Very low[1, 6] |

High quality: further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: we are very uncertain about the estimate

*SBP* systolic blood pressure, *MDs* mean differences, *CI* confidence interval, *DBP* diastolic blood pressure, *eGFR* estimated glomerular filtration rate, *$HbA_{1c}$* glycated hemoglobin, *SMD* standard mean difference

[a]Studies were excluded from the meta-analysis due to non-availability of data. GRADE Working Group grades of evidence

[1]The majority of the studies were not blinded to patients or outcome assessors and they did not report allocation concealment. The quality of evidence was downgraded by 2

[2]There was a considerable degree of inconsistency with several studies reporting effects in opposite directions. The quality of evidence was downgraded by 1

[3]One study reported on eGFR, but there was no data

[4]Relative estimate was not estimable. There were some discrepancies in responses as participants reported that they had no problem remembering to take their medications but at the same time they forgot to take their medications and vice versa. This study had allocation concealment and was blinded to investigators and outcome assessors. We did not downgrade based on limitations

[5]Heterogeneity was moderate ($I^2 = 63\%$). The 95% confidence intervals for some individual studies were narrower

[6]Death was reported by three studies (for the subgroup of patients with diabetes and chronic kidney disease), but the relative effect was not estimable

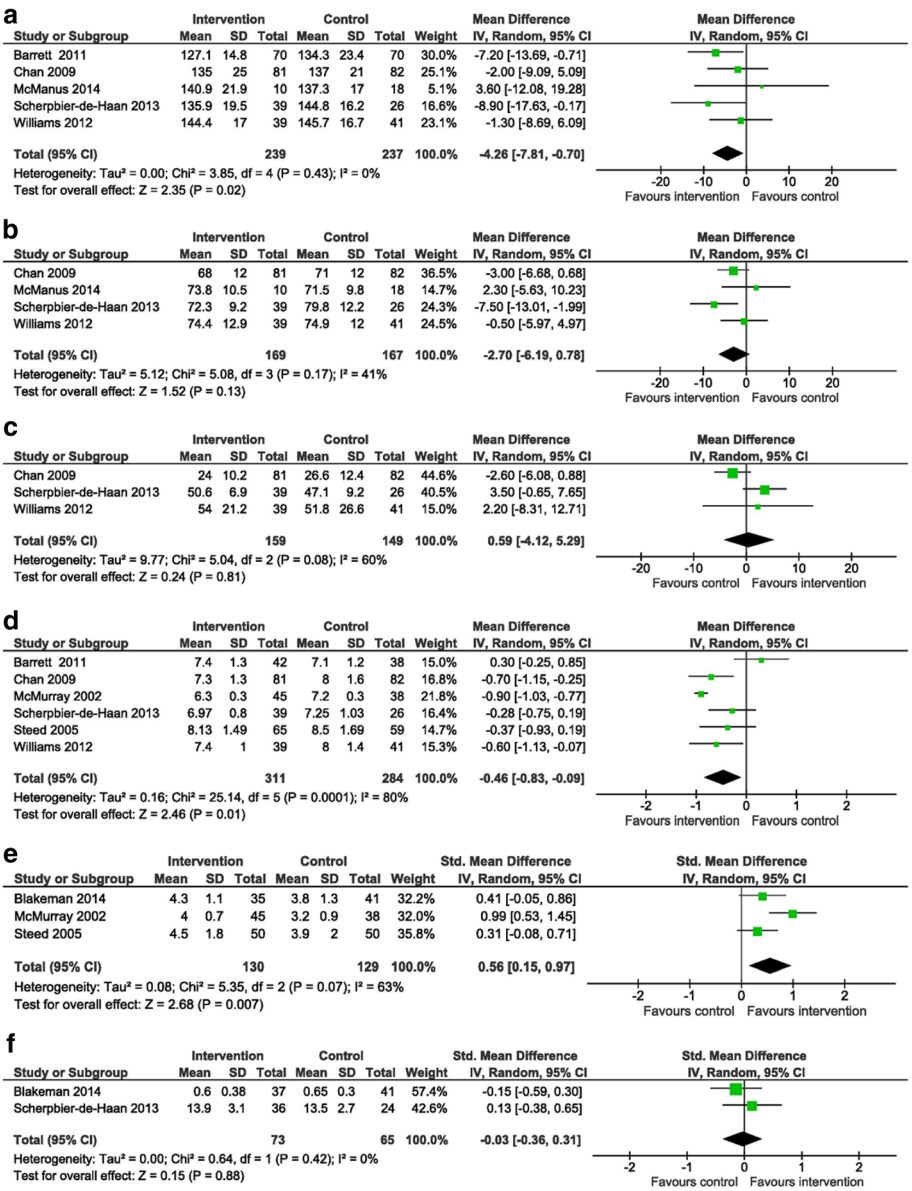



**Fig. 3** Forest plots displaying the effectiveness of self-management support interventions in improving outcomes for patients with diabetes and chronic kidney disease: **a** systolic blood pressure, **b** diastolic blood pressure, **c** estimated glomerular filtration rate, **d** hemoglobin $A_{1c}$, **e** self-management activity, and **f** health-related quality of life. The *x*-axis represents mean differences or standard mean differences. The 95% confidence intervals (CI) for individual studies are represented by a horizontal line and by a diamond for pooled effect. SD standard deviation, IV inverse variance

ranging from − 0.90 to − 0.60%) than the control groups (Fig. 3d). In one study [29], which utilized the nurse-coordinated care intervention, there was a similar increase in the proportion of patients meeting $HbA_{1c}$ targets in both the intervention and control groups. Data from the six studies were available for a meta-analysis. The intervention group had significantly lower $HbA_{1c}$ levels than the control group [Fig. 3d; MD of − 0.5% (95% CI − 0.8 to − 0.1) $p = 0.01$]. However, a high degree of heterogeneity was detected ($I^2 = 80\%$, $p = 0.0001$). A sensitivity analysis excluding the study with patients who had ESRD [32] confirmed that the intervention group had significantly lower $HbA_{1c}$ levels than the control group [MD of − 0.3% (95% CI − 0.68 to − 0.01) $p = 0.04$].

## Secondary outcomes

### *Self-management activity*

Three studies [28, 32, 34] assessed self-management activity and reported significant improvements in most self-management activities evaluated. Two studies utilized the Summary of Diabetes Self-Care Activity [28, 34] questionnaire, while one used the Diabetes Self-Care Knowledge

questionnaire and Diabetes Self-Care Behaviour Inventory [32]. The SMD in self-care for the three studies ranged from 0.31 to 0.99. Data from all three studies were included in a meta-analysis. There was a significant increase in self-care activities in the intervention groups compared to the control groups [Fig. 3e; SMD of 0.56 (95% CI 0.15 to 0.97) $p$ = 0.007]. However, a moderate degree of heterogeneity was detected ($I^2$ = 63%, $p$ = 0.07). A sensitivity analysis excluding the study with patients who had ESRD [32] showed significant improvements in most self-management activities evaluated [SMD of 0.35 (95% CI 0.06 to 0.65) $p$ = 0.02].

#### *Health service utilization*

Three studies [28, 30, 32] evaluated the effect of self-management support interventions on health service utilization. Chan et al. [30] reported similar rates of clinical events, hospitalization, and emergency room visits. Among the nine study sites, the structured care group reported lower event rates than the usual care group in five hospitals, higher event rates than the usual care group in two hospitals, and similar event rates in two hospitals. After a 2-year period, the structured care group were more likely to achieve three or more treatment goals [61% ($n$ = 63) vs. 28% ($n$ = 28)] and those who attained three or more treatment goals ($n$ = 91) had a 60% lower risk of the primary end point (death and/or renal end point creatinine > 500 μmol/L or dialysis) compared with those who did not attain three or more treatment goals ($n$ = 114) [14 vs. 34; RR 0.43 (95% CI 0.21 to 0.86)]. Blakeman et al. [28] reported a mean (SD) service use of 7.6 (7.7) and 6.1 (3.6) for the intervention and control groups respectively ($p$ = 0.27). McMurray et al. [32] reported a significant progression in diabetic-related peripheral vascular/neuropathic disease in the control group from a baseline score of 2.7 to a 12-month foot risk assessment score of 3.3, whereas the study group did not show this progression ($p$ < 0.02). The intervention group also had a statistically significant lower hospitalization rate for diabetes, peripheral vascular disease, infection, and amputation-related admissions ($p$ < 0.05).

#### *Health-related quality of life*

Four studies examined health-related quality of life [28, 32–34]. Two studies [32, 34] which had missing summary data were not included in the meta-analysis. There was no significant difference in HRQOL scores between the intervention and control groups [Fig. 3f; SMD of − 0.03 (95% CI − 0.36 to 0.31) $p$ = 0.88]. A low degree of heterogeneity was detected ($I^2$ = 0%, $p$ = 0.42). All the four studies used different instruments for measuring HRQOL. Blakeman et al. [28] measured HRQOL with the EuroQol five dimensions questionnaire (EQ-5D) and reported no significant difference in mean (SD) EQ5D scores in the intervention and control groups respectively ($p$ = 0.52). Steed et al. [34] showed differences in diabetes specific quality of life as measured by the Audit of Diabetes-Dependent Quality of Life (ADDQoL) questionnaire ($p$ < 0.01). McMurray et al. [32] evaluated patient quality of life using a questionnaire adapted from the standardized Diabetes Form 2.1 and found that the intervention group had significant improvement in the quality-of-life assessment category of diabetes symptoms ($p$ < 0.001). Scherpbier-de Haan et al. [33] reported no significant difference in mean (SD) WONCA scores in the intervention and control groups respectively ($p$ = 0.40).

#### *Medication adherence*

Medication adherence was assessed in one study [35], which reported no difference in medication adherence between groups using pill counts. The mean adherence rate to the medications at the completion of the study was 66% in the control group and 58.4% in the intervention group ($p$ = 0.16).

#### *Death*

Three studies [30–32] reported on death. Chan et al. [30] reported eight deaths in the structured care group ($N$ = 104) and 11 in the usual care group ($N$ = 101). In a study by McManus et al. [31], one patient died in each group and neither death was study-related. McMurray et al. reported no difference in mortality between the control and intervention groups.

## Discussion

In this systematic review of eight studies among 835 patients with comorbid diabetes and CKD, there was moderate-quality evidence that self-management support interventions significantly improved self-management activity compared to usual care and low-quality evidence that these interventions significantly improved $HbA_{1c}$ and systolic blood pressure but not diastolic blood pressure, eGFR, and HRQOL. The self-management components that were effective across these outcomes included provider reminders, patient education, and goal setting provided in multidisciplinary settings. In addition, treatment effects could not be quantitatively estimated for medication adherence, health service utilization, and death due to marked heterogeneity and insufficient data.

Our findings suggest that provider reminders, patient education, and goal setting may be associated with improved systolic blood pressure, $HbA_{1c}$, and self-management activity. This is consistent with results from other studies among patients with hypertension [40] and type 2 diabetes mellitus [41]. Goal setting, reported in three studies [28, 32, 34], appeared to be an important self-management element to enhance self-care. This supports evidence from a previous study among patients with diabetes [42], which has suggested that a goal setting intervention along with a diabetes

self-management guide help patients set and achieve healthy behavioral goals.

Although we found statistically significant increases in self-management activity with the self-management support interventions studied, the clinical relevance of these effects must be considered. A SMD of 0.5 has previously been reported as likely to represent a meaningful change or a minimal important difference in patient-reported outcomes [43, 44]. Our pooled estimate of 0.56 SMD units (range 0.15 to 0.97) thus suggests that an appreciable number of patients with diabetes and CKD may benefit from the self-management support interventions studied.

The Chronic Care Model (CCM) [45] provides a useful framework which explains how the multidisciplinary setting drives behaviour change especially for patients with complex diseases who require multi-faceted approaches to care. The benefits of the CCM include improved clinical outcomes [46–48], patient empowerment, and education [49]. Components of self-management support have been shown to be particularly effective when delivered by a multidisciplinary team for patients with CKD [50]. The reasons for this are that multidisciplinary members bring self-management expertise and they provide opportunities for further self-management support. In support of this, the KDIGO guidelines suggest that people with progressive CKD should be managed in a multidisciplinary care setting [51]. In this review, we cannot fully ascertain whether multidisciplinary settings led to the effectiveness of self-management support interventions since all included studies consisted of multidisciplinary teams.

These findings need to be considered in light of the very low to moderate quality of evidence examined. Reasons include potential biases in the methodological conduct of studies (including challenges in blinding investigators, participants, and outcome assessors in behavioral intervention studies [52]) and the small numbers of studies per outcome which limited interpretation of efficacy for the specific self-management support interventions investigated. There was marked heterogeneity especially for studies that reported on eGFR, $HbA_{1c}$, and self-management activity. The reasons for this could be (1) the size of the included studies (small studies have been shown to be more heterogeneous than larger studies [53]) and (2) the variability related to the quality of the studies, characteristics of enrolled participants, and administered interventions. Our results could have also been biased by the exclusion of 28 studies due to non-response from corresponding authors and failure to specify subgroup analysis. Additionally, some studies compared interventions with usual care, which included key intervention components such as patient education, and specialist consult that could not be withheld due to ethical concerns [29, 30]. Consequently, these biases may have weakened the effects of self-management support interventions on outcomes.

The review has a number of strengths. Firstly, to our knowledge, this is the first comprehensive review of evidence on self-management support interventions for patients with both diabetes and CKD. Secondly, this review is underpinned by the use of reliable tools, a peer-reviewed and published protocol, and rigorous methods that included efforts to retrieve additional methods, information, and data from study authors to ensure that accurate data were included and synthesized.

The review had a number of limitations. We excluded studies published in languages other than English. Another limitation was the assumption that self-management support interventions were standardized when practically many aspects of self-management, particularly those delivered outside the health care setting, are not. Therefore, we relied on subjective judgment to include or exclude studies when self-management support interventions were not explicitly stated. There was also considerable threat to internal validity due to the low quality of evidence from included studies stemming from difficulties in blinding of behavioral interventions [52]. Lastly, the interpretation of results from this review should take into consideration marked variation in self-management support interventions and outcome measures in the included studies.

Findings from this review have several implications to research and practice. First, a gap of research focusing on diabetes self-management support interventions and outcomes for patients with comorbid diabetes and CKD has been highlighted. Future research should therefore focus on studies designed primarily for people with both diabetes and CKD, and when a study among people with other chronic diseases includes this sub-population, a consistent approach to the conduct and reporting of secondary analysis should be rigorously followed. Second, there should be standardization of outcome measures such as HRQOL to reduce between-study heterogeneity and more studies should measure hard clinical end points and patient-reported outcomes like medication adherence. Additionally, we have shown that self-management support interventions may improve outcomes for people with comorbid diabetes and CKD, but the effect of these interventions beyond 24 months and the intensity of the interventions required still need to be explored. Well-designed longitudinal studies that compare the components of multifaceted interventions are required to understand which components are essential for producing beneficial effects. Such studies may also gather data essential for the development of a complex RCT that can test self-management as an intervention.

## Conclusion

Self-management support interventions may improve self-care activities, systolic blood pressure, and $HbA_{1c}$ in patients with comorbid diabetes and CKD. This evidence is

based on low to moderate quality studies with relatively few study participants. It was not possible to determine which self-management support components and elements were more effective, but interventions that utilized provider reminders, patient education, and goal setting provided in multidisciplinary settings were associated with improved outcomes. More evidence from high-quality studies is required to support future self-management programs.

## Additional files

**Additional file 1: Table S1.** Ovid MEDLINE search strategy conducted on 19 December 2017. (DOCX 17 kb)

**Additional file 2: Table S2.** Template for critical appraisal of a randomized controlled trial. (DOCX 20 kb)

**Additional file 3: Table S3.** Characteristics of excluded studies (ordered alphabetically). (DOCX 12 kb)

**Additional file 4: Figure S1.** Risk of bias: review authors' judgements about each risk of bias item presented as percentages across all included studies. (PNG 205 kb)

**Additional file 5: Figure S2.** Methodological quality summary: review authors' judgements about each methodological quality item for each included study. (PNG 583 kb)

### Abbreviations

ADDQoL: Audit of Diabetes-Dependent Quality of Life; CCM: Chronic Care Model; CI: Confidence intervals; CINAHL: Cumulative Index to Nursing and Allied Health Literature; CKD: Chronic kidney disease; EBM: Evidence-based medicine; eGFR: Estimated glomerular filtration rate; EMBASE: Excerpta Medica database; EQ5D: European Quality of Life-5 Dimensions questionnaire; ESRD: End-stage renal disease; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; $HbA_{1c}$: Glycated hemoglobin; HRQOL: Health-related quality of life; MCHRI: Monash Centre for Health Research and Implementation; MD: Mean difference; PICO: Population, Intervention, Comparison, and Outcome; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCTs: Randomized controlled trials; SDSCA: Summary of Diabetes Self-Care Activity questionnaire; SMD: Standard mean difference; SURE study: Structured versus usual care on renal endpoint in type 2 diabetes; WONCA scores: World Organization of National Colleges, Academies, and Academic Associations of General Practitioners/Family Physicians

### Acknowledgements

We thank Blakeman et al., Barret et al., McManus et al., Scherpbier-de Haan et al., and Williams et al. for providing additional data required for this review.

### Availability of data and materials

All materials relevant to this review including results of the search, included and excluded studies, the PRISMA flow diagram, and risk of bias and assessment of methodological quality are included in the article and additional information files. Data abstraction forms are available from the corresponding author on request.

### Authors' contributions

EZ, CL, SR, MM, PGK, HJT, and SZ contributed to the research idea and study design. EZ, CL, MM, SR, and SZ contributed to the data acquisition. EZ, CL, SR, and SZ contributed to the data analysis/interpretation. EZ, CL, SR, and SZ contributed to the statistical analysis. SZ, PGK, and HJT contributed to the supervision or mentorship. Each author contributed significant intellectual content during the drafting of the manuscript and revisions and accepts accountability for the overall work. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

## Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

### Author details

[1]Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, 43-51 Kanooka Grove, Clayton, Melbourne, Victoria, Australia. [2]Department of Nephrology, Monash Health, Melbourne, Victoria, Australia. [3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Victoria, Australia. [4]Department of Medicine, School of Clinical Sciences at Monash Health, Monash University, Melbourne, Victoria, Australia. [5]The George Institute for Global Health, University of Sydney, Sydney, New South Wales, Australia.

Received: 20 November 2017 Accepted: 24 May 2018
Published online: 13 June 2018

### References

1. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137–49.
2. Ogurtsova K, da Rocha Fernandes JD, Huang Y, et al. IDF diabetes atlas: global estimates for the prevalence of diabetes for 2015 and 2040. Diabetes Res Clin Pract. 2017;128:40–50.
3. Chowdhury TA, Shaho S, Moolla A. Complications of diabetes: progress, but significant challenges ahead. Ann Transl Med. 2014;2(12):120.
4. Mills KT, Xu Y, Zhang W, et al. A systematic analysis of worldwide population-based data on the global burden of chronic kidney disease in 2010. Kidney Int. 2015;88(5):950–7.
5. Schernthaner G. Kidney disease in diabetology. Nephrol Dialysis Transplantation. 2007;22(3):703–7.
6. Tuttle KR, Bakris GL, Bilous RW, et al. Diabetic kidney disease: a report from an ADA consensus conference. Am J Kid Dis. 2014;64(4):510–33.
7. Palsson R, Patel UD. Cardiovascular complications of diabetic kidney disease. Adv Chronic Kidney Dis. 2014;21(3):273–80.
8. Zimbudzi E, Lo C, Ranasinha S, et al. Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease. PLoS One. 2016;11(12):e0168491.
9. Ko GT, Yeung CY, Leung WY, et al. Cost implication of team-based structured versus usual care for type 2 diabetic patients with chronic renal disease. Hong Kong Med J. 2011;17(6):9–12.
10. Welch JL, Johnson M, Zimmerman L, Russell CL, Perkins SM, Decker BS. Self-management interventions in stages 1 to 4 chronic kidney disease: an integrative review. West J Nurs Res. 2015;37(5):652–78.
11. Griva K, Mooppil N, Khoo E, Lee VYW, Kang AWC, Newman SP. Improving outcomes in patients with coexisting multimorbid conditions—the development and evaluation of the combined diabetes and renal control trial (C-DIRECT): study protocol. BMJ Open. 2015;5(2):e007253.
12. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration; 2011. Available from www.handbook.cochrane.org.
13. Moher DL, Tetzlaff A, Altman J, G D. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6(7):e1000097.
14. Zimbudzi E LC, Misso M, Ranhasinha S, Zoungas S. Effectiveness of management models for facilitating self-management and patient outcomes in people with diabetes and chronic kidney disease PROSPERO 2015:CRD42015017316; [Available from: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=17316. Accessed 10 Mar 2017.
15. Zimbudzi E, Lo C, Misso M, Ranasinha S, Zoungas S. Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease. Syst Rev. 2015;4:81.
16. The National Kidney Foundation (NKF). Kidney Disease Outcomes Quality Initiative (K/DOQI) clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis. 2002;39(2-1):S1–266.
17. Adams K, Greiner AC, Corrigan JM. Report of a summit. The 1st annual crossing the quality chasm summit—a focus on communities. Washington, DC: National Academies Press; 2004.

18. Monash Centre for Health Research and Implementation (MCHRI). Evidence Synthesis Program templates for critical appraisal and risk of bias (adapted from Critical Appraisal Templates, Centre for Clinical Effectiveness, Southern Health, Melbourne, 2010). Melbourne: MCHRI-Monash University and Monash Health; 2013.
19. Guyatt GH, Oxman AD, Schünemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the journal of clinical epidemiology. J Clin Epidemiol. 2011;64(4):380–2.
20. Viechtbauer W. Accounting for heterogeneity via random-effects models and moderator analyses in meta-analysis. Z Psychol. 2007;215(2):104–21.
21. Strand H, Parker D. Effects of multidisciplinary models of care for adult pre-dialysis patients with chronic kidney disease: a systematic review. Int J Evid Based Healthc. 2012;10(1):53–9.
22. McDonald HP, Garg AX, Haynes RB. Interventions to enhance patient adherence to medication prescriptions: scientific review. JAMA. 2002; 288(22):2868–79.
23. Santschi V, Chiolero A, Burnand B, Colosimo AL, Paradis G. Impact of pharmacist care in the management of cardiovascular disease risk factors: a systematic review and meta-analysis of randomized trials. Arch Intern Med. 2011;171(16):1441–53.
24. Roshanov PS, Misra S, Gerstein HC, et al. Computerized clinical decision support systems for chronic disease management: a decision-maker-researcher partnership systematic review. Implement Sci. 2011;6:92.
25. Bowles KH, Baugh AC. Applying research evidence to optimize telehomecare. J Cardiovasc Nurs. 2007;22(1):5–15.
26. Sintchenko V, Magrabi F, Tipper S. Are we measuring the right end-points? Variables that affect the impact of computerised decision support on patient outcomes: a systematic review. Med Inform Internet Med. 2007;32(3):225–40.
27. Li T, Wu HM, Wang F, et al. Education programmes for people with diabetic kidney disease. Cochrane Database Syst Rev. 2011;(6):Cd007374.
28. Blakeman T, Blickem C, Kennedy A, et al. Effect of information and telephone-guided access to community support for people with chronic kidney disease: randomised controlled trial. PLoS One. 2014;9(10):e109135.
29. Barrett BJ, Garg AX, Goeree R, Levin A, Molzahn A, Rigatto C, Singer J, Soltys G, Soroka S, Ayers D, Parfrey PS. A nurse-coordinated model of care versus usual care for stage 3/4 chronic kidney disease in the community: a randomized controlled trial. Clin J Am Soc Nephrol. 2011;6(6):1241–7.
30. Chan JC, So WY, Yeung CY, et al. Effects of structured versus usual care on renal endpoint in type 2 diabetes: the SURE study: a randomized multicenter translational study. Diabetes Care. 2009;32(6):977–82.
31. McManus RJ, Mant J, Haque MS, et al. Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: the TASMIN-SR randomized clinical trial. JAMA. 2014;312(8):799–808.
32. McMurray SD, Johnson G, Davis S, McDougall K. Diabetes education and care management significantly improve patient outcomes in the dialysis unit. Am J Kidney Dis. 2002;40(3):566–75.
33. Scherpbier-de Haan ND, Vervoort GM, van Weel C, et al. Effect of shared care on blood pressure in patients with chronic kidney disease: a cluster randomised controlled trial. Br J Gen Pract. 2013;63(617):e798–806.
34. Steed L, Lankester J, Barnard M, Earle K, Hurel S, Newman S. Evaluation of the UCL diabetes self-management programme (UCL-DSMP): a randomized controlled trial. J Health Psychol. 2005;10(2):261–76.
35. Williams A, Manias E, Walker R, Gorelik A. A multifactorial intervention to improve blood pressure control in co-existing diabetes and kidney disease: a feasibility randomized controlled trial. J Adv Nurs. 2012;68(11):2515–25.
36. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. Milbank Q. 1996;74(4):511–44.
37. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care. 1999;37(1):5–14.
38. Rogers A, Kennedy A, Bower P, et al. The United Kingdom Expert Patients Programme: results and implications from a national evaluation. Med J Aust. 2008;189(10):S21–4.
39. Battersby M, Harvey P, Mills PD, et al. SA HealthPlus: a controlled trial of a statewide application of a generic model of chronic illness care. Milbank Q. 2007;85(1):37–67.
40. Bosworth HB, Olsen MK, Grubber JM, et al. Two self-management interventions to improve hypertension control: a randomized trial. Ann Intern Med. 2009;151(10):687–95.
41. Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: a systematic review of the effect on glycemic control. Patient Educ Couns. 2016;99(6):926–43.
42. DeWalt DA, Davis TC, Wallace AS, et al. Goal setting in diabetes self-management: taking the baby steps to success. Patient Educ Couns. 2009;77(2):218–23.
43. Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care. 2003;41(5):582–92.
44. Cuijpers P, Turner EH, Koole SL, van Dijke A, Smit F. What is the threshold for a clinically relevant effect? The case of major depressive disorders. Depress Anxiety. 2014;31(5):374–8.
45. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? Eff Clin Pract. 1998;1(1):2–4.
46. MacLean CD, Littenberg B, Gagnon M, Reardon M, Turner PD, Jordan C. The Vermont Diabetes Information System (VDIS): study design and subject recruitment for a cluster randomized trial of a decision support system in a regional sample of primary care practices. Clinical trials (London, England). 2004;1(6):532–44.
47. Piatt GA, Orchard TJ, Emerson S, et al. Translating the chronic care model into the community: results from a randomized controlled trial of a multifaceted diabetes care intervention. Diabetes Care. 2006;29(4):811–7.
48. Smith SA, Shah ND, Bryant SC, et al. Chronic care model and shared care in diabetes: randomized trial of an electronic decision support system. Mayo Clin Proc. 2008;83(7):747–57.
49. Siminerio LM, Piatt G, Zgibor JC. Implementing the chronic care model for improvements in diabetes care and education in a rural primary care practice. Diabetes Educ. 2005;31(2):225–34.
50. Chen YR, Yang Y, Wang SC, et al. Effectiveness of multidisciplinary care for chronic kidney disease in Taiwan: a 3-year prospective cohort study. Nephrol Dial Transplant. 2013;28(3):671–82.
51. Kidney Disease Improving Global Outcomes (KDIGO CKD) Work Group. "Chapter 5: referral to specialists and models of care" in KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease Kidney Int Suppl. 2013;3(1):112–119.
52. Friedberg JP, Lipsitz SR, Natarajan S. Challenges and recommendations for blinding in behavioral interventions illustrated using a case study of a behavioral intervention to lower blood pressure. Patient Educ Couns. 2010;78(1):5–11.
53. IntHout J, Ioannidis JP, Borm GF, Goeman JJ. Small studies are more heterogeneous than large ones: a meta-meta-analysis. J Clin Epidemiol. 2015;68(8):860–9.



**Ready to submit your research? Choose BMC and benefit from:**

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

**At BMC, research is always in progress.**

**Learn more** biomedcentral.com/submissions

BMC

## 5.4 Conclusion

Self-management support interventions may improve self-management ability, systolic blood pressure and glycated haemoglobin in patients with co-morbid diabetes and CKD. However, it was not possible to determine which self-management components and elements were most effective, but interventions that utilised provider reminders, patient education and goal setting were associated with improved outcomes. Based on these findings, this thesis prioritised developing a co-designed educational resource for patients with comorbid diabetes and CKD to optimise their self-management ability. This body of work is presented in the following Chapter.

**Online resources**

**Additional file 1:** Table S1. Ovid MEDLINE search strategy conducted on **19 December 2017**

| | | |
|---|---|---|
| 1 | exp Chronic Disease/ | 265 711 |
| 2 | (chronic adj3 (illness* or disease* or condition*)).mp. | 478 794 |
| 3 | chronic disease therapy.mp. | 91 |
| 4 | or/1-3 | 478 794 |
| 5 | kidney diseases/ or anuria/ or diabetic nephropathies/ or hypertension, renal/ or hypertension, renovascular/ or renal insufficiency, chronic/ | 149 471 |
| 6 | chronic kidney disease.mp. | 35 707 |
| 7 | (chronic kidney or chronic renal).mp. | 69 323 |
| 8 | (CKD or CRD).mp. | 22 382 |
| 9 | diabetes mellitus/ or diabetes mellitus, type 1/ or wolfram syndrome/ or diabetes mellitus, type 2/ or diabetes mellitus, lipoatrophic/ or diabetic ketoacidosis/ or donohue syndrome/ | 302 724 |
| 10 | (MODY or NIDDM or T2DM or T2D).mp. | 25 653 |
| 11 | (non insulin* depend* or noninsulin* depend* or noninsulin?depend* or non insulin?depend*).mp. | 13 377 |
| 12 | ((typ? 2 or typ? II or typ?2 or typ?II) adj3 diabet*).mp. | 155 407 |
| 13 | (((late or adult* or matur* or slow or stabl*) adj3 onset) and diabet*).mp. | 4 327 |
| 14 | (IDDM or T1DM or T1D).mp. | 14 813 |
| 15 | (insulin* depend* or insulin?depend*).mp. | 31 751 |
| 16 | ((typ? 1 or typ? I or typ?1 or typ?I) adj3 diabet*).mp. | 87 507 |
| 17 | (insulin* defic* adj2 absolut*).mp. | 103 |
| 18 | or/5-17 | 520 728 |
| 19 | exp Consumer Participation/ | 40 341 |
| 20 | exp Self Care/ | 53 884 |
| 21 | exp Self Concept/ | 105 711 |

| | | |
|---|---|---|
| 22 | ((self or self directed or self-directed or self monitor* or self-monitor* or symptom*) adj (care or help or manag* or efficacy or admin* or concept)).mp. | 181 439 |
| 23 | patient financial incentives.mp. | 12 |
| 24 | health education/ or consumer health information/ or health literacy/ or patient education as topic/ | 149 039 |
| 25 | Health Communication/ | 1 536 |
| 26 | interdisciplinary communication/ | 16 493 |
| 27 | ((consumer or patient*) adj2 (educat* or information or particip* or behavio?r*)).mp. | 196 797 |
| 28 | ((health educat* or health information) adj2 (program* or intervention* or meeting* or session* or strategy* or workshop* or visit* or method* or material* orcampaign*)).mp. | 5 505 |
| 29 | access to expertise.mp. | 51 |
| 30 | availability of clinical information.mp. | 24 |
| 31 | Reminder Systems/ | 3 309 |
| 32 | patient reminders.mp. | 98 |
| 33 | Pamphlets/ | 3 860 |
| 34 | (leaflet* or booklet* or poster* or pamphlet*).mp. | 301 903 |
| 35 | ((written or printed or oral) adj information).mp. | 1 896 |
| 36 | (provider adj2 (educat* or feedback or remind* or behavio?r)).mp. | 1 448 |
| 37 | Health Care Reform/ | 32 276 |
| 38 | health care reform.mp. | 34 456 |
| 39 | exp Patient Care Management/ | 731 770 |
| 40 | (care co-ordinat* or care coordinat*).mp. | 2 869 |
| 41 | chronic disease management model.mp. | 42 |
| 42 | exp "Continuity of Patient Care"/ | 228 607 |
| 43 | continuity of patient care.mp. | 18 387 |
| 44 | behavio?r change.mp. | 10 139 |
| 45 | models, nursing/ or models, organizational/ | 30 837 |
| 46 | or/19-45 | 1 591 897 |
| 47 | (model* or strateg* or intervention* or program*).mp. | 6 780 |
| 48 | 22 or 27 or 28 or 36 or 40 or 43 or 44 | 389 743 |

| | | |
|---|---|---|
| 49 | 47 and 48 | 161 602 |
| 50 | 46 or 49 | 1 591 897 |
| 51 | 4 and 18 and 50 | 6 780 |
| 52 | Meta-Analysis as Topic/ | 17 942 |
| 53 | meta analy$.tw | 112 322 |
| 54 | metaanaly$.tw | 1 801 |
| 55 | Meta-Analysis/ | 97 340 |
| 56 | (systematic adj (review$1 or overview$1)).tw | 98 850 |
| 57 | Exp Review Literature as Topic/ | 10 551 |
| 58 | or/52-57 | 205 167 |
| 59 | cochrane.ab. | 52 749 |
| 60 | embase.ab. | 55 499 |
| 61 | (psychlit or psyclit).ab | 934 |
| 62 | (psychinfo or psycinfo).ab | 16 230 |
| 63 | (cinahl or cinahl).ab. | 17 468 |
| 64 | science citation index.ab. | 2 678 |
| 65 | bids.ab. | 441 |
| 66 | cancerlit.ab | 657 |
| 67 | or/59-66 | 87 674 |
| 68 | reference list$.ab | 14 276 |
| 69 | bibliography$.ab. | 14 552 |
| 70 | hand-search$.ab. | 5 304 |
| 71 | relevant journals.ab. | 989 |
| 72 | manual search$.ab. | 3 312 |
| 73 | or/68-72 | 34 473 |
| 74 | selection criteria.ab. | 26 460 |
| 75 | data extraction.ab. | 14 509 |
| 76 | 74 or 75 | 38 888 |
| 77 | Review/ | 2 429 942 |
| 78 | 76 and 77 | 28 024 |
| 79 | Comment/ | 717 040 |
| 80 | Letter/ | 1 003 380 |
| 81 | Editorial/ | 433 328 |

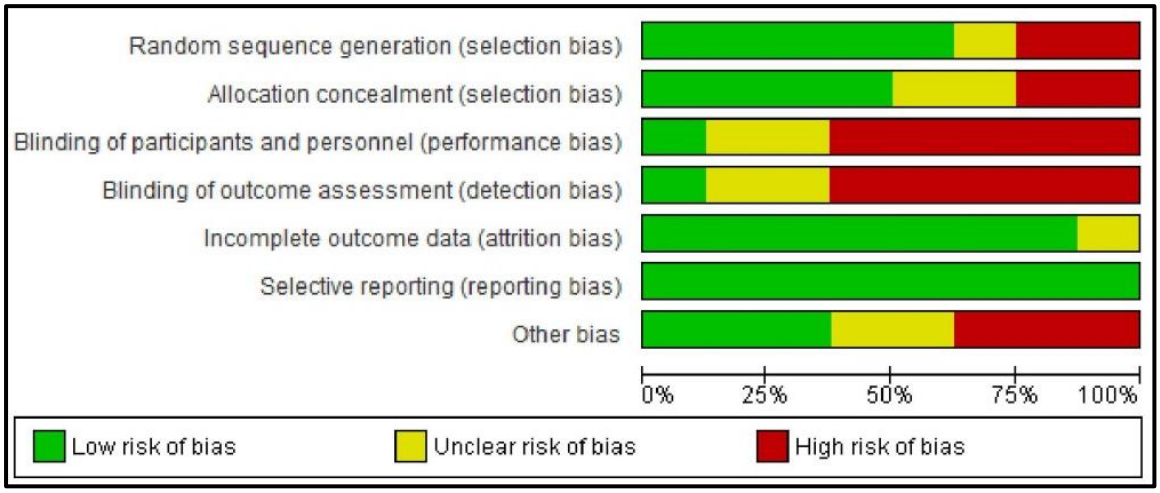
| | | |
|---|---|---|
| 82 | animal/ | 6 687 808 |
| 83 | human/ | 18 317 354 |
| 84 | 82 not (82 and 83) | 4 770 502 |
| 85 | or/79-81,84 | 6 303 117 |
| 86 | 58 or 67 or 73 or 78 | 244 089 |
| 87 | 86 not 85 | 230 274 |
| 88 | randomi?ed controlled trial.pt | 513 947 |
| 89 | controlled clinical trial.pt. | 101 674 |
| 90 | randomi?ed.ti,ab. | 514 531 |
| 91 | placebo.ti,ab. | 198 627 |
| 92 | clinical trials as topic.sh. | 202 274 |
| 93 | randomly.ti,ab. | 272 141 |
| 94 | trial.ti. | 178 776 |
| 95 | or/88-94 | 1 191 787 |
| 96 | exp animals/not exp humans/ | 4 805 331 |
| 97 | 95 not 96 | 1 092 542 |
| 98 | 87 or 97 | 1 245 737 |
| 99 | 51 and 98 | 1 144 |
| 100 | Limit 99 to (english language and yr=”1994-Current”) | 1 112 |

**Additional file 2:** Table S2. Template for critical appraisal of a randomized controlled trial (as per protocol in Chapter 5.2).

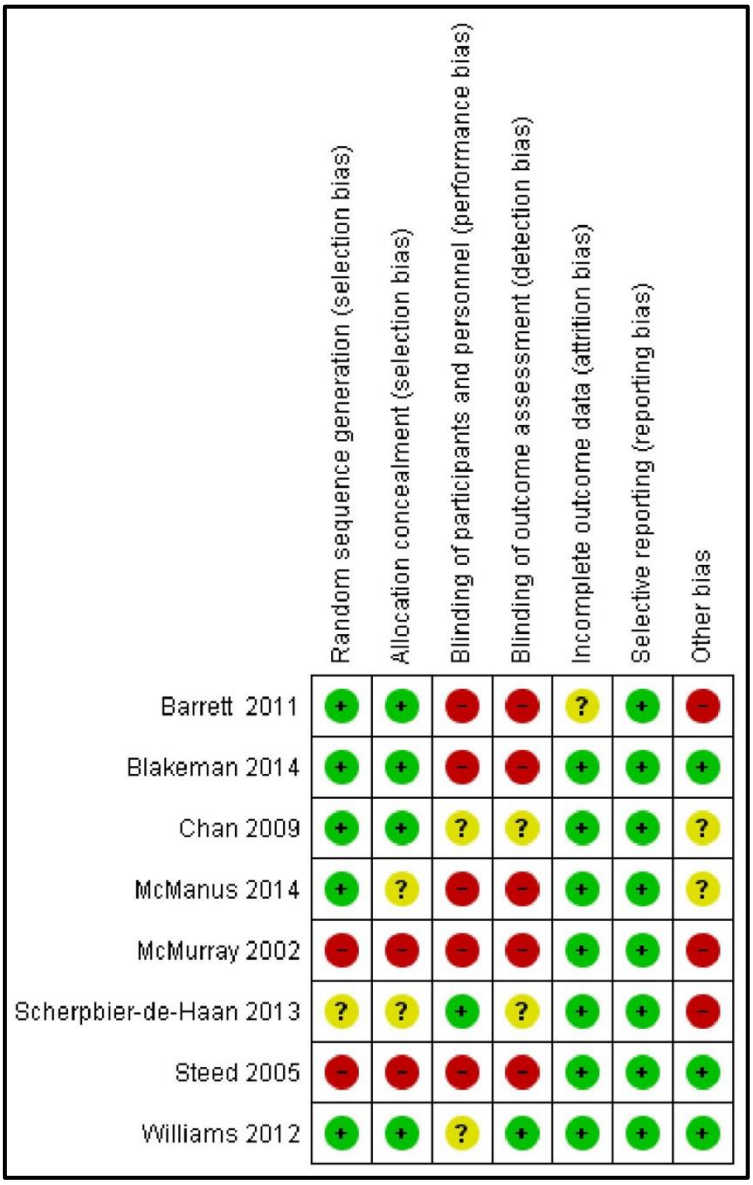
**Additional file 3:** Table S3. Characteristics of excluded studies (ordered alphabetically).

| Study | Reason for exclusion |
|---|---|
| Abdel-Kader 2009 | No response from authors to clarify study queries |
| Adair 2013 | No subgroup analysis to confirm right population |
| Adepoju 2014 | No subgroup analysis to confirm right population |
| Chao 2014 | No response from authors to clarify study queries |
| Chen 2011 | No response from authors to clarify study queries |
| Crowley 2013 | No subgroup analysis to confirm right population |
| Dansky 2003 | No subgroup analysis to confirm right population |
| De Brito-Ashurst 2012 | No subgroup analysis to confirm right population |
| Desroches 2013 | No subgroup analysis to confirm right population |
| Devins 2003 | No response from authors to clarify study queries |
| Drawz 2012 | No response from authors to clarify study queries |
| Eakin 2009 | No subgroup analysis to confirm right population |
| Flesher 2011 | No subgroup analysis to confirm right population |
| Foy 2011 | Not in relevant population |
| Glasgow 2012 | No response from authors to clarify study queries |
| Harris 1998 | No subgroup analysis to confirm right population |
| Holbrook 2009 | No subgroup analysis to confirm right population |
| Hung 2014 | Not an RCT (Commentary of RCT) |
| Isbel 2006 | No subgroup analysis to confirm right population |
| Ishani 2016 | No response from authors to clarify study queries |
| Leonardis 2012 | Study is incomplete |
| Lusignan 2013 | No subgroup analysis to confirm right population |
| Manns 2005 | No response from authors to clarify study queries |
| McCall 2011 | No response from authors to clarify study queries |
| Ong 2016 | No subgroup analysis to confirm right population |
| Peeters 2012 | No response from authors to clarify study queries |
| Piette 2000 | No response from authors to clarify study queries |
| Rifkin 2013 | No response from authors to clarify study queries |
| Selea 2011 | Not in relevant population |
| Sintchenko 2007 | Not in relevant population |
| Strand 2012 | Not in relevant population |
| Tricco 2012 | Not in relevant population |
| Walker 2013 | Not an RCT |
| Weber 2012 | No response from authors to clarify study queries |
| Wentzlaff 2011 | No response from authors to clarify study queries |
| Wong 2010 | No response from authors to clarify study queries |
| Yamagata 2016 | Study is incomplete |

**Additional file 4:** Figure S1. Risk of bias: review authors' judgements about each risk of bias item presented as percentages across all included studies.



**Additional file 5:** Figure S2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



# CHAPTER 6

# EDUCATIONAL NEEDS FOR PATIENTS WITH DIABETES AND CHRONIC KIDNEY DISEASE

## 6.1 Introduction

In Chapter 5, patient education was identified as among the most important self-management support components. This has also been reported for people with diabetes alone [115, 116]. For patient education to be successful, it must address the specific education needs of patients. Although self-management education needs have been assessed for patients with single diseases, including CKD [117-120] and diabetes [121, 122], they have not been assessed for patients with co-morbid diabetes and CKD. This is an important gap given that patients with complex diseases may have competing self-management strategies and challenges [42], which put them at risk of negating the management of additional conditions especially later diagnoses.

Chapter 6 utilises a qualitative study design to assess the education needs of patients with diabetes and CKD. A DVD with education material co-designed by patients was produced as discussed in this Chapter. The study described in this Chapter was published in *BMC Nephrology Journal* (Zimbudzi et al., 2019). The Chapter is presented as a pdf version of the manuscript.

## 6.2 Published: A need-based approach to self-management education for adults with co-morbid diabetes and chronic kidney disease

Citation: **Zimbudzi E**., Lo C., Kerr PG., Zoungas S. A need-based approach to self-management education for adults with co-morbid diabetes and chronic kidney disease. BMC Nephrology 2019.

Zimbudzi et al. BMC Nephrology (2019) 20:113
https://doi.org/10.1186/s12882-019-1296-z

BMC Nephrology

RESEARCH ARTICLE Open Access

# A need-based approach to self-management education for adults with co-morbid diabetes and chronic kidney disease

Edward Zimbudzi[1,2], Clement Lo[2,4], Peter G. Kerr[1] and Sophia Zoungas[2,3,4*]

## Abstract

**Background:** Self-management education needs have not been assessed in patients with complex co-morbid conditions such as diabetes and chronic kidney disease (CKD). The objectives of this study were to 1) determine the self-management education needs for patients with co-morbid diabetes and CKD and 2) co-develop an educational resource meeting the self-management education needs of patients with co-morbid diabetes and CKD.

**Methods:** Patients with co-morbid diabetes and CKD attending a co-designed, patient-centred outpatient diabetes and kidney clinic at a tertiary metropolitan hospital were recruited for semi-structured interviews. Maximal variation sampling was used, ensuring adequate representation of different gender, age, diabetes duration and stage of CKD. Data were thematically analysed using grounded theory.

**Results:** Forty-two patients participated. Most were male (67%) and the mean age was 64.8 (11.1) years. The majority of patients preferred an educational resource in the form of a Digital Versatile Disc (DVD) and they thought that current education could be improved. In particular patients wanted further education on 1) management of diabetes and kidney disease (including nutrition and lifestyle, and prevention of the progression of kidney disease) and 2) complications of comorbid diabetes and kidney disease.

**Conclusion:** Patients with co-morbid diabetes and kidney disease have education gaps on the management of, and complications of diabetes and kidney disease. Interventions aimed at improving patient education need to be delivered through education resources co-developed by patients and health staff. A targeted education resource in the form of a DVD, addressing these needs, may potentially close these gaps.

**Keywords:** Diabetes, Chronic kidney disease, self-management education, Patient engagement, Patient-centred care

## Background

The terms 'self-management education', 'self-management support' and 'patient education' are often used interchangeably especially when describing the management of patients with diabetes. Diabetes self-management education (DSME) is designed to help patients develop skills and techniques to enhance diabetes self-care [1–3] leading to improved clinical and self-reported outcomes such as health related quality of life [4]. Diabetes self-management support (DSMS) refers to the support that is required for implementing and sustaining coping skills and behaviours needed to self-manage [2, 3]. In contrast, patient education primarily involves increasing a patient's knowledge about a disease in order to change behaviour [5]. Self-management education underpinned by self-management support and patient education are paramount for acquisition of problem-solving skills that empower patients to self-care [6, 7].

Assessment of self-management education needs among patients with chronic diseases such as diabetes [8] and chronic kidney disease (CKD) [9] has indicated a

* Correspondence: sophia.zoungas@monash.edu
[2]School of Public Health and Preventive Medicine, Monash University, Alfred Centre, 99 Commercial Road, Melbourne 3004, Australia
[3]The George Institute for Global Health, University of Sydney, Sydney, Australia
Full list of author information is available at the end of the article

© The Author(s). 2019 **Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

wide variation between the information made available to patients and their specific knowledge needs. For example, studies in patients with CKD [10, 11] have highlighted gaps in awareness of the disease while another study reported poor self-management education levels among patients with diabetes [8].

Patient involvement in the development of self-management education resources may ensure content is relevant, understandable and actionable. Indeed, previous studies among patients with diabetes [12, 13] highlight the importance of seeking patients' perspectives on what they value about an education intervention and the requirement for a needs assessment before the development of self-management education resources. One study [14] suggested the importance of considering patients' different knowledge 'starting points' and the origins of their knowledge deficits as these are likely to inform how patients engage with, and comprehend education.

Although patient self-management education needs have been assessed for single diseases such as diabetes [15] and CKD [16], they have not been assessed for complex co-morbid conditions such as diabetes and CKD. This is despite the fact that self-management may be particularly important for the outcomes of this group of patients [17]. People with complex co-morbid diseases may have competing self-management strategies and challenges [18], which put them at risk of negating the management of other conditions especially later diagnoses. This can be explained by the concept of "dual task theory" where individuals are likely to perform self-care tasks for conditions in which they have an emotional investment at the expense of others [19]. For example, patients with diabetes and CKD may pay particular attention to the management of diabetes at the expense of kidney disease. In this regard, robust, pragmatic and patient-centred self-management educational tools for patients with co-morbid diabetes and CKD are required.

The overarching objectives of the present study were to 1) qualitatively determine the self-management education needs for patients with diabetes and CKD and 2) co-develop an educational resource meeting the self-management education needs of patients with co-morbid diabetes and CKD.

## Methods

### Design and setting

We utilised a design-based research (DBR) framework [20] to develop an educational resource in the form of a Digital Versatile Disc (DVD) for patients with co-morbid diabetes and CKD (Fig. 1). The DBR approach allowed researchers, practitioners, patient advocate groups and patients to be more directly engaged in the conduct of the research as well as providing a platform for the cyclic nature that enabled the continual collaboration between all groups of people involved [20]. Patients involved in the study were attending the Diabetes Kidney Service (DKS), an outpatient diabetes and kidney clinic of a tertiary referral hospital. Recruitment took place over a three months period from June to August 2017.

### Patients

Eligible patients were at least 18 years of age, had a diagnosis of diabetes (either type 1 or type 2) and CKD stages 3 to 5 (eGFR< 60 mL/min/1.73 $m^2$) including dialysis. The CKD-EPI formula [21] was used to estimate eGFR. The diagnosis of diabetes followed the World Health Organisation definition [22] and was recorded from patients' prior inpatient or outpatient contacts. Patients were excluded from the study if they could not speak fluently in English and had cognitive impairment. Patients meeting the inclusion criteria were invited to participate when they presented for their routine diabetes and kidney clinic appointment. We used maximal variation sampling to ensure adequate representation by gender, age, diabetes duration and stage of CKD. The interviewer (EZ) was a registered nurse and PhD student who did not provide clinical care to the patients in the clinic setting. The interviewer had received formal training in qualitative research methods.

### The diabetes kidney service

The Diabetes Kidney Service [23], launched in 2015 is a co-designed model of care, tailored to the needs of patients, their care givers, and health-professionals. It is staffed by an interdisciplinary team including endocrinologists, nephrologists, nurse practitioners and a dietitian. Patients are referred to the service from general practice, following hospital admissions and from existing diabetes and nephrology clinics. Eligibility for referral include an eGFR< 60 ml/min/1.73 $m^2$ and diabetes. Patients referred to this integrated clinic do not need to be seen in individual endocrine and nephrology clinics unless they are discharged back to these services at their request. Apart from providing clinical care, the interdisciplinary clinic uses a person-centred approach for self-management education for patients and their families. Patient education is delivered verbally or through standard pamphlets and brochures. Interventions embedded within the Diabetes Kidney Service are expected to improve patient outcomes such as slowing CKD progression, better glycemic control and increased patient satisfaction from attending one clinic instead of multiple clinics.

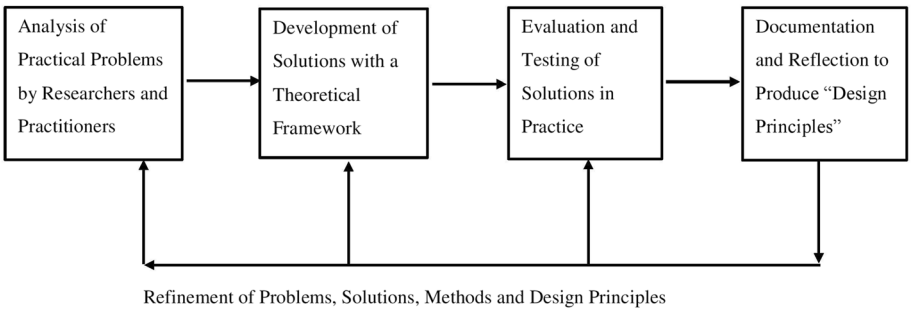



**Fig. 1** Development research (Design-Based Research)-adapted from Reeves (2000)

### Semi-structured interviews

Semi-structured interviews (of 15 to 20 min duration) were conducted amongst patients to determine the information required by patients to facilitate self-management of co-morbid diabetes and CKD. One question was close-ended, and three questions were open-ended (Additional file 1). The closed-ended question assessed patients' preferences of watching a DVD if it was available as a mode of delivering self-management education. Open-ended questions assessed overall the self-management education needs for patients with co-morbid diabetes and CKD and prompted them to highlight questions they would like a diabetes/kidney disease expert to address. Semi-structured interviews were conducted until thematic saturation was reached. Verbatim reports of the conversations were written during the interviews and transcripts were de-identified.

Transcripts underwent thematic analysis independently by two researchers (CL and EZ), informed by grounded theory [24]. Themes in the data were identified using an inductive approach. The resultant themes were reviewed by a multidisciplinary team (endocrinologists, nephrologists, diabetes and renal nurse practitioners and a dietician) and key stakeholders. The key stakeholders included a Clinical Director and Project Officer for Kidney Health Australia and consumer representative for Diabetes Australia.

### Script production

Using the identified educational needs two authors (EZ and CL) drafted the script for the DVD which was then reviewed by the other authors (including Endocrinologists and Nephrologists) and the consumer advocacy groups (Diabetes Australia and Kidney Health Australia) in an iterative process until all were happy with the script. The DVD script was written at 6th grade level to allow comprehension by patients at all levels of health literacy (Additional file 2).

### Ethical considerations

Monash University and Monash Health Human Research Ethics Committees approved the study. Patient data was de-identified and treated confidentially.

## Results

Forty-two patients participated. Most were male (67%) and the mean age was 64.8 (11.1) years. Patients were born in 14 different countries with the majority having been born in Australia (41%). Chronic kidney disease stages 3a–5 including those on dialysis were represented as follows: 3a (24%), 3b (36%), 4 (21%) and 5 (19%). Demographic and clinical characteristics are presented in Table 1.

The majority of participants preferred an educational resource in the form of a DVD if it was made available at clinic while a few wanted to watch general television while waiting to be reviewed.

"Yes, I would benefit from watching something educational" (Patient 6).

"I prefer watching the TV. I can get education from the internet" (Patient 15).

The interview data produced 20 codes, which resulted in three main themes. The themes were varying patient satisfaction with current resources, limited knowledge on management of diabetes and kidney disease and inadequate knowledge on complications of diabetes and kidney disease (Table 2).

### Varying patient satisfaction with current resources

Some patients were aware of the education materials currently available but had no confidence in them and thought the materials were too prescriptive. Patients also reported that they could benefit from new self-management education resources.

"Current education is prescriptive; must do this or else … " (Patient 17).

**Table 1** Characteristics of interview patients

| Characteristic | *N* = 42 |
|---|---|
| Age, mean (SD) | 64.8 (11.1) |
| Male, % | 28 (66.7) |
| Country of birth, *N* (%) | |
| Australia | 17 (40.5) |
| Cambodia | 1 (2.4) |
| England | 2 (4.8) |
| Germany | 2 (4.8) |
| India | 3 (7.1) |
| Italy | 1 (2.4) |
| Mauritius | 4 (9.5) |
| Malaysia | 1 (2.4) |
| New Zealand | 2 (4.8) |
| Samoa | 3 (7.1) |
| Serbia | 1 (2.4) |
| Sri Lanka | 3 (7.1) |
| Turkey | 1 (2.4) |
| Vietnam | 1 (2.4) |
| Type of diabetes, N (%) | |
| Type 1 | 2 (4.8) |
| Type 2 | 40 (95.2) |
| Diabetes duration (years), mean (SD) | 18.0 (9.2) |
| Stage of kidney disease | |
| 3a | 10 (23.8) |
| 3b | 15 (35.7) |
| 4 | 9 (21.4) |
| 5 (not on dialysis) | 1 (2.4) |
| 5 (on hemodialysis) | 7 (16.7) |

*N* = number of patients, *SD* = standard deviation

"Most pamphlets are sugar-coated. How can I know the truth?" (Patient 16).

"Want to know more about new educational materials" (Patient 10).

Other patients did not appear bothered by their limited understanding of diabetes and kidney disease. They acknowledged their inadequate knowledge on diabetes and kidney disease and were happy with the current self-management education.

"I don't know; I listen to what they tell me. I don't have much trouble with my kidneys. Generally OK" (Patient 22).

On the other hand, some patients, especially those with a longer diabetes duration, expressed satisfaction with current education resources provided by their specialists and that they could access further education from the internet. As such, they did not feel that they could benefit from other forms of education.

"It is going to be repeating what I already know" (Patient 13).

"I see doctors often and do not believe I require further education" (Patient 22).

"I can get the education I want from the internet" (Patient 15).

### Limited knowledge on management of diabetes and kidney disease

#### *General knowledge*

A number of patients demonstrated limited general knowledge on the management of diabetes and kidney disease. This was especially evident about the treatment

**Table 2** Categories and themes derived from the interview data

| Categories | Themes |
|---|---|
| Wanting to know more about new educational materials | 1. Varying patient satisfaction with current resources |
| Current educational materials inadequate | |
| General knowledge about diabetes and kidney disease management | 2. Limited knowledge on management of diabetes and kidney disease<br>i. General knowledge<br>ii. Nutrition and lifestyle<br>iii. Prevention of the progression of kidney disease |
| Medications involved | |
| Role of exercising, fitness and healthy lifestyle | |
| Diabetes and kidney disease diet | |
| Complications of diabetes and kidney disease | 3. Inadequate knowledge on complications of diabetes and kidney disease |
| Connection between diabetes and kidney disease | |
| How to slow down kidney damage | |
| How diabetes causes kidney disease | |

of diabetes and kidney disease where several patients thought that these conditions could be 'cured'.

"I would like to know whether there is a cure for my diabetes and kidneys" (Patient 27).

Other patients needed more education on how to take their current medications as well as interpreting their blood glucose readings.

"How do I titrate my insulin?" (Patient 39).

"I want to know how to interpret my blood sugar readings" (Patient 40).

#### *Nutrition and lifestyle*

Nutrition and lifestyle were mentioned by most patients, including those with longer diabetes duration. They understood that adhering to specific diets was important to successfully self-manage diabetes and kidney disease. They also emphasised the importance of being educated about the necessary diets and expressed particular knowledge gaps regarding these diets.

"I want to know more about diet, fluids and how much sugar to eat" (Patient 20).

"I need education about the diet required to manage kidney disease" (Patient 39).

"I need to know about carb counting" (Patient 37).

"…. how can I live with kidney disease; can I do something about my diet and medications to reduce kidney damage" (Patient 3).

Patients were aware of the importance of healthy lifestyle but wanted to know more about the role of exercise in improving quality of life and health. This knowledge gap was evident even in patients with longer diabetes duration and those with end stage kidney disease and in both men and women.

"I want to know more about fitness and health in general" (Patient 6).

#### *Prevention of progression of kidney disease*

Several patients demonstrated that they were keen to take some action to slow the progression of kidney disease, but they lacked knowledge on the self-management interventions they were supposed to follow. Other patients also highlighted some interventions they could use to slow kidney disease progression, but they lacked confidence; they needed a health professional to validate their opinion.

"What can I do to prevent further deterioration of my kidneys?" (Patient 1).

"What is the condition of my kidneys and does my weight impact on my kidney function?" (Patient 5).

#### Inadequate knowledge on complications of diabetes and kidney disease

A number of patients reported the need for more education regarding prevention of complications associated with co-morbid diabetes and kidney disease. Others seemed to have some knowledge regarding the complications of diabetes and kidney disease, discussing some of these complications and mentioning that kidney disease was the most common complication of diabetes.

"Which body organs are affected by diabetes?" (Patient 4).

"I want to know about diabetes complications such as foot and eye problems" (Patient 16).

"I need education on complications of diabetes and renal disease" (Patient 20).

"How do I reduce kidney damage from the sugar?" (Patient 25).

While a majority of patients knew that diabetes causes kidney disease, there was a knowledge gap in terms of the actual pathophysiology. Patients felt that this understanding was important in empowering them to improve diabetes control and reduce kidney damage.

"How does diabetes cause kidney disease"? (Patient 40).

"How is diabetes going to affect my kidneys?" (Patient 21).

"How are kidneys affected by diabetes and how to control it so there is no further damage"? (Patient 25).

## Discussion

In this study, we qualitatively assessed the self-management education needs of patients with co-morbid diabetes and CKD through interviews and co-developed an educational DVD for use by patients with these complex chronic disease conditions. The majority of patients preferred an educational resource in the form of a DVD if it was made available and they thought that current education could be improved. In particular patients wanted further education on 1) management of diabetes and kidney

disease (including nutrition and lifestyle, and prevention of the progression of kidney disease) and 2) complications of comorbid diabetes and kidney disease.

Our results highlight that the educational needs of patients with co-morbid diabetes and CKD are not currently being met. Patients had general knowledge deficits about their disease, which may be limiting their engagement in the management of their disease. Possible reasons include that currently available self-management education resources may exist in forms that are too hard to understand [25–27] and/or that patients [28, 29] lack of co-ownership of the education resources. There may also be poor acquisition and retention of self-management education especially in the sub-theme of nutrition and lifestyle as previously reported in patients with diabetes [30–32]. We expected that patients with a longer duration of diabetes would have lessor education needs regarding diet compared to those with recent diagnoses of diabetes. However, we did not notice any difference between these two groups of patients suggesting that repetitive educational interventions are needed along the disease continuum to maintain any gains from the initial intervention [32, 33]. Additionally, patients that develop CKD as a complication of diabetes may already have reduced self-management capabilities for managing another condition that develops from suboptimal management of another, leaving them overwhelmed.

The results confirm that there may be fragmentation of patient education resulting in patients opting to concentrate on self-management for one condition and not the other. For example, there were a number of patients who were not aware that diabetes was the cause of their kidney disease and that treating their diabetes could impact the progression of the disease. Patients with complex conditions have been known to have competing self-management strategies and challenges [18, 34], which put them at risk of managing later diagnoses poorly. Patients with multiple chronic conditions often have to prioritise conditions or reconcile their physicians' advice. In this regard, the provision of self-management education, which covers both diabetes and CKD ensures that patients understand how inter-related these diseases are. This knowledge can potentially improve their self-management capabilities.

However, the main obstacle is that patients have very limited knowledge on treatment and self-management interventions required to reduce kidney disease progression. While there are several self-management interventions that may reduce kidney disease progression such provision of health information, patient education and telephone-based support [35, 36], the challenge is to incorporate the most pragmatic and effective interventions into patient education resources.

In this study some patients indicated that they preferred accessing education from the internet rather than from formal education resources. This attitude may raise concerns among health professionals as the advent of unapproved education resources on the internet may contribute to misunderstanding or incorrect knowledge about disease management particularly complex comorbid diseases such as diabetes and CKD. Indeed, unapproved resources may lead to dangerous practices that contribute to or accelerate disease progression or other adverse outcomes.

The strength of this study lies in the inclusion of patients, key stakeholders and different health specialists in designing the patient education resource. To our knowledge, the education needs of those with co-morbid diabetes and CKD have not previously been reported. Perspectives from patients of different ethnic groups were also captured thereby increasing the generalisability of the results. Additionally, researcher bias was addressed by giving patients an opportunity to verify their responses during the interview process. A limitation of this study is that interviews were conducted in the clinic where patients were receiving care, and hence this setting may have predisposed participants to give positive responses. To address this, all patients were informed prior to their interviews that participation in the study would not affect their medical care and that responses would be kept confidential.

## Conclusions

Patients with co-morbid diabetes and kidney disease, wanted better-quality self-management resources. Additionally, they wanted to be educated on the management and complications of diabetes and kidney disease. These education needs can be addressed through multidisciplinary team involvement and co-designed education resources such as a DVD.

## Additional files

**Additional file 1:** Semi-structured interview questions. (DOCX 14 kb)
**Additional file 2:** Patient education script. (DOCX 25 kb)

### Abbreviations

CKD: Chronic Kidney Disease; DBR: Design-Based Research; DSME: Diabetes Self-Management Education; DSMS: Diabetes Self-Management Support; DVD: Digital Versatile Disc; eGFR: estimated Glomerular Filtration Rate

### Acknowledgements

The authors would like to thank patients who took part in this study as well as Kidney Health Australia and Diabetes Australia.

### Funding

This work was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175). An Australian Postgraduate Award Scholarship supported CL.

**Availability of data and materials**
The datasets used for the current study are available from the corresponding author on reasonable request.

**Authors' contributions**
EZ, CL, PK and SZ conceptualised the study. Data were collected by EZ. EZ designed the analysis in consultation with CL, PK and SZ. All authors analysed and interpreted data. EZ drafted the original manuscript and all authors reviewed and edited the final manuscript.

**Ethics approval and consent to participate**
All participants provided written informed consent and this study was approved by Monash University and Monash Health ethics research committees.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare that they have no competing interests.

## Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

**Author details**
[1]Department of Nephrology, Monash Health, Melbourne, Australia. [2]School of Public Health and Preventive Medicine, Monash University, Alfred Centre, 99 Commercial Road, Melbourne 3004, Australia. [3]The George Institute for Global Health, University of Sydney, Sydney, Australia. [4]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Australia.

Received: 28 October 2018 Accepted: 13 March 2019
Published online: 02 April 2019

**References**

1. Jordan JE, Osborne RH. Chronic disease self-management education programs: challenges ahead. Med J Aust. 2007;186(2):84–7.
2. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes. The Diabetes Educator. 2017;43(1):40–53.
3. Haas L, Maryniuk M, Beck J, Cox CE, Duker P, Edwards L, et al. National Standards for diabetes self-management education and support. Diabetes Care. 2012;35(11):2393.
4. Zimbudzi E, Lo C, Ranasinha S, Kerr PG, Usherwood T, Cass A, et al. Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. J Diabetes Complicat. 2017;31(2):427–32.
5. Coleman MT, Newton KS. Supporting self-management in patients with chronic illness. Am Fam Physician. 2005;72(8):1503–10.
6. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2005;(18).
7. Clark M. Diabetes self-management education: a review of published studies. Prim Care Diabetes. 2008;2(3):113–20.
8. Elliott JA, Abdulhadi NN, Al-Maniri AA, Al-Shafaee MA, Wahlström R. Diabetes self-management and education of people living with diabetes: a survey in primary health Care in Muscat Oman. PLoS One. 2013;8(2):e57400.
9. Lederer S, Fischer MJ, Gordon HS, Wadhwa A, Popli S, Gordon EJ. A question prompt sheet for adult patients with chronic kidney disease. BMC Nephrol. 2016;17(1):155.
10. Plantinga LC, Boulware LE, Coresh J, Stevens LA, Miller ER, Saran R. Patient awareness of chronic kidney disease: trends and predictors. Arch Intern Med. 2008;168:2268–75.
11. Shah A, Fried LF, Chen SC, Qiu Y, Li S, Cavanaugh KL, et al. Associations between access to care and awareness of CKD. American journal of kidney diseases : the official journal of the National Kidney Foundation. 2012;59(3 Suppl 2):S16–23.
12. Cooper HC, Booth K, Gill G. Patients' perspectives on diabetes health care education. Health Educ Res. 2003;18(2):191–206.
13. Jackie Sturt HH, Barlow JH, Hainsworth J, Whitlock S. Education for people with type 2 diabetes: what do patients want? J Diabetes Nurs. 2005;9(4):145–50.
14. Rankin D, Heller S, Lawton J. Understanding information and education gaps among people with type 1 diabetes: a qualitative investigation. Patient Educ Couns. 2011;83(1):87–91.
15. Wikblad KF. Patient perspectives of diabetes care and education. J Adv Nurs. 1991;16(7):837–44.
16. Havas K, Bonner A, Douglas C. Self-management support for people with chronic kidney disease: patient perspectives. J Ren Nutr. 2016;42(1):7–14.
17. Lo C, Ilic D, Teede H, Cass A, Fulcher G, Gallagher M, et al. The perspectives of patients on health-Care for co-Morbid Diabetes and Chronic Kidney Disease: a qualitative study. PLoS One. 2016;11(1):e0146615.
18. Bower P, Harkness E, Macdonald W, Coventry P, Bundy C, Moss-Morris R. Illness representations in patients with multimorbid long-term conditions: qualitative study. Psychol Health. 2012;27(10):1211–26.
19. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. Milbank Q. 1996;74(4):511–44.
20. Reeves T, Hedberg J. Interactive learning systems evaluation. Englewood Cliffs: Educational Technology Publications Inc; 2003.
21. Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF 3rd, Feldman HI, et al. A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009;150(9):604–12.
22. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. Geneva; 2006.
23. Lo C, Zimbudzi E, Teede H, Cass A, Fulcher G, Gallagher M, et al. Review: an Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology. 2018;(8):711–7.
24. Corbin JSA. Basics of qualitative research: techniques and procedures for developing grounded theory. California. Thousand Oaks: Sage Publications; 2008.
25. Eames S, McKenna K, Worrall L, Read S. The suitability of written education materials for stroke survivors and their carers. Top Stroke Rehabil. 2003;10(3):70–83.
26. Aldridge MD. Writing and designing readable patient education materials. Nephrol Nurs J. 2004;31(4):373–7.
27. Aguilera C, Pérez MA, Alonso Palacio LM. La legibilidad de los materiales educativos sobre la diabetes: Implicaciones para la educación de pacientes con materiales escritos. Revista Salud Uninorte. 2010;26:12–26.
28. Duchin SP, Brown SA. Patients should participate in designing diabetes educational content. Patient Educ Couns. 1990;16(3):255–67.
29. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res. 2014;16(4):e104.
30. Klupa T, Mozdzan M, Kokoszka-Paszkot J, Kubik M, Masierek M, Czerwinska M, et al. Diet-related knowledge and physical activity in a large cohort of insulin-treated type 2 diabetes patients: PROGENS ARENA study. Int J Endocrinol. 2016;2016:2354956.
31. Al-Adsani AM, Moussa MA, Al-Jasem LI, Abdella NA, Al-Hamad NM. The level and determinants of diabetes knowledge in Kuwaiti adults with type 2 diabetes. Diabetes Metab. 2009;35(2):121–8.
32. Breen C, Ryan M, Gibney MJ, O'Shea D. Diabetes-related nutrition knowledge and dietary intake among adults with type 2 diabetes. Br J Nutr. 2015;114(3):439–47.
33. Norris SL, Nichols PJ, Caspersen CJ, Glasgow RE, Engelgau MM, Jack L, et al. Increasing diabetes self-management education in community settings. A systematic review. Am J Prev Med. 2002;22(4 Suppl):39–66.
34. Liddy C, Blazkho V, Mill K. Challenges of self-management when living with multiple chronic conditions: systematic review of the qualitative literature. Can Fam Physician. 2014;60(12):1123–33.
35. Chen SH, Tsai YF, Sun CY, Wu IW, Lee CC, Wu MS. The impact of self-management support on the progression of chronic kidney disease--a prospective randomized controlled trial. Nephrol Dial Transplant. 2011;26(11):3560–6.
36. Bonner A, Havas K, Douglas C, Thepha T, Bennett P, Clark R. Self-management programmes in stages 1-4 chronic kidney disease: a literature review. J Ren Nutr. 2014.

### 6.3 Conclusion

Patients with co-morbid diabetes and kidney disease have unmet self-management education needs. Knowledge gaps were seen in 1) management of diabetes and renal disease (including nutrition and lifestyle, and prevention of the progression of renal disease) and 2) complications of comorbid diabetes and renal disease. Partnering with patients to produce a targeted education resource may assist in addressing the knowledge gaps and ultimately improving self-management ability.

**Additional file 1**: Semi-structured interview questions

1. Would you benefit from watching a video on information about diabetes and kidney disease self-management? Yes No

2. What topics would you like to be covered in the video with regards to your

    a. diabetes

    b. kidney disease?

3. If you were to ask a diabetes expert one question, what would this question be?

4. If you were to ask a kidney disease expert one question, what would this question be?

**Additional file 2:** Patient education script

| Slide | Audio |
|---|---|
| 1 | Welcome to the Diabetes Kidney Clinic. My name is ... I am one of the nurse practitioners in the clinic and I can help you look after both of your diabetes and kidney disease. |
| 1 | My name is … and I am one the diabetes specialists at the clinic. |
| 1 | My name is … and I am one of the kidney specialists at the clinic. |
| 1 | My name is … and I am the dietician at the clinic. |
| 2 | Here at the Diabetes Kidney Clinic, we work with you and your local doctor to take care of your diabetes and kidney disease.<br>You will see either a diabetes specialist or a kidney specialist who will review both your diabetes and kidney disease.<br>Sometimes you may see both specialists depending on your situation.<br>Other people you may see during your time in the clinic are the Diabetes Nurse educator, Nurse practitioners (either diabetes or renal) and a Dietician. |
| 3 | In this clinic, a team of staff provides your care.<br>Staff may come and go while you are being seen, but we will work together to help you. |
| 4 | Education about Diabetes and Kidney Disease |
| 5 | Before we start, it is important to remember that the information shared during this video presentation is of a general nature ONLY.<br>The aim of this information is to increase your knowledge about diabetes and kidney disease.<br>It is not intended to replace the advice given to you by your doctor for your particular situation.<br>It may raise questions that you may wish to ask your diabetes or kidney doctor during your visit to the clinic. |
| 6 | **Diabetes** |

| | |
|---|---|
| 7 | You may already know about diabetes, but generally people with diabetes have high amounts of sugar/glucose in their blood. This is because the body is unable to convert the sugar/glucose from food into energy.<br>The hormone that controls sugar is insulin.<br>The insulin system does not work properly when you have diabetes - either insulin is no longer produced, or not enough insulin is produced by the body. |
| 8 | But what is insulin?<br>Insulin is a hormone produced by the pancreas.<br>The pancreas is an organ located in the middle of the abdomen, below the stomach.<br>When carbohydrate or sugar in food is digested from the stomach, it can be absorbed into the blood stream as glucose.<br>Insulin then allows the glucose to be absorbed by the body's cells either for storage or for use as energy. |
| 9 | You may already know about the two types of diabetes, which are Type 1, and Type 2. I will explain a little bit more about them. |
| 10, 11 | In Type 1 diabetes, the glucose levels become elevated because the part of the pancreas that makes insulin no longer works.<br>Due to this, no insulin is produced to allow absorption of glucose from the blood into the body's cells.<br>Type 1 diabetes occurs when the body's defence system attacks the insulin producing cells in the pancreas. When the body defence system attacks itself, it is called an autoimmune condition.<br>Type 1 diabetes occurs in children or young adults but can be diagnosed at any age.<br>It is also common among people with a family history of type 1 diabetes and those with other autoimmune conditions such as thyroid or coeliac disease. |
| 12, 13 | On the other hand, in Type 2 diabetes, glucose levels become elevated because the body is unable to effectively use the insulin. This is called insulin resistance. In addition, not enough insulin is produced by the pancreas. |

| | |
|---|---|
| | Type 2 diabetes usually occurs in middle-aged to older adults although it has been diagnosed in younger people too.<br>It is more common in people who have a family history of type 2 diabetes,<br>are overweight, are older, are of particular ethnic groups for example Indigenous Australian, Asian, Pacific Islander, have an inactive lifestyle, have an unhealthy diet with a lot of fast food and sugar, or have a history of diabetes during pregnancy also called gestational diabetes. |
| 14 | **Complications of Diabetes** |
| 15 | What sort of complications can diabetes cause? |
| 16 | Diabetes can cause some long-term complications such as damaging blood vessels.<br>Organs affected due to damaged blood vessels include the heart, brain, kidneys, eyes and nerves. |
| 17 | Regarding complications to the heart and kidneys, if you have one complication, you are at greater risk of having others.<br>The risk factors for heart and kidney complications for diabetes are often the same and they feed off each other and make each other worse.<br>But the good news is that the treatments to prevent complications are often quite similar. They include managing your diet, lifestyle (such as doing regular exercise), blood pressure, limiting salt, and maintaining the glucose at accepted levels. |
| 18 | Diabetes can also cause blockage of a blood vessel supplying the brain, which can cause a stroke.<br>The symptoms vary depending on the part of the brain affected.<br>Typically, if someone with diabetes suddenly develops arm or leg weakness; numbness on one side; difficulty speaking; or droopiness on one side of their face, then a stroke should be suspected.<br>A stroke is a medical emergency and one would need to be brought to hospital as soon as possible. |
| 19 | Diabetes can cause nerve damage in the feet, causing tingling, burning, or a feeling similar to ants crawling on the feet. |

| | |
|---|---|
| | Diabetic related nerve damage in the feet may also cause foot problems such as foot ulcers, foot deformities or even bone infections of the foot.<br>Foot ulcers or bone infections of the foot are serious and can result in the person losing part of or the whole foot.<br>To prevent these complications, you should check your feet daily to make sure your feet (and the skin of your feet) have not been damaged. |
| 20 | Symptoms of eye disease may only occur in the late stages of diabetic eyes disease.<br>It is therefore important to have your eyes checked soon after diagnosis to allow treatment and to prevent these complications from developing and progressing.<br>Your doctor will advise you on how often you will need your eyes to be checked thereafter. |
| 21 | **Kidney Diseases** |
| 22 | You may be aware of how kidneys work. In short, the kidneys are two bean-shaped organs, each about the size of a fist.<br>They are located just below the rib cage, one on each side of the spine.<br>Every day, the two kidneys filter about 180 litres of blood to produce 1 to 3 litres of urine.<br>Urine flows down through narrow tubes called ureters to the bladder where it is stored until you pass urine. |
| 23 | Functions of the kidneys include, filtering your blood, to remove toxins and balance water, regulating your blood pressure, producing a hormone called erythropoietin to help the body produce red blood cells and activating vitamin D. |
| 24 | People with diabetes are at greater risk of developing kidney disease especially if they have high blood sugar, high blood pressure, lifestyle habits such as smoking and drinking a lot of alcohol, heart disease and a family history of kidney failure. |
| 25 | Kidney disease is often silent until very late in kidney failure. Symptoms of kidney disease may include swelling of hands, legs or more generalized puffiness, poor appetite, nausea and vomiting, weakness, drowsiness, itchiness and rash, and muscle twitchiness. |

| | |
|---|---|
| 26, 27 | You can keep your kidneys healthy by monitoring blood pressure, taking blood pressure tablets if prescribed and working with your healthcare team to manage your diabetes as best as you can.<br>You should also try to keep a healthy body weight, exercise regularly, and eat a balanced diet avoiding salt, sugar and saturated fat.<br>If you smoke, stop smoking- you can call QUIT on 13 78 48 and ask for a free Quit Pack.<br>Try to lose weight if you are overweight and exercise regularly. |
| 28 | How is kidney disease treated?<br>If you have diabetes and kidney damage, several things can be done to slow kidney damage.<br>Apart from maintaining a healthy lifestyle, keep your blood sugar within range. Ask your diabetic specialist what your optimal HbA1C is and keep your blood pressure below 140/90.<br>If you have diabetes, you can also manage your blood pressure and slow kidney damage by taking medications called angiotensin-converting enzyme inhibitors (ACE) and angiotensin receptor blockers (ARBs). |
| 29 | Your kidneys may eventually fail requiring renal replacement therapy. The 4 treatment options, which are available, are haemodialysis, peritoneal dialysis, transplantation and conservative management.<br>You may be invited to attend an education session to learn more about these options. |
| 30 | **Diet** |
| 31, 32 | The best diet for patients with diabetes is one that provides adequate nutrition and aims to prevent long term complications while assisting in keeping your blood sugar levels within the target range. |
| 33 | Different types of foods will affect your blood sugar levels.<br>The amount of food eaten will also affect your blood sugar levels.<br>There is no specific diet for all people with diabetes.<br>The diet you may be recommended may be very different to the person sitting next to you! |
| 34 | A few things need to be considered to determine the most appropriate diet for you if you have diabetes. These include the type of diabetes you have Type 1 or Type 2, your age, body weight, |

| | |
|---|---|
| | and medications including glucose lowering medications (including insulin), your activity and whether you are well or unwell or have other illness or disease.<br>Your food budget and cooking habits are also important considerations. |
| 35 | If you have kidney disease, your stage of kidney disease may mean that your recommended dietary intake may be very different to that of the person sitting next to you.<br>There is no specific diet for all people with kidney disease. |
| 36 | For people with kidney disease, a few things have to be considered about their diet. These include your weight (including any weight loss or weight gain), your stage of kidney disease, if you are planning to have dialysis and what type, your blood test results and your appetite. |
| 37 | If you have any questions about diet, a dietician is available in the clinic to review your intake, make some recommendations, assist you with getting the right nutrition for your body and assist you with food choices to help you with your diabetes and kidney disease. |
| 38 | Thank you and remember to ask your doctor if you have any questions. |

# CHAPTER 7

# IMPACT OF A NEW INTERGRATED PERSON-CENTRED MODEL OF CARE ON HEALTH-RELATED QUALITY OF LIFE

## 7.1 Introduction

Chapters 2 to 6 have highlighted the need for well-designed and disease-specific longitudinal studies that examine the impact of self-management interventions on health-related quality of life (HRQOL) of patients with comorbid diabetes and CKD. In Chapter 7, the impact of a self-management intervention on HRQOL of patients with comorbid diabetes and CKD is examined in a 12 month follow-up study. The intervention was delivered as part of an integrated, patient-centred diabetes and kidney disease model of care (the Diabetes Kidney Service) [102], which was co-designed by health providers, consumer advocate groups, carers and patients. The paper associated with this Chapter was submitted to the *Diabetic Medicine.* The Chapter is presented as the pdf version of the submitted manuscript.

## 7.2 Submitted manuscript: Health-related quality of life among patients with comorbid diabetes and kidney disease attending a co-designed integrated model of care: a longitudinal study

## Introduction

Diabetes has become a major challenge to health care delivery in the 21st century [1] and data from economic modelling suggest a substantial increase in global health expenditure attributable to diabetes care [2]. The global prevalence of diabetes is expected to rise to 592 million cases by 2035 up from 415 million cases of diabetes reported in 2015 [3]. This increase in the number of people with diabetes has led to an upsurge in the number of patients with chronic kidney disease (CKD) and those commencing renal replacement therapy (RRT), in combination with an overall trend of earlier commencement of dialysis [4]. The accelerating growth in patients with co-morbid diabetes and CKD requiring RRT and the associated health and resource implications highlight the need for new directions in managing this high-risk population.

The management of patients with co-morbid diabetes and CKD is complex and requires considerable coordination and facilitation of care during the disease continuum. Integrated person-centred diabetes and kidney disease clinics have emerged as a promising approach to the management of patients with co-morbid diabetes and CKD [5]. These clinics reduce the unnecessary burden of multiple appointments for patients who already have multiple co-morbidities. Patients attending these clinics also have input from a multidisciplinary team including endocrinologists, nephrologists, nurse educators and dietitians [6, 7]. Additionally, some combined diabetes and kidney disease specialty clinics have reported improvements in metabolic and blood pressure control [5, 7], a reduction in progression of renal disease [8] and outpatient cost savings [9]. However, previous studies have not reported the effects on patient reported outcomes such as health-related quality of life (HRQOL).

Among patients with CKD, HRQOL gradually declines as the disease progresses [10] with the worst scores reported by those with advanced renal disease [11]. When CKD co-exists with

diabetes, a marked deterioration in HRQOL is expected [12]. The objective of this study was to evaluate the impact of an integrated diabetes and kidney disease model of care [13], on HRQOL of patients with co-morbid diabetes and CKD.

## Materials and methods

### Study design and population

This was a longitudinal study with a follow up period of 12 months for adult patients (over 18 years) with diabetes and CKD who were referred to the DKS [13] at Monash Health between January 2015 and August 2017. The diagnosis of diabetes was noted in medical records and/or confirmed by laboratory results as per the World Health Organisation (WHO) criteria [14, 15]. Patients were considered to have CKD if they had a sustained eGFR < 60 mL/min/1.73 $m^2$ calculated using the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation [16] (i.e. two or more eGFR readings) over a three month period. The reporting in this study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [17]. Ethics approval was obtained from Monash University and Monash Health Human Ethics Review Committees.

### The diabetes and kidney disease model of care

The diabetes and kidney disease model of care used by the DKS has been described in detail before [13]. In brief, this model of care was co-designed by general practitioners (GPs), endocrinologists, nephrologists, nurse practitioners, patients with diabetes and CKD and patient advocacy groups such as Diabetes Australia and Kidney Health Australia in 2015. The design was informed by findings from a large multi-site formative evaluation of the barriers and enablers of current health services for diabetes and CKD, and the needs of patients, carers, and their health professionals [18].

The diabetes and kidney disease model of care provides patient-centred, coordinated multi-disciplinary assessment and management of patients with co-morbid diabetes and CKD in partnership with primary care. This service is designed to improve patient self-management and improve communication and coordination of care between endocrinologists, nephrologists and GPs, who remain the coordinator of patient care. As a new initiative, the service also provides a Liaison Service/General Practitioner phone advice hotline to discuss referrals and patient queries during office hours (9 am to 5 pm) and education on managing diabetes and CKD. The team includes a consultant endocrinologist and nephrologist, specialist registrars in endocrinology and nephrology, diabetes and renal nurse practitioners, dietician, administration and a research officer (for continual service evaluation and improvement). Consistency is maintained by using standard patient assessment templates and minimising staff attrition. Fidelity assessment is performed monthly to ensure that all aspects of the clinic run as per design. Criteria for referral to the integrated clinic include type 1 or type 2 diabetes with an estimated glomerular filtration rate (eGFR) <60 ml/min/1.73m$^2$.

**Measures**

**Demographic and clinical variables**

Age, gender, ethnicity, alcohol and smoking history, stage of kidney disease, duration of kidney disease and duration of diabetes were obtained from the first questionnaire (Appendix 1) which was prospectively completed by site study staff or the clinician, using standardised procedures from the doctor's notes and laboratory results from the clinic.

Socioeconomic status was estimated using the Australian Bureau of Statistics data. Postcodes were coded according to the Index of Relative Social Disadvantage (IRSD), a composite measure based on selected census variables, which include income, educational attainment and employment status. The IRSD scores for each postcode were then grouped into quintiles. The

first quintile had individuals from the most disadvantaged areas and the 5th quintile comprised individuals from the least disadvantaged areas [19].

**Health related quality of life**

Health related quality of life was assessed using the English version of the Kidney Disease Quality of Life (KDQOL™-36) questionnaire. The KDQOL-36™ comprises two composite scores for physical and mental health with a population mean of 50 (SD=10) and three kidney disease specific scales. The three kidney disease specific scales are the burden of kidney disease, symptom/problems list and the effects of kidney disease subscales [20] (Appendix 4). Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQOL. The scores of the two summary measures and the total SF-36 are based on the average of the respective scale components.

**Statistical analysis**

First, participants with missing values in the KDQOL measure (that did not allow for calculation of the subscales) were excluded following the recommendations of the instrument's developers [21]. Second, means and standard deviations for all HRQOL subscales were calculated for baseline and follow-up scores. Change scores were calculated as the difference between follow-up and baseline scores. Deteriorations in HRQOL were denoted by a negative value in change scores while a positive value denoted improvements. Third, we compared baseline and follow-up scores of the HRQOL subscales by paired samples t-tests. Lastly, we performed multiple regression analyses using the change scores as dependent variables to determine factors associated with the change scores. Potential predictor variables for change in HRQOL scores were age, gender, stage of kidney stage, duration of diabetes and SES which we have described previously [22]. To determine whether changes in scores were clinically meaningful, we used the guidelines set by the developers of the SF-36, which suggest that a 5

to 10 point change along any of the instrument's subscales is clinically meaningful [23]. In our analysis, we defined clinically meaningful results as a 5-point difference in scores from baseline to 12 months. Confidence intervals (CIs) were reported at the 95% level and results were considered significant at conventional $p<0.05$ level. All analyses were performed with Stata version 15.0 (Statacorp, College Station, TX).

## RESULTS

### Participants

Of a total of 393 patients screened, 290 entered the study. During follow up, 11 died (before the 12 month visit) and 179 (64%) completed the 12 month questionnaires (Figure 1). The baseline demographic and clinical characteristics of the study population are shown in Table 1. Thirty-six percent of the participants were women. At baseline, the mean (SD) age for all participants was 65.9±11.3 years and 64.3±11.8 and 68.6±9.8 years for men and women respectively. Participants came from various racial and ethnic groups with only 24% having been born in Australia. Forty percent of the participants lived in the most disadvantaged areas (quintile 1) (Figure 2). All had diabetes with most having type 2 diabetes (97%) and moderate to advanced CKD (83% stages 3 to 4 CKD). For all patients, mean subscale scores at baseline were 72.5±20.5, 74.4 ±23.4, 59.2±30.8, 35.5±10.6 and 48.3±10.5 for the symptom problem list, effect of kidney disease, burden of kidney disease, physical composite summary and mental composite summary scales respectively (Table 2). Patients who did not complete the 12 month follow up were comparable to patients who did with respect to age, gender, duration of diabetes, type of diabetes and stage of CKD (Table S1).

### Changes of health related quality of life scores from baseline to follow-up

Across all subscales, HRQOL did not significantly change over time (p value for all mean differences >0.05 and all change scores less than 5 points) (Table 2). However, on sub-group analysis, symptom problem list and physical composite summary scores increased for women

(MD=9.0, 95% CI: 1.25 to 16.67, p=0.02 and MD=4.5, 95% CI: 0.57 to 8.42, p=0.03 respectively) and physical composite scores decreased for men (MD = -3.35, 95% CI: -6.26 to -0.44; p=0.03) (Table 3 and Figure 3).

**Factors associated with change scores**

The changes in the symptom problem list and physical composite summary scores were 11 points and 8 points greater in women than in men (Table 4). The changes in the effect of kidney disease, burden of kidney disease and mental composite score for patients with stage 5 kidney disease were 21, 38 and 9 points greater than for patients with mild kidney disease respectively (Table 4).

In men, the changes in the symptom problem list and effect of kidney disease scores in those with stage 5 kidney disease were 48 and 44 points greater than in those with mild kidney disease (Supplementary Table S2). In women, the symptom problem list change score for those aged 67 years or older was on average 12 points less than for those aged less than 67 years. In addition, women with stage 5 kidney disease had greater change in scores (39 points) than women with mild kidney disease (Supplementary Table S3).

## DISCUSSION

In this longitudinal study of patients with comorbid diabetes and CKD, we have shown that health related quality of life was preserved over 12 months among those attending a co-designed integrated diabetes and kidney disease model of care. Scores across all the subscales of the KDQOL instrument were similar at entry into the new service and at 12 month follow up. When women and men were considered separately, the symptom problem list and physical composite scores significantly improved among women whilst the physical composite score slightly deteriorated among men. Among all patients, those with stage 5 kidney disease

experienced a greater improvement in scores for the effect of kidney disease, burden of kidney disease and mental composite summary scores than those with mild kidney disease.

Several studies of patients with CKD have reported that HRQOL significantly deteriorates over time [24, 25] with the major predictors of the decline being a reduction in eGFR, age and other co-morbidities [26]. Notably, in studies of patients with comorbid diabetes and CKD, HRQOL deteriorated at a faster rate than in patients with CKD alone [24]. Our longitudinal study has found that a co-designed integrated diabetes and kidney disease model of care may prevent deterioration of HRQOL among patients with comorbid diabetes and CKD especially among those with stage 5 CKD. Reasons for this may be that the integrated service provides patient centred care, higher quality of care, appropriate patient referrals and greater convenience for the patient which when put together, maintain HRQOL. However, the impact of the integrated service on HRQOL may have been influenced by response-shift, a phenomenon which occurs when patients change their values and the conceptualization of quality of life over time [27].

Cross sectional studies among patients with comorbid diabetes and CKD [22, 28] have previously reported that women have lower HRQOL scores compared to men especially in the physical composite score. In our study, we had expected the physical composite scores for both men and women to decline over time as reported previously [29]. However, the physical composite scores for women remained stable while those for men declined minimally. This suggests that women may have been more amenable to the interventions embedded within the integrated service than men. To optimise the benefits of the integrated service to men, peer support-based interventions may need to be provided [30].

Our data demonstrates that an integrated clinic especially improved HRQOL in patients with advanced kidney disease who are known to have very low quality of life [25]. Patients with stage 5 kidney disease experienced a greater change in scores for the effect of kidney disease,

burden of kidney disease and mental composite summary scores than those with mild kidney disease. A reason for this is that those with advanced kidney disease may have better accepted their diagnosis [31] and been ready to embrace interventions embedded within the integrated clinic to improve their HRQOL. Another reason is that patients with advanced kidney disease may get more attention from clinicians compared to patients with mild kidney disease leading to improved quality of life in particular subscales as seen in this study. This especially applies to those on or commencing dialysis where frequent interactions with nursing and medical staff is the norm. Additionally, an improvement in quality of life may be perceived differently by patients with advanced kidney disease and those with mild kidney disease. A slight improvement in quality of life for patients with stage 5 kidney disease may have a greater influence on how they feel than in patients with mild kidney disease. We did not expect patients with advanced kidney disease to have clinically significant change scores in the physical composite scale compared to those with mild kidney disease due to the physical limitations associated with comorbid diabetes and CKD.

Findings in this longitudinal study have important implications for practice and future research. First, the determinants of HRQOL in patients with comorbid diabetes and CKD are clearer and most importantly, HRQOL may be improved or preserved by interventions co-designed by patients and health professionals. Second, HRQOL should be routinely measured in patients with comorbid diabetes and CKD to enable the provision of tailored interventions. Currently, HRQOL measurement in patients with comorbid diabetes and CKD remains largely a research endeavour, although monitoring HRQOL in routine clinical care has been shown to be feasible [32].

Our findings should be interpreted in light of the strengths and limitations of our study design. The strengths include the use of a study design that allowed us to evaluate the impact of co-

designed integrated diabetes and kidney disease model of care on HRQOL of patients with comorbid diabetes and CKD over time. Additionally, our participants were drawn from a diverse population allowing for generalisability of study findings. Lastly, there were no differences between patients who completed the study and those who were lost to follow up. The limitations include that two measurement points may provide less stable results compared to multiple data collection points. However, we chose not to survey patients more frequently to avoid bias associated with repeated testing. Furthermore, patients were followed up for a period of 12 months which may not be enough to realise the full impact of the integrated diabetes and kidney disease model of care on HRQOL. Finally, the interpretation of results from this study was limited by the lack of a control group. A randomised controlled study design although preferable was not feasible due to the complexity of interventions embedded within the integrated diabetes and kidney disease model of care.

In conclusion, this longitudinal study is the first to report on the impact of a co-designed, integrated diabetes and kidney disease model of care on HRQOL among patients with comorbid diabetes and CKD. We have shown that quality of life was maintained, and even improved across some subscales, among patients with comorbid diabetes and CKD. Integrated diabetes and kidney disease care may be particularly important for improving patient experience and clinical outcomes.

**Funding source**

This work was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. An Australian Postgraduate Award

Scholarship supported C Lo.  H Teede was supported by a NHMRC, Practitioner Fellowship. A NHMRC Senior Research Fellowship supported S Zoungas.

**Competing interests**

The authors declare no competing interests.

**Acknowledgements**

We acknowledge D Giannopoulos for help in study conduct.

**SUPPLEMENTARY MATERIAL**

Table S1: Characteristics of patients who completed the study and those consented but did not complete.

Table S2: Multiple linear regression analysis of change scores for male patients.

Table S3: Multiple linear regression analysis of change scores for female patients.

## REFERENCES


1. Zimmet PZ, Magliano DJ, Herman WH, Shaw JE. Diabetes: a 21st century challenge. Lancet Diabetes Endocrinol. 2014;2(1):56-64.
2. Ogurtsova K, da Rocha Fernandes JD, Huang Y, Linnenkamp U, Guariguata L, Cho NH, et al. IDF Diabetes Atlas: Global estimates for the prevalence of diabetes for 2015 and 2040. Diabetes Res Clin Pract. 2017;128:40-50.
3. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137-49.
4. Assogba FG, Couchoud C, Hannedouche T, Villar E, Frimat L, Fagot-Campagna A, et al. Trends in the epidemiology and care of diabetes mellitus-related end-stage renal disease in France, 2007-2011. Diabetologia. 2014;57(4):718-28.
5. O'Brien S, Hardy K. Improved management and 10-year outcomes in diabetic kidney disease in routine clinical care. The British Journals of Diabetes & Vascular Disease. 2015;15(1):27-30.
6. Bayliss EA, Bhardwaja B, Ross C, Beck A, Lanese DM. Multidisciplinary team care may slow the rate of decline in renal function. Clin J Am Soc Nephrol. 2011;6(4):704-10.
7. Chen YR, Yang Y, Wang SC, Chiu PF, Chou WY, Lin CY, et al. Effectiveness of multidisciplinary care for chronic kidney disease in Taiwan: a 3-year prospective cohort study. Nephrol Dial Transplant. 2013;28(3):671-82.
8. Tuttle KR, Bakris GL, Bilous RW, Chiang JL, de Boer IH, Goldstein-Fuchs J, et al. Diabetic kidney disease: a report from an ADA Consensus Conference. Am J Kidney Dis. 2014;64(4):510-33.
9. Weber C, Beaulieu M, Djurdjev O, Er L, Taylor P, Ignaszewski A, et al. Towards rational approaches of health care utilization in complex patients: an exploratory randomized trial comparing a novel combined clinic to multiple specialty clinics in patients with renal disease-cardiovascular disease-diabetes. Nephrol Dial Transplant. 2012;27 Suppl 3:iii104-10.
10. Aggarwal HK, Jain D, Pawar S, Yadav RK. Health-related quality of life in different stages of chronic kidney disease. Qjm. 2016;109(11):711-6.
11. Paniagua R, Amato D, Vonesh E, Guo A, Mujais S. Health-related quality of life predicts outcomes but is not affected by peritoneal clearance: The ADEMEX trial. Kidney Int. 2005;67(3):1093-104.

12. Kumar R, Krishan P, Jhajj R. Health-related quality of life and factors affecting it in type-2 diabetic nephropathy patients: a cross sectional observational study. International Journal of Research in Medical Sciences; Vol 4, No 5 (2016): May 2016. 2016.
13. Lo C, Zimbudzi E, Teede H, Cass A, Fulcher G, Gallagher M, et al. Review: An Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology (Carlton, Vic). 2018.
14. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a WHO/IDF Consultation. Geneva; 2006.
15. WHO. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus. Geneva, Switzerland: World Health Organisation; 2011.
16. Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. Ann Intern Med. 1999;130.
17. Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007;370.
18. Lo C, Ilic D, Teede H, Cass A, Fulcher G, Gallagher M, et al. The Perspectives of Patients on Health-Care for Co-Morbid Diabetes and Chronic Kidney Disease: A Qualitative Study. PLoS One. 2016;11(1):e0146615.
19. Clapperton A, Cassell E. The impact of area socioeconomic inequity on serious injury in Victoria. Injury Prevention. 2010;16(1):A113.
20. Hareri HA AM. Assessments of Adherence to Hypertension Medications and Associated Factors among Patients Attending Tikur Anbessa Specialized Hospital Renal Unit, Addis Ababa, Ethiopia 2012. International Journal of Nursing Science. 2013;3(1):6.
21. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care. 1992;30(6):473-83.
22. Zimbudzi E, Lo C, Ranasinha S, Gallagher M, Fulcher G, Kerr PG, et al. Predictors of Health-Related Quality of Life in Patients with Co-Morbid Diabetes and Chronic Kidney Disease. PLoS One. 2016;11(12):e0168491.
23. Ware J, Kosinski M, Gandek B. SF-36 health survey: manual and interpretation guide Lincoln. RI: QualityMetric Incorporated. 2000.
24. Mujais SK, Story K, Brouillette J, Takano T, Soroka S, Franek C, et al. Health-related quality of life in CKD Patients: correlates and evolution over time. Clin J Am Soc Nephrol. 2009;4(8):1293-301.

25. Pagels AA, Soderkvist BK, Medin C, Hylander B, Heiwe S. Health-related quality of life in different stages of chronic kidney disease and at initiation of dialysis treatment. Health Qual Life Outcomes. 2012;10:71.
26. Soni RK, Weisbord SD, Unruh ML. Health-related quality of life outcomes in chronic kidney disease. Curr Opin Nephrol Hypertens. 2010;19(2):153-9.
27. Sprangers MAG, Schwartz CE. Integrating response shift into health-related quality of life research: a theoretical model. Social Science & Medicine. 1999;48(11):1507-15.
28. Coffey JT, Brandle M, Zhou H, Marriott D, Burke R, Tabaei BP, et al. Valuing health-related quality of life in diabetes. Diabetes Care. 2002;25(12):2238-43.
29. Wong MG, Ninomiya T, Liyanage T, Sukkar L, Hirakawa Y, Wang Y, et al. Physical component quality of life reflects the impact of time and moderate chronic kidney disease, unlike SF-6D utility and mental component SF-36 quality of life: An AusDiab analysis. Nephrology (Carlton, Vic). 2019;24(6):605-14.
30. Ghahramani N. Potential impact of peer mentoring on treatment choice in patients with chronic kidney disease: a review. Arch Iran Med. 2015;18(4):239-43.
31. Poppe C, Crombez G, Hanoulle I, Vogelaers D, Petrovic M. Improving quality of life in patients with chronic kidney disease: influence of acceptance and personality. Nephrol Dial Transplant. 2013;28(1):116-21.
32. Duman-Lubberding S, van Uden-Kraan CF, Jansen F, Witte BI, Eerenstein SEJ, van Weert S, et al. Durable usage of patient-reported outcome measures in clinical practice to monitor health-related quality of life in head and neck cancer patients. Supportive Care in Cancer. 2017;25(12):3775-83.

## 7.3 Conclusion

When CKD co-exists with diabetes, a marked deterioration in HRQOL is inevitable. This study has demonstrated that a patient-centred model of care prevents deterioration of HRQOL among patients with comorbid diabetes and CKD over 12 months. However, it is important to note that the impact of the integrated diabetes and kidney disease model of care on HRQOL may have been underestimated due to response-shift, a phenomenon which occurs when patients change their values and the conceptualization of quality of life over time.

**Table 1**: Characteristics of patients who competed the study

| Characteristic | N (%) / mean ±SD |
|---|---|
| Age (years) | 65.9±11.3 |
| Age groups | |
| <67 years | 81 (45.3) |
| ≥ 67 years | 98 (54.7) |
| Age by gender (years) | |
| Female | 68.6±9.8 |
| Male | 64.3±11.8 |
| Gender, (female) | 65 (36) |
| Country of birth | |
| Australia | 42 (23.6) |
| Sri Lanka | 20 (11.2) |
| Mauritius | 11 (6.2) |
| Samoa | 9 (5.1) |
| India | 9 (5.1) |
| England | 8 (4.5) |
| Fiji | 8 (4.5) |
| Italy | 6 (3.4) |
| Vietnam | 6 (3.4) |
| New Zealand | 5 (2.8) |
| Others | 55 (30.7) |
| Socioeconomic status | |
| Upper | 9 (5.0) |
| Upper middle | 32 (17.9) |
| Lower middle | 54 (30.2) |
| Upper lower | 11 (6.2) |
| Lower | 73 (40.8) |
| Smoking, current | 6 (3.4) |
| Alcohol, current | 53 (33.5) |
| Diabetes | |
| Type 1 | 6 (3.4) |
| Type 2 | 173 (96.6) |
| Duration (years) | 16.4±8.6 |
| Glycated Haemoglobin, % | 8.1±1.6 |
| Chronic kidney disease | |
| Stage 3a | 36 (20.1) |
| Stage 3b | 75 (41.9) |
| Stage 4 | 38 (21.2) |
| Stage 5 | 30 (16.8) |
| Dialysis, current | 21 (11.9) |

**Table 2**: Change in health related quality of life scores for all patients (N=179)

| **Scale (range, 0-100)** | **Baseline** | **Follow up** | **Change scores (95% CI)** | p-value[a] |
|---|---|---|---|---|
| Symptom problem list | 72.5±20.5 | 74.3±20.1 | 1.7 (-2.6 to 6.0) | 0.43 |
| Effect of kidney disease | 74.4 ±23.4 | 73.2±23.8 | -1.2 (-6.5 to 4.2) | 0.67 |
| Burden of kidney disease | 59.2±30.8 | 57.1±32.3 | -2.1 (-9.3 to 5.0) | 0.56 |
| Physical composite summary | 35.5±10.6 | 35.1±11.1 | -0.4 (-2.8 to 2.0) | 0.73 |
| Mental composite summary | 48.3±10.5 | 46.8±11.2 | -1.5 (-3.9 to 1.0) | 0.24 |

[a]*p*-value of Student's t-test

**Table 3:** Change in health-related quality of life scores from baseline to follow up by gender

| | Female (N=65) | | | | Male (N=114) | | | |
|---|---|---|---|---|---|---|---|---|
| **Scale (range, 0-100)** | **Baseline** | **Follow up** | **Change scores (95% CI)** | **p-value** | **Baseline** | **Follow up** | **Change scores (95% CI)** | p-value |
| Symptom problem list | 66.9±23.5 | 75.8±19.0 | 9.0 (1.3 to 16.7) | 0.02* | 75.8±17.9 | 73.4±20.7 | -2.4 (-7.5 to 2.6) | 0.35 |
| Effect of kidney disease | 72.0±24.6 | 74.8±22.2 | 2.8 (-6.0 to 11.7) | 0.52 | 75.7±22.6 | 72.3±24.7 | -3.4 (-10.2 to 3.4) | 0.32 |
| Burden of kidney disease | 56.0±30.6 | 56.9±32.1 | 0.9 (-11.0 to 12.7) | 0.89 | 61.0± 30.9 | 57.2±32.6 | -3.8 (-12.8 to 5.3) | 0.41 |
| Physical composite summary | 32.3±10.6 | 36.8±11.1 | 4.5 (0.57 to 8.4) | 0.03* | 37.5± 10.1 | 34.1±11.1 | -3.3 (-6.3 to -0.4) | 0.02* |
| Mental composite summary | 45.9±9.4 | 46.3±9.9 | 0.4 (-2.9 to 3.8) | 0.80 | 49.7±10.9 | 47.1±11.9 | -2.6 (-6.0 to 0.8) | 0.12 |

*p*-value of Student's t-test

*p<0.05

**Table 4:** Multiple linear regression analysis of change scores for all patients

| Variable | △SPL after 12 months | | △EKD after 12 months | | △BKD after 12 months | | △PCS after 12 months | | △MCS after 12 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** |
| Gender, male (ref) | 11.43* | 1.79 to 21.08 | 7.61 | -4.66 to 19.88 | 11.49 | -4.33 to 27.33 | 8.12* | 2.96 to 13.25 | 4.87 | -0.65 to 10.39 |
| Age group (ref<67 years) | | | | | | | | | | |
| >67 years | -6.84 | -16.23 to 2.55 | -8.07 | -20.25 to 4.11 | -11.09 | -26.81 to 4.64 | 1.98 | -3.16 to 7.12 | -3.23 | -8.76 to 2.28 |
| CKD stage, 3a (ref) | | | | | | | | | | |
| Stage 3b | 0.99 | -11.42 to 21.08 | 2.50 | -13.86 to 18.85 | -5.72 | -26.28 to 14.85 | -1.64 | -8.66 to 5.38 | 0.98 | -6.55 to 8.51 |
| Stage 4 | 5.87 | -8.03 to 19.78 | 15.91 | -1.81 to 33.64 | 5.06 | -17.63 to 27.75 | 1.36 | -6.47 to 9.19 | 1.58 | -6.82 to 9.98 |
| Stage 5 | 14.77 | -0.08 to 29.62 | 21.41* | 2.49 to 40.33 | 37.67* | 12.94 to 62.39 | 5.36 | -2.86 to 13.58 | 9.34* | 0.52 to 18.16 |
| Diabetes duration (years) | 0.01 | -0.51 to 0.53 | 0.32 | -0.36 to 1.00 | 0.32 | -0.54 to 1.17 | -0.25 | -0.53 to 0.03 | -0.02 | -0.32 to 0.28 |
| SES, [i] quintile 5 (ref) | | | | | | | | | | |
| Quintile 4 | -10.83 | -36.32 to 14.65 | -3.10 | -37.20 to 31.00 | -17.08 | -58.11 to 23.95 | 3.27 | -10.10 to 16.63 | 8.74 | -5.59 to 23.08 |
| Quintile 3 | -15.19 | -39.58 to 9.21 | 5.06 | -27.67 to 37.80 | -7.17 | -46.07 to 31.72 | 4.21 | -8.44 to 16.86 | 6.51 | -7.06 to 20.09 |
| Quintile 2 | -14.75 | -43.52 to 14.03 | -5.54 | -43.27 to 32.18 | -12.70 | -59.32 to 33.92 | 6.35 | -8.81 to 21.52 | -1.07 | -17.33 to 15.20 |
| Quintile 1 | -3.39 | -27.47 to 20.70 | 0.23 | -32.24 to 32.18 | -17.15 | -55.52 to 21.22 | 7.26 | -5.25 to 19.78 | 8.74 | -4.69 to 22.16 |

*p<0.05

[i]- Quintile 1 (had individuals from the most disadvantaged areas)

B-beta-coefficient

CI-95% confidence interval

△-Change score

SPL (symptom problem list), EKD (effect of kidney disease), BKD (burden of kidney disease), PCS (physical composite summary) and MCS (mental composite summary)

SES-Socioeconomic status

CKD-Chronic kidney disease; Ref-reference group

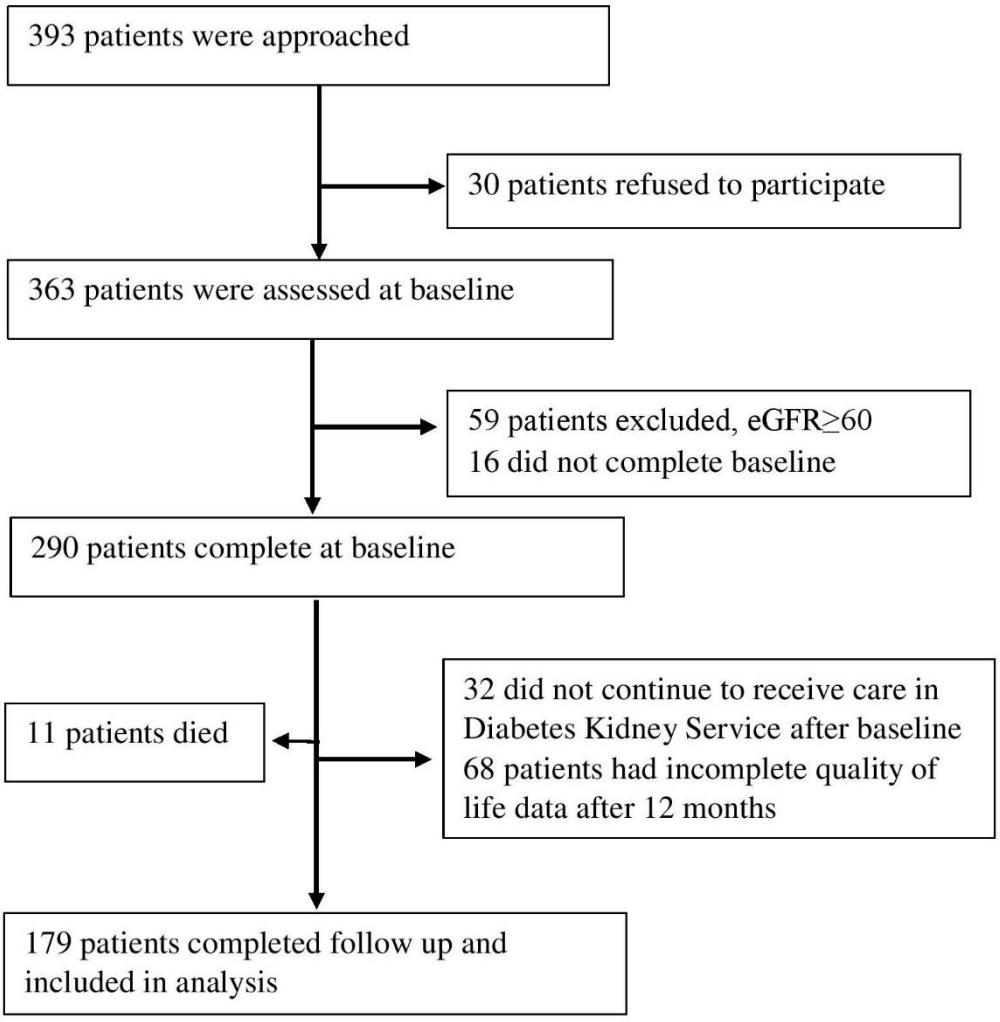



**Figure 1**: Flow chart of patient recruitment into the study

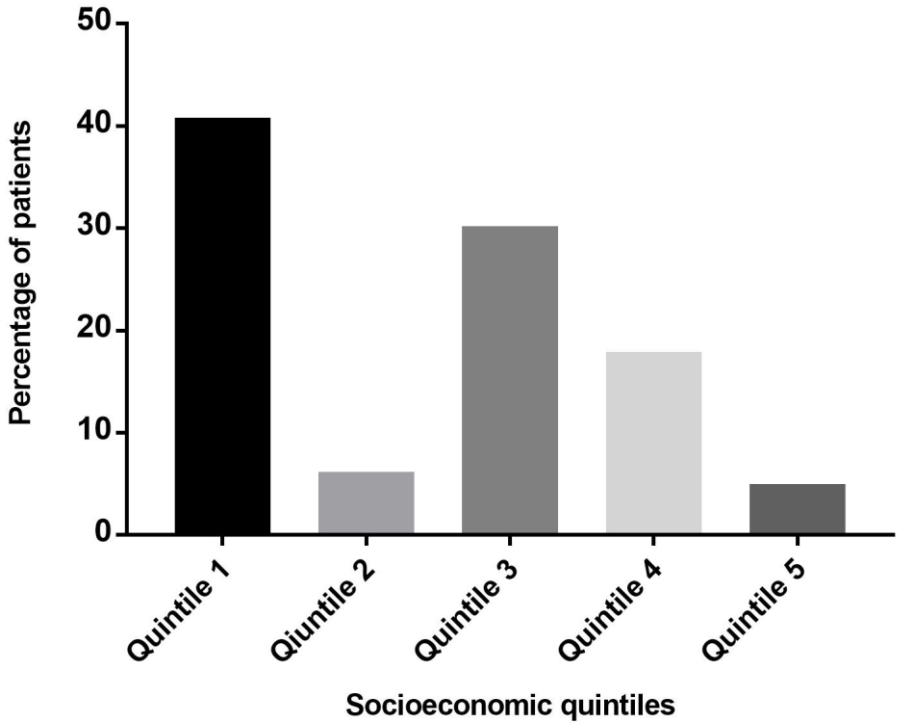



**Figure 2**: Socioeconomic status in quintiles with quintile one being the most disadvantaged

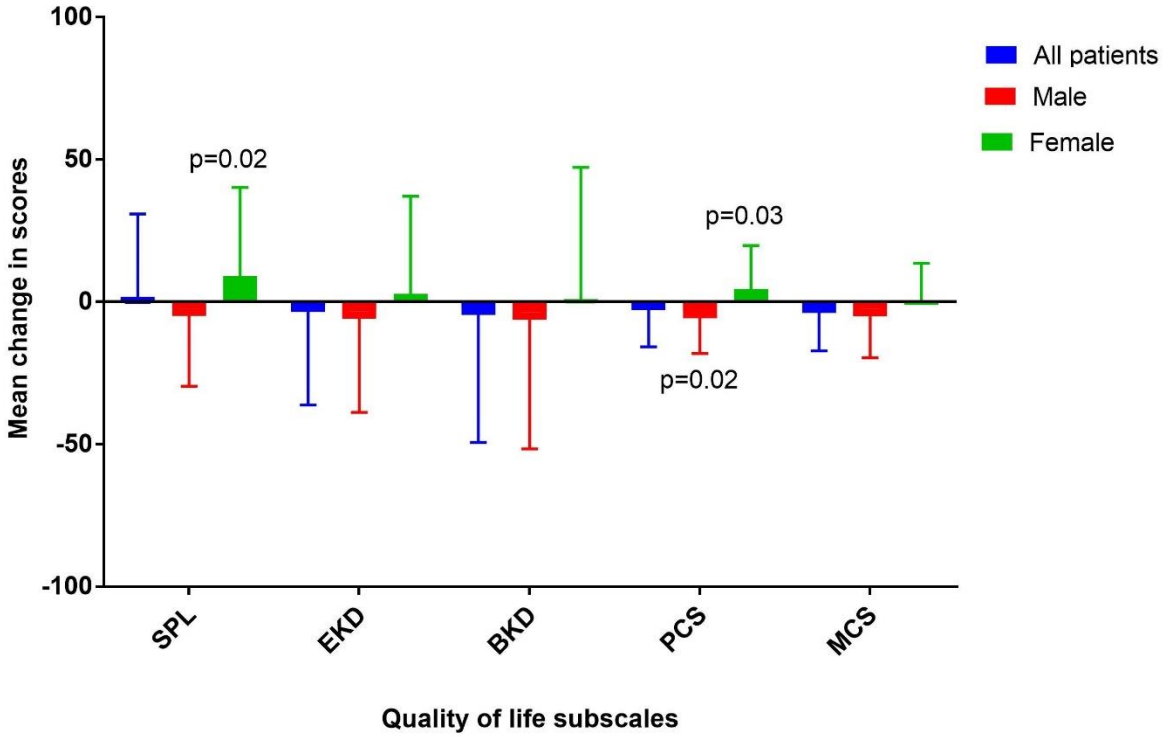



**Figure 3**: Change scores for the symptom problem list (SPL), effect of kidney disease (EKD), burden of kidney disease (BKD), physical composite (PCS) and mental composite (MCS) scores by gender.

**Table S1**: Characteristics of patients who completed the study and those consented but did not complete

| Characteristic | Completed study | Dropped out | P-value |
|---|---|---|---|
| Age | 65.9±11.3 | 66.7±12.4 | 0.56 |
| Gender | | | |
| Male, n (%) | 114 (64) | 84 (64) | 1.00 |
| Female, n (%) | 65 (36) | 47 (36) | |
| Diabetes duration, years | 16.4±8.6 | 15.2±9.2 | 0.24 |
| Diabetes type | | | |
| Type 1, n (%) | 6 (3.4) | 2 (1.5) | 0.63 |
| Type 2, n (%) | 173 (96.6) | 129 (98.5) | |
| CKD stage | | | |
| 3a | 36 (20.1) | 23 (17.4) | 0.28 |
| 3b | 75 (41.9) | 41 (31.1) | |
| 4 | 38 (21.2) | 36 (27.3) | |
| 5 | 30 (16.8) | 32 (24.2) | |

**Table S2:** Multiple linear regression analysis of change scores for male patients

| Variable | △SPL after 12 months | | △EKD after 12 months | | △BKD after 12 months | | △PCS after 12 months | | △MCS after 12 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** |
| Age group (ref<67 years) | | | | | | | | | | |
| >67 years | 0-10 | -17.81 to 17.62 | -7.15 | -28.51 to 14.20 | 1.06 | -25.55 to 27.67 | 6.54 | -2.38 to 15.45 | -0.13 | -8.17 to 7.92 |
| CKD stage, 3a (ref) | | | | | | | | | | |
| Stage 3b | 12.24 | -12.96 to 37.46 | 8.73 | -19.66 to 37.12 | -29.28 | -66.36 to 7.81 | 6.80 | -6.31 to 19.90 | 2.56 | -9.27 to 14.38 |
| Stage 4 | 20.40 | -7.86 to 48.67 | 30.24 | -0.39 to 60.87 | -14.41 | -55.54 to 26.73 | 9.69 | -4.64 to 24.01 | 3.81 | -9.12 to 16.74 |
| Stage 5 | 47.67* | 16.74 to 78.61 | 43.88* | 9.34 to 78.42 | 30.77 | -15.08 to 76.62 | 14.59 | -1.71 to 30.89 | 13.88 | -0.83 to 28.59 |
| Diabetes duration (years) | -0.25 | -1.20 to 0.70 | -0.24 | -1.31 to 0.83 | 0.97 | -0.47 to 2.41 | -0.40 | -0.87 to 0.06 | 0.13 | -0.29 to 0.55 |
| SES, [i] quintile 5 (ref) | | | | | | | | | | |
| Quintile 4 | -34.61 | -89.56 to 20.34 | -39.43 | -99.11 to 20.24 | -2.56 | -79.00 to 73.88 | -6.25 | -33.14 to 20.64 | -15.82 | -40.08 to 8.45 |
| Quintile 3 | -32.72 | -78.71 to 13.27 | -9.62 | -60.17 to 40.93 | 22.19 | -41.88 to 86.27 | -1.37 | -23.71 to 20.97 | -4.01 | -24.17 to 16.15 |
| Quintile 2 | -22.74 | -76.78 to 31.30 | -33.94 | -92.45 to 24.58 | 8.45 | -70.06 to 86.95 | 3.52 | -22.77 to 29.81 | -10.52 | -34.24 to 13.21 |
| Quintile 1 | -28.77 | -73.78 to 16.24 | -26.03 | -74.90 to 22.84 | -14.70 | -77.26 to 47.85 | -2.66 | -24.56 to 19.25 | -5.35 | -25.12 to 14.42 |

*p<0.05

[i]- Quintile 1 (had individuals from the most disadvantaged areas)

B-beta-coefficient

CI-95% confidence interval

△-change score

SPL (symptom problem list), EKD (effect of kidney disease), BKD (burden of kidney disease), PCS (physical composite summary) and MCS (mental composite summary)

SES-socioeconomic status

CKD-chronic kidney disease; Ref-reference group

**Table S3:** Multiple linear regression analysis of change scores for female patients

| Variable | △SPL after 12 months | | △EKD after 12 months | | △BKD after 12 months | | △PCS after 12 months | | △MCS after 12 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** | **B** | **CI** |
| Age group (ref< 67 years) | | | | | | | | | | |
| >67 years | -11.58* | -22.56 to -0.60 | -9.74 | -25.49 to 6.01 | -15.81 | -36.23 to 4.61 | -0.97 | -7.64 to 5.70 | -6.87 | -14.64 to 0.89 |
| CKD stage, 3a (ref) | | | | | | | | | | |
| Stage 3b | -0.27 | -14.10 to 13.55 | 2.76 | -17.91 to 23.44 | 4.70 | -20.89 to 30.30 | -4.06 | -12.62 to 4.51 | 1.76 | -8.20 to 11.73 |
| Stage 4 | 1.72 | -13.62 to 17.07 | 10.22 | -12.08 to 32.52 | 9.05 | -18.99 to 37.09 | -1.08 | -10.58 to 8.42 | 0.83 | -10.23 to 11.89 |
| Stage 5 | 0.77 | -15.60 to 17.17 | 14.48 | -9.02 to 37.99 | 38.76* | 8.38 to 69.14 | 1.52 | -8.26 to 11.29 | 7.96 | -3.42 to 19.34 |
| Diabetes duration (years) | 0.18 | -0.42 to 0.78 | 0.59 | -0.31 to 1.49 | 0.14 | -0.95 to 1.23 | -0.17 | -0.52 to 0.18 | -0.15 | -0.56 to 0.26 |
| SES, [i] quintile 5 (ref) | | | | | | | | | | |
| Quintile 4 | 1.41 | -26.85 to 29.68 | 12.87 | -31.71 to 57.46 | -22.49 | -73.68 to 28.69 | 9.35 | -6.69 to 25.39 | 19.03 | 0.36 to 37.71 |
| Quintile 3 | -4.59 | -32.34 to 23.17 | 15.60 | -28.16 to 59.36 | -22.76 | -72.42 to 26.90 | 8.33 | -7.23 to 23.88 | 11.71 | -6.40 to 29.82 |
| Quintile 2 | -8.01 | -40.92 to 24.90 | 11.47 | -38.80 to 61.74 | -22.24 | -81.13 to 36.66 | 10.06 | -8.89 to 29.02 | 4.23 | -17.84 to 26.29 |
| Quintile 1 | 13.96 | -13.55 to 41.47 | 18.54 | -25.40 to 62.48 | -17.14 | -36.23 to 4.61 | 14.74 | -0.74 to 30.21 | 16.28 | -1.74 to 34.30 |

*p<0.05

[i]- Quintile 1 (had individuals from the most disadvantaged areas)

B-beta-coefficient

CI-95% confidence interval

△-change score

SPL (symptom problem list), EKD (effect of kidney disease), BKD (burden of kidney disease), PCS (physical composite summary) and MCS (mental composite summary)

SES-socioeconomic status

CKD-chronic kidney disease; Ref-reference group

# CHAPTER 8

# SUMMARY AND FUTURE DIRECTIONS

## 8.1 Introduction

This Chapter provides a summary of the key results drawn from Chapters 2 to 7 and discusses the implications of these findings and recommendations for future directions based on key learnings and insights gained from this research. The strengths and limitations of work presented in this thesis are also explored. Final remarks are highlighted in the conclusion section.

## 8.2 Main findings, implications and recommendations for future directions

The primary objective of this thesis was to **'determine whether optimising self-management ability can lead to improved health related quality of life in patients with co-morbid diabetes and chronic kidney disease'.**

### 8.2.3 Factors associated with patient activation in an Australian population with co-morbid diabetes and chronic kidney disease: a cross-sectional study

Patients with co-morbid diabetes and CKD reported low levels of activation. Additionally, older age and worse self-reported health were associated with lower activation. Older people are prone to frailty which results in them needing help in managing their health and healthcare needs. This data may serve as the basis for the development of interventions needed to enhance activation and outcomes for patients with co-morbid diabetes and CKD. These findings reinforce the evidence base for integration of patient activation programs in health care especially for subgroups with low activation such as elderly patients with co-morbid diabetes and CKD. This is important especially when considering that financial resources are constrained and insufficient to be able to build, sustain and provide patient activation

interventions to all patients with co-morbid diabetes and CKD. Lastly, longitudinal studies are needed to better understand the effects over time of factors influencing patient activation in this population. This is especially important to address questions about reverse causality where for instance lower activation may cause worse self-reported health or vice versa (Zimbudzi et al., 2017, Chapter 2).

### 8.2.4 The association between patient activation and self-management practices in patients with co-morbid diabetes and chronic kidney disease

In people with co-morbid diabetes and CKD, a high level of patient activation was positively associated with a higher overall level of self-management. Additionally, patient age, gender, duration of diabetes and stage of CKD influenced patient self-management in co-morbid diabetes and CKD. This section of the thesis has several practice and research implications. First, these results identify sub-groups of people who may benefit from tailored interventions to further improve their health outcomes. The importance of assessment of patient activation in this patient group, which is already suffering a double burden of chronic disease, is highlighted. Second, timely patient activation assessments ensure that resources are directed to those who need those most, thereby improving efficiency on resource utilisation and reduction in health inequalities. Furthermore, in clinical practice, the focus is often on self-management and maintenance [113], but these results have shown that the degree of patient activation also has utility. Well-designed and disease-specific longitudinal studies are required to validate and extend our findings (Zimbudzi et al., 2017, Chapter 2).

### 8.2.5 Predictors of health-related quality of life in patients with co-morbid diabetes and chronic kidney disease

Younger age was associated with lower scores in all HRQOL subscales except the physical composite summary and female gender, obese or normal weight and more advanced stages of

CKD were associated with lower scores in one or more subscales. Older patients have better emotional well-being which explains why they may have reported higher scores in several HRQOL subscales including the mental composite summary. These findings highlight the importance of individualized care for patients with comorbid diabetes and CKD and suggest future directions for research in this important area. Sub-groups of the population of patients with co-morbid diabetes and CKD who otherwise may not be considered for interventions due to assumptions that they do not need them were identified. Recognizing risk groups for lower HRQOL informs timely implementation of targeted interventions to improve patients' HRQOL. In clinical practice, patients identified at high risk of poor HRQOL provide a smaller, targeted population for more costly intervention measures. Above all, this study has shown that in patients with diabetes and CKD, HRQOL is compromised even in early stages of the disease. This suggests that assessment of HRQOL early in the disease course may help to identify high risk patients in whom modifying factors may improve outcomes. (Zimbudzi et al., 2016, Chapter 3, section 3.2).

### 8.2.6 Patient reported barriers are associated with low physical and mental well-being in patients with co-morbid diabetes and chronic kidney disease

Patient reported barriers to health care were associated with low physical and mental well-being. Additionally, a greater number of patient reported barriers was associated with lower mental health status. Findings from this study carry important practice, policy and research implications. First, the approach taken by health services providing care to patients with comorbid diabetes and CKD should consider the barriers to health care for this patient group in order to maintain or improve physical and mental well-being. Second, this study has shown that it is possible to directly assess patients' well-being in order to tailor interventions appropriately rather than relying on reports from relatives or caregivers. Well designed and

disease-specific longitudinal studies are required to determine the impact of patient-reported barriers on patients' well-being. (Zimbudzi et al., 2018, Chapter 3 section 3.3).

### 8.2.7 Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in health-related quality of life

In people with diabetes and moderate to severe CKD, participation in diabetes self-management activities, particularly those focused on general diet, exercise and medication taking was associated with higher HRQOL. This finding needs to be confirmed in longitudinal studies designed to determine if optimizing individual self-management activities may improve HRQOL. This study also revealed the self-management domains across which there was no association with HRQOL such as specific diet and foot checking. Interventions that address general diet, exercise and medication taking may be particularly important for improving HRQOL among adults with diabetes and moderate to severe CKD. (Zimbudzi et al., 2016, Chapter 4).

### 8.2.8 Effectiveness of self-management support interventions for patients with co-morbid diabetes and chronic kidney disease -a systematic review and meta-analysis

Self-management support interventions may improve self-care activities, systolic blood pressure and glycated haemoglobin in patients with co-morbid diabetes and CKD. It was not possible to determine which self-management components and elements were most effective, but interventions that utilised provider reminders, patient education and goal setting were associated with improved outcomes. These findings have important implications for research and practice. First, this study highlighted the lack of high-quality evidence for self-management support interventions and outcomes for patients with co-morbid diabetes and CKD. It is imperative for future research to focus on high quality studies to support future self-management programs. Second, to reduce between-study heterogeneity there should be

standardization of outcome measures, such as HRQOL, and more studies should measure hard clinical endpoints and patient reported outcomes like medication adherence. Lastly, future studies should examine the impact of self-management interventions over a longer period and any lasting effects should be examined even after the study period (Zimbudzi et al, 2018, Chapter 5).

### 8.2.9 A need-based approach to self-management education for adults with diabetes and chronic kidney disease

Patients with co-morbid diabetes and kidney disease have unmet self-management education needs. In particular patients wanted further education on 1) management of diabetes and renal disease (including nutrition and lifestyle, and prevention of the progression of renal disease) and 2) complications of comorbid diabetes and renal disease. Interventions aimed at improving patient education need to be delivered through education resources co-developed by patients and health staff. Additionally, fragmentation of patient education may result in patients opting to concentrate on self-management for one condition and not the other. For example, there were a number of patients who were not aware that diabetes was the cause of their kidney disease and that treating their diabetes could impact the progression of the disease. To address this, patients with comorbid diabetes and CKD may benefit from the provision of self-management education, which covers both content on diabetes and CKD. A targeted education resource in the form of a DVD, addressing these needs, may potentially close these gaps (Zimbudzi et al, 2019, Chapter 6).

### 8. 2.10 Health-related quality of life among patients with comorbid diabetes and kidney disease attending a co-designed integrated model of care: a longitudinal study

Among patients with CKD, it is known that HRQOL gradually declines as the disease progresses with the lowest scores reported by those with advanced renal disease. When CKD

co-exists with diabetes, a marked deterioration in HRQOL is inevitable. Interestingly, we have demonstrated that a patient-centred model of care prevents deterioration of HRQOL among patients with comorbid diabetes and CKD over 12 months. However, HRQOL may have been underestimated due to response-shift, a phenomenon which occurs when patients change their values and the conceptualization of quality of life over time. The findings of this longitudinal study have important implications for practice and future research. First, this study demonstrates that interventions that are co-designed by patients and health professionals may improve patient experience and outcomes. Second, HRQOL should be routinely measured in patients with comorbid diabetes and CKD to enable the provision of tailored interventions. Currently, HRQOL measurement in patients with comorbid diabetes and CKD remains largely a research endeavour, although this study showed that monitoring HRQOL in routine clinical care was feasible (Zimbudzi et al, 2019, Chapter 7).

### 8.3 Strengths and limitations

This doctoral thesis has the following key strengths;

1. A gap in literature has existed regarding the understanding of the relationship between self-management and HRQOL in patients with co-morbid diabetes and CKD. The closest previous research that has come to address this question has been in patients with either diabetes or CKD. The present study has therefore explored this relationship in patients with co-morbid diabetes and CKD both cross-sectionally and longitudinally and provided insights for key evidence gaps.

2. The conduct of this thesis was done using reliable and validated, disease-specific research tools such as the SDSCA and the KDQOL questionnaires. This produced comprehensive Patient Reported Outcomes (PROMS) data that can be used for advancing quality improvement alongside other metrics such as patient safety and experience.

3. Most of the data for the cross-sectional studies included in this thesis came from multiple sites in two Australian states. This enhanced the external validity of our results, increased the statistical power of the study and ensured rapid recruitment that enabled the provision of timely results to health care organizations and policy makers.

4. Reports in the literature of inconsistent effectiveness of self-management interventions were examined [123, 124]. Reasons raised for reduced impact of self-management interventions include the failure to involve patients and health care staff in the designing of these interventions [39]. To address this problem, an integrated, patient-centred diabetes and kidney disease model of care co-designed by patients, carers, health professionals and patient advocate groups [102] guided the delivery of self-management interventions for the project described in this thesis.

While every attempt was made to uphold rigor and transparency in the analysis and reporting of the findings, there were several notable limitations, which include the following;

1. Data described in this thesis were mainly self-reported. The limitations of self-reported data are that they cannot be independently verified. Consequently, such data may introduce bias due to selective memory [125], telescoping [126, 127], attribution [128] and exaggeration [129]. However, most of the instruments utilised in this research have desirable psychometric properties [130-132], including relatively high levels of reliability, convergent, discriminant, and construct validity which could have minimised bias attributed to self-report measures.

2. Even though patients were followed up for 12 months, this period may not have been enough to demonstrate whether the effects of the intervention could be sustained beyond this follow-up period. A longer follow up period may have provided data on whether the intervention needed to be modified or whether patient visits needed to be altered over time. However, long-term follow-up often introduces selection bias where only willing, compliant participants agree

to return for visits [133]. Additionally, long term follow up is associated with a risk of differential attrition where a large number of participants may be lost from the intervention condition over time (usually those who miss their clinic appointments). In our study, besides being feasible, the 12 months follow up period ensured the collection of data of very good quality which is a challenge for any type of real-world behavioural intervention study.

3. In all studies described, recruitment was limited to patients who could speak and understand English. As a result, our findings may not be generalised to culturally and linguistically diverse populations. Additionally, the systematic review in Chapter 5 included studies published in English only. However, the effect of restriction to English language has generally been reported as minimal, although this may be dependent on a specific review question and whether studies on a given topic are likely to have been performed in countries that publish in languages other than English [134-136].

### 8.4 Final remarks

The central question addressed in this thesis is whether optimising self-management ability can lead to improved HRQOL in patients with co-morbid diabetes and CKD. At the outset, this work explores the factors that influence self-management among patients with comorbid diabetes and CKD. We highlight that a certain level of activation is necessary for self-management to occur. Through this work, sub-groups of patients with comorbid diabetes and CKD who may benefit more from tailored activation and self-management interventions were identified for the first time. Delivering these interventions to a targeted group may be cost effective and sustainable. Most importantly, this thesis has demonstrated that the ability to self-manage is associated with improved HRQOL in patients with comorbid diabetes and CKD thereby addressing a long-standing research gap. The next steps are to test the transferability and scalability of this research to other health services within and outside Australia. It will also

be important to integrate the HRQOL measures into electronic medical records, as it will not be viable to continue evaluating these initiatives through third parties such as research studies.

## REFERENCES

1. Guariguata L, Whiting DR, Hambleton I, Beagley J, Linnenkamp U, Shaw JE. Global estimates of diabetes prevalence for 2013 and projections for 2035. Diabetes Res Clin Pract. 2014;103(2):137-49.

2. de Boer IH, Rue TC, Hall YN, Heagerty PJ, Weiss NS, Himmelfarb J. Temporal trends in the prevalence of diabetic kidney disease in the United States. Jama. 2011;305(24):2532-9.

3. Ogurtsova K, da Rocha Fernandes JD, Huang Y, et al. IDF Diabetes Atlas: Global estimates for the prevalence of diabetes for 2015 and 2040. Diabetes Res Clin Pract. 2017;128:40-50.

4. International Diabetes Federation. IDF Diabetes Atlas, 8th edn. Brussels, Belgium: International Diabetes Federation; 2017.

5. Chowdhury TA, Shaho S, Moolla A. Complications of diabetes: progress, but significant challenges ahead. Ann Transl Med. 2014;2(12):120.

6. World Health Organization. Global atlas on cardiovascular disease prevention and control. Geneva; 2011.

7. da Rocha Fernandes JD, Ogurtsova K, Linnenkamp U, et al. IDF Diabetes Atlas estimates of 2014 global health expenditures on diabetes2016.

8. Cho NH, Shaw JE, Karuranga S, et al. IDF Diabetes Atlas: Global estimates of diabetes prevalence for 2017 and projections for 2045. Diabetes Research and Clinical Practice. 2018;138:271-81.

9. Levey AS, Coresh J, Balk E, et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Ann Intern Med. 2003;139(2):137-47.

10. Tonelli M, Wanner C. Lipid management in chronic kidney disease: synopsis of the Kidney Disease: Improving Global Outcomes 2013 clinical practice guideline. Ann Intern Med. 2014;160(3):182.

11. Levey AS, Atkins R, Coresh J, et al. Chronic kidney disease as a global public health problem: approaches and initiatives - a position statement from Kidney Disease Improving Global Outcomes. Kidney Int. 2007;72(3):247-59.

12. Kainz A, Hronsky M, Stel VS, et al. Prediction of prevalence of chronic kidney disease in diabetic patients in countries of the European Union up to 2025. Nephrol Dial Transplant. 2015;30 Suppl 4:iv113-8.

13. Mills KT, Xu Y, Zhang W, et al. A systematic analysis of worldwide population-based data on the global burden of chronic kidney disease in 2010. Kidney Int. 2015;88(5):950-7.

14. Lok CE, Oliver MJ, Rothwell DM, Hux JE. The growing volume of diabetes-related dialysis: a population based study. Nephrology, dialysis, transplantation : official publication

of the European Dialysis and Transplant Association - European Renal Association. 2004;19(12):3098-103.

15. Schroijen MA, van de Luijtgaarden MW, Noordzij M, et al. Survival in dialysis patients is different between patients with diabetes as primary renal disease and patients with diabetes as a co-morbid condition. Diabetologia. 2013;56(9):1949-57.

16. Brancati FL, Whelton PK, Randall BL, Neaton JD, Stamler J, Klag MJ. Risk of end-stage renal disease in diabetes mellitus: a prospective cohort study of men screened for MRFIT. Multiple Risk Factor Intervention Trial. Jama. 1997;278(23):2069-74.

17. Schernthaner G. Kidney disease in diabetology. Nephrology Dialysis Transplantation. 2007;22(3):703-7.

18. Tuttle KR, Bakris GL, Bilous RW, et al. Diabetic kidney disease: a report from an ADA Consensus Conference. Am J Kidney Dis. 2014;64(4):510-33.

19. Perkovic V, Agarwal R, Fioretto P, et al. Management of patients with diabetes and CKD: conclusions from a "Kidney Disease: Improving Global Outcomes" (KDIGO) Controversies Conference. Kidney Int. 2016;90(6):1175-83.

20. The United Kingdom Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837-53.

21. Slabaugh SL, Curtis BH, Clore G, Fu H, Schuster DP. Factors associated with increased healthcare costs in Medicare Advantage patients with type 2 diabetes enrolled in a large representative health insurance plan in the US. Journal of medical economics. 2015;18(2):106-12.

22. Golestaneh L, Alvarez PJ, Reaven NL, et al. All-cause costs increase exponentially with increased chronic kidney disease stage. The American journal of managed care. 2017;23(10 Suppl):S163-s72.

23. Meyer A, Bunzemeier H, Hausberg M, et al. Impact of different stages of chronic kidney disease on in-hospital costs in patients with coronary heart disease. Nephrology Dialysis Transplantation. 2008;23(6):1955-60.

24. Li R, Bilik D, Brown MB, et al. Medical costs associated with type 2 diabetes complications and comorbidities. The American journal of managed care. 2013;19(5):421-30.

25. Sarnak MJ, Levey AS, Schoolwerth AC, et al. Kidney Disease as a Risk Factor for Development of Cardiovascular Disease. A Statement From the American Heart Association Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. 2003;108(17):2154-69.

26. Chen J, Budoff MJ, Reilly MP, et al. Coronary artery calcification and risk of cardiovascular disease and death among patients with chronic kidney disease. JAMA Cardiology. 2017;2(6):635-43.

27. Herzog CA, Asinger RW, Berger AK, et al. Cardiovascular disease in chronic kidney disease. A clinical update from Kidney Disease: Improving Global Outcomes (KDIGO). Kidney Int. 2011;80(6):572-86.

28. Eriksen BO, Ingebretsen OC. The progression of chronic kidney disease: a 10-year population-based study of the effects of gender and age. Kidney Int. 2006;69(2):375-82.

29. Min TZ, Stephens MW, Kumar P, Chudleigh RA. Renal complications of diabetes. British Medical Bulletin. 2012;104(1):113-27.

30. Palsson R, Patel UD. Cardiovascular complications of diabetic kidney disease. Adv Chronic Kidney Dis. 2014;21(3):273-80.

31. Schneider CA, Ferrannini E, Defronzo R, Schernthaner G, Yates J, Erdmann E. Effect of pioglitazone on cardiovascular outcome in diabetes and chronic kidney disease. J Am Soc Nephrol. 2008;19(1):182-7.

32. Manjunath G, Levey AS, Sarnak MJ. How can the cardiac death rate be reduced in dialysis patients? Semin Dial. 2002;15(1):18-20.

33. Locatelli F, Marcelli D, Conte F, et al. Survival and development of cardiovascular disease by modality of treatment in patients with end-stage renal disease. J Am Soc Nephrol. 2001;12(11):2411-7.

34. Wheeler DC, Becker GJ. Summary of KDIGO guideline. What do we really know about management of blood pressure in patients with chronic kidney disease? Kidney Int. 2013;83(3):377-83.

35. Rijken M, Jones, M., Heijmans, M., Dixon, A. Supporting self-management. In: E. Nolte, M. McKee (Eds.). Caring for people with chronic conditions: a health system perspective. McKee M, editor. Maidenhead: Open University Press; 2008.

36. Suckling RJ, He FJ, Macgregor GA. Altered dietary salt intake for preventing and treating diabetic kidney disease. Cochrane Database Syst Rev. 2010(12):Cd006763.

37. Phisitkul K, Hegazy K, Chuahirun T, et al. Continued smoking exacerbates but cessation ameliorates progression of early type 2 diabetic nephropathy. Am J Med Sci. 2008;335(4):284-91.

38. Thomas N, Bryar R. An evaluation of a self-management package for people with diabetes at risk of chronic kidney disease. Prim Health Care Res Dev. 2013;14(3):270-80.

39. Donald M, Kahlon BK, Beanlands H, et al. Self-management interventions for adults with chronic kidney disease: a scoping review. BMJ Open. 2018;8(3):e019814.

40. Marta N, Lucia C, Sabrina S, Heather B. Approaches to Self‐Management in Chronic Illness. Seminars in Dialysis. 2013;26(2):188-94.

41. Al Shamsi S, Al Dhanhani A, Sheek-Hussein MM, Bakoush O. Provision of care for chronic kidney disease by non-nephrologists in a developing nation: a national survey. BMJ Open. 2016;6(8):e010832.

42. Bower P, Harkness E, Macdonald W, Coventry P, Bundy C, Moss-Morris R. Illness representations in patients with multimorbid long-term conditions: qualitative study. Psychol Health. 2012;27(10):1211-26.

43. Morris RL, Sanders C, Kennedy AP, Rogers A. Shifting priorities in multimorbidity: a longitudinal qualitative study of patient's prioritization of multiple conditions. Chronic Illn. 2011;7(2):147-61.

44. Glasgow NJ, Jeon YH, Kraus SG, Pearce-Brown CL. Chronic disease self-management support: the way forward for Australia. Med J Aust. 2008;189(10 Suppl):S14-6.

45. Richard AA, Shea K. Delineation of self-care and associated concepts. J Nurs Scholarsh. 2011;43(3):255-64.

46. Institute of Medicine. Institute of Medicine (IOM) Priority areas for national action: transforming health care quality Washington, DC: National Academy Press; 2003 [Available from: http://www.iom.edu/Reports/2003/Priority-Areas-for-National-Action-Transforming-Health-Care-Quality.aspx.

47. Northern Territory Department of Health. The Northern Territory Chronic Conditions Self Management Framework 2012 - 2020. Darwin; 2012

48. Bandura A. Self-efficacy mechanism in human agency. American Pyschologist. 1982;37(2):122-47.

49. Zimbudzi E, Lo C, Misso M, Ranasinha S, Zoungas S. Effectiveness of management models for facilitating self-management and patient outcomes in adults with diabetes and chronic kidney disease. Syst Rev. 2015;4:81.

50. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health services research. 2005;40(6 Pt 1):1918-30.

51. Shubrook JH, Brannan GD, Wapner A, Klein G, Schwartz FL. Time Needed for Diabetes Self-Care: Nationwide Survey of Certified Diabetes Educators. Diabetes Spectrum. 2018.

52. Funnell M, Anderson RM. The problem with compliance in diabetes. JAMA. 2000;284(13):1709-.

53. The National Institute for Health and Care Excellence (NICE). Chronic kidney disease: early identification and management of CKD in adults in primary and secondary care. London; 2008. Report No.: CG73.

54. Johnson DW, Atai E, Chan M, et al. KHA-CARI guideline: Early chronic kidney disease: detection, prevention and management. Nephrology (Carlton, Vic). 2013;18(5):340-50.

55. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease. Am J Kidney Dis. 2007;49(2 Suppl 2):S12-154.

56. Bray P, Thompson D, Wynn JD, Cummings DM, Whetstone L. Confronting disparities in diabetes care: the clinical effectiveness of redesigning care management for minority patients in rural primary care practices. The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association. 2005;21(4):317-21.

57. Davis RM, Hitch AD, Salaam MM, Herman WH, Zimmer-Galler IE, Mayer-Davis EJ. TeleHealth improves diabetes self-management in an underserved community: diabetes TeleCare. Diabetes care. 2010;33(8):1712-7.

58. Shea S, Weinstock RS, Teresi JA, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. Journal of the American Medical Informatics Association : JAMIA. 2009;16(4):446-56.

59. Murray E, Sweeting M, Dack C, et al. Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care. BMJ Open. 2017;7(9).

60. Cai C, Hu J. Effectiveness of a Family-based Diabetes Self-management Educational Intervention for Chinese Adults With Type 2 Diabetes in Wuhan, China. The Diabetes Educator. 2016;42(6):697-711.

61. Anderson-Loftin W, Barnett S, Bunn P, Sullivan P, Hussey J, Tavakoli A. Soul food light: culturally competent diabetes education. Diabetes Educ. 2005;31(4):555-63.

62. Brown SA, Blozis SA, Kouzekanani K, Garcia AA, Winchell M, Hanis CL. Dosage effects of diabetes self-management education for Mexican Americans: the Starr County Border Health Initiative. Diabetes care. 2005;28(3):527-32.

63. Ciemins E, Coon P, Peck R, Holloway B, Min SJ. Using telehealth to provide diabetes care to patients in rural Montana: findings from the promoting realistic individual self-management program. Telemedicine journal and e-health : the official journal of the American Telemedicine Association. 2011;17(8):596-602.

64. Skelly AH, Carlson J, Leeman J, Soward A, Burns D. Controlled trial of nursing interventions to improve health outcomes of older African American women with type 2 diabetes. Nursing research. 2009;58(6):410-8.

65. Cunningham AT, Crittendon DR, White N, Mills GD, Diaz V, LaNoue MD. The effect of diabetes self-management education on HbA1c and quality of life in African-Americans: a systematic review and meta-analysis. BMC health services research. 2018;18(1):367.

66. Logan AG, Irvine MJ, McIsaac WJ, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension. 2012;60(1):51-7.

67. Chen SH, Tsai YF, Sun CY, Wu IW, Lee CC, Wu MS. The impact of self-management support on the progression of chronic kidney disease--a prospective randomized controlled trial. Nephrol Dial Transplant. 2011;26(11):3560-6.

68. Lee M-C, Wu S-FV, Hsieh N-C, Tsai J-M. Self-Management Programs on eGFR, Depression, and Quality of Life among Patients with Chronic Kidney Disease: A Meta-Analysis. Asian Nursing Research. 2016;10(4):255-62.

69. Sugiyama T, Steers WN, Wenger NS, Duru OK, Mangione CM. Effect of a community-based diabetes self-management empowerment program on mental health-related quality of life: a causal mediation analysis from a randomized controlled trial. BMC health services research. 2015;15(1):115.

70. Cunningham P. Patient perceptions of clinician self-management support for chronic conditions. The American journal of managed care. 2016;22(4):e125-33.

71. Stokes J, Man MS, Guthrie B, Mercer SW, Salisbury C, Bower P. The Foundations Framework for Developing and Reporting New Models of Care for Multimorbidity. Annals of family medicine. 2017;15(6):570-7.

72. Johnston SE, Liddy CE, Ives SM. Self-management support: a new approach still anchored in an old model of health care. Canadian journal of public health = Revue canadienne de sante publique. 2011;102(1):68-72.

73. Fraser SD, Roderick PJ, Casey M, Taal MW, Yuen HM, Nutbeam D. Prevalence and associations of limited health literacy in chronic kidney disease: a systematic review. Nephrol Dial Transplant. 2013;28.

74. Shirazian S, Crnosija N, Weinger K, et al. The self-management experience of patients with type 2 diabetes and chronic kidney disease: A qualitative study. Chronic Illn. 2016;12(1):18-28.

75. Rogers A, Kennedy A, Bower P, et al. The United Kingdom Expert Patients Programme: results and implications from a national evaluation. Med J Aust. 2008;189(10 Suppl):S21-4.

76. Schillinger D, Handley M, Wang F, Hammer H. Effects of Self-Management Support on Structure, Process, and Outcomes Among Vulnerable Patients With Diabetes. Diabetes Care. 2009;32(4):559.

77. Yuan C, Lai CW, Chan LW, Chow M, Law HK, Ying M. The effect of diabetes self-management education on body weight, glycemic control, and other metabolic markers in patients with type 2 diabetes mellitus. J Diabetes Res. 2014;2014:789761.

78. Olry de Labry Lima A, Bermúdez Tamayo C, Pastor Moreno G, et al. Effectiveness of an intervention to improve diabetes self-management on clinical outcomes in patients with low educational level. Gaceta Sanitaria. 2017;31(1):40-7.

79. Lin CC, Tsai FM, Lin HS, Hwang SJ, Chen HC. Effects of a self-management program on patients with early-stage chronic kidney disease: a pilot study. Appl Nurs Res. 2013;26(3):151-6.

80. Bullinger M. Quality of life – definition, conceptualization and implications – a methodologists view. Theoretic Surgery. 1991;6:143-9.

81. Hornbrook MC, Goodman MJ. Chronic disease, functional health status, and demographics: a multi-dimensional approach to risk adjustment. Health services research. 1996;31(3):283.

82. Aggarwal HK, Jain D, Pawar S, Yadav RK. Health-related quality of life in different stages of chronic kidney disease. Qjm. 2016;109(11):711-6.

83. Detmar SB, Muller MJ, Schornagel JH, Wever LV, Aaronson NK. Health-related quality-of-life assessments and patient-physician communication: A randomized controlled trial. JAMA. 2002;288(23):3027-34.

84. Karner-Hutuleac A. Health related quality of life of diabetic and chronic renal failure patients. Procedia - Social and Behavioral Sciences. 2012;33(0):85-9.

85. Moreno F, Lopez Gomez JM, Sanz-Guajardo D, Jofre R, Valderrabano F. Quality of life in dialysis patients. A spanish multicentre study. Spanish Cooperative Renal Patients Quality of Life Study Group. Nephrol Dial Transplant. 1996;11 Suppl 2:125-9.

86. Adriaanse MC, Drewes HW, van der Heide I, Struijs JN, Baan CA. The impact of comorbid chronic conditions on quality of life in type 2 diabetes patients. Qual Life Res. 2016;25(1):175-82.

87. Pagels AA, Soderkvist BK, Medin C, Hylander B, Heiwe S. Health-related quality of life in different stages of chronic kidney disease and at initiation of dialysis treatment. Health Qual Life Outcomes. 2012;10:71.

88. Zimbudzi E, Lo C, Ranasinha S, et al. Predictors of Health-Related Quality of Life in Patients with Co-Morbid Diabetes and Chronic Kidney Disease. PloS one. 2016;11(12):e0168491.

89. Park JI, Baek H, Jung HH. CKD and Health-Related Quality of Life: The Korea National Health and Nutrition Examination Survey. Am J Kidney Dis. 2016;67(6):851-60.

90. Wyld M, Morton RL, Hayen A, Howard K, Webster AC. A systematic review and meta-analysis of utility-based quality of life in chronic kidney disease treatments. PLoS Med. 2012;9(9):e1001307.

91. Wyld ML, Chadban SJ, Morton RL. Improving Our Understanding of Quality of Life in CKD. Am J Kidney Dis. 2016;67(6):820-1.

92. Soni RK, Weisbord SD, Unruh ML. Health-related quality of life outcomes in chronic kidney disease. Curr Opin Nephrol Hypertens. 2010;19(2):153-9.

93. Mujais SK, Story K, Brouillette J, et al. Health-related quality of life in CKD Patients: correlates and evolution over time. Clin J Am Soc Nephrol. 2009;4(8):1293-301.

94. De los Ríos Castillo JL, Sánchez Sosa JJ, Barrios Santiago P, Avila Rojas TL. Quality of life in patients with diabetic nephropathy. Investigación y Educación en Enfermería. 2005;23:30-61.

95. Coffey JT, Brandle M, Zhou H, et al. Valuing health-related quality of life in diabetes. Diabetes Care. 2002;25(12):2238-43.

96. Osthus TB, von der Lippe N, Ribu L, et al. Health-related quality of life and all-cause mortality in patients with diabetes on dialysis. BMC Nephrol. 2012;13:78.

97. Anees M, Hameed F, Mumtaz A, Ibrahim M, Saeed Khan MN. Dialysis-related factors affecting quality of life in patients on hemodialysis. Iran J Kidney Dis. 2011;5(1):9-14.

98. Sorensen VR, Mathiesen ER, Watt T, Bjorner JB, Andersen MV, Feldt-Rasmussen B. Diabetic patients treated with dialysis: complications and quality of life. Diabetologia. 2007;50(11):2254-62.

99. Wouters OJ, apos, Donoghue DJ, Ritchie J, Kanavos PG, Narva AS. Early chronic kidney disease: diagnosis, management and models of care. Nature Reviews Nephrology. 2015;11:491+.

100. Cooke D, Bond R, Lawton J, et al. Structured type 1 diabetes education delivered within routine care: impact on glycemic control and diabetes-specific quality of life. Diabetes Care. 2013;36(2):270-2.

101. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. Diabetes Educ. 2008;34(5):815-23.

102. Lo C, Zimbudzi E, Teede H, et al. Review: An Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology (Carlton, Vic). 2018.

103. Zimbudzi E, Lo C, Robinson T, et al. The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals in Australia: A qualitative study. PloS one. 2019;14(7):e0219685.

104. Zimbudzi E, Lo C, Kerr PG, Zoungas S. A need-based approach to self-management education for adults with co-morbid diabetes and chronic kidney disease. BMC Nephrol. 2019;20(1):113.

105. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. Health services research. 2004;39(4 Pt 1):1005-26.

106. Turner A, Anderson JK, Wallace LM, Bourne C. An evaluation of a self-management program for patients with long-term conditions. Patient Education and Counseling.98(2):213-9.

107. Mosen DM, Schmittdiel J, Hibbard J, Sobel D, Remmers C, Bellows J. Is patient activation associated with outcomes of care for adults with chronic conditions? J Ambul Care Manage. 2007;30(1):21-9.

108. Masterson Creber R, Chen T, Wei C, Lee CS. Brief Report: Patient Activation Among Urban Hospitalized Patients With Heart Failure. J Card Fail. 2017;23(11):817-20.

109. Shah-Hamze M, Yeganeh T, Kabir K, Montazeri A, Asadi-Shoki M, Saee V. The Relationship between Self-Management and Quality of Life in Epileptic Patients who referred to Iranian Epilepsy Association. Journal of Health and Care. 2017;19(2):189-98.

110. Benzo RP, Abascal-Bolado B, Dulohery MM. Self-management and quality of life in chronic obstructive pulmonary disease (COPD): The mediating effects of positive affect. Patient Educ Couns. 2016;99(4):617-23.

111. Heng‐Hsin T, Chun‐Yu L, Kuei‐Ying C, Chien‐Jung C, Yu‐Ping L, Cheng‐Hui C. Self‐Management Intervention to Improve Self‐Care and Quality of Life in Heart Failure Patients. Congestive Heart Failure. 2013;19(4):E9-E16.

112. Babazadeh T, Dianatinasab M, Daemi A, Nikbakht HA, Moradi F, Ghaffari-Fam S. Association of Self-Care Behaviors and Quality of Life among Patients with Type 2 Diabetes Mellitus: Chaldoran County, Iran. Diabetes & metabolism journal. 2017;41(6):449-56.

113. Buck HG, Lee CS, Moser DK, et al. Relationship between self-care and health-related quality of life in older adults with moderate to advanced heart failure. J Cardiovasc Nurs. 2012;27(1):8-15.

114. Magwood GS, Zapka J, Jenkins C. A review of systematic reviews evaluating diabetes interventions: focus on quality of life and disparities. Diabetes Educ. 2008;34(2):242-65.

115. Burke SD, Sherr D, Lipman RD. Partnering with diabetes educators to improve patient outcomes. Diabetes Metab Syndr Obes. 2014;7:45-53.

116. Powers MA, Bardsley J, Cypress M, et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care. 2015;38(7):1372-82.

117. Havas K, Bonner A, Douglas C. Self-management support for people with chronic kidney disease: Patient perspectives. J Ren Care. 2016;42(1):7-14.

118. Narva AS, Norton JM, Boulware LE. Educating Patients about CKD: The Path to Self-Management and Patient-Centered Care. Clin J Am Soc Nephrol. 2016;11(4):694-703.

119. Mason J, Stone M, Khunti K, Farooqi A, Carr S. Educational needs for blood pressure control in chronic kidney disease. J Ren Care. 2007;33(3):134-8.

120. Mason J, Khunti K, Stone M, Farooqi A, Carr S. Educational interventions in kidney disease care: a systematic review of randomized trials. Am J Kidney Dis. 2008;51(6):933-51.

121. Lepard MG, Joseph AL, Agne AA, Cherrington AL. Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review. Curr Diab Rep. 2015;15(6):608.

122. Heinrich E, Schaper NC, de Vries NK. Self-management interventions for type 2 diabetes: a systematic review. European Diabetes Nursing. 2010;7(2):71-6.

123. Greenhalgh T. Patient and public involvement in chronic illness: beyond the expert patient. Bmj. 2009;338:b49.

124. Batalden M, Batalden P, Margolis P, et al. Coproduction of healthcare service. BMJ Quality & Safety. 2016;25(7):509.

125. Warriner G, McDougall G, Claxton J. Any Data or None at All?: Living with Inaccuracies in Self-Reports of Residential Energy Consumption. Environment and Behavior. 1984;16(4):503-26.

126. Kjellsson G, Clarke P, Gerdtham U-G. Forgetting to remember or remembering to forget: A study of the recall period length in health care survey questions. Journal of Health Economics. 2014;35:34-46.

127. Gaskell GD, Wright DB, O'Muircheartaigh CA. Telescoping of landmark events: implications for survey research. Public Opin Q. 2000;64(1):77-89.

128. Edwards AL. The social desirability variable in personality assessment and research. New York: New York : Dryden; 1957.

129. Barr S. Factors Influencing Environmental Attitudes and Behaviors: A U.K. Case Study of Household Waste Management. Environment and Behavior. 2007;39(4):435-73.

130. Peipert JD, Bentler PM, Klicko K, Hays RD. Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States. Am J Kidney Dis. 2018;71(4):461-8.

131. Skolasky RL, Green AF, Scharfstein D, Boult C, Reider L, Wegener ST. Psychometric properties of the patient activation measure among multimorbid older adults. Health services research. 2011;46(2):457-78.

132. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care. 2000;23(7):943-50.

133. World Health Organization. Adherence to long term therapies: evidence for action. Annex 2003;1:143.

134. Juni P, Holenstein F, Sterne J, Bartlett C, Egger M. Direction and impact of language bias in meta-analyses of controlled trials: empirical study. Int J Epidemiol. 2002;31(1):115-23.

135. Morrison A, Polisena J, Husereau D, et al. The effect of English-language restriction on systematic review-based meta-analyses: a systematic review of empirical studies. Int J Technol Assess Health Care. 2012;28(2):138-44.

136. Pham B, Klassen TP, Lawson ML, Moher D. Language of publication restrictions in systematic reviews gave different results depending on whether the intervention was conventional or complementary. J Clin Epidemiol. 2005;58(8):769-76.

## ADDITIONAL PUBLICATIONS

**Published manuscript: Review: An Australian model of care for co-morbid diabetes and chronic kidney disease**

Citation: Lo C., **Zimbudzi E**., Teede H., Cass A., Fulcher G., Gallagher M., Kerr PG., Jan S., Johnson G., Mathew T., Polkinghorne K., Russell G., Usherwood T., Walker R. and Zoungas S. Review: An Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology 2018, doi:10.1111/nep.13232.

NEPHROLOGY

*Nephrology* **23** (2018) 711–717

Review Article

# Models of care for co-morbid diabetes and chronic kidney disease

CLEMENT LO,[1,2] EDWARD ZIMBUDZI,[1,3] HELENA TEEDE,[1,2] ALAN CASS,[4,5] GREG FULCHER,[6] MARTIN GALLAGHER,[5,7] PETER G KERR,[3] STEPHEN JAN,[5] GREG JOHNSON,[8] TIM MATHEW,[9] KEVAN POLKINGHORNE,[3] GRANT RUSSELL,[10] TIM USHERWOOD,[5,11] ROWAN WALKER[12] and SOPHIA ZOUNGAS[1,2,5]

Schools of [1]Public Health and Preventive Medicine, [10]Primary Health Care, Monash University, [2]Diabetes and Vascular Medicine Unit, [3]Department of Nephrology, Monash Health, [12]Department of Renal Medicine, Alfred Health, Melbourne, [9]Kidney Health Australia, South Melbourne, Victoria, [4]Menzies School of Health Research, Darwin, Northern Territory, [5]The George Institute for Global Health, [11]Department of General Practice, Westmead Clinical School, University of Sydney, Sydney, [6]Department of Diabetes and Endocrinology, Royal North Shore Hospital, St Leonards, [7]Department of Nephrology, Concord Hospital, Concord, New South Wales, and [8]Diabetes Australia, Canberra, ACT, Australia

**KEY WORDS:**
chronic kidney disease, diabetes, models of care, multi-morbidity.

**Correspondence:**
Dr Clement Lo, School of Public Health and Preventive Medicine, Monash University, Level 1, 43-51 Kanooka Grove, Clayton, Vic. 3168, Australia. Email: clement.lo@monash.edu

Accepted for publication 30 January 2018.
Accepted manuscript online 5 February 2018.

doi: 10.1111/nep.13232

## SUMMARY AT A GLANCE

The review outlines the development of a model of care for patients with diabetes mellitus and chronic kidney disease, involving the multiple stake holders. Other distinctive features of this model of care are routine screening for psychological morbidity; patient-support through a phone advice line; and focused primary health-care support in the management of diabetes and CKD.

**ABSTRACT:**

**Diabetes and chronic kidney disease (CKD) are two of the most prevalent co-morbid chronic diseases in Australia. The increasing complexity of multi-morbidity, and current gaps in health-care delivery for people with co-morbid diabetes and CKD, emphasize the need for better models of care for this population. Previously, proposed published models of care for co-morbid diabetes and CKD have not been co-designed with stake-holders or formally evaluated. Particular components of health-care shown to be effective in this population are interventions that: are structured, intensive and multifaceted (treating diabetes and multiple cardiovascular risk factors); involve multiple medical disciplines; improve self-management by the patient; and upskill primary health-care. Here we present an integrated patient-centred model of health-care delivery incorporating these components and co-designed with key stake-holders including specialist health professionals, general practitioners and Diabetes and Kidney Health Australia. The development of the model of care was informed by focus groups of patients and health-professionals; and semi-structured interviews of care-givers and health professionals. Other distinctives of this model of care are routine screening for psychological morbidity; patient-support through a phone advice line; and focused primary health-care support in the management of diabetes and CKD. Additionally, the model of care integrates with the patient-centred health-care home currently being rolled out by the Australian Department of Health. This model of care will be evaluated after implementation across two tertiary health services and their primary care catchment areas.**

Diabetes and chronic kidney disease (CKD) are two of the most prevalent co-existing chronic diseases in Australia,[1] and are a common example of multi-morbidity. Multi-morbidity can be defined as the coexistence of two or more chronic conditions where one is not necessarily more central than the other.[2] Together, diabetes and CKD pose a growing public health problem, with increasing disability and mortality, especially due to associated cardiovascular disease.[3] Health-care of patients with these co-morbidities is often suboptimal. Studies of both Australian and non-Australian primary and/or specialist care services report that a significant proportion of these patients fail to meet glycaemic and blood pressure targets, and other recommended indicators of quality care: regular HbA1c monitoring, screening for albuminuria (in patients with both diabetes and early CKD) or treatment of anaemia (in patients with both diabetes and later stage CKD).[4–10]

These gaps in care may be a reflection of health systems poorly equipped to deal with multiple co-morbidities in general[11] or specifically patients with both diabetes and CKD. Individuals with multi-morbidity require a broader therapeutic approach compared to those with a single chronic

© 2018 Asian Pacific Society of Nephrology

disease. However, many general practitioners (GPs) from developed countries, including Australia, have reported that their practices are ill-equipped to deal with patients with complex needs. Further, they reported problems with communication and coordination of care between primary care and other parts of the health system, including with specialist health services.[12,13] This may be a consequence of health-care systems and models of care being framed around single chronic diseases.[11,14] Given that the prevalence of multiple co-morbidities is increasing with the ageing of the world's population,[11,15] models of care for patients with multiple co-morbidities, such as co-morbid diabetes and CKD, are now vital and being examined across many jurisdictions including in Australia.

Here, we present a review of published contemporary models of care for co-morbid diabetes and chronic kidney disease. We then present a new model informed by both qualitative and quantitative research, and co-designed and developed with key stakeholders including primary and specialist health-care professionals, and patient advocacy groups (NHMRC Partnership Grant ID 1055175).

## OVERVIEW OF CONTEMPORARY MODELS OF CARE FOR CO-MORBID DIABETES AND CHRONIC KIDNEY DISEASE

There is a paucity of evidence-based models of health-care for people with both diabetes and CKD derived inductively through formative research and co-designed with key stakeholders (including patients, tertiary health professionals and GPs). Previously, proposed models of health-care for co-morbid diabetes and CKD have not been co-designed with key stake-holders or formally evaluated. They have been derived either from clinical experience, or through the deductive synthesis and extrapolation of evidence from literature pertaining to the care of diabetes, CKD and/or other chronic conditions.[16–18] Common themes and elements drawn from these proposed models of care include multidisciplinary specialist teams and care; quality improvement strategies; effective communication and coordination of care especially across the primary/specialist care interface; and patient education including support for self-management.[16–18]

However, there are several studies demonstrating the effectiveness of particular components of health-care: interventions that: are structured, intensive and multifaceted; involve multiple medical disciplines (multi-disciplinary); improve patient self-management; and upskill primary health-care.

Structured multi-faceted medical care for patients with diabetes and CKD (i.e. care that is structured according to predefined scheduled visits, assessment items and treatment targets, and care that not only targets one management facet such as glucose control, but other facets such as blood pressure control and hypercholesterolaemia) has been shown to improve clinical outcomes.[19] In one randomized multicentre study amongst 205 Chinese patients with type 2 diabetes and established CKD, patients who received structured multifaceted care had better glycaemic and blood pressure control compared to those who did not.[19] Structured care compared to usual care was more cost-effective (saving HK $631 300 over a 2 year period) and reduced length of stay in hospital: 933 versus 1169 hospital days.[20] Such an approach is also effective in earlier stages of CKD. A randomized controlled parallel study amongst Scandinavian patients with co-morbid diabetes and early CKD (microalbuminuria), applied multifaceted care (behaviour modification and pharmacological therapy targeting hyperglycaemia, hypertension, dyslipidaemia, and microalbuminuria) and reported a reduction in albuminuria, retinopathy, neuropathy, and a composite outcome of cardiovascular disease (CVD) events or death compared to conventional treatment.[21,22]

Multidisciplinary care (where health-care is simultaneously delivered by a group of health professionals from different disciplines) in the form of a combined diabetes and renal clinic has also been reported to improve patient outcomes. Several observational and pre- and post-design audit studies evaluating combined diabetes and kidney clinics, reported that these initiatives attenuated decline of kidney function and improved clinical target attainment such as HbA1c.[23–26] In one study, the slowed rate of progression of kidney disease delayed the necessity for dialysis by about 2 years.[27] The mechanism by which combined diabetes and renal services achieve these outcomes is not understood. Possible reasons include more frequent follow-up, and the multidisciplinary expertise – allowing more effective management of multiple risk factors.[23–27] Better coordination of care and communication between specialists may also contribute.[28]

Empowering patients by improving self-management is also important in the management of co-morbid diabetes and CKD. In one randomized controlled trial of patients with diabetes and early CKD (microalbuminuria), patients who received an education programme to improve self-management demonstrated improved self-management behaviours, quality of life and illness-belief. Further there was a trend towards an improvement in their HbA1c.[29] Improving self-management of diabetes is also important in end-stage CKD. A programme of intensive diabetes education and care management (including foot-care), in a small single-centre randomized trial of 83 patients with diabetes on dialysis, led to improvements in glycaemic control.[30] Additionally, there were improvements in patient-reported quality of life and reductions in foot amputations and hospital admissions.[30] Similarly, a pre- and post-design study evaluating an education programme, designed to improve self-efficacy and self-management skills of patients with diabetic nephropathy, reported improvement in glycaemic control and maintenance of renal function.[31] These studies


© 2018 Asian Pacific Society of Nephrology

demonstrate the importance of self-management in improving disease control and quality of life.

Up-skilling GPs to manage both diabetes and CKD is also important as they see a large proportion of patients with co-morbid diabetes and CKD who do not access specialist services.[13,32] In support of this, a pilot study of an educational intervention for Mexican family physicians in the management of type 2 diabetes with early nephropathy found that family physicians receiving the intervention improved clinical competence compared to those who did not. Additionally, among patients managed by physicians with improved competence, there was more appropriate use of medications, a reduction in albuminuria and slight improvement in renal function.[33]

## CO-DESIGNING AN EVIDENCE-BASED MODEL OF CARE FOR PATIENTS WITH CO-MORBID DIABETES AND CHRONIC KIDNEY DISEASE

A new model of care for patients with both diabetes and CKD was developed as part of a research collaboration between tertiary hospitals from two of Australia's most populous cities (Alfred and Monash Health in Melbourne and the Royal North Shore and Concord Hospitals in Sydney), academic organizations (Monash Centre for Health Research and Implementation and the George Institute for Global Health) and national consumer advocacy organizations (Diabetes Australia and Kidney Health Australia). The model of care was developed over three phases including a: (i) formative phase; (ii) a workshop; and (iii) a post workshop iterative review of the model of care.

The formative phase had four main components:

1. A review of the literature inclusive of the needs and health-care experiences of patients with co-morbid diabetes and CKD.
2. A qualitative needs analysis of patients, their carers and health-professionals delivering health-care for co-morbid diabetes and CKD. Participants were recruited from four tertiary health services across Melbourne and Sydney. Twelve focus groups were conducted with 58 patients, with a further six focus group performed with 35 tertiary health professionals and four focus groups with 22 GPs. Semi-structured interviews were conducted with eight care-givers and eight heads of specialist units.[28,34]
3. A quantitative study of GPs evaluating the commonest reported health-service barriers to health-care. This consisted of a survey (informed by previous GP focus groups) and was administered to 840 GPs.[13]
4. A quantitative evaluation documenting: (i) the gap between optimal health-care according to guidelines versus received health-care; and (ii) the commonest barriers to health-care reported by patients. This was a cross-sectional study of 308 patients recruited from four tertiary health services across Melbourne and Sydney.[10]

The detailed methodology and results of these qualitative and quantitative studies have been previously published.[10,13,28,34]

The workshop was a closed one day meeting in Melbourne, Australia. Prior to the workshop, an agenda containing the research methodology and findings from the formative phase was sent to invited delegates. Invited delegates included clinical and academic endocrinologists, nephrologists and nurse practitioners (from Alfred Health, Monash Health, the Royal North Shore Hospital, Concord Hospital, Monash Centre for Health Research and Implementation and the George Institute for Global Health), a biostatistician, academic GPs (from Monash University and the University of Sydney) and the chief executive officers of Diabetes Australia and Kidney Health Australia. The workshop commenced with an overview of the workshop's objectives, projected outcomes of health-care improvement, and the methodology used for the formative phase. Findings from the formative phase were reviewed and discussed, leading to the formulation of a new model of care. Post-workshop, the co-designed model of care was iteratively reviewed by all participants until consensus was reached.

## OVERVIEW OF THE CO-DESIGNED MODEL OF CARE

Key findings from the formative phase are summarized in Table 1 and have been previously published.[28,34] They were incorporated into the new co-designed model of care which complements and leverages off the patient-centred health-care home (PCHCH) (Fig. 1). The PCHCH has been shown to improve patient satisfaction, clinical quality and to decrease health-care utilization,[35,36] and costs[37] in non-Australian settings. It emphasizes the centrality of primary care/general practice offering and coordinating ongoing, comprehensive, holistic patient-centred medical care, minimising fragmentation and duplication of care.[38] Key elements have already been adopted by the professional body of GPs in Australia, the RACGP.[39] In addition, the PCHCH is currently being implemented in a staged process by the Australian Department of Health in partnership with Primary Health Networks.[40] In our co-designed model of care, the patient's GP and GP clinic coordinates care and provides the 'patient-centred health-care home' for management of all chronic diseases including diabetes and CKD (Fig. 1).

Furthermore, specialized input for those patients with diabetes and more advanced CKD (with an eGFR <60 mL/min per 1.73 $m^2$) is provided by a multidisciplinary, integrated diabetes-kidney service consisting of diabetes and renal physicians, nurse practitioners and a dietitian. Each patient completes a pre-consultation assessment tool to screen for psychological co-morbidity. If psychological co-morbidity is identified, the patient is either treated, referred to a psychiatric service directly, or a recommendation is made to the

© 2018 Asian Pacific Society of Nephrology

**Table 1** Reported suggestions to improve health-care for co-morbid diabetes and chronic kidney disease (CKD)

| Factor to be improved | Suggestions |
|---|---|
| Patient and carer empowerment | Education is simplified and patient-centred.<br>Education about early kidney disease.<br>Provision of dietary information for both diabetes and CKD.<br>Care plan given to patient. |
| Access | Decentralizing specialist tertiary health services to the community.<br>Simplify and improve referral processes.<br>An advice and triage hot-line accessible to both health professionals and patients. |
| Coordination and continuity of care | Facilitate general practitioners to remain the primary coordinator of patients' care.<br>Educate general practitioners about managing patients with both diabetes and CKD.<br>Greater role clarification between health professionals.<br>Improve communication pathways between health professionals.<br>Utilize diabetes and CKD care plans for communication.<br>A c multidisciplinary specialist diabetes and CKD service.<br>Each patient sees the same specialist health professional for continuity of care. |
| Detection and management of psychological co-morbidity | Routine screening for psychological morbidity and co-morbidity. |

managing GP to refer the patient to a community psychology service. In addition, each patient sees the same specialist each visit to improve continuity of care. If required, the patient is referred to see other disciplines within the clinic. Care is structured according to an electronic history proforma. To facilitate multidisciplinary input into each patient's management plan, all patients are discussed at the end of the clinic. The design of this service is anticipated to improve coordination of care and communication between diabetes and kidney specialities. Additionally, this service is anticipated to decrease the number of clinic visits for patients with both diabetes and CKD (instead of having two separate appointments for each condition, each patient will have one appointment for the management of both conditions).

The multi-disciplinary diabetes-kidney service complements and integrates with the patient-centred medical home in a few ways (Fig. 1). Firstly, the diabetes-kidney service is patient-centred, focusing on patient and carer empowerment to encourage self-management of disease. This is achieved through motivational interviewing, education, and a diabetes-kidney care plan that is given to the patient after each visit (to reinforce the management plan agreed upon by the service and the patient). Secondly, the diabetes-kidney service provides patients with: (i) the contacts of peer and patient support groups such as Diabetes Australia and Kidney Health Australia; and (ii) a phone advice line. Thirdly, the diabetes-kidney service interfaces with the patient's primary care home team/GP through two dedicated communication pathways: (i) the same diabetes-kidney care plan that is given to a patient is faxed to his/her GP on the same day as the consultation; and (ii) a dedicated phone advice service is available to allow GPs to clarify treatment decisions or to seek advice on the management of acute issues. Fourthly, the diabetes-kidney service supports the patient's primary care home team/GP through education sessions (concerning management of diabetes and CKD, referral criteria, and disease prevention), specialist outreach services (either in person or through telehealth) and if required, case management by a care facilitator.

The whole model of care is underpinned by quality improvement activities (a process evaluation with regular auditing to ensure fidelity to the model), with modification of the model after an embedded evaluation process.

## DIFFERENCES FROM OTHER MODELS OF CARE

This model of care differs from previous models in several ways. Firstly, this model of care was developed after consultation with both end-users (patients and their carers) and health-care staff currently delivering care. It was then co-designed with key stake-holders (consumer advocacy groups and health-care professionals). Secondly, psychological morbidity is routinely screened for in the model of care. This ensures that psychological morbidity, which may affect patient quality of life and self-management, is identified and appropriately managed. Thirdly, the model of care integrates and interfaces with the patient-centred health-care home with established bi-directional communication pathways – through a diabetes-kidney care plan and also through a phone advice line. Finally, primary health-care is supported through education sessions, telehealth, and a specialist outreach service.

## PLANNED EVALUATION OF THE NEW MODEL OF CARE

The model of care is currently being implemented at two tertiary centres and their primary care catchment areas. The model of care will subsequently be evaluated across four aspects:

1. Process evaluation (specifically evaluating the fidelity to the new model of care during implementation).
2. Outcome evaluation of the effectiveness and safety of the new model of care in decreasing rate and length of


© 2018 Asian Pacific Society of Nephrology

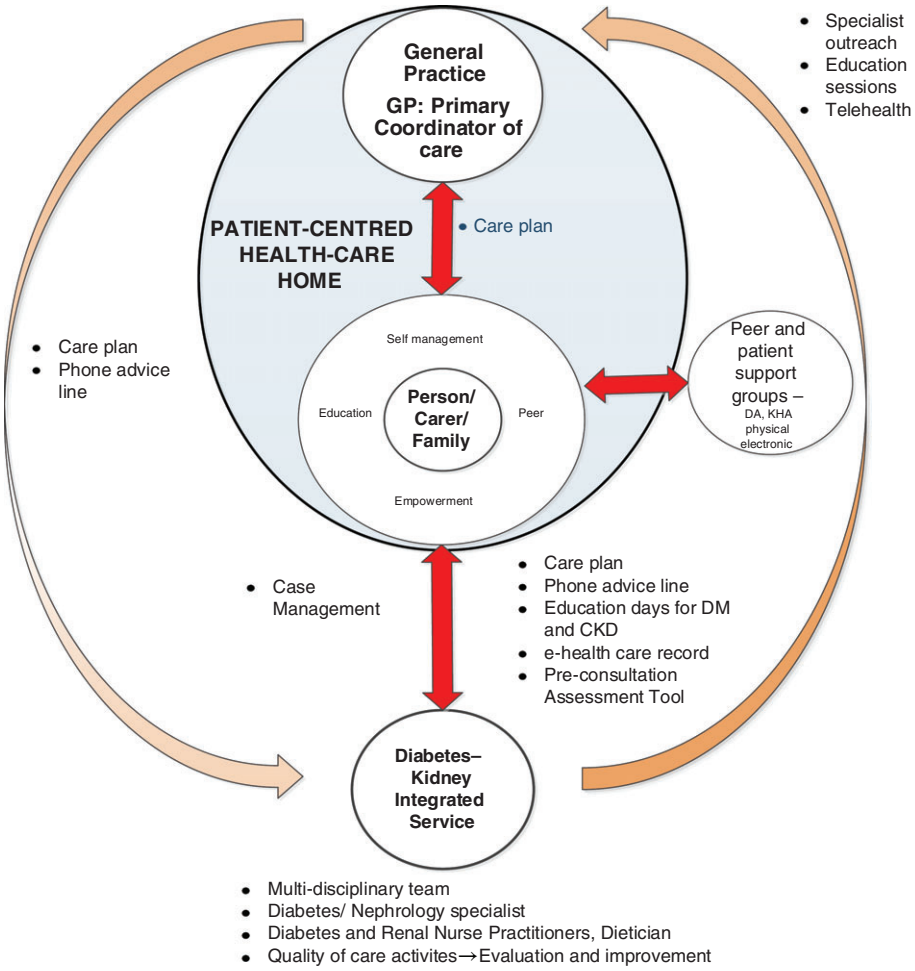



**Fig. 1** Consensus model of care for co-morbid diabetes and chronic kidney disease. (DA) Diabetes Australia, (DM) Diabetes Mellitus, (GP) General Practitioner, (KHA) Kidney Health Australia.

hospitalizations and improving treatment target attainment (for management of glycaemia, blood pressure, dyslipidaemia, CKD-Metabolic Bone Disease and anaemia), patient self-efficacy and quality of life. Patient outcomes will be compared to patients cared for in standard outpatient clinics and those who do not have access to the new model of care.

3. Examination of the strengths and weaknesses of the model of care. This will include evaluation of patients' and health professionals' satisfaction with the model of care and evaluation of the accessibility of the health service (provided by the model of care).
4. Health economics and cost-effectiveness modelling.

In conclusion, health-care improvement for patients with both diabetes and CKD is required because care is often suboptimal. Key components of health-care shown to be effective include care that: is structured, intensive and multifaceted (treating diabetes and multiple cardiovascular risk factors); is multidisciplinary; improves patient self-management; and upskills primary health-care. Here, we build on these evidence-based components by co-designing an integrated, patient-centred model of care with key stakeholders. This model of care integrates with the patient-centred health-care home, allows coordination between primary and tertiary levels of care, and promotes patient self-management and empowerment. Its impact will be formally evaluated after implementation across two metropolitan health networks and their primary care catchment areas.

## ACKNOWLEDGEMENTS

Development of the model of care was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. The NHMRC had no role in the design, data collection, data analysis or interpretation of data for this study. C Lo (Monash Health and Monash University) was supported by an Australian Postgraduate Award Scholarship. H Teede (Monash Health and Monash University) was supported by a

© 2018 Asian Pacific Society of Nephrology

NHMRC, Australia Fellowship. S Zoungas (Monash Health, Monash University and the George Institute for Global Health) was supported by a National Heart Foundation of Australia Fellowship. We want to acknowledge all participants of focus groups and semi-structured interviews (patients and health-professionals), Diabetes Australia and Kidney Health Australia. They were involved in the consultation for and the co-design of the model of care. C Lo, E Zimbudzi and S Zoungas (Monash Health and Monash University) contributed to the original conception of the work, literature review, co-design of the model of care and drafting of this manuscript. H Teede (Monash Health and Monash University), A Cass (Menzies School of Health Research), G Fulcher (Royal North Shore Hospital), M Gallagher (Concord Hospital and the George Institute of Global Health), P Kerr (Monash Health), S Jan (The George Institute for Global Health), G Johnson (Diabetes Australia), T Mathew (Kidney Health Australia), K Polkinghorne (Monash Health), G Russell (Monash University), T Usherwood (University of Sydney), and R Walker (Alfred Health) contributed to the co-design of the model of care, and drafting and critical revision of the manuscript. All authors approved the final version to be published.

## REFERENCES

1. Ceramidas DM, Glasgow NJ. Multi-morbidity: A system design challenge in delivering patient-centred care. *Aust. Health Rev.* 2013; **37**: 309–11.
2. Fortin M, Soubhi H, Hudon C, Bayliss EA, van den Akker M. Multimorbidity's many challenges. *BMJ* 2007; **334**: 1016–7.
3. Foley RN, Murray AM, Li S *et al*. Chronic kidney disease and the risk for cardiovascular disease, renal replacement, and death in the United States Medicare population, 1998 to 1999. *J. Am. Soc. Nephrol.* 2005; **16**: 489–95.
4. 2014 US Renal Data System Annual Data Report Ann Arbor, Michigan, USRDS Coordinating Center, 2014.
5. Penfornis A, Blickle JF, Fiquet B, Quere S, Dejager S. How are patients with type 2 diabetes and renal disease monitored and managed? Insights from the observational OREDIA study. *Vasc. Health Risk Manag.* 2014; **10**: 341–52.
6. Hill CJ, Cardwell CR, Patterson CC *et al*. Chronic kidney disease and diabetes in the national health service: A cross-sectional survey of the U.K. national diabetes audit. *Diabet. Med.* 2014; **31**: 448–54.
7. De Cosmo S, Viazzi F, Pacilli A *et al*. Achievement of therapeutic targets in patients with diabetes and chronic kidney disease: Insights from the Associazione Medici Diabetologi Annals initiative. *Nephrol. Dial. Transplant.* 2015; **30**: 1526–33.
8. Stevens PE, Schernthaner G, Raptis S, Wanner C, Scherhag A, Lameire N. Characteristics, cardiovascular comorbidity and medicines management in patients with type 2 diabetes and CKD: Results of the IRIDIEM study. *Kidney Blood Press. Res.* 2010; **33**: 119–28.
9. *2014 US Renal Data System Annual Data Report Volume 1: Chronic Kidney Disease*. Ann Arbor, Michigan: USRDS Coordinating Center, 2014.
10. Lo C, Teede H, Fulcher G *et al*. Gaps and barriers in health-care provision for co-morbid diabetes and chronic kidney disease: A cross-sectional study. *BMC Nephrol.* 2017; **18**: 80.
11. Atun R. Transitioning health systems for multimorbidity. *Lancet* 2015.
12. Osborn R, Moulds D, Schneider EC, Doty MM, Squires D, Sarnak DO. *Primary Care Physicians In Ten Countries Report Challenges Caring For Patients With Complex Health Needs. (1544–5208 (Electronic))*.
13. Lo C, Teede H, Ilic D *et al*. Identifying health service barriers in the management of co-morbid diabetes and chronic kidney disease in primary care: A mixed-methods exploration. LID - cmw041 [pii]. *Fam. Pract.* 2016; **33**: 492–7.
14. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: A cross-sectional study. *Lancet* 2012; **380**: 37–43.
15. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990–2013: A systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015; **386**:743–800.
16. DJ. Organising care for people with diabetes and renal disease. *J. Ren. Care* 2012; **38** (Suppl 1): 23–9.
17. Bowman BT, Kleiner A, Bolton WK. Comanagement of diabetic kidney disease by the primary care provider and nephrologist. *Med. Clin. North Am.* 2013; **97**: 157–73.
18. Mahnensmith RL, Zorzanello M, Hsu YH, Williams ME. A quality improvement model for optimizing care of the diabetic end-stage renal disease patient. *Semin. Dial.* 2010; **23**: 206–13.
19. Chan JC, So WY, Yeung CY *et al*. Effects of structured versus usual care on renal endpoint in type 2 diabetes: The SURE study: A randomized multicenter translational study. *Diabetes Care* 2009; **32**: 977–82.
20. Ko GT, Yeung CY, Leung WY *et al*. Cost implication of team-based structured versus usual care for type 2 diabetic patients with chronic renal disease. *Hong Kong Med.* 2011; **17** (Suppl 6): 9–12.
21. Gaede P, Vedel P, Parving HH, Pedersen O. Intensified multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: The steno type 2 randomised study. *Lancet (London, England)* 1999; **353**: 617–22.
22. Gaede P, Vedel P, Larsen N, Jensen GV, Parving HH, Pedersen O. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *N. Engl. J. Med.* 2003; **348**: 383–93.
23. Jayapaul MK, Messersmith R, Bennett-Jones DN, Mead PA, Large DM. The joint diabetic-renal clinic in clinical practice: 10 years of data from a District General Hospital. *QJM* 2006; **99**: 153–60.
24. Joss N, Paterson KR, Deighan CJ, Simpson K, Boulton-Jones JM. Diabetic nephropathy: How effective is treatment in clinical practice? *QJM* 2002; **95**: 41–9.
25. Patel M, Shilliday IR, McKay GA. A combined diabetes renal clinic improves risk factor management and progression of renal disease in a district general hospital. *J. Eval. Clin. Pract.* 2009; **15**: 832–5.
26. Slade H, Williams SM, Manning PJ, Walker RJ. High-risk diabetic nephropathy patients: The outcome of evidence-based clinical practice in an outpatient clinic. *Diabetes Res. Clin. Pract.* 2011; **92**: 356–60.
27. Liew BS, Perry C, Boulton-Jones JM, Simpson K, Paterson K. Diabetic nephropathy: An observational study on patients attending a joint diabetes renal clinic. *QJM* 1997; **90**: 353–8.
28. Lo C, Ilic D, Teede H *et al*. Primary and tertiary health professionals' views on the health-care of patients with co-morbid diabetes and chronic kidney disease - a qualitative study. *BMC Nephrol.* 2016; **17**: 50.
29. Steed L, Lankester J, Barnard M, Earle K, Hurel S, Newman S. Evaluation of the UCL diabetes self-management programme (UCL-DSMP): A randomized controlled trial. *J. Health Psychol.* 2005; **10**: 261–76.
30. McMurray SD, Johnson G, Davis S, McDougall K. Diabetes education and care management significantly improve patient outcomes in the dialysis unit. *Am. J. Kidney Dis.* 2002; **40**: 566–75.


© 2018 Asian Pacific Society of Nephrology

31. Kazawa K, Moriyama M. Effects of a self-management skills-acquisition program on pre-dialysis patients with diabetic nephropathy. *Nephrol. Nurs. J.* 2013; **40**: 141–8; quiz 9.
32. Jones RK, Hampton D, O'Sullivan DJ, Phillips AO. Diabetes and renal disease: Who does what? *Clin. Med. (Lond.)* 2013; **13**: 460–4.
33. Cortes-Sanabria L, Cabrera-Pivaral CE, Cueto-Manzano AM *et al*. Improving care of patients with diabetes and CKD: A pilot study for a cluster-randomized trial. *Am. J. Kidney Dis.* 2008; **51**: 777–88.
34. Lo C, Ilic D, Teede H *et al*. The perspectives of patients on health-care for co-morbid diabetes and chronic kidney disease: A qualitative study. *PLoS One* 2016; **11**: e0146615.
35. Nelson KM, Helfrich C, Sun H *et al*. Implementation of the patient-centered medical home in the veterans health administration: Associations with patient satisfaction, quality of care, staff burnout, and hospital and emergency department use. *JAMA Intern. Med.* 2014; **174**: 1350–8.
36. David G, Gunnarsson C, Saynisch PA, Chawla R, Nigam S. Do patient-centered medical homes reduce emergency department visits? *Health Serv. Res.* 2015; **50**: 418–39.
37. van Hasselt M, McCall N, Keyes V, Wensky SG, Smith KW. Total cost of care lower among Medicare fee-for-service beneficiaries receiving care from patient-centered medical homes. *Health Serv. Res.* 2015; **50**: 253–72.
38. Azur L, Parchman M, Meyers D. *The Medical Home: What do we know, what do we need to know?* Rockville: Agency for Healthcare Research and Quality, 2014.
39. Jackson CL. Australian general practice: Primed for the "patient-centred medical home"? *Med. J. Aust.* 2012; **197**: 365–6.
40. Jackson CL, Hambleton SJ. *Australia's Health Care Homes: Laying the Right Foundations.* Med J Aust 2017 May 15; **206**: 380–81.

© 2018 Asian Pacific Society of Nephrology

**Published manuscript: Patient-centred factors associated with poor glycaemic and blood pressure control in co-morbid diabetes and chronic kidney disease**

Citation: Lo C., **Zimbudzi E**., Teede HJ., Kerr PG., Ranasinha S., Cass A., Fulcher G., Gallagher M., Polkinghorne KR., Russell G., Usherwood T., Walker R., Zoungas S. Patient-centred factors associated with poor glycaemic and blood pressure control in co-morbid diabetes and chronic kidney disease. Journal of Diabetes Complications 2019:33 (1):63-68. doi: 10.1016/j.jdiacomp.2018.09.020.

Journal of Diabetes and Its Complications 33 (2019) 63–68

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

# Patient-reported barriers and outcomes associated with poor glycaemic and blood pressure control in co-morbid diabetes and chronic kidney disease

Clement Lo [a,b], Edward Zimbudzi [a,c], Helena J. Teede [a,b], Peter G. Kerr [c], Sanjeeva Ranasinha [a], Alan Cass [d,e], Gregory Fulcher [f], Martin Gallagher [e,g], Kevan R. Polkinghorne [a,c], Grant Russell [h], Tim Usherwood [e,i], Rowan Walker [j], Sophia Zoungas [a,b,e,*]

[a] School of Public Health and Preventive Medicine, Monash University, VIC, Australia
[b] Diabetes and Vascular Medicine Unit, Monash Health, VIC, Australia
[c] Department of Nephrology, Monash Health, VIC, Australia
[d] Menzies School of Health Research, Casuarina, NT, Australia
[e] The George Institute for Global Health, NSW, Australia
[f] Department of Diabetes and Endocrinology, Royal North Shore Hospital, NSW, Australia
[g] Department of Nephrology, Concord Hospital, NSW, Australia
[h] Department of General Practice, School of Primary and Allied Health Care, Monash University, VIC, Australia
[i] Department of General Practice, Sydney Medical School Westmead, NSW, Australia
[j] Department of Renal Medicine, Alfred Health, VIC, Australia

ARTICLE INFO

*Article history:*
Received 15 April 2018
Received in revised form 18 June 2018
Accepted 26 September 2018
Available online 12 October 2018

*Keywords:*
Diabetes
Chronic kidney disease
Treatment targets
Patient-reported outcomes
Patient activation
Health-related quality of life

ABSTRACT

*Aims:* In patients with comorbid diabetes and chronic kidney disease, the extent to which patient-reported barriers to health-care and patient reported outcomes influence the quality of health care is not well established. This study explored the association between patient-reported barriers to health-care, patient activation, quality of life and diabetes self-care, with attainment of glycaemic and blood pressure (BP) targets.

*Methods:* This cross-sectional study recruited adults with diabetes and CKD (eGFR 20 to <60 ml/min/1.73m$^2$) across four hospitals. We combined clinical data with results from a questionnaire comprising measures of patient-identified barriers to care, the Patient Activation Measure (PAM), 12-Item Short Form Survey (SF-12), and the Summary of Diabetes Self-Care Activity (SDSCA).

*Results:* 199 patients, mean age 68.7 (SD 9.6), 70.4% male and 90.0% with type 2 diabetes were studied. Poor glycaemic control was associated with increased odds of patient reported "poor family support" (OR 4.90; 95% CI 1.80 to 13.32, $p < 0.002$). Poor BP control was associated with increased odds of patient reported, "not having a good primary care physician" (OR 6.01; 2.42 to 14.95, $p < 0.001$). The number of barriers was not associated with increased odds of poor control (all $p > 0.05$).

*Conclusions:* Specific patient-reported barriers, lack of patient perceived family and primary care physician support, are associated with increased odds of poor glycaemic and blood pressure control respectively. Interventions addressing these barriers may improve treatment target attainment.

© 2018 Elsevier Inc. All rights reserved.

## 1. Introduction

Diabetes is the commonest cause of end-stage kidney disease (ESKD),[1] with approximately 40% of individuals with chronic kidney disease (CKD) and ESKD having co-morbid diabetes.[1] Co-morbid diabetes and CKD is a substantial public health problem and associated with a very high risk of cardiovascular disease.[2] Health-care costs due to co-morbid diabetes and CKD are substantial with $US14,856 million spent by the USA Medicare system for patients aged 65 and older in 2014.[1]

A series of consensus statements have recently been published to optimise management of co-morbid diabetes and CKD.[3–6] Recommendations have included optimising glycaemic and blood pressure management.[3–6] Despite these recommendations, there is evidence

Disclosures: The authors declare no conflicts of interest.

* Corresponding author at: Division of Metabolism, Ageing and Genomics, Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, 99 Commercial Road, Melbourne, VIC 3004, Australia.
*E-mail address:* sophia.zoungas@monash.edu (S. Zoungas).

https://doi.org/10.1016/j.jdiacomp.2018.09.020
1056-8727/© 2018 Elsevier Inc. All rights reserved.

that many patients still fail to meet glycaemic and blood pressure targets, along with other indicators of quality care (anaemia/haemoglobin targets, HbA1c monitoring and albuminuria screening).[7–9]

To improve the quality of care of patients with complex diseases, including diabetes and CKD, leading health-care and policy organisations have recommended patient-centred models of care.[10,11] Patient-centred care involves the formation of a patient-health provider partnership that is mutual, holistic and prioritises the patient in his or her social and caregiving context. Patient-centred care empowers people through health literacy to make personalised and realistic decisions for health.[12] Additionally, an individual's specific health needs and desired health outcomes drive health care decisions and quality improvement. Consequently, patient perspectives of the barriers to health care and patient reported outcomes (PROs) defined as outcomes reported directly by patients without interpretation by clinicians[13] are important parameters to consider in the design, evaluation and improvement of patient-centred models of care. However, whether these patient-reported barriers and outcomes are associated with attainment of treatment targets in diabetes and CKD is not known.

The objective of this study was to explore the association between patient-reported barriers to health-care and patient reported outcomes (that is patient activation, quality of life and diabetes self-care), with attainment of glycaemic and blood pressure targets. Our hypothesis was that the presence of patient-reported barriers, and poorer health-related quality of life, patient self-care and patient activation scores would be associated with a failure to attain treatment targets.

## 2. Subjects, materials and methods

The design, setting and recruitment of participants for this Australian multi-centre cross-sectional study has been described previously.[14] In brief, this study included adults (over 18 years) with diabetes and CKD stages 3 and 4 specifically with an eGFR between 20 to <60 ml/min/1.73m$^2$. Potential participants were recruited from either outpatient diabetes or renal clinics of each participating tertiary hospital over a 3-month period between January and September 2014 and were fluent in English. We excluded patients with an eGFR <20 ml/min/1.73m$^2$, as once the eGFR progresses to <20, renal replacement therapy is imminent and other management issues besides blood pressure and glycaemic control often take priority.

Methods and results are presented in accordance with the STROBE (Strengthening The Reporting of Observational Studies in Epidemiology) guidelines.[15] Monash Health (12,340 L), Monash University (CF12/4030–2012001924), Alfred Health (526/12), Concord Repatriation Hospital (LNR/12/HAWKE/417; CH62/6/2013–100; LNRSSA/13/CRGH/139), Royal North Shore Hospital (1212-431 M) and University of Sydney (2013/672) human research ethics committees approved the study.

### 2.1. Study conduct and variables

Data collection for each patient consisted of a survey composed of five questionnaires.

Site study staff or the clinician, using standardised procedures, prospectively completed the first questionnaire from the doctor's notes and laboratory results from clinic. Demographic information and disease-specific characteristics such as diabetes duration, type of diabetes treatment, complication status, current HbA1c, systolic and diastolic blood pressure, haemoglobin, CKD duration, CKD stage and current eGFR (Supplementary Appendix S1) was collected.

The second questionnaire was completed by the patient and examined patient-reported barriers to health-care (Supplementary Appendix S2) identified from the content analysis of 12 focus groups of 58 participants with co-morbid diabetes and CKD and 8 semi-structured interviews of carers from our previous multi-centre qualitative study.[16]

The third questionnaire was the validated American version of the Patient Activation Measure (PAM-13)[17] which examined patients' level of engagement in their healthcare (Supplementary Appendix S3). The questionnaire assessed each individual's knowledge, skill and confidence for self-management. Each item of the PAM was scored on a 5-point Likert response scale to yield raw scores (range 13–52) which were transformed from the original metric to a 0–100 metric with higher scores indicating increasing patient involvement.[17]

The fourth questionnaire was the validated Summary of Diabetes Self-Care Activities (SDSCA) questionnaire (Supplementary Appendix S4).[18] The SDSCA has previously been evaluated in numerous studies and settings.[19,20] The scale contains 11 main items, which are subdivided into five sub-scales. These subscales include diet, which is comprised of general diet, and diabetes specific diet, exercise, blood-glucose testing, foot-care and smoking. Scoring was performed on an 8-point Likert scale from 0 to 7.[18] The mean number of days the specific self-care activities were performed over the past 7 days was calculated for each subscale, with reverse scoring done for the item on dietary fat; higher scores signifying better self-care practice.[18] A composite score of self-care activity was generated from SDSCA ratings for general diet, specific diet, exercising, glucose testing, and foot checking.

The fifth questionnaire was the validated English version of the SF-12 and examined Health Related Quality Of Life (HRQoL) (Supplementary Table S5). The SF-12 measures physical and mental functioning. Utilising the two non-disease specific summary measures permitted comparison between other conditions[21] and the general population.[22] Item scores were summed for each scale and transformed on a scale of 0 to 100 with a higher score indicating better HRQoL.[23]

### 2.2. Outcome measures

The main outcome measures were failure to attain glycaemic and blood pressure targets. Poor glycaemic control was defined as an HbA1c ≥ 8% (64 mmol/mol), a target suggested by the American Diabetes Association.[3] Poor blood pressure control was defined as a systolic blood pressure ≥140 mm Hg, a target suggested by the European Renal Best Practice Group[4] and the American Diabetes Association.[3] Systolic blood pressure was used rather than diastolic blood pressure.

### 2.3. Statistical analysis

For baseline characteristics, continuous variables were reported as means and standard deviations or medians with interquartile ranges if distributions were skewed. Categorical variables were reported as frequencies and percentages. Socioeconomic status was analysed as quintiles obtained from the coding of postcodes according to the Index of Relative Social Disadvantage (IRSD),[24] a composite measure based on selected census variables, which include income, educational attainment and employment status. SF 12 physical composite and SF 12 mental composite were stratified according to the general population mean. To analyse barriers, Likert scales were collapsed into 2 categories (disagree and agree).

First, Pearson's chi squared test examined the relationship between study variables and poor glycaemic and blood pressure control. Second, univariable logistic regression analyses were performed to examine the relationship between potential predictor variables and poor glycaemic and blood pressure control. Third, separate multivariable logistic regression models were used to estimate the association between patient predictor variables and the likelihood of poor glycaemic and blood pressure control. Variables that showed a tendency of association with poor glycaemic and blood pressure control ($p < 0.05$) in univariable models inclusive of age, gender and diabetes duration and type were used to build the most parsimonious multivariable models. All logistic regression analyses standard errors were adjusted for clustering by hospital.

A dose response analysis adjusted for clustering by hospital was used to examine the association between the number of patient-

identified barriers and poor glycaemic and blood pressure control. The cohort was divided into quartiles according to the number of identified barriers and a univariable logistic regression examined the association between the number of barriers and poor glycaemic or blood pressure control.

Stata version 13.1 (Statacorp, College Station, TX) was used. Statistical significance was indicated by a $p$ value of <0.05.

## 3. Results

### 3.1. Patient characteristics

A total of 199 patients with diabetes and CKD (with an eGFR 20 to <60 ml/min/1.73 $m^2$) were included in the analysis. Clinical characteristics are reported in Table 1. The mean age was 68.7 (SD 9.6), and most were male (70.4%) and had type 2 diabetes (90.0%) with 36.2%, 38.7% and 25.1% having CKD stages 3a, 3b and 4 respectively. Optimal blood glucose (HbA1c <8%) and blood pressure control (systolic blood pressure < 140mm Hg) were achieved by 58% and 69% of the participants respectively. At least 60% of the participants reported optimal self-care scores (mean SDSCA score > 37.7, range 0 to 70). A third of the participants scored above the general population mean ($\mu = 50$) in the physical composite summary and 53% in the mental composite summary. Participants were evenly distributed across patient activation levels (level 1—19.6%, level 2—22.6%, level 3—29.2% and level 4—28.6%).

**Table 1**
Demographic and clinical characteristics of patients with diabetes and CKD.

| Variable | Mean ± SD or N (%) | Range |
|---|---|---|
| Age (years) | 68.7 ± 9.6 | 36–88 |
| Male (%) | 140 (70.4) | |
| Hospital (N, %) | | |
| A | 58 (29.1) | |
| B | 25 (12.6) | |
| C | 71 (35.7) | |
| D | 45 (22.6) | |
| English speaking | 155 (78.7) | |
| Socio-economic status | | |
| Upper | 38 (19.1) | |
| Higher middle | 45 (22.6) | |
| Middle | 40 (20.1) | |
| Lower middle | 39 (19.6) | |
| Lower | 37 (18.6) | |
| Currently smoking (%) | 9 (6.3) | |
| Weight (kilograms) | 91.9 ± 22.9 | 37–159.8 |
| Diabetes type (%) | | |
| Type 1 | 13 (6.5) | |
| Type 2 | 179 (90.0) | |
| Other | 7 (3.5) | |
| Diabetes duration (median, IQR) years | 18 (10 to 23) | 1–57 |
| HbA1c % | 7.6 ± 1.4 | 4.9–13.3 |
| eGFR categories (%) | | |
| 20–29 | 50 (25.1) | |
| 30–44 | 77 (38.7) | |
| 45–59 | 72 (36.2) | |
| Systolic blood pressure (mm Hg) | 132.1 ± 17.1 | 100–195 |
| Diastolic blood pressure (mm Hg) | 71.3 ± 10.7 | 40–113 |
| Summary of diabetes self-care activities | 37.7 ± 11.1 | 5–60 |
| Patient activation measure | 59.9 ± 15.2 | 32–100 |
| Health related quality of life | | |
| SF-12 Physical Composite Summary | 47.6 ± 11.1 | 17–64 |
| SF-12 Mental Composite Summary | 36.6 ± 11.3 | 10–68 |
| *Medications (%)* | | |
| On insulin only | 74 (37.2) | |
| On oral hypoglycaemic agents and insulin | 58 (29.2) | |
| Oral hypoglycaemic agents | 118 (59.3) | |
| On hypertensives | 187 (94.0) | |
| On renin-angiotensin system blockers | 141 (70.8) | |
| *Complications/other cardiovascular risk factors (%)* | | |
| Heart disease | 99 (50) | |
| Neuropathy | 63 (31.8) | |
| Stroke | 25 (12.6) | |
| Nephropathy | 138 (69.7) | |
| Peripheral vascular disease | 50 (22.2) | |
| Hypertension | 191 (96) | |
| Retinopathy | 76 (38.4) | |
| Dyslipidaemia | 166 (83.4) | |

### 3.2. Differences between patients with poor versus good glycaemic or blood pressure control

There were no differences in the proportion of patients with poor glycaemic and blood pressure control across age groups, gender, language, socio economic status, smoking status, eGFR, diabetes duration and activation levels (Table 2).

### 3.3. Clinical factors associated with poor glycaemic or blood pressure control

Higher weight in kilograms (OR 1.02; 1.01 to 1.03, $p < 0.02$) and being on insulin (OR 3.06; 1.74 to 5.40, $p < 0.001$) was associated with an increased odds of poor glycaemic control (Fig. 2, Supplementary Table S1). The presence of retinopathy was associated with an increased odds of poor blood pressure control (OR 3.34; 3.06 to 3.66, $p < 0.001$) (Fig. 3, Supplementary Table S2).

### 3.4. Patient-reported barriers and poor glycaemic and blood pressure control

Patient-reported "poor family support" was associated with increased odds of poor glycaemic control (OR 4.90; 95% CI 1.80 to 13.32, $p < 0.002$) (Fig. 2, Supplementary Table S1). Patient-reported "not having a good primary care physician" (OR 6.01; 2.42 to 14.95, $p < 0.001$) was associated with an increased odds of poor blood pressure control (Fig. 3, Supplementary Table S2). Patient-reported "receiving conflicting advice from specialists", "poor continuity of care", "inadequate understanding and education about CKD" and "trouble maintaining dietary and fluid restrictions" were all not associated with poor glycaemic or blood pressure control. In addition, lower patient activation and lower diabetes self-care behaviour scores, and physical and mental health well-being scores were not associated with poor glycaemic or blood pressure control (all $p > 0.05$, Fig. 1, Supplementary Tables S1 and S2).

### 3.5. Association between number of barriers and poor glycaemic or blood pressure control

An increased number of patient-reported barriers was not associated with increased odds of having poor glycaemic or blood pressure control.

## 4. Discussion

In this study, we sought to identify patient-reported barriers and outcomes associated with failure to attain glycaemic and blood pressure targets in patients with co-morbid diabetes and CKD. Particular patient-reported barriers rather than the total number of barriers or patient activation, diabetes self-care and QOL, were associated with poor glycaemic and blood pressure control. Patient perceived lack of family support was associated with a lack of attainment of glycaemic targets. Patient perceived lack of primary care physician support was associated with a lack of attainment of blood pressure targets. Other patient-reported barriers to health-care such as "receiving conflicting advice from specialists", "poor continuity of care", "inadequate understanding and education about CKD" and "trouble maintaining dietary and fluid restrictions" were not associated with a lack of attainment of glycaemic or blood pressure targets.

Patient-reported "poor family support" was associated with increased odds of poor glycaemic control. This is consistent with the

**Table 2**
Demographic and clinical characteristics stratified according to glycaemic and blood pressure targets.

| Variables | Sample distribution ($n = 199$) | HbA1c < 8% ($n = 115$) | HbA1c ≥ 8% ($n = 67$) | Systolic blood pressure < 140 mm Hg ($n = 137$) | Systolic blood pressure ≥ 140 mm Hg ($n = 57$) |
|---|---|---|---|---|---|
| Age (mean ± SD) yrs. | 68.7 ± 9.6 | 68.9 ± 9.3 | 68.1 ± 9.6 | 68.5 ± 9.9 | 69.2 ± 1.2 |
| Gender: | | | | | |
| Male | 140 (70.4) | 81 (70.4) | 48 (71.6) | 96 (70.1) | 42 (73.7) |
| Female | 59 (29.6) | 34 (29.6) | 19 (29.4) | 41 (29.9) | 15 (26.3) |
| English speaking | | | | | |
| Yes | 155 (78.7) | 91 (79.8) | 54 (80.6) | 107 (79.3) | 46 (80.7) |
| No | 42 (21.3) | 23 (20.2) | 13 (19.4) | 28 (20.3) | 11 (19.3) |
| Socioeconomic status | | | | | |
| Upper | 38 (19.1) | 26 (22.6) | 11 (16.4) | 22 (16.1) | 14 (24.6) |
| Higher middle | 45 (22.6) | 23 (20.0) | 19 (28.4) | 30 (21.9) | 14 (24.6) |
| Middle | 40 (20.1) | 22 (19.1) | 13 (19.4) | 31 (22.6) | 8 (14.0) |
| Lower middle | 39 (19.6) | 20 (17.4) | 14 (20.9) | 29 (21.2) | 9 (15.8) |
| Lower | 37 (18.6) | 24 (20.9) | 10 (14.9) | 25 (18.3) | 12 (21.1) |
| Smoking | | | | | |
| Yes | 9 (6.3) | 6 (7.5) | 3 (5.8) | 6 (5.9) | 3 (7.7) |
| No | 134 (93.7) | 74 (92.5) | 49 (94.2) | 95 (94.1) | 36 (92.3) |
| eGFR | | | | | |
| 20–29 | 50 (25.1) | 27 (23.5) | 20 (29.9) | 32 (23.4) | 16 (28.1) |
| 30–44 | 77 (38.7) | 43 (37.4) | 24 (35.8) | 58 (42.3) | 17 (29.8) |
| 45–59 | 72 (36.2) | 45 (39.1) | 23 (34.3) | 47 (34.3) | 24 (42.1) |
| Diabetes duration | 18 (10 to 23) | 19 (7 to 23) | 17 (11 to 24) | 18 (10.5 to 23) | 17 (8 to 22) |
| Patient activation | | | | | |
| 1 | 39 (19.6) | 23 (20.0) | 13 (19.4) | 29 (21.2) | 10 (17.5) |
| 2 | 45 (22.6) | 27 (23.5) | 11 (16.4) | 30 (21.9) | 15 (26.3) |
| 3 | 58 (29.2) | 41 (35.7) | 26 (38.8) | 46 (33.6) | 21 (36.8) |
| 4 | 57 (28.6) | 24 (20.8) | 17 (25.4) | 32 (23.4) | 11 (19.3) |
| Self-care score (0–70) | 37.7 ± 11.1 | 37.3 ± 11.7 | 38.4 ± 10.4 | 36.9 ± 10.7 | 38.7 ± 11.5 |
| Physical composite | | | | | |
| <50 | 152 (82.6) | 91 (85.0) | 53 (85.5) | 110 (85.9) | 43 (84.3) |
| ≥50 | 32 (17.4) | 16 (15.0) | 9 (14.5) | 18 (14.1) | 8 (15.7) |
| Mental composite | | | | | |
| <50 | 87 (47.3) | 53 (49.5) | 32 (51.6) | 63 (49.2) | 28 (54.9) |
| ≥50 | 97 (52.7) | 54 (50.5) | 30 (48.4) | 65 (50.8) | 23 (45.1) |

No significant differences in mean (SD), median (IQR) and proportions were found for all variables ($p > 0.05$ for all variables); SF 12 physical composite (0—100) and SF 12 mental composite (0–100) were stratified by the general population mean ($\mu = 50$). Diabetes duration was measured in years (median, IQR). Patient activation levels were categorised into 4 levels thus Level 1—(<47), Level 2—(47.1–55.1), Level 3—(55.2–67) and Level 4—(>67).

majority of studies in patients with diabetes, although the results in type 2 diabetes are mixed. A 2013 systematic review of observational studies examining the association between social support and glycaemic control found that adequate family support was most frequently associated with a lower HbA1c.[25] Similarly, more recent observational studies have shown that obstructive family behaviours are associated with a higher HbA1c either directly[26] or indirectly through an association with self-care.[27] Here we advance the literature by showing that patient-reported "poor support from their family", is associated with poor glycaemic control, in a complex sub-population of patients with diabetes and CKD. These findings support the consideration of increasing awareness and engagement of family members in diabetes education and management activities and targeting family support.

Patient-reported "not having a good primary care physician" was associated with poor blood pressure control. This may be a reflection of the Australian publicly funded health system, where primary care physicians play a key role in patient management and care co-ordination with referrals from primary care required for patients to access allied health and both public and private specialist services. The finding emphasises the importance of primary care for the attainment of treatment targets in patients with co-morbid diabetes and CKD. This is especially the case when patients are primarily managed by their primary care physician.[28,29] In contrast, previous studies of primary care identified poor communication and coordination of care with specialty services and poor knowledge and awareness about CKD as barriers.[29–31] Interventions supporting primary care by improving coordination of care and communication between specialist care and primary care, and improving primary care knowledge and management of co-morbid diabetes and CKD may improve patient care and treatment target attainment.

Of note, patient activation was not associated with poor glycaemic and blood pressure control in patients with co-morbid diabetes and CKD. Previous studies examining the association between patient activation and glycaemic control amongst patients with diabetes have mainly reported a positive association.[32–35] Similarly, studies examining the association between blood pressure control and patient activation have not only shown mixed results but have occurred in a heterogeneous population with not all patients having both diabetes and CKD.[36,37] In a study of patients with diabetes, better patient activation was associated with better blood pressure control.[36] Conversely in another study in black patients with 61% having diabetes and/or CKD there was no association between patient activation and good blood pressure control.[37] Here we studied patients with both diabetes and CKD. The lack of an association is of interest and may be a reflection of the management of complex co-morbidity but needs to be further examined by longitudinal studies.

In our study, lower diabetes self-care behaviour or self-management scores as evaluated by the SDSCA were not associated with poor glycaemic control. Previous studies have examined this association in patients with diabetes and reported no[38] or a weak association.[39,40] The lack of consistency in these studies and ours may reflect subjective patient reporting of diabetes self-care. In addition, health related quality of life (as measured by lower physical and mental health well-being scores on the SF-12) was not associated with poor glycaemic and blood pressure control. Our study is consistent with previous studies showing no association between HRQOL and glycaemic control[41–43] in patients with diabetes alone. However, it differs from studies of patients with hypertension that have reported an association between better blood pressure control and better HRQOL.[44–47] These difference could

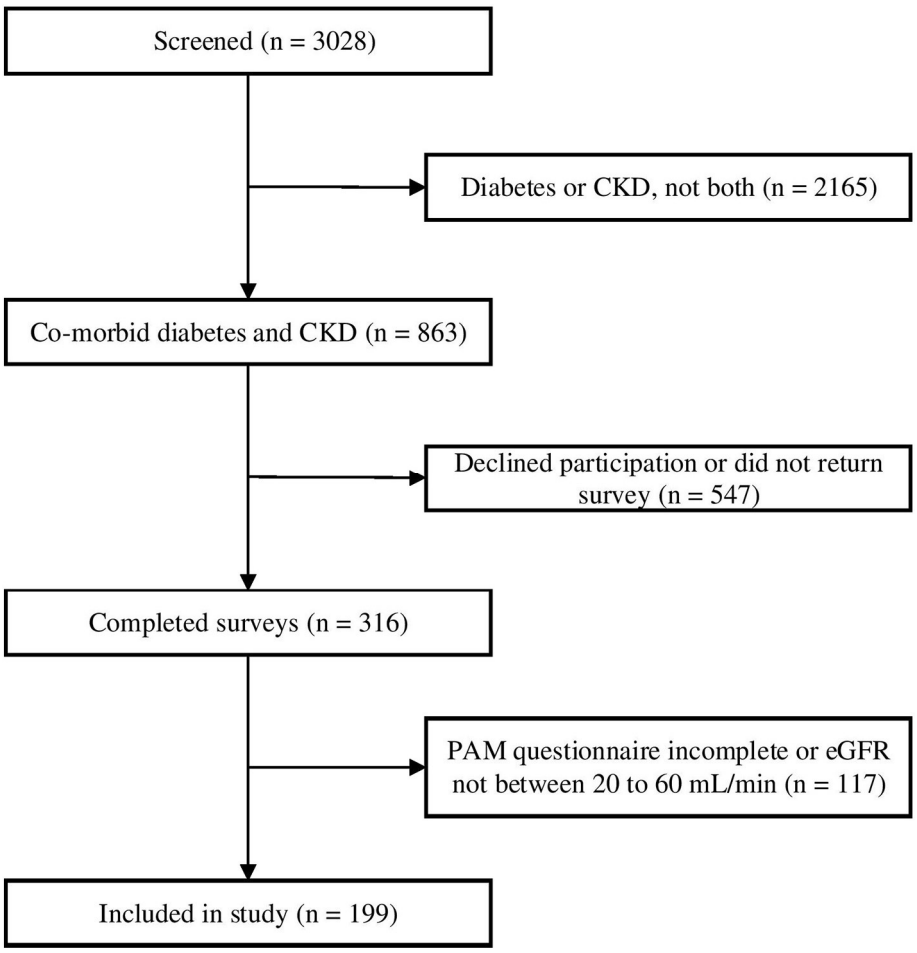



**Fig. 1.** Patient recruitment.

be explained by differences in the populations studied.[44–46] Together with our results, the overall evidence suggests that achieving good glycaemic and blood pressure control does not seem to adversely impact patients' HRQOL and vice versa, and may even be associated with greater levels of HRQOL in patients with co-morbid diabetes and CKD (excluding ESKD).

Our study's strengths include multi-site patient recruitment from geographically distinct large metropolitan areas, ensuring generalisability to urban populations. However, due to the cross-sectional study design, we were unable to make definitive causal inferences. In addition, despite the test–retest reliability not being performed for the patient-reported barriers questionnaire, partnering with patients in developing this survey ensured a form of reliability in the study. We were also unable to account for the individualisation of patient care, especially when therapeutic goals are appropriately different from treatment targets. Finally, because only participants speaking English were included, our findings cannot be generalised to culturally and linguistically diverse (CALD) populations.

In summary, specific patient-reported barriers, rather than the total number of barriers or lower scores on patient activation, diabetes self-care and QOL, were associated with poor glycaemic and blood pressure

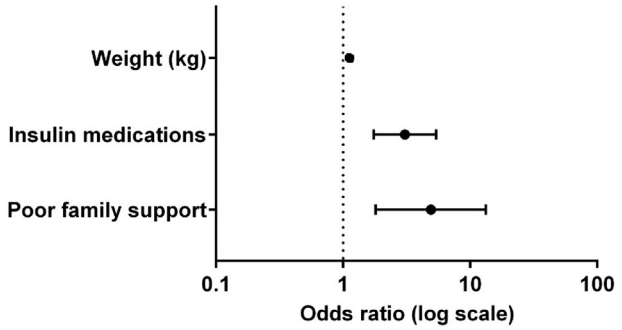



**Fig. 2.** Factors associated with poor glycaemic control (weight OR: 1.02 CI-1.01 to 1.03, insulin medications OR: 3.06 CI–1.74 to 5.40 and patient-reported "poor family support" OR: 4.90 CI–1.80 to 13.3).

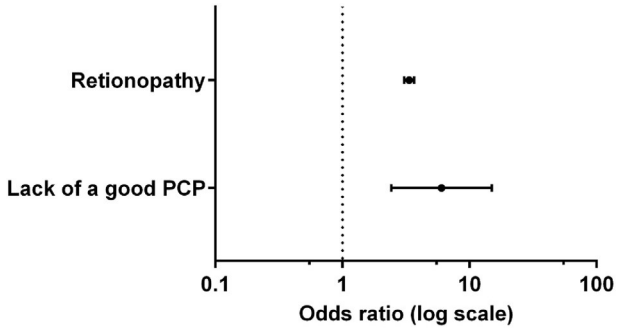



**Fig. 3.** Risk factors associated with poor blood pressure control (retinopathy OR: 3.34 CI–3.06 to 3.66 and patient-reported "lack of a good primary care physician [PCP]" OR: 6.01 CI–2.42 to 15.0).

control. Lack of patient perceived family and primary care physician support were associated with increased odds of poor glycaemic and blood pressure control respectively. Interventions building the capacity of the family to support an individual with chronic disease, and which support primary care in managing co-morbid diabetes and CKD may improve patient care and treatment target attainment.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jdiacomp.2018.09.020.

## Acknowledgements

We want to acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

## Funding

This study was supported by a National Health and Medical Research Council, Australia (NHMRC) Partnership Grant (ID 1055175) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. The NHMRC had no role in the design, data collection, data analysis or interpretation of data for this study.

An Australian Postgraduate Award Scholarship supported C Lo. H Teede was supported by a NHMRC, Australia Fellowship. A National Heart Foundation of Australia Fellowship supported S Zoungas.

## References

1. 2016 US Renal Data System Annual Data Report. 2017.
2. Radbill B, MB, LeRoith D. Rationale and strategies for early detection and management of diabetic kidney disease. Mayo Clin Proc 2008;83:1373-81.
3. Tuttle KR, Bakris GL, Bilous RW, et al. Diabetic kidney disease: a report from an ADA consensus conference. Diabetes Care 2014;37:2864-83.
4. Clinical Practice Guideline on management of patients with diabetes and chronic kidney disease stage 3b or higher (eGFR <45 mL/min)Nephrol Dial Transplant 2015;30: ii1-ii142.
5. KDOQI Clinical Practice Guideline for diabetes and CKD: 2012 updateAm J Kidney Dis 2012;60:850-86.
6. Chadban S, Howell M, Twigg S, et al. The CARI guidelines. Prevention and management of chronic kidney disease in type 2 diabetes. Nephrology (Carlton) 2010;15: S162-94.
7. Penfornis A, Blickle JF, Fiquet B, Quere S, Dejager S. How are patients with type 2 diabetes and renal disease monitored and managed? Insights from the observational OREDIA study. Vasc Health Risk Manag 2014;10:341-52.
8. Hill CJ, Cardwell CR, Patterson CC, et al. Chronic kidney disease and diabetes in the national health service: a cross-sectional survey of the U.K. national diabetes audit. Diabet Med 2014;31:448-54.
9. De Cosmo S, Viazzi F, Pacilli A, et al. Achievement of therapeutic targets in patients with diabetes and chronic kidney disease: insights from the Associazione Medici Diabetologi Annals initiative. Nephrol Dial Transplant 2015 Sept;30(9):1526-33.
10. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycaemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 2012;55:1577-96.
11. World Health Organisation (WHO). *People-centred health care—a policy framework*. 2007.
12. Mead EL, Doorenbos AZ, Javid SH, et al. Shared decision-making for cancer care among racial and ethnic minorities: a systematic review. Am J Public Health 2013;103:e15-29.
13. Speight J, Barendse SM. FDA guidance on patient reported outcomes. BMJ 2010;340, c2921.
14. Zimbudzi E, Lo C, Ranasinha S, et al. Self-management in patients with diabetes and chronic kidney disease is associated with incremental benefit in HRQOL. J Diabetes Complications 2017;31:427-32.
15. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet 2007;370:1453-7.
16. Lo C, Teede H, Fulcher G, et al. Gaps and barriers in health-care provision for co-morbid diabetes and chronic kidney disease: a cross-sectional study. BMC Nephrol 2017;18:80.
17. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res 2005;40:1918-30.
18. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care 2000;23:943-50.
19. Aljohani KA, Kendall GE, Snider PD. Psychometric Evaluation of the Summary of Diabetes Self-Care Activities-Arabic (SDSCA-Arabic): translation and analysis process. J Transcult Nurs 2016 Jan;27(1):65-72.
20. Jalaludin M, Fuziah M, Hong J, Mohamad Adam B, Jamaiyah H. Reliability and Validity of the Revised Summary of Diabetes Self-Care Activities (SDSCA) for Malaysian children and adolescents. Malays Fam Physician 2012;7:10-20.
21. Pagels AA, Soderkvist BK, Medin C, Hylander B, Heiwe S. Health-related quality of life in different stages of chronic kidney disease and at initiation of dialysis treatment. Health Qual Life Outcomes 2012;10:71.
22. Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.
23. Agrawal V, Jaar BG, Frisby XY, et al. Access to health care among adults evaluated for CKD: findings from the Kidney Early Evaluation Program (KEEP). Am J Kidney Dis 2012;59:S5-15.
24. Australian Bureau of Statistics. *Census of population and housing: Socio-Economic Indexes for Areas (SEIFA)*. 2011. [2033.0.55.001].
25. Stopford R, Winkley K, Ismail K. Social support and glycemic control in type 2 diabetes: a systematic review of observational studies. Patient Educ Couns 2013;93: 549-58.
26. Mayberry LS, Osborn CY. Family involvement is helpful and harmful to patients' self-care and glycemic control. Patient Educ Couns 2014 Dec;97(3):418-25. (1873-5134 (Electronic)).
27. Gao J, Wang J, Zheng P, Haardorfer R, et al. Effects of self-care, self-efficacy, social support on glycemic control in adults with type 2 diabetes. BMC Fam Pract 2013 May 24;14:66. (1471–2296 (Electronic)).
28. Jones RK, Hampton D, O'Sullivan DJ, Phillips AO. Diabetes and renal disease: who does what? Clin Med 2013;13:460-4.
29. Lo C, Teede H, Ilic D, et al. Identifying health service barriers in the management of co-morbid diabetes and chronic kidney disease in primary care: a mixed-methods exploration. Fam Pract 2016;33:492-7. [LID - cmw041 [pii]].
30. Israni RK, Shea JA, Joffe MM, Feldman HI. Physician characteristics and knowledge of CKD management. Am J Kidney Dis 2009;54:238-47.
31. Boulware LE, Troll MU, Jaar BG, Myers DI, Powe NR. Identification and referral of patients with progressive CKD: a national study. Am J Kidney Dis 2006;48:192-204.
32. Remmers C, Hibbard J, Mosen DM, Wagenfield M, Hoye RE, Jones C. Is patient activation associated with future health outcomes and healthcare utilization among patients with diabetes? J Ambul Care Manage 2009 Oct-Dec;32(4):320-7. (0148-9917 (Print)).
33. Rogvi S, Tapager I, Almdal TP, Schiotz ML, Willaing I. Patient factors and glycaemic control–associations and explanatory power. Diabet Med 2012 Oct;29(10):e382-9. (1464-–5491 (Electronic)).
34. Bolen SD, Chandar A, Falck-Ytter C, et al. Effectiveness and safety of patient activation interventions for adults with type 2 diabetes: systematic review, meta-analysis, and meta-regression. J Gen Intern Med 2014;29:1166-76.
35. Mayberry R, Willock RJ, Boone L, Lopez P, Qin H, Nicewander D. A High Level of Patient Activation Is Observed But Unrelated to Glycemic Control Among Adults With Type 2 Diabetes. Diabetes Spectr 2010 Jul 2;23(3):171-6. (1040–9165 (Print)).
36. Sacks RM, Greene J, Hibbard J, Overton V, Parrotta CD. Does patient activation predict the course of type 2 diabetes? A longitudinal study. Patient Educ Couns 2017 Jul;100 (7):1268-75. (1873–5134 (Electronic)).
37. Ryvicker M, Feldman PH, Chiu YL, Gerber LM. The role of patient activation in improving blood pressure outcomes in black patients receiving home care. Med Care Res Rev 2013 Dec;70(6):636-52. (1552–6801 (Electronic)).
38. Martinez YV, Campbell SM, Hann M, Bower P. The individual contribution and relative importance of self-management and quality of care on glycaemic control in type 2 diabetes. Salud Publica Mex 2016 Aug;58(4):404-11. (1606–7916 (Electronic)).
39. Schmitt A, Reimer A, Hermanns N, et al. Assessing Diabetes Self-Management with the Diabetes Self-Management Questionnaire (DSMQ) Can Help Analyse Behavioural Problems Related to Reduced Glycaemic Control. PLoS One 2016 Mar 3;11(3), e0150774. (1932-–6203 (Electronic)).
40. Egede LE, Osborn CY. Role of motivation in the relationship between depression, self-care, and glycemic control in adults with type 2 diabetes. Diabetes Educ 2010 Mar-Apr;36(2):276-83. (1554–6063 (Electronic)).
41. Weinberger M, Kirkman MS, Samsa GP, Cowper PA, et al. The relationship between glycemic control and health-related quality of life in patients with non-insulin-dependent diabetes mellitus. Med Care 1994;32:1173-81.
42. Davidson MB. SF-36 and diabetes outcome measures. Diabetes Care 2005;28:1536-7.
43. Quah JH, Luo N, Ng WY, Ch How, Tay EG. Health-related quality of life is associated with diabetic complications, but not with short-term diabetic control in primary care. Ann Acad Med Singapore 2011;40:276-86.
44. Gong Y, Handberg EM, Gerhard T, Cooper-Dehoff RM, et al. Systolic blood pressure and subjective well-being in patients with coronary artery disease. Clin Cardiol 2009;21:627-32.
45. Marques da Silva P, Haag U, Guest JF, Brazier JE, Soro M. Health-related quality of life impact of a triple combination of olmesartan medoxomil, amlodipine besylate and hydrochlorotiazide in subjects with hypertension. Health Qual Life Outcomes 2015;13.
46. Zygmuntowicz M, Owczarek A, Elibol A, Olszanecka-Glinianowicz M, Chudek J. Blood pressure for optimal health-related quality of life in hypertensive patients. J Hypertens 2013;31:830-9.
47. Adedapo AD, Akunne OO, Adedokun BO. Comparative assessment of determinants of health-related quality of life in hypertensive patients and normal population in south-west Nigeria. Int J Clin Pharmacol Ther 2015;53:265-71.

**Published manuscript: The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals in Australia: A qualitative study**

Citation: **Zimbudzi E**., Lo C., Robinson T., Ranasinha S., Teede HJ., Usherwood T., Polkinghorne KR., Kerr PG., Fulcher G., Gallagher M., Jan S., Cass A., Walker R., Russell G., Johnson G., Zoungas S. The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals in Australia: A qualitative study. PLoS ONE 14(7): e0219685. https://doi.org/10.1371/journal.pone.0219685

PLOS ONE

RESEARCH ARTICLE

# The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals in Australia: A qualitative study

**Edward Zimbudzi[1,2], Clement Lo[1,3], Tracy Robinson[1], Sanjeeva Ranasinha[1], Helena J. Teede[1,3], Tim Usherwood[4,5], Kevan R. Polkinghorne[2,6], Peter G. Kerr[2,6], Gregory Fulcher[7,8], Martin Gallagher[4,9], Stephen Jan[4,10], Alan Cass[4,11], Rowan Walker[12], Grant Russell[13], Greg Johnson[14], Sophia Zoungas[1,3,4]***

**1** School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia, **2** Department of Nephrology, Monash Health, Melbourne, Australia, **3** Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Australia, **4** The George Institute for Global Health, University of New South Wales, Sydney, Australia, **5** Department of General Practice, Sydney Medical School, University of Sydney, Sydney, Australia, **6** School of Clinical Sciences, Monash University, Melbourne, Australia, **7** Department of Diabetes, Endocrinology & Metabolism, Royal North Shore Hospital, University of Sydney, Sydney, Australia, **8** Northern Clinical School, University of Sydney, Sydney, Australia, **9** Concord Clinical School, University of Sydney, Sydney, Australia, **10** Sydney Medical School, University of Sydney, Sydney, Australia, **11** Menzies School of Health Research, Darwin, Australia, **12** Department of Renal Medicine, Alfred Health, Melbourne, Australia, **13** School of Primary Health Care, Monash University, Melbourne, Australia, **14** Diabetes Australia, Canberra, Australia

* sophia.zoungas@monash.edu

Check for updates

OPEN ACCESS

**Citation:** Zimbudzi E, Lo C, Robinson T, Ranasinha S, Teede HJ, Usherwood T, et al. (2019) The impact of an integrated diabetes and kidney service on patients, primary and specialist health professionals in Australia: A qualitative study. PLoS ONE 14(7): e0219685. https://doi.org/10.1371/journal.pone.0219685

**Editor:** Karen-Leigh Edward, Swinburne University of Technology, AUSTRALIA

**Received:** April 1, 2019

**Accepted:** June 30, 2019

**Published:** July 15, 2019

**Copyright:** © 2019 Zimbudzi et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

**Data Availability Statement:** All relevant data are within the paper and its Supporting Information files.

**Funding:** This study was supported by a National Health and Medical Research Council, Australia Partnership Grant (ID 1055175)-(URL https://www.nhmrc.gov.au/) between the following health services, research institutes and national consumer stakeholder groups – Alfred Health; Concord Hospital; Royal North Shore Hospital; Monash

## Abstract

### Background

To address guideline-practice gaps and improve management of patients with both diabetes and chronic kidney disease (CKD), we involved patients, health professionals and patient advocacy groups in the co-design and implementation of an integrated diabetes-kidney service.

### Objective

In this study, we explored the experiences of patients and health-care providers, within this integrated diabetes and kidney service.

### Methods

5 focus groups and 2 semi-structured interviews were conducted amongst attending patients, referring primary health professionals, and attending specialist health professionals. Maximal variation sampling was used for both patients and referring primary health professionals to ensure an equal representation of males and females, and patients of different CKD stages. All discussions were audiotaped and transcribed verbatim, before being thematically analysed independently by 2 researchers.

Health; Monash Centre for Health Research and Implementation, Monash University; The George Institute for Global Health, University of Sydney; Diabetes Australia; and Kidney Health Australia. CL was supported by an Australian Postgraduate Award Scholarship. HT was supported by a NHMRC, Australia Fellowship. SZ was supported by a National Heart Foundation of Australia Fellowship. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** The authors have declared that no competing interests exist.

## Results

The mean age (SD) for specialist health professionals, primary care professionals and patients who participated was 45 (11), 44 (15) and 68 (5) years with men being 50%, 80% and 76% of the participants respectively. Key strengths of the diabetes and kidney service were noted to be better integration of care and a perception of improved health and management of health. Whilst some aspects of access such as time between referral and initial appointment and having fewer appointments improved, other aspects such as in-clinic waiting times and parking remained problematic. Specialist health professionals noted that health professional education could be improved. Patient self-management was also noted by to be an issue with some patients requesting more information and some health professionals expressing difficulty in empowering some patients.

## Conclusions

Health professionals and patients reported that a co-designed integrated diabetes kidney service improved integration of care and improved health and management of health. However, some aspects of the process of care, health professional education and patient self-management remained challenging.

## Introduction

Multimorbidity, the co-occurrence of multiple chronic conditions in an individual, is increasing as our global population is living longer but with more chronic, non-communicable diseases [1, 2]. Patients with multimorbidity often have complex health needs which transcend the traditional disease-orientated specialist service approach and this may lead to fragmentation of and suboptimal care [2]. For example, patients with co-morbid diabetes and chronic kidney disease (CKD) often do not receive monitoring consistent with recommended standards of care such as regular HbA1c monitoring or screening for albuminuria, and many do not attain recommended glycaemic and blood pressure targets [3–9].

There is a clear need to integrate across specialty health services especially for patients with complex health-care needs such as those with both diabetes and CKD. Thus, we co-designed an integrated model of care for patients with both diabetes and CKD involving patients, health professionals and also consumer advocacy organisations (Diabetes Australia and Kidney Health Australia). This was informed by findings from a large multi-site formative evaluation of the barriers and enablers of optimal health-care for diabetes and CKD, and the needs of patients, carers, and their health professionals published [9–12]. The model of care has been described in detail previously [13], but key components of the integrated service are:

1. The primary health professional (general practitioner GP) remains the patient's primary care giver and coordinator of care
2. Specialist services are provided by an integrated diabetes-kidney service consisting of diabetes and renal physicians, nurse practitioners and a dietitian.
3. Care is person-centred, focusing on facilitating self-management of disease. A key component of this is a diabetes-kidney care plan that is given to the patient after each visit (to reinforce the management plan agreed upon by the service and the patient).
4. Care is structured according to an electronic history proforma.

5. To facilitate interdisciplinary management of each patient, each health professional manages both the patients' diabetes and CKD, with additional input from a health professional from the other specialty if required, and all patients are discussed at an end of clinic audit. An education program for staff was held prior to initiation of the service.
6. The diabetes-kidney service communicates with the patient's primary care home team/GP through–i) the same diabetes-kidney care plan that is given to a patient is sent to his/her GP via facsimile on the same day as the consultation ii) a dedicated phone advice service is available to allow GPs to in the event the GP requires clarification of treatment decisions or to seek advice on the management of acute issues.

The model of care (Diabetes Kidney Service) was implemented in 2016 at Monash Health, one of Australia's largest health service located across Melbourne's south-eastern suburbs.

Previous longitudinal and pre- and post-design audit studies have reported that combined diabetes and kidney service (similar to the one studied here) may improve clinical target attainment such as HbA1c [14, 15] and enhance patients' capacity to self-manage their diabetes [16, 17]. Additionally, these studies have suggested that such clinics may attenuate kidney function decline [14, 18, 19]. None of these studies have qualitatively explored the effect of combined services on both attending patients and health-care providers.

The objective of this study was to explore the experiences of patients and health-care providers, with a person-centred, integrated diabetes and kidney service located at Monash Health in the south eastern suburbs of Melbourne.

## Materials and methods

This qualitative study was underpinned by a pragmatic approach [20] and its design framework was guided by grounded theory [21]. Despite the limitations of using grounded theory with focus groups for data collection, the method was appropriate in this hard to reach population where we allowed themes to emerge in order to capture the participants' health care experiences [22]. We utilised focus groups amongst patients attending the service to explore their experiences and perspectives and triangulated findings with focus groups and semi-structured interviews of health-care providers from the service and primary health-care professionals referring to the service [23]. The study was approved by Monash Health and Monash University Human Research Ethics Committees.

### Participant selection

Patients with diabetes and CKD (stages 3–5, eGFR $< 60$ mL/min/1.73 $m^2$) attending the Diabetes Kidney Service were sampled purposively to ensure a diverse range of experiences was captured. Maximal variation sampling ensured adequate representation of both genders. Separate focus groups were facilitated with participants according to their CKD disease progression (stages 3, 4 and 5) because patients' experiences are likely to differ according to their CKD stage [11, 23]. All clinical staff from the service, and primary health professionals referring patients to the service (purposively sampled for information rich cases) were also recruited for two separate focus groups. Again, maximal variation sampling ensured adequate representation of both genders in the primary health-care focus group. As some of the primary health-care professionals could not logistically be involved in the focus groups, they participated in a separate semi-structured interview. All participants gave written consent, and patients were ensured that their involvement would not affect their normal medical treatment.

## Data collection and analysis

Discussion questions used for the focus groups and semi-structured interviews (S1 Table) were based on previous questions used in two prior qualitative studies concerning health-care of patients with diabetes and CKD [10, 11]. They were developed in consultation with one Endocrinologist and one Renal Nurse. The discussion were facilitated by the same experienced qualitative researcher (TR). Discussions were audiotaped verbatim, with another facilitator noting behavioural interactions. The de-identified audiotaped discussions were transcribed verbatim and analysed independently by two researchers (CL and EZ) using a generic inductive thematic approach [24, 25]. After immersing themselves in the data by reading the transcript several times, primary patterns within the data were identified and coded into themes in a constant comparative manner. Consensus of the emerging themes was then reached between the three researchers (CL, EZ and TR).

# Results

We conducted five focus groups with patients (CKD stages 3 to 5), specialist health professionals working within the Diabetes Kidney Service and primary care professionals. Additionally we performed two semi-structured interviews with primary care professionals who were not included in the focus group (Table 1). The mean [SD] ages for patients, specialist health professionals and primary care professionals who participated were 68 [5], 45 [11], and 44 [15] years with men being 76%, 50% and 80% of the participant populations respectively.

Six descriptive themes emerged (Table 2). Three themes were related to the strengths of the Diabetes Kidney Service and these were improved access to services, better integration of care and a perception of improved health and management of health. Three themes were related to

**Table 1. Demographic and professional roles of clinic and community participants.**

| ***Clinic participants (N = 6)*** | **N (Percentage)** |
|---|---|
| Demographics | |
| Male | 3 (50) |
| Mean age ± SD | 45± 11 years |
| Roles | |
| Nurse practitioners | 2 (33) |
| Endocrinologist | 1 (17) |
| Nephrologist | 1 (17) |
| Renal nurse | 1 (17) |
| Dietitian | 1 (17) |
| *Primary care professionals* (N = 5) | |
| Demographics | |
| Male | 4 (80) |
| Mean age ± SD | 44 ± 15 years |
| *Patients* (N = 21) | |
| Demographics | |
| Male | 16 (76) |
| Mean age ± SD | 68 ± 5 years |
| Chronic kidney disease stage | |
| 3 | 6 (29) |
| 4 | 9 (43) |
| 5 | 6 (29) |

https://doi.org/10.1371/journal.pone.0219685.t001

**Table 2. Illustrative quotes for themes.**

| Themes | Strengths of the service |
|---|---|
| Improved access to services | "The–yeah the whole processing of the referral where we refer and then the patient gets in, he's seen and then feedback is given back. So that timeframe has reduced drastically" Primary care professional 3. |
| Better integration and continuity of care | ". . .but because there's a variety of experts, they've all got different fields, actually; some are more diabetes, some are more kidney, and whatever else. And I think that is important, that—because they're interlinked with one another. . ." CKD 3 patient 24. |
| Perception of improved health and management of health | "The feedback from the patient was good. She seemed to be well taken care of. Perhaps this is a touch different I think" Primary care professional 1. |
| | **Areas for improvement** |
| Process of care | "Yeah. If there was some way that they could maybe, I don't know, shorten that–that waiting time or to give an individual–oh it's difficult I know to give everybody individual times" CKD 4 patient 15. |
| Health professional education | "And just a last point on team education, we did have, early on, some idea about doing regular team, sort of, education sessions and I think—I think that'd be worthwhile to pursue, you know, sort of like a diabetes update, or maybe a renal update, maybe you know, once every six months or something" Specialist health professional 5. |
| Patient self-management | "Yeah because every time you consult a kidney doctor or a diabetic doctor, they only concentrate on that curative method not on the preventive one" CKD 4 patient 12. |

https://doi.org/10.1371/journal.pone.0219685.t002

areas for improvement and these were improving the process of care, health professional education and patient self-management.

## Strengths of the service

**Improved access to services.** Some primary care professionals who refer patients to the Diabetes Kidney Service felt that referrals for new patients were triaged and processed in a timely way compared to other individual specialist services.

> "*The–yeah the whole processing of the referral where we refer and then the patient gets in, he's seen and then feedback is given back. So that timeframe has reduced drastically" Primary care professional 3.*

> "*I had the same idea with the referral. Before it was quite hard but now it is–the referral process is very good. There's some patients that I–that I think that it needs to be followed up by the diabetic clinic" Primary care professional 4.*

Additionally, one primary care professional felt that the referral process was simplified and the Diabetes Kidney Service staff were always available to facilitate this.

> "*The access to the clinic was pretty easy. She told me exactly where to send it and what to put on there as far as which consultant to name and etc. And she got an appointment within 2 to 3 weeks" Primary care professional 1.*

There was consensus among all participants that the Diabetes Kidney Service resulted in fewer appointments for patients who were already faced with the possibility of attending multiple clinics due to their comorbid conditions.

"*I think for the patients they've got at least one less appointment" Specialist health professional 4.*

"*. . .in Dandenong, I'll be so happy. So, they put both together and they made it the kidney and diabetic clinic for me so that I don't have to go to two places. You know, it's always appointments, appointments" CKD 4 patient 11.*

**Better integration and continuity of care.** Patients were confident that having staff from two specialities working together improved the quality and integration of care.

"*. . .but because there's a variety of experts, they've all got different fields, actually; some are more diabetes, some are more kidney, and whatever else. And I think that is important, that —because they're interlinked with one another. . ." CKD 3 patient 24.*

Specialist health professionals working at the Diabetes Kidney Service also identified better integration of care as a key strength of the service.

"*I think the aim of trying to address multiple comorbidities is also a very good aim, so I think that's also a strength of the service. And having the interaction with our diabetes colleagues, from my perspective has been good in terms of learning more about diabetes management, so it's been good for that, for my own personal learning, to learn more about diabetes and the diabetes service and how that works. So, there's quite a few strengths" Specialist health professional 5.*

Participants thought that the processes of the Diabetes Kidney Service resulted in better communication between specialist health professionals and primary care professionals. In particular, the process of sending each patients' Diabetes-Kidney care plan to primary care after each appointment was notably effective.

"*The feedback that we get is quite detailed. There is a general particular template that they follow" Primary care professional 3.*

"*I've got 5 to 6 patients and I haven't had any bad feedback. The notes are actually pretty good" Primary care professional 2.*

A majority of specialist health staff working within the Diabetes Kidney Service identified continuity of care as one of the key strengths of the service. Some patients viewed continuity of care as being seen by the same health professional every time they present for clinic and they felt that they were not being seen regularly by the health professionals they were comfortable with.

"*I like the continuity of the patients, because you get to know them and it makes for an easier consult, and I think it's nicer for them" Specialist health professional 7.*

"*I want to say that why don't we have the same specialist every time we come to clinic? Why do they keep on changing?" CKD 3 patient 17.*

**Perception of improved health and management of health.** A number of patients felt that they were enjoying better health and were able to manage their health better due to attending the Diabetes Kidney Service.

"*So I have to control all that. And by doing all this, I think I can achieve. And the support, what you get from the centre, the centre here, I think is fantastic" CKD 3 patient 23.*

"*Yes. Yeah. I feel—I feel coming here doing my blood test before—the week before when I come here, that's normal, 14, anyway, that they keep me on track and, if something should be going off track, they will warn me, and that's important to me" CKD 3 patient 24.*

One primary care professional noted an improvement in their patients' health which they attributed to the Diabetes Kidney Service.

"*The feedback from the patient was good. She seemed to be well taken care of. Perhaps this is a touch different I think" Primary care professional 1.*

## Areas for improvement

**Process of care.** All participants generally agreed that the process of care for the Diabetes Kidney Service needed to be improved. Patients felt that they were spending a lot of time in the waiting room before being seen.

"*Yeah. If there was some way that they could maybe, I don't know, shorten that–that waiting time or to give an individual–oh it's difficult I know to give everybody individual times" CKD 4 patient 15.*

Additionally, patients reported prolonged consultations due to interruptions that occurred during their review.

"*The service here is good, but sometimes I find—after waiting a couple of hours to see the specialist, I find that they're interrupted a lot by other people coming in to find out—to ask a question. . ." CKD 3 patient 19.*

Specialist health professionals were also concerned by these interruptions and they understood that this could have a negative impact on the process of care within the service. However, they accepted that this practice was the nature of an integrated clinic.

"*My constant concern that I'm always nagging the consultants but I understand that that's part of the role and, and I don't know how that impacts on the patients as well" Specialist health professional 7.*

Both patients and specialist health professionals highlighted that the service had limited physical space. This led to the waiting room being crowded at times.

"*The aesthetics of the room; probably can't do anything about that, but that little area does get very, very crowded around the 10 o'clock time, and so forth" CKD 3 patient 20.*

Patients, primary care professionals and specialist health professionals suggested that the service could be improved by integrating with other specialties, decentralising the service and increasing the number of staff members who work within the service.

"*But the thing that I find really frustrating is that all of–well many of these diabetic people who have kidney disease also have cardiac disease and you don't have a triple clinic" Primary care professional 5.*

It was noted that if the number of staff members working within the service is increased, this would need to be matched with an increase in physical space. To help manage the currently available space, one specialist health professional suggested increasing the support given to primary care.

"*And that's perhaps where we could build the capacity with the primary care in terms of being a liaison type, kind of like what we're doing with that travelling person. We could sort of, provide that peripheral support, which is keeping people in their primary care setting" Specialist health professional 7.*

In addition, some health professionals identified a need to streamline the referral criteria so that only patients who can benefit from the service are referred to the service.

"*And having, just some clearer referrals so that some of those patient who perhaps could be seen, are not being missed" Specialist health professional 3.*

**Health professional education.** Primary care professionals wanted more renal education specifically on guidelines, when to make a referral to a nephrologist and dialysis. The specialist health professionals within the Diabetes Kidney Service reflected on the success of an education session they had a few years back and thought that this would be beneficial to current and new staff to the service.

"*I find that the diabetes side of things is very well dealt with in educational sessions for doctors. . .. But we have very little education on the renal side of things. There's hardly ever a topic to do with the kidney" Primary care professional 5.*

"*And just a last point on team education, we did have, early on, some idea about doing regular team, sort of, education sessions and I think—I think that'd be worthwhile to pursue, you know, sort of like a diabetes update, or maybe a renal update, maybe you know, once every six months or something" Specialist health professional 5.*

**Patient self-management.** Most patients reported that the education and health support they received enhanced their self-management. Some patients thought that current self-management support was adequate and that there was an opportunity to reinforcing their current knowledge.

*". . .because I said it before, it's important to have that six-monthly or four-monthly, whatever it may be, reinforcement of, "Yeah, you're on the right track" or, "You're not dying tomorrow" or whatever. . ." CKD 3 patient 24.*

However, others found the education repetitive, with some patients taking the initiative to find their own patient education material.

"*Yes, so it's repeating the whole thing or what I know" CKD 4 patient 11.*

Still other patients found the education material inadequate, and wanted more patient education.

"*Yeah because every time you consult a kidney doctor or a diabetic doctor, they only concentrate on that curative method not on the preventive one" CKD 4 patient 12.*

"*Can they give us a diet for the kidneys to improve it? Yeah diet for the kidneys? Not to improve it, just to–yeah to keep it stable" CKD 4 patient 10.*

On the other hand, some health professionals reported that certain patients took longer to process information and needed more support in self-management. This variation in experiences exemplifies the need for patient education and the level of self-management support to be tailored and individualised to the patient. This point was highlighted by both patients and health professionals.

"*I don't know how they could possibly—whether there's a flag on the software that says, "Look, this person probably understands quite a bit and just is too lazy to do it" as opposed to, "This person's new to diabetes and hasn't got the knowledge" and then it may make their time more efficient" CKD 3 patient 20.*

"*. . .all the patients seeing so many practitioners or dieticians in the one session, and then they can be somewhat overwhelmed, so they may be a bit disgruntled with the information or the education that they're given due to the memory and their. . .ability to recall, and I'm wondering, there seems to be some patients who are really organised with their bringing in a folder of heir glucose, bringing in that folder, having what medications they're on and so on" Specialist health professional 3.*

## Discussion

This qualitative study involving patients with diabetes and CKD, primary care professionals and specialist health professionals identified three key strengths and three areas of improvement for the new integrated diabetes kidney service. The strengths were improved access to services, better integration of care and perception of improved health and management of health. Potential areas for improvement were the process of care, health professional education and patient self-management.

Patients and primary care professionals reported improved access to healthcare through the integrated diabetes and kidney service. The ability of the service to merge two specialist appointments to at least one appointment is likely to improve attendance leading to improved outcomes such as better glycaemic control [26]. The primary care professionals attributed improved access to presence of clear communication from the time of referral up to the time the patient is seen in the Diabetes Kidney Service. However, some primary care professionals were not familiar with the referral criteria highlighting the need for disseminating information about the service to all the primary care professionals within the catchment area of the Diabetes Kidney Service.

All the participants pointed out that the service had resulted in better integration of care. However, primary care professionals thought that the service could be improved further by incorporating other specialties such as cardiology as most of the patients with comorbid diabetes and CKD have cardiovascular diseases. One study reported cost savings when a diabetes and kidney service had cardiology input [27]. However, no patient reported outcomes such as health related quality of life have been reported. An evaluation of the health-related quality of life of patients attending the Diabetes Kidney Service is currently being done.

Perception of improved health and management of health was identified as an important outcome of the Diabetes Kidney Service by both patients and primary care professionals. Patients thought that they were engaged in their care and that necessary investigations were done in the service to monitor their progress. Additionally, primary care professionals received

positive feedback about the service from their patients and they also noted that some patients felt better. This could have been due to improvements in clinical outcomes such HbA1c and eGFR as reported previously [28].

Health professional education was highlighted by both primary care professionals and specialist health professionals as an important area for improvement. In this regard, the service may need to address the professional development needs of both primary care professionals and specialist health professionals to promote effective delivery of integrated care. This can be done by implementing rigorous on boarding practices for new clinicians, networking with organisations who have similar integrated models of care and providing learning opportunities to existing personnel through multidisciplinary meetings [29]. It is important, however, to engage both the service users and clinicians in the development and delivery of targeted education programs.

One of the key features of the Diabetes Kidney Service is its ability to incorporate patient self-management education. In this study, some patients preferred the education to be tailored to their needs to avoid having the same information repeated regularly. To effectively address the self-management education needs of patients, the service may need to develop self-management algorithms specific to people with comorbid diabetes and CKD. Up till now, self-management algorithms have been successfully used for patients with type 2 diabetes [30] and these may need to be adapted to suit patients with comorbid diabetes and CKD. Additionally, electronic and mobile education and self-management approaches have been shown to be effective in education and promoting behaviour change in patients with type 2 diabetes [31–33]. This could be extrapolated to and explored in patients with co-morbid diabetes and CKD, to allow individual dose adjustment, reduce cost and health provider burden and address barriers around education and self-empowerment.

The strengths of this study include the rigor in the methodology where two researchers were involved in data synthesis and development of themes. Additionally, the perspectives of all groups of key stake-holders utilising, referring to, or involved in the integrated service were captured, enabling triangulation of data.

Overall, health professionals and patients reported that a co-designed integrated diabetes kidney service improved integration of care and improved health and management of health. However, some aspects of the process of care, health professional education and patient self-management needed improvement highlighting the need to address some patient, health professional and health system barriers to health care.

## Supporting information

**S1 Table. Patient and health professional interview questions.** Interview questions.
(DOCX)

## Acknowledgments

We acknowledge S Chaviaras, D Giannopoulos, R McGrath and S Coggan for help in study conduct.

## Author Contributions

**Conceptualization:** Edward Zimbudzi, Clement Lo, Helena J. Teede, Tim Usherwood, Kevan R. Polkinghorne, Peter G. Kerr, Gregory Fulcher, Martin Gallagher, Stephen Jan, Alan Cass, Rowan Walker, Grant Russell, Greg Johnson, Sophia Zoungas.

**Data curation:** Edward Zimbudzi, Clement Lo, Tracy Robinson, Sophia Zoungas.

**Formal analysis:** Edward Zimbudzi, Clement Lo, Tracy Robinson, Sanjeeva Ranasinha, Sophia Zoungas.

**Funding acquisition:** Clement Lo, Sophia Zoungas.

**Investigation:** Edward Zimbudzi, Clement Lo, Sophia Zoungas.

**Methodology:** Edward Zimbudzi, Clement Lo, Sophia Zoungas.

**Project administration:** Edward Zimbudzi, Clement Lo, Sophia Zoungas.

**Resources:** Sophia Zoungas.

**Supervision:** Clement Lo, Helena J. Teede, Peter G. Kerr, Sophia Zoungas.

**Writing – original draft:** Edward Zimbudzi.

**Writing – review & editing:** Edward Zimbudzi, Tracy Robinson, Sanjeeva Ranasinha, Helena J. Teede, Tim Usherwood, Kevan R. Polkinghorne, Peter G. Kerr, Gregory Fulcher, Martin Gallagher, Stephen Jan, Alan Cass, Rowan Walker, Grant Russell, Greg Johnson, Sophia Zoungas.

## References


1. Kurella Tamura M, Li S, Chen SC, Cavanaugh KL, Whaley-Connell AT, McCullough PA, et al. Educational programs improve the preparation for dialysis and survival of patients with chronic kidney disease. Kidney Int. 2014;85. https://doi.org/10.1038/ki.2014.216
2. Palmer K, Marengoni A, Forjaz MJ, Jureviciene E, Laatikainen T, Mammarella F, et al. Multimorbidity care model: Recommendations from the consensus meeting of the Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle (JA-CHRODIS). (1872–6054 (Electronic)).
3. Hill CJ, Cardwell CR, Patterson CC, Maxwell AP, Magee GM, Young RJ. Chronic kidney disease and diabetes in the national health service: a cross-sectional survey of the U.K. national diabetes audit. Diabet Med. 2014;31. https://doi.org/10.1111/dme.12266
4. Penfornis A, Blickle JF, Fiquet B, Quere S, Dejager S. How are patients with type 2 diabetes and renal disease monitored and managed? Insights from the observational OREDIA study. Vascular health and risk management. 2014; 10:341–52. https://doi.org/10.2147/VHRM.S60312 PMID: 24966684
5. Hill CJ, Cardwell CR, Patterson CC, Maxwell AP, Magee GM, Young RJ, et al. Chronic kidney disease and diabetes in the national health service: a cross-sectional survey of the U.K. national diabetes audit. Diabet Med. 2014; 31(4):448–54. https://doi.org/10.1111/dme.12312 PMID: 24102856
6. De Cosmo S, Viazzi F, Pacilli A, Giorda C, Ceriello A, Gentile S, et al. Achievement of therapeutic targets in patients with diabetes and chronic kidney disease: insights from the Associazione Medici Diabetologi Annals initiative. Nephrol Dial Transplant. 2015.
7. Stevens PE, Schernthaner G, Raptis S, Wanner C, Scherhag A, Lameire N. Characteristics, cardiovascular comorbidity and medicines management in patients with type 2 diabetes and CKD: results of the IRIDIEM study. Kidney & blood pressure research. 2010; 33(2):119–28.
8. 2014 US Renal Data System Annual Data Report Volume 1: Chronic Kidney Disease. Ann Arbor, Michigan: USRDS Coordinating Center; 2014.
9. Lo C, Teede H, Fulcher G, Gallagher M, Kerr PG, Ranasinha S, et al. Gaps and barriers in health-care provision for co-morbid diabetes and chronic kidney disease: a cross-sectional study. BMC Nephrol. 2017; 18(1):80. https://doi.org/10.1186/s12882-017-0493-x PMID: 28245800
10. Lo C, Ilic D, Teede H, Cass A, Fulcher G, Gallagher M, et al. The Perspectives of Patients on Health-Care for Co-Morbid Diabetes and Chronic Kidney Disease: A Qualitative Study. PloS one. 2016;Jan 5; 11(1):e0146615. https://doi.org/10.1371/journal.pone.0146615 PMID: 26730708
11. Lo C, Ilic D, Teede H, Fulcher G, Gallagher M, Kerr PG, et al. Primary and tertiary health professionals' views on the health-care of patients with co-morbid diabetes and chronic kidney disease—a qualitative study. BMC Nephrol. 2016; 17(1):50. https://doi.org/10.1186/s12882-016-0262-2 PMID: 27189462
12. Lo C, Teede H, Ilic D, Russell G, Murphy K, Usherwood T, et al. Identifying health service barriers in the management of co-morbid diabetes and chronic kidney disease in primary care: a mixed-methods exploration. LID—cmw041 [pii]. Fam Pract. 2016; 33(5):492–7. https://doi.org/10.1093/fampra/cmw041 PMID: 27256480

13. Lo C, Zimbudzi E, Teede H, Cass A, Fulcher G, Gallagher M, et al. Review: An Australian model of care for co-morbid diabetes and chronic kidney disease. Nephrology (Carlton). 2018.
14. Bayliss EA, Bhardwaja B, Ross C, Beck A, Lanese DM. Multidisciplinary team care may slow the rate of decline in renal function. Clin J Am Soc Nephrol. 2011; 6(4):704–10. https://doi.org/10.2215/CJN.06610810 PMID: 21273376
15. Kutz TL, Roszhart JM, Hale M, Dolan V, Suchomski G, Jaeger C. Improving comprehensive care for patients with diabetes. BMJ Open Quality. 2018; 7(4):e000101. https://doi.org/10.1136/bmjoq-2017-000101 PMID: 30397656
16. McGill M, Blonde L, Chan JCN, Khunti K, Lavalle FJ, Bailey CJ. The interdisciplinary team in type 2 diabetes management: Challenges and best practice solutions from real-world scenarios. J Clin Transl Endocrinol. 2017; 7:21–7. https://doi.org/10.1016/j.jcte.2016.12.001 PMID: 29067246
17. Lorig K, Ritter PL, Turner RM, English K, Laurent DD, Greenberg J. A Diabetes Self-Management Program: 12-Month Outcome Sustainability From a Nonreinforced Pragmatic Trial. J Med Internet Res. 2016; 18(12):e322. https://doi.org/10.2196/jmir.6484 PMID: 27979790
18. Jiamjariyapon T, Ingsathit A, Pongpirul K, Vipattawat K, Kanchanakorn S, Saetie A, et al. Effectiveness of Integrated Care on Delaying Progression of stage 3–4 Chronic Kidney Disease in Rural Communities of Thailand (ESCORT study): a cluster randomized controlled trial. BMC Nephrol. 2017; 18(1):83–. https://doi.org/10.1186/s12882-016-0414-4 PMID: 28253839
19. Chen PM, Lai TS, Chen PY, Lai CF, Yang SY, Wu V, et al. Multidisciplinary Care Program for Advanced Chronic Kidney Disease: Reduces Renal Replacement and Medical Costs. The American Journal of Medicine. 2015; 128(1):68–76. https://doi.org/10.1016/j.amjmed.2014.07.042 PMID: 25149427
20. Pistrang N, Barker C. Varieties of qualitative research: A pragmatic approach to selecting methods. APA handbook of research methods in psychology, Vol 2: Research designs: Quantitative, qualitative, neuropsychological, and biological. Washington, DC, US: American Psychological Association; 2012. p. 5–18.
21. Chun Tie Y, Birks M, Francis K. Grounded theory research: A design framework for novice researchers. SAGE open medicine. 2019; 7:2050312118822927. https://doi.org/10.1177/2050312118822927 PMID: 30637106
22. Foley G, Timonen V. Using Grounded Theory Method to Capture and Analyze Health Care Experiences. Health services research. 2015; 50(4):1195–210. https://doi.org/10.1111/1475-6773.12275 PMID: 25523315
23. Krueger RA, Casey, Mary Anne. Focus Groups: A practical guide for applied research. Thousand Oaks, California: Sage; 2009.
24. Harding J. Qualitative Data Analysis from Start to Finish. Thousand Oaks, California: Sage; 2013.
25. Kahlke RM. Generic Qualitative Approaches: Pitfalls and Benefits of Methodological Mixology. International Journal of Qualitative Methods. 2014; 13(1):37–52.
26. Zhang X, Bullard KM, Gregg EW, Beckles GL, Williams DE, Barker LE, et al. Access to health care and control of ABCs of diabetes. Diabetes Care. 2012; 35(7):1566–71. https://doi.org/10.2337/dc12-0081 PMID: 22522664
27. Weber C, Beaulieu M, Djurdjev O, Er L, Taylor P, Ignaszewski A, et al. Towards rational approaches of health care utilization in complex patients: an exploratory randomized trial comparing a novel combined clinic to multiple specialty clinics in patients with renal disease-cardiovascular disease-diabetes. Nephrol Dial Transplant. 2012; 27 Suppl 3:iii104–10.
28. Low S, Lim SC, Wang J, Yeoh LY, Liu YL, Lim EK, et al. Long-term outcomes of patients with type 2 diabetes attending a multidisciplinary diabetes kidney disease clinic. J Diabetes. 2018; 10(7):572–80. https://doi.org/10.1111/1753-0407.12626 PMID: 29154443
29. Hall J, Cohen DJ, Davis M, Gunn R, Blount A, Pollack DA, et al. Preparing the Workforce for Behavioral Health and Primary Care Integration. J Am Board Fam Med. 2015; 28 Suppl 1:S41–51.
30. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes Self-Management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. J Acad Nutr Diet. 2015; 115(8):1323–34. https://doi.org/10.1016/j.jand.2015.05.012 PMID: 26054423
31. Alotaibi MM, Istepanian R, Philip N. A mobile diabetes management and educational system for type-2 diabetics in Saudi Arabia (SAED). mHealth. 2016; 2:33–. https://doi.org/10.21037/mhealth.2016.08.01 PMID: 28293606
32. Hou C, Xu Q, Diao S, Hewitt J, Li J, Carter B. Mobile phone applications and self-management of diabetes: A systematic review with meta-analysis, meta-regression of 21 randomized trials and GRADE. Diabetes Obes Metab. 2018; 20(8):2009–13. https://doi.org/10.1111/dom.13307 PMID: 29582538

33. El-Gayar O, Timsina P, Nawar N, Eid W. Mobile Applications for Diabetes Self-Management: Status and Potential. Journal of Diabetes Science and Technology. 2013; 7(1):247–62. https://doi.org/10.1177/193229681300700130 PMID: 23439183

**Table S1**: Patient and health professional interview questions

| **Patients** | **Health Professionals** |
|---|---|
| What are the strengths of the Diabetes Kidney Service (DKS)? | Think about the experiences that you have had with the DKS at Monash Health; |
| What impact has attending the DKS made to your health? | What are the strengths of the Diabetes kidney service? |
| What are the weaknesses of the DKS? | What impact has attending the DKS made to patients' health? |
| How easy is it to get the healthcare that you need from the DKS (locality, cost, waiting times and parking)? | What are the weaknesses of the DKS? |
| How could this be improved? | How accessible do you think current health services are to patients? |
| Have you ever missed out a DKS disease appointment if so why? | What could be done to make health services more accessible to patients (locality, cost, waiting times and parking)? |
| What do you think about the education provided to help manage your diabetes and kidney disease? How could it be improved? | What do you think about the education provided to help manage patients' diabetes and kidney disease? How could it be improved? |
| In your experience, what aspects of the health service could be improved? | In your experience, what aspects of the health service could be improved? |
| Is there anything that we have missed or that you came wanting to say that you haven't? | Is there anything that we have missed or that you came wanting to say that you haven't? |

**Published manuscript: How much is enough? An investigation of the relationship between haemodialysis adequacy and quality of life of elderly patients**

Citation: **Zimbudzi E**., Samlero R., Kerr PG., Zoungas S. How much is enough? An investigation of the relationship between haemodialysis adequacy and quality of life of elderly patients. Nephrology 2016; 21: 314–320.

NEPHROLOGY

*Nephrology* **21** (2016) 314–320

Original Article

# How much is enough? An investigation of the relationship between haemodialysis adequacy and quality of life of elderly patients

EDWARD ZIMBUDZI,[1,2] REGGIE SAMLERO,[1] PETER G KERR[1] and SOPHIA ZOUNGAS[2,3,4]

[1]Department of Nephrology, Monash Health and Monash University, Melbourne, Victoria, Australia [2]Monash Centre for Health Research and Implementation – MCHRI, School of Public Health and Preventive Medicine, Monash University, Melbourne, Victoria, Australia [3]Diabetes and Vascular Medicine Unit, Monash Health, Melbourne, Victoria, Australia and [4]The George Institute for Global Health, University of Sydney, Sydney, New South Wales, Australia

**KEY WORDS:**
comorbidity, dialysis adequacy, elderly, quality of life, urea reduction ratio.

**Correspondence:**
Mr Edward Zimbudzi, Monash Centre for Health Research and Implementation – MCHRI, School of Public Health and Preventive Medicine, Monash University, Level 1, 43–51 Kanooka Grove, Clayton, Vic. 3168, Australia. Email: edward.zimbudzi@monash.edu

Accepted for publication 15 August 2015.
Accepted manuscript online 15 September 2015.

doi: 10.1111/nep.12594

**Conflicts of interest:** The authors declare no conflict of interest

## SUMMARY AT A GLANCE

A small but important study looking at the quality of life in elderly patients on hemodialysis. The study suggested that a higher dose of hemodialysis is not associated with an improved quality of life.

## ABSTRACT:

*Aim:* **The average age of patients requiring haemodialysis is on the rise and has resulted in an increase in the number of elderly people receiving dialysis. While haemodialysis is one of the treatment options for this patient group, questions about its effectiveness have been raised. A second question centres on how much haemodialysis is actually needed to maintain quality of life (QoL). This study examined the relationship between dialysis adequacy and the QoL of elderly patients on haemodialysis.**

*Method:* **A prospective cohort of 40 haemodialysis patients aged 75 years and above was recruited and studied over 3 months. Quality of life was assessed with the European Quality of Life-5 Dimensions questionnaire and dialysis adequacy with the urea reduction ratio (URR), and the relationship between the two examined using a simple linear regression model.**

*Results:* **The average age of the participants was 79.8 ± (3.9 years; 45% were women, and diabetes was the main cause of kidney disease (42.5%). The mean URR, visual analogue scale, European Quality of Life-5 Dimensions indices score and Charlson comorbidity index scores were 78.1 ± (5.5)%, 65.4 ± (13.7)%, 0.7 ± (0.27) and 6.3 ± (2.15), respectively. There was no clear relationship between dialysis adequacy and QoL, $r = 0.093$. Dialysis adequacy did not significantly predict QoL ($P = 0.09$).**

*Conclusion:* **There was no evidence for an association between haemodialysis adequacy and QoL in elderly patients receiving haemodialysis across a URR range of 64.0% to 88.9%. Attempts to improve dialysis adequacy beyond these levels may not be necessary for maintaining the QoL of elderly patients on dialysis.**

*Key message:* **Modern therapy should embrace the concept of quality of life and focus more on symptom relief and optimization of self-management skills to improve the well-being of the elderly patients with ESKD.**

The average age of patients undergoing renal replacement therapy is on the rise. The United States Renal Data System reported that 26% of all patients commenced on haemodialysis in 2011 were over the age of 75 years (26 639 patients).[1] In Australia, 452 patients (21% of all new cases) in this age group were started on haemodialysis in 2012.[2] The 2013 Australian and New Zealand Dialysis and Transplantation Registry further revealed that there were 2484 people aged 75 years and above receiving haemodialysis, being 27% of all haemodialysis patients, and this number includes 447 people aged over 85 years, a rise of 7% from 2011.[2] This trend has been attributed to an increase in the life expectancy, improvement of the therapeutic arsenal, and knowledge and control of comorbid diseases.[3] As a result, the number of elderly patients requiring replacement therapy is growing. Several studies have also noted this drastic increase of the elderly population receiving dialysis.[4–6]

There are several challenges associated with caring for elderly patients on dialysis. Most of the problems stem from the complexity of their comorbidities, need for interdisciplinary care and assessment of their functional status,[3] late referrals, limited treatment alternatives, difficulties with dialysis vascular



© 2015 Asian Pacific Society of Nephrology

access[6] and the need to balance their quality of life (QoL) with a suitable therapeutic approach. The benefit of dialysis to this population group has received widespread scrutiny. Demoulin and associates in a Belgian study concluded that octogenarians with chronic kidney disease were more prone to dying of an associated comorbidity than to need dialysis,[7] and Chandna and colleagues report no differences in survival between the elderly who were on dialysis and those who had conservative management.[8]

Currently, there is ambiguity on who should be commenced on dialysis in this older age group, the dose they should receive and when they should cease treatment because of their accumulated comorbidities. The use of reliable and valid assessment and prognostic tools is therefore recommended as well as the evaluation of the QoL of elderly patients with end-stage kidney disease (ESKD). QoL assessment helps to plan the individual strategy of treatment, to determine the efficacy of medical intervention, and to evaluate the quality of medical care.[9] Patients' perception of their symptoms is a critical determinant of their mental and physical well-being.[10] For patients commenced on dialysis, inadequacy of haemodialysis is one of the determinants of morbidity and mortality. The purpose of this study was to examine the relationship between QoL and haemodialysis adequacy with an overall objective of gaining vital information that could be embraced in the design of suitable medical and self-management interventions for elderly patients even before they commence dialysis.

## METHODS

This single-centre, prospective cohort study took place at an acute dialysis unit of a large public teaching hospital located in the south-eastern part of Melbourne, Australia, which caters for approximately 450 haemodialysis patients dialysing at satellite centres within its catchment area. The study was conducted between January 2013 and June 2014.

There were 81 patients aged 75 years and above who received haemodialysis at this unit. Those on haemodialysis for at least 3 months, English speaking and not having cognitive impairment, dementia, active psychosis or terminal illnesses were invited to participate ($n = 51$), and 40 agreed to participate and provided informed consent.

According to the a priori sample size calculation by G*Power, a statistical analysis program developed by Faul and associates,[11] a sample size of 33 was required to detect at least a moderate effect (d=0.4) on the European Quality of Life-5 Dimensions Visual Analogue Scale (EQ-5D-VAS) on a significance level of 5% (two-tailed) with a statistical power of 80%. To account for possible attrition, we increased the sample size to 40 participants. Cohen's *d* effect size was interpreted as follows: small (0.2), medium (0.5) or large (0.8).[12] A medium effect size on the EQ-5D-5L VAS has been previously reported to be medium.[13,14]

The questionnaires were administered by trained dialysis staff during the participants' midweek dialysis session. The participants were followed up for 3 months, and they had their routine monthly bloods and assessment of study outcomes performed during this period. The 3 months follow-up period was chosen as the most pragmatic period over which complete data collection could be achieved. Given the widely reported high attrition levels[15–18] observed in studies of this cohort of patients and our sample size, a longer follow-up period may have resulted in loss of a significant number of participants, thereby affecting the overall power the overall power of the study to show any difference. The study received ethical approval from Monash Health (HREC Ref: 12396L).

### Outcome variable

#### Quality of life

The primary outcome for this study was QoL. Health-related QoL was measured with the EQ-5D-5L questionnaire,[19] which has been shown to be feasible, reliable and valid by previous studies.[20–22] Gerard and colleagues[23] also suggest that in patients undergoing haemodialysis, and potentially older chronically ill patient groups, EQ-5D is the primary preference-based generic health-related QoL instrument because older people find it easier to follow and complete. The questionnaire uses five dimensions, which describe an individual's self-rated QoL, and these are mobility, self-care, usual care, pain/discomfort and anxiety/depression. The respondents have an opportunity to rate themselves according to five levels of severity, which are no problems, slight problems, moderate problems, severe problems and extreme problems. For this study, the EQ-5D-5L-reported problems were dichotomized into 'no problems' (level 1) and 'problems' (levels 2 to 5), thereby changing the profile into frequencies of reported problems (Fig. 1). The EQ-5D-5L also uses a VAS with the end points labelled best imaginable health state at the top and worst imaginable health state at the bottom having numeric values of 100 and 0, respectively.

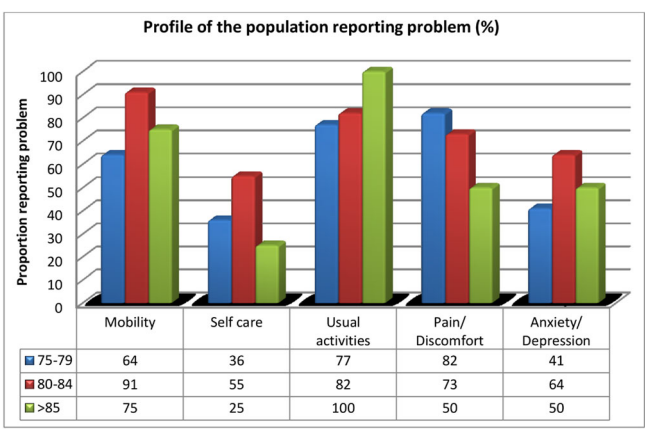



**Fig. 1** Frequency of reported problems by dimension and age group.

© 2015 Asian Pacific Society of Nephrology

Participants were asked to mark on the scale an estimate of what their health status was on the day they completed the questionnaire.

### Predictor variables

Dialysis adequacy was measured using the urea reduction ratio (URR). A URR is a number expressed as a percentage that is used to quantify dialysis treatment adequacy. The URR was calculated by (pre-dialysis$_{urea}$ − post-dialysis$_{urea}$) divided by pre-dialysis$_{urea}$, and it was expressed as a percentage. Available literature has suggested that a URR >65% improves the outcome of patients on haemodialysis;[2,24,25] hence, 65% is the minimum accepted level. Blood tests for urea were obtained pre-dialysis and post-dialysis in the third week of every month for 3 months, and the average result was used. This method was meant to reduce bias because serum urea levels may be confounded by other variables such as diet.

The demographic characteristics of the participants were recorded as well as the time that each patient spent on dialysis also known as dialysis duration, another important measure of dialysis adequacy.

### Comorbidity

The Charlson comorbidity index (CCI) was used to quantify comorbidity.[26] Based on the CCI score, the severity of comorbidity was categorized into three grades[27]: mild, with CCI scores of 1–2; moderate, with CCI scores of 3–4; and severe, with CCI scores ≥5 (Table 1).

### Follow-up

All participants were followed for a period of 3 months (after their baseline assessment) for ascertainment of hospitalizations.

### Statistical methods

Descriptive variables are provided as the arithmetic mean and 95% confidence intervals for normally distributed variables and median (interquartile range) for skewed variables. Relationships between the slope changes in QoL measurements, and URR levels were analysed by Pearson's correlation coefficient tests. For the purpose of the statistical analysis, the VAS was chosen as the measure of QoL. The null hypothesis tested was that there was no relationship between these two variables (regression coefficient = 0). A simple linear regression analysis adjusted for age, sex and comorbidity index was also conducted to determine if QoL could be predicted from dialysis adequacy scores. To optimize the reliability of the analysis, data were inspected for missing values. There were three missing values, which were managed by the listwise deletion technique. Data were also checked for normality. Statistical significance was accepted at $P < 0.05$. The analysis was conducted using STATA version 12.0 (StataCorp LP, College Station, TX, USA).

**Table 1** Distribution of the Charlson comorbidity scores

| Category | Frequency | Percentage (%) |
|---|---|---|
| Mild (1–2) | 0 | 0 |
| Moderate (3–4) | 9 | 22.5 |
| Severe (≥5) | 31 | 77.5 |
| Total | 40 | 100.0 |

## RESULTS

### Characteristics of study participants

Forty patients with an average age of 79.8 years (standard deviation (SD) ± 3.9) participated in the study (45% women). Three patients were consented but subsequently excluded because they did not complete the questionnaires. Table 2 shows the clinical characteristics of the cohort. Seventeen patients (42.5%) reported having diabetes, which happened to be the most common cause of ESKD, while 28 (70%) reported having cardiovascular disease.

**Table 2** Demographic and clinical characteristics (*N* = 40)

| Variables | Value (SD/%/CI) |
|---|---|
| Demographic characteristics | |
| Gender (male *n*† %) | 22 (55) |
| Age ($\mu$‡ ± SD years) | 79.8 (3.9) |
| English as first language | 23 (57.5) |
| Australian born | 15 (37.5) |
| Private health insurance | 4 (10) |
| Clinical characteristics | |
| Dialysis access (AVF *n* %) | 35 (87.5) |
| Time on HD ($\mu$ ± SD years) | 4.4 ± 4.2 |
| HD duration ($\mu$ ± 95% CI hours) | 4.45 (4.3–4.6) |
| Diabetes (yes *n* %) | 17 (42.5) |
| Cardiovascular Disease (yes *n* %) | 28 (70) |
| Hospitalization§ (yes *n* %) | 19 (47.5) |
| QBE ($\mu$ + SD mls/min) | 280.6 ± 23.8 |
| Comorbidity index (CCI) scoring ($\mu$ ± SD) | 6.3 (2.2) |
| URR (% ± 95% CI) | 78.14 (76.4–79.9) |
| Pathological characteristics | |
| Haemoglobin ($\mu$ ± SD g/L) | 103.3 ± 15.4 |
| Calcium ($\mu$ ± SD mmol/L) | 2.2 ± 0.2 |
| Phosphate ($\mu$ ± SD mmol/L) | 1.4 ± 0.4 |
| Parathyroid hormone ($\mu$ ± SD pg/ml) | 29.4 ± 24.1 |
| Albumin ($\mu$ ± SD g/L) | 32 ± 4.0 |
| Outcome variables | |
| VAS (% + SD) | 65.4 ± 13.7 |
| EQ-5D index scores ($\mu$ ± SD) | 0.7 ± 0.21 |

†Number of patients in that category. ‡Mean. §Number of patients hospitalized during the 3-month period of the study. QBE, Blood flow rate in millimeters per minute. AVF, arteriovenous fistula; CI, confidence interval; CCI, Charlson comorbidity index scoring; VAS, visual analogue scale expressed as a percentage; SD, standard deviation.


© 2015 Asian Pacific Society of Nephrology

### Dialysis parameters and adequacy

The mean period on haemodialysis was 4 years 4 months (SD ± 4.2). Most patients (87.5%) were dialysing with an arteriovenous fistula, and the average duration of dialysis was 4.5 hrs (SD ± 0.4). The mean URR was 78.1% (SD ± 5.5) with a range of 64.0–88.9% (Fig. 2).

### Quality-of-life scores

The mean VAS and EQ-5D-5L scores were 65.4% (SD ± 13.7) and 0.7 (SD ± 0.2). The reported frequencies of the problem dimensions assessed by the EQ-5D were usual activity (81%), pain/discomfort (76%), mobility (73%), anxiety/depression (49%) and self-care (41%). Participants generally reported problems across all dimensions, but the effect of age was strongest for usual activity and weakest for self-care (Table 3).

### Comorbidity scores

The mean CCI score for the elderly patients was 6.3 (SD ± 2.2). The majority of patients (77.5%) had severe comorbidity (CCI ≥ 5). The mean CCI score for those with diabetes was 6.6 (SD ± 2.4) and not significantly different to those without diabetes ($P = 0.29$).

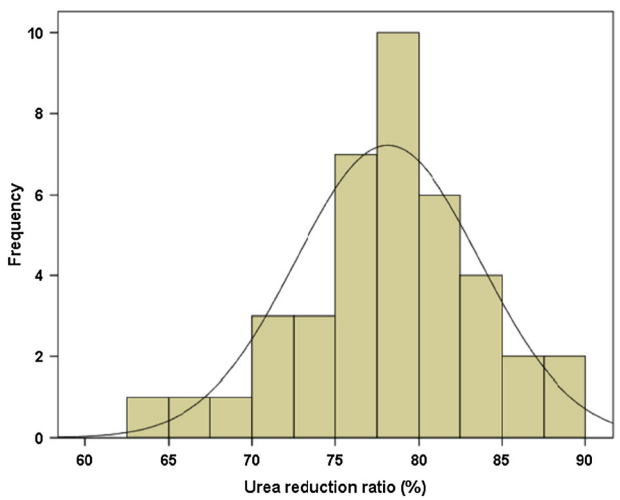



**Fig. 2** Histogram showing distribution of urea reduction ratio.

**Table 3** Frequency of reported problems by dimension and age group

| EQ-5D dimension | | Age groups 75–79 | 80–84 | >85 | Total |
|---|---|---|---|---|---|
| Mobility | No problem | 8 | 1 | 1 | 10 |
| | Problems | 14 | 10 | 3 | 27 |
| Self-care | No problems | 14 | 5 | 3 | 22 |
| | Problems | 8 | 6 | 1 | 15 |
| Usual activity | No problems | 5 | 2 | 0 | 7 |
| | Problems | 17 | 9 | 4 | 30 |
| Pain/discomfort | No problems | 4 | 3 | 2 | 9 |
| | Problems | 18 | 8 | 2 | 28 |
| Anxiety/depression | No Problems | 13 | 4 | 2 | 19 |
| | Problems | 9 | 7 | 2 | 18 |

### Hospitalization

A total of 14 patients (35%) were hospitalized during the 3 months study follow-up (12 patients had one episode of hospitalization and two patients had two episodes of hospitalization). Participants were mainly hospitalized for infection and vascular access related procedures (Table 4). The mean VAS score for hospitalized patients was slightly lower than for non-hospitalized patients but not significantly so (61.7% (SD ± 11.9) *vs* 67.8% (SD ± 13.6), $P = 0.46$).

### Association between dialysis adequacy and quality of life

Age, gender and dialysis adequacy were not significantly associated with the VAS score (Table 5). In a univariable analysis (model 1), dialysis adequacy was not significantly associated with VAS score $P = 0.085$ (Table 5). Similar non-significant trends were observed in a multivariable analysis (model 2) including predictor variables whose association with QoL was highly expected, that is, age, gender and comorbidity (Table 5).

To check whether our non-significant results were due to a lack of statistical power, we conducted a post hoc power analyses using G*Power[11] with power $(1 - \beta)$ set at 0.80 and $\alpha = 0.05$, two-tailed. The power analysis revealed that on the basis of the mean and effect sizes observed in the present study ($d = 0.41$), a minimum of 40 participants would be needed to obtain statistical power at the recommended 0.80 level. Thus, it is unlikely that our findings can be attributed to a limited sample size.

## DISCUSSION

Our study found that over the URR spectrum studied, there was no clear relationship between dialysis adequacy and the QoL of elderly patients on haemodialysis. This was observed despite elderly patients on haemodialysis reporting significant problems on all QoL domains especially usual activity and mobility. At least 77.5% of the participants had severe comor-

**Table 4** Reasons for hospitalization

| Reason | Hospitalization episodes (%) | Average length of stay (days) |
|---|---|---|
| Infection | 4 (28.6) | 10.25 |
| Vascular | 3 (21.4) | 4 |
| Cardiac | 2 (14.3) | 5.5 |
| Gastrointestinal | 2 (14.3) | 12 |
| Fluid overload | 2 (14.3) | 2.5 |
| Anaemia | 1 (7.1) | 12 |

© 2015 Asian Pacific Society of Nephrology

**Table 5** Main determinants of quality of life by multiple linear regression

| Dependent variable | Models | β coefficient | *t* | *P*-value | 95% CI |
|---|---|---|---|---|---|
| VAS | Model 1 ($R^2 = 0.076$)† | | | | |
| | URR | −0.682 | −1.77 | 0.085 | −1.464 .099 |
| | Model 2 ($R^2 = 0.177$)‡ | | | | |
| | URR | −0.709 | −1.65 | 0.108 | −1.583 .164 |
| | Comorbidity | −0.505 | −0.51 | 0.614 | −2.519 1.508 |
| | Age | 0.998 | 1.78 | 0.084 | −0.141 2.137 |
| | Gender | 2.637 | 0.57 | 0.574 | −6.791 12.065 |
| | Model 3 ($R^2 = 0.049$)§ | | | | |
| | Hospitalization | −6.488 | 1.39 | 0.171 | −2.935 15.911 |

†Univariate model. ‡Ran with other covariates: comorbidity, age and gender. §Showing hospitalization as a predictor variable. CI, confidence interval; VAS, visual analogue scale (quality-of-life measurement scale); URR, urea reduction ratio, which is a measure of dialysis adequacy.

bidity, a finding which is consistent with this study group. During the 3-month follow-up period, 35% of the participants were hospitalized, and there was no significant difference between the QoL of the hospitalized and non-hospitalized patients.

Although much work has been reported on dialysis adequacy as an outcome in the general dialysis population, this is the first study that has examined the association of haemodialysis adequacy with QoL in the elderly (75 years and above).[28] Similarly, a recent cross-sectional study of haemodialysis patients (mean age of 52.5 ± 12.0 years) did not find any significant correlation between dialysis adequacy and different domains of the 36-Item Short Form Health Survey.[29] Another larger study using cross-sectional data from China reported no meaningful difference in reported QoL for patients dialysing two times *versus* three times weekly.[30] Several other studies comparing QoL and dialysis adequacy using Kt/V report no association[31,32] including a study of peritoneal dialysis patients on continuous ambulatory peritoneal dialysis or automated peritoneal dialysis that reported no significant difference between dialysis adequacy and various parameters of physical and mental QoL.[33] In contrast, there are a few studies of the general dialysis population that have shown that QoL may be influenced by dialysis adequacy.[34,35] Simic-Ogrizovi and others report that haemodialysis patients managed to maintain all four QoL dimensions unchanged over 6 years, and this was due to the quality of haemodialysis, anaemia treatment and a significant increase in their mean Kt/V which can be used as a measure of dialysis adequacy.[36] Similarly, Manns and associates[37] in a cross-sectional study with 128 haemodialysis patients (mean age 61.8 years) report that dialysis adequacy is significantly associated with QOL in haemodialysis patients.

Our study highlights the problems with usual activity and mobility reported by older patients. A study by de Wit and others[38] also stresses that patients experienced most problems with daily activities leading to 61% of these patients failing to perform their daily activities normally. This can be attributed to the nature of the haemodialysis procedure, which can be physically taxing and burdensome even for young and otherwise healthy individuals, and many of the challenges and problems related to dialysis are magnified in older adults.[39] This is consistent with findings of several studies, which have reported significantly lower QoL scores on the physical domain of many dialysis patients.[40–45]

The elderly haemodialysis patients in our study had a mean CCI of 6.3, which puts them in the severe comorbidity category. The score was calculated without the age component. Previous work reveals that mortality in elderly patients is closely correlated to comorbidities independent of age.[46–48] A higher CCI score is therefore a strong predictor of mortality in elderly dialysis. Patients with low CCI scores are likely to benefit more from optimization of their dialysis compared with the majority of the elderly patients with much comorbidity. Elderly patients choosing conservative kidney management have managed to maintain their QoL,[49] while those who had chosen dialysis had a high risk of mortality in a nationwide population-based study in Taiwan.[50] Renal palliative care is therefore recommended in these circumstances,[8] but only after application of objective tools to measure the patients' comorbidity status. In this regard, Murtagh and associates[51] highlight that comorbidity should therefore be considered when advising elderly patients for or against dialysis.

This investigation draws its strengths from the use of valid and reliable tools (EQ-5D-5L questionnaire and VAS) for measuring QoL in elderly patients. Patients were requested to report about their health status on the day they completed the questionnaire to reduce recall bias. Furthermore, the design of this study allowed for a prospective assessment of the participants' comorbidity and hospitalization status during the 3-month follow-up period. On the other hand, our study was limited by the fact that the URR results were not broadly spread for us to ascertain the relationship between the two variables across a wider URR range. In addition, our study was limited by a short follow-up duration, and this could be the reason why a significant difference in QoL could not be detected. No difference in QoL was shown between hospitalized and non-hospitalized elderly dialysis patients. In conclusion, no evidence for an association between haemodialysis adequacy and QoL in elderly patients receiving haemodialysis was found. The relationship between these two variables may require further exploration. We recommend the need for an individualized approach when managing the elderly with ESKD.


© 2015 Asian Pacific Society of Nephrology

Modern therapy should also embrace the concept of QoL and focus more on symptom relief and optimization of self-management skills to improve the well-being of the elderly patients with ESRD.

## REFERENCES


1. United States Renal Data System. United States Renal Data System, 2014 annual data report: epidemiology of kidney disease in the United States. 2014; National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.
2. Polkinghorne K, Briggs N, Khanal N, Hurst K, Clayton P. Australia and New Zealand Dialysis and Transplant Registry. ANZDATA Registry Report, 2013; 5-2–5-41.
3. Franco MR, Fernandes NM. Dialysis in the elderly patient: a challenge of the XXI century – narrative review. *J. Bras. Nefrol.* 2013; **35**(2): 132–41.
4. Jager KJ, van Dijk PC, Dekker FW, Stengel B, Simpson K, Briggs JD. The epidemic of aging in renal replacement therapy: an update on elderly patients and their outcomes. *Clin. Nephrol.* 2003; **60**(5): 352–60.
5. Roderick P, Davies R, Jones C, Feest T, Smith S, Farrington K. Simulation model of renal replacement therapy: predicting future demand in England. *Nephrol. Dial. Transplant.* 2004; **19**(3): 692–701.
6. Hansberry MR, Whittier WL, Krause MW. The elderly patient with chronic kidney disease. *Adv. Chronic Kidney Dis.* 2005; **12**(1): 71–7.
7. Demoulin N, Beguin C, Labriola L, Jadoul M. Preparing renal replacement therapy in stage 4 CKD patients referred to nephrologists: a difficult balance between futility and insufficiency. A cohort study of 386 patients followed in Brussels. *Nephrol. Dial. Transplant.* 2011; **26**(1): 220–6.
8. Chandna SM, Da Silva-Gane M, Marshall C, Warwicker P, Greenwood RN, Farrington K. Survival of elderly patients with stage 5 CKD: comparison of conservative management and renal replacement therapy. *Nephrol. Dial. Transplant.* 2011; **26**(5): 1608–14.
9. Mollaoğlu M. Quality of life in patients undergoing hemodialysis. in Hiromichi S (ed). *Hemodialysis.* Croatia: InTech, Rijeka, 2013; 823–43.
10. Brown EA, Johansson L, Farrington K *et al*. Broadening Options for Long-term Dialysis in the Elderly (BOLDE): differences in quality of life on peritoneal dialysis compared to haemodialysis for older patients. *Nephrol. Dial. Transplant.* 2010; **25**(11): 3755–63.
11. Faul F, Erdfelder E, Buchner A, Lang AG. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behav. Res. Methods.* 2009; **41**(4): 1149–60.
12. Cohen J. *Statistical Analysis for the Behavioral Sciences*. Hillsdale, NJ: Erlbaum, 1988.
13. Sakthong P, Sonsa-Ardjit N, Sukarnjanaset P, Munpan W. *Psychometric Properties of the EQ-5D-5L in Thai Patients with Chronic Diseases*. Qual Life Res. 2015.
14. Brettschneider C, Konig HH, Herzog W, Kaufmann C, Schaefert R, Konnopka A. Validity and responsiveness of the EQ-5D in assessing and valuing health status in patients with somatoform disorders. *Health Qual. Life Outcomes.* 2013; **11**: 3.
15. Unruh M, Benz R, Greene T. Effects of hemodialysis dose and membrane flux on health-related quality of life in the HEMO Study. *Kidney Int.* 2004; **66**(1): 355–66.
16. Curran D, Molenberghs G, Aaronson NK, Fossa SD, Sylvester RJ. Analysing longitudinal continuous quality of life data with dropout. *Stat. Methods Med. Res.* 2002; **11**(1): 5–23.
17. Billingham LJ, Abrams KR. Simultaneous analysis of quality of life and survival data. *Stat. Methods Med. Res.* 2002; **11**(1): 25–48.
18. Ribaudo HJ, Thompson SG, Allen-Mersh TG. A joint analysis of quality of life and survival using a random effect selection model. *Stat. Med.* 2000; **19**(23): 3237–50.
19. Herdman M, Gudex C, Lloyd A *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual. Life Res.* 2011; **20**(10): 1727–36.
20. Janssen MF, Pickard AS, Golicki D *et al*. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. *Qual. Life Res.* 2013; **22**(7): 1717–27.
21. Horowitz E, Abadi-Korek I, Shani M, Shemer J. EQ-5D as a generic measure of health-related quality of life in Israel: reliability, validity and responsiveness. *Isr. Med. Assoc. J.* 2010; **12**(12): 715–20.
22. Ravens-Sieberer U, Wille N, Badia X *et al*. Feasibility, reliability, and validity of the EQ-5D-Y: results from a multinational study. *Qual. Life Res.* 2010; **19**(6): 887–97.
23. Gerard K, Nicholson T, Mullee M, Mehta R, Roderick P. EQ-5D versus SF-6D in an older, chronically Ill patient group. *Appl. Health Econ. Health Policy.* 2004; **3**(2): 91–102.
24. Lindsay RM, Spanner E. Adequacy of haemodialysis in the elderly. *Geriatr. Nephrol. Urol.* 1997; **7**(3): 147–56.
25. NKF-K/DOQI Clinical Practice Guidelines for Hemodialysis Adequacy, *I*. NKF-K/DOQI clinical practice guidelines for hemodialysis adequacy: update 2000. *Am. J. Kidney Dis.* 2001; **37**(1 Suppl 1): S7–64.
26. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J. Chronic Dis.* 1987; **40**(5): 373–83.
27. Huang Y-Q, Gou, R, Diao, Y-S *et al*. Charlson comorbidity index helps predict the risk of mortality for patients with type 2 diabetic nephropathy. *Journal of Zhejiang University SCIENCE B.* 2014; **15**(1): 58–66.
28. Adas H, Al-Ramahi, R, Jaradat, N, Badran, R. Assessment of adequacy of hemodialysis dose at a Palestinian hospital. *Saudi J. Kidney Dis. Transpl.* 2014. **25**(2): 438–42.
29. Donciu MD, Tasmoc A, Dumea R, *et al*. A cross-sectional study regarding the impact of end-stage renal disease on quality of life. *Rev. Med. Chir. Soc. Med. Nat. Iasi.* 2013; **117**(4): 908–15.
30. Daugirdas JT. Dialysis time, survival, and dose-targeting bias. *Kidney Int.* 2013; **83**(1): 9–13.
31. Morton AR, Meers C, Singer MA *et al*. Quantity of dialysis: quality of life – what is the relationship? *Asaio j.* 1996; **42**(5): M713–7.
32. Arenas VG, Barros LFNM, Lemos FB, Martins MA, David-Neto E. Qualidade de Vida: comparação entre diálise peritoneal automatizada e hemodiálise. *Acta Paulista de Enfermagem.* 2009; **22**: 535–9.
33. Sunder S, Kalra OP, Nashine S, Waghmare V, Ruchi R. Comparative study of adequacy of dialysis and health-related quality of life in patients on CAPD and APD. *Perit. Dial. Int.* 2008; **28**(5): 542–4.
34. Kalender N, Tosun N. Determination of the relationship between adequacy of dialysis and quality of life and self-care agency. *J. Clin. Nurs.* 2014; **23**(5-6): 820–8.
35. Hamilton G, Locking-Cusolito H. Hemodialysis adequacy and quality of life: how do they relate? *Cannt j.* 2003; **13**(4): 24–9.
36. Simic-Ogrizovic S, Jemcov T, Pejanovic S, Stosovic M, Radovic M, Djukanovic L. Health-related quality of life, treatment efficacy, and hemodialysis patient outcome. *Ren. Fail.* 2009. **31**(3): 201–6.
37. Manns BJ, Johnson JA, Taub K, Mortis G, Ghali WA, Donaldson C. Dialysis adequacy and health related quality of life in hemodialysis patients. *Asaio j.* 2002; **48**(5): 565–9.
38. de Wit GA, Merkus MP, Krediet RT, de Charro FT. Health profiles and health preferences of dialysis patients. *Nephrol. Dial. Transplant.* 2002; **17**(1): 86–92.
39. Dannelke L. Dialysis: a forever decision. *Aging Well.* 2011; **4**(1).
40. Vasilieva IA, Quality of life in chronic hemodialysis patients in Russia. *Hemodial. Int.* 2006; **10**(3): 274–8.
41. Lopes AA, Bragg-Gresham JL, Goodkin DA *et al*. Factors associated with health-related quality of life among hemodialysis patients in the DOPPS. *Qual. Life Res.* 2007; **16**(4): 545–57.
42. Madhan K. The CARI guidelines. Quality of life. *Nephrology (Carlton).* 2010; **15**(Suppl 1): S32–4.


© 2015 Asian Pacific Society of Nephrology

43. Sathvik BS, Parthasarathi G, Narahari MG, Gurudev KC. An assessment of the quality of life in hemodialysis patients using the WHOQOL-BREF questionnaire. *Indian J Nephrol.* 2008; **18**(4): 141–9.
44. Apostolou T. Quality of life in the elderly patients on dialysis. *Int. Urol. Nephrol.* 2007; **39**(2): 679–83.
45. Blake C, Codd MB, Cassidy A, O' Meara YM. Physical function, employment and quality of life in end-stage renal disease. *J. Nephrol.* 2000; **13**(2): 142–9.
46. Joly D, Anglicheau D, Alberti C *et al.* Octogenarians reaching end-stage renal disease: cohort study of decision-making and clinical outcomes. *J. Am. Soc. Nephrol.* 2003; **14**(4): 1012–21.
47. Lamping DL, Constantinovici N, Roderick P *et al.* Clinical outcomes, quality of life, and costs in the North Thames Dialysis Study of elderly people on dialysis: a prospective cohort study. *Lancet* 2000; **356**(9241): 1543–50.
48. Fried L, Bernardini J, Piraino B. Charlson comorbidity index as a predictor of outcomes in incident peritoneal dialysis patients. *Am. J. Kidney Dis.* 2001; **37**(2): 337–42.
49. Da Silva-Gane M, Wellsted D, Greenshields H, Norton S, Chandna SM, Farrington K. Quality of life and survival in patients with advanced kidney failure managed conservatively or by dialysis. *Clin. J. Am. Soc. Nephrol.* 2012; **7**(12): 2002–9.
50. Shih CJ, Chen YT, Ou SM, Yang WC, Kuo SC, Tarng DC. The impact of dialysis therapy on older patients with advanced chronic kidney disease: a nationwide population-based study. *BMC Med.* 2014; **12**(1): 169.
51. Murtagh FE, Marsh JE, Donohoe P, Ekbal NJ, Sheerin NS, Harris FE. Dialysis or not? A comparative survival study of patients over 75 years with chronic kidney disease stage 5. *Nephrol. Dial. Transplant.* 2007; **22**(7): 1955–62.


© 2015 Asian Pacific Society of Nephrology

## STUDY INSTRUMENTS

1. DRP: Diabetes Renal Project -(Patient Survey - Health Experiences) (Chapter 2.2)
2. DRP: Diabetes Renal Project (Doctors Survey - Health Indicators) (Chapter 2.2; Chapter 3.2; Chapter 4.2)
3. The Summary of Diabetes Self- Care Activities for Diabetes and Kidney Disease (Chapter 2.2; Chapter 4.2)
4. Kidney Disease and Quality of Life (KDQOL™-36) (Chapter 2.2; Chapter 3.2; Chapter 4.2)
5. Patient Activation Measure (PAM) 13™ (Chapter 2.2)

# DRP: Diabetes Renal Project - (Patient Survey - Health Experiences)

Thank-you for participating in this large multi-centre research project, called the Diabetes Renal Project (DRP). This National Health and Medical Research Council (NHMRC) partnership project is being conducted by Monash University, in partnership with Monash Health, Alfred Health, Royal North Shore Hospital, Concord Repatriation General Hospital, The George Institute for Global Health, Diabetes Australia, and Kidney Health Australia.

## INSTRUCTIONS

**PLEASE:**
Use a black **BIRO**, (DO NOT use a pencil or a fountain or felt tip pen)

Please **PRINT** in **CAPITAL** letters and stay within the box provided for text.

If you make a **mistake when writing**, cross it out with one thick line and write your correct answer above the box.

To answer a multiple choice question place a **CROSS INSIDE** the box like this: ☒

If you make a **mistake**, place a diagonal line through the incorrect answer like this: ☒ and then put a cross in the box of your preferred response.

Write dates using leading zeros (e.g. **6th April 2011 = 06/04/2011**)

**DO NOT USE** liquid paper to correct mistakes.

**AVOID** folding the form.

Please complete every page of the questionnaire. Sometimes questions may seem very similar or repetitious but they are all a little different, so please answer each question.

**THANK YOU**

34067

Hospital ID: Site Staff ID: Participant ID:

**Date** day / month / year

## Part 1: Health Indicators (Patient Survey)

### Section 1: General Information

**1. Age** (years)

**2. Country of birth** _____

**3. Main language spoken at home?**

☐ English ☐ Italian ☐ Spanish ☐ Greek

☐ Arabic ☐ Vietnamese ☐ Cantonese ☐ Hindi

☐ Mandarin ☐ Other, (please specify) → _____

### Section 2: Diabetes

**4. What type of diabetes do you have?** ☐ Type 1 ☐ Type 2 ☐ Unsure ☐ Other

**5. How many years have you had diabetes?** *years* *months*

**6. How do you manage your diabetes?** *(select all that apply)*

☐ Diet and lifestyle only ☐ Insulin injections (3 or fewer per day)

☐ Tablets to lower blood glucose ☐ Insulin injections (4 or more per day)

☐ Byetta injections (2 per day) ☐ Insulin pump therapy

☐ Other (please specify) → _____

**7. If you use insulin how confident are you in self- adjusting your insulin dose?** *(select one option)*

*Not at all confident* ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 *Extremely Confident*

### Section 3: Kidney Disease

**8. How many years have you had kidney disease?** *years* *months*

**9. Did you develop kidney disease as a result of your diabetes?** ☐ No ☐ Yes ☐ Unsure

### Section 4: Medication

**10. Who explains your medications to you?** *(select all that apply)*

☐ GP ☐ Diabetes nurse

☐ GP Practice Nurse ☐ Kidney doctor at a public hospital clinic

☐ Private kidney specialist ☐ Diabetes doctor at a public hospital clinic

☐ Kidney nurse ☐ Pharmacist

☐ Private endocrinologist/diabetes specialist

☐ Other (please specify) → _____

## Section 4: Medication (cont)

**11. Which health professional(s) do you see to manage your diabetes and kidney disease?** *(select all that apply)*

- ☐ GP
- ☐ GP Practice Nurse
- ☐ Private kidney specialist
- ☐ Kidney nurse
- ☐ Private endocrinologist/diabetes specialist
- ☐ Diabetes nurse
- ☐ Kidney doctor at a public hospital clinic
- ☐ Diabetes doctor at a public hospital clinic
- ☐ Dietitian
- ☐ Podiatrist
- ☐ Optometrist
- ☐ Ophthalmologist
- ☐ Other (please specify) → _____

**12. Please record the last time you saw the following health professionals.** (S*elect the appropriate frequency for each professional)*

| | | 0-3 months ago | 4-6 months ago | 7-12 months ago | Over 12 months ago | Never | Uncertain |
|---|---|---|---|---|---|---|---|
| **a.** | Endocrinologist (diabetes doctor) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **b.** | Nephrologist (kidney doctor) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **c.** | Diabetes Nurse Educator | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **d.** | Kidney Nurse Practitioner | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **e.** | Optometrist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **f.** | Ophthalmologist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **g.** | Podiatrist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **h.** | Dentist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **i.** | Dietitian | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **j.** | Social Worker | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**13. If you run out of medication what would you do?** (S*elect all that apply)*

- ☐ Obtain a supply from my local pharmacy, even if I didn't have a prescription
- ☐ Obtain a prescription from my GP then have it filled at my local pharmacy
- ☐ Wait until I next saw a doctor to obtain another prescription
- ☐ I never run out because I always ensure I have a spare supply

## Section 5. Barriers and support

**14. Barriers causing difficulty in caring for your diabetes and kidney disease** *(Mark disagree or somewhat disagree or somewhat agree or agree to each listed barrier. Please choose only one option per barrier).*

| | Disagree | Somewhat disagree | Somewhat agree | Agree |
|---|---|---|---|---|
| **a.** My diabetes and kidney specialist does not spend enough time with me | ☐ | ☐ | ☐ | ☐ |
| **b.** My diabetes and kidney specialist does not provide me with enough information/education about my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| **c.** I am often seen by a different doctor each time I attend my diabetes or kidney disease appointment | ☐ | ☐ | ☐ | ☐ |
| **d.** My specialists give me conflicting advice | ☐ | ☐ | ☐ | ☐ |
| **e.** I do not have a good relationship with my specialist or other specialist health service staff | ☐ | ☐ | ☐ | ☐ |
| **f.** Specialist health service staff are not caring, polite and helpful | ☐ | ☐ | ☐ | ☐ |
| **g**. My specialists do not communicate well with my GP | ☐ | ☐ | ☐ | ☐ |
| **h.** My specialists don't communicate well with each other | ☐ | ☐ | ☐ | ☐ |
| **i**. I do not have a good GP | ☐ | ☐ | ☐ | ☐ |
| **j.** I need more education and understanding of my diabetes | ☐ | ☐ | ☐ | ☐ |
| **k.** I need more education and understanding of my kidney disease | ☐ | ☐ | ☐ | ☐ |
| **l.** The information provided by my doctors or health professionals is hard to understand because English is not my first language or the information is not culturally relevant | ☐ | ☐ | ☐ | ☐ |
| **m.** The information provided by my doctors or health professionals is too complicated | ☐ | ☐ | ☐ | ☐ |
| **n**. It is difficult to obtain medical support and advice for my diabetes when I need it | ☐ | ☐ | ☐ | ☐ |
| **o.** It is difficult to obtain medical support and advice for my kidney disease when I need it | ☐ | ☐ | ☐ | ☐ |
| **p.** I have had an unsatisfactory prior experience with a diabetes or kidney health service/specialist | ☐ | ☐ | ☐ | ☐ |
| **q.** I am unable to afford the cost of attending appointments or buying medication for my diabetes | ☐ | ☐ | ☐ | ☐ |
| **r.** I have trouble adjusting to the impact that diabetes and kidney disease has made on my life and/or that of my family and friends | ☐ | ☐ | ☐ | ☐ |
| **s.** My diabetes and kidney disease makes me feel very unwell | ☐ | ☐ | ☐ | ☐ |
| **t.** My other illnesses affect my ability to look after my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |

## Section 5: Barriers and support (cont)

| | Disagree | Somewhat disagree | Somewhat agree | Agree |
|---|---|---|---|---|
| **u.** I have many other stressors in my life, and taking care of my diabetes and kidney disease is not a high priority | ☐ | ☐ | ☐ | ☐ |
| **v.** My job makes it difficult to take care of my diabetes and kidney disease well | ☐ | ☐ | ☐ | ☐ |
| **w.** My mood (e.g. feeling down, worried, frustrated) gets in the way of me looking after my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| **x.** I do not feel motivated enough to look after my diabetes and kidney disease well | ☐ | ☐ | ☐ | ☐ |
| **y.** I have trouble maintaining the right diet or fluid restriction for my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| **z.** I have difficulty knowing what I can eat/drink, for my diabetes and kidney disease | ☐ | ☐ | ☐ | ☐ |
| **aa**. I experience unpleasant side-effects from my medication | ☐ | ☐ | ☐ | ☐ |
| **bb.** I do not receive support from my family | ☐ | ☐ | ☐ | ☐ |
| **cc**. I do not receive support from my friends | ☐ | ☐ | ☐ | ☐ |
| **dd.** I find it difficult to get services for home-help | ☐ | ☐ | ☐ | ☐ |

**ee**. Please list any additional problems: _____

## Section 6: Diabetes Service and Kidney Service

**15. Are you registered with the National Diabetes Service Scheme (NDSS)?** *This service supports people living with diabetes by providing subsidised blood glucose strips and free insulin pen needles/syringes. It is not the same as being a member of Diabetes Australia.* ☐ No ☐ Yes

**16. Do you have difficulty in accessing a diabetes service?**

☐ No → Skip to Q 17

☐ Yes → **16.1. Why is it difficult for you to access a diabetes service?** *(select all that apply)*

- ☐ No private transport e.g. car/ driver
- ☐ Parking (e.g. cost, locality to the clinic)
- ☐ Disability
- ☐ Cost (e.g. appointments, prescription costs)
- ☐ Time of appointment (e.g. during work hours)
- ☐ Location of the service (e.g. distance from home)
- ☐ Time spent each week at dialysis
- ☐ I have too many appointments
- ☐ Long waiting times before I get an appointment
- ☐ Long waiting times in the waiting room before I see a doctor
- ☐ I don't have a problem with accessing a service
- ☐ Other (please specify) → _____

## Section 6: Diabetes Service and Kidney Service (cont)

**17. How satisfied are you with the care provided by your diabetes service?** *(select one option)*

*Not at all satisfied* ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 *Extremely Satisfied*

**18. Do you have difficulty in accessing a kidney service?**

☐ No → Skip to Q 19

☐ Yes → **18.1. Why is it difficult for you to access a kidney service?** *(select all that apply)*

- ☐ No private transport e.g. car/ driver
- ☐ Parking (e.g. cost, locality to the clinic)
- ☐ Disability
- ☐ Cost (e.g. appointments, prescription costs)
- ☐ Time of appointment (e.g. during work hours)
- ☐ Location of the service (e.g. distance from home)
- ☐ Other (please specify) →
- ☐ Time spent each week at dialysis
- ☐ I have too many appointments
- ☐ Long waiting times before I get an appointment
- ☐ Long waiting times in the waiting room before I see a doctor
- ☐ I don't have a problem with accessing a service

**19. How satisfied are you with the care provided by your kidney service?** *(select one option)*

*Not at all satisfied* ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 *Extremely Satisfied*

**20. An ideal health service to look after my diabetes and kidney disease would include:** *(please cross either no or yes in the table below)*

| | | |
|---|---|---|
| **a.** Regular contact with a case manager, nurse or doctor who knows my entire medical history and who will help me coordinate the management of my health | ☐ No | ☐ Yes |
| **b.** Education sessions to help me manage my diabetes, including information about correct food choices and what support is available | ☐ No | ☐ Yes |
| **c.** Education sessions to help me manage my kidney disease, including information about correct food choices and what support is available | ☐ No | ☐ Yes |
| **d.** Education sessions for my family so that they can understand my condition | ☐ No | ☐ Yes |
| **e.** Education sessions targeted to the public/community about diabetes and kidney disease | ☐ No | ☐ Yes |
| **f.** Education handouts that are culturally relevant, in my native language, easy to understand, and in an appropriate format (e.g. DVD) | ☐ No | ☐ Yes |
| **g.** Seeing the same doctor or health professional when I attend my diabetes and kidney disease appointments | ☐ No | ☐ Yes |
| **h.** All my doctors giving me the same information/advice, instead of conflicting information/advice | ☐ No | ☐ Yes |
| **i.** Good communication between my doctors | ☐ No | ☐ Yes |
| **j.** Centralised Electronic health medical records with investigation results, which all my doctors can access | ☐ No | ☐ Yes |
| **k.** Friendly, caring, supportive and knowledgeable staff and medical professionals | ☐ No | ☐ Yes |

## Section 6: Diabetes Service and Kidney Service (cont)

| | | |
|---|---|---|
| **l.** A combined multidisciplinary clinic with both diabetes and kidney doctors, as well as other health staff (such as dietitian, nurse educators, podiatrists etc) in the one place | ☐ No | ☐ Yes |
| **m.** Shorter waiting times in the waiting room | ☐ No | ☐ Yes |
| **n.** Routine access to a psychologist for emotional support | ☐ No | ☐ Yes |
| **o.** Routine access to a dietitian | ☐ No | ☐ Yes |
| **p.** Routine access to a podiatrist | ☐ No | ☐ Yes |
| **q.** Routine access to an eye doctor | ☐ No | ☐ Yes |
| **r.** Routine access to a diabetes nurse educator | ☐ No | ☐ Yes |
| **s.** Routine access to a kidney nurse | ☐ No | ☐ Yes |
| **t.** Routine access to a pharmacist | ☐ No | ☐ Yes |
| **u.** Routine access to a social worker | ☐ No | ☐ Yes |
| **v.** Routine access to an occupational therapist | ☐ No | ☐ Yes |
| **w.**Routine review by doctors and health professionals for my diabetes and kidney disease (e.g. diabetes doctor, dietitian, podiatrist) while I am on dialysis | ☐ No | ☐ Yes |
| **x.** Appointment reminders (e.g. phone call/text message/email) prior to my appointment | ☐ No | ☐ Yes |
| **y.** Incentives to staff members to provide good patient service (e.g. Monthly prize) | ☐ No | ☐ Yes |
| **z.** Debriefing groups and education sessions for staff members to improve patient care | ☐ No | ☐ Yes |
| **aa.** Affordable parking close to clinic/dialysis | ☐ No | ☐ Yes |
| **bb.** Diabetes and renal services being offered in my local community, rather than primarily based in the hospital | ☐ No | ☐ Yes |
| **cc.** 24 hour hotline to staff in case I need advice or assistance | ☐ No | ☐ Yes |

## Section 7: Summary of Diabetes Self Care Activities for Diabetes and Kidney Disease

*Please recall the last 7 days that you were well when answering the following questions. (Please select one response per question).*

*Diet*

**21. How many of the last 7 days have you followed a healthy eating plan?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**22. Over the past month how many days per week have you followed your eating plan?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

## Section 7: Summary of Diabetes Self Care Activities for Diabetes and Kidney Disease (cont)

**23. On how many of the last 7 days did you eat five or more servings of fruit?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**24. On how many of the last 7 days did you eat high fat foods such as red meat or full dairy products?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

*Excercise*

**25. On how many of the last 7 days did you participate in at least 30min of exercise?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**26. On how many of the last 7 days did you participate in a specific exercise session?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

*Blood Sugar Testing*

**27. On how many of the last 7 days did you test your blood sugar?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**28. On how many of the last 7 days did you test your blood sugar the number of times recommended by your health care provider?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

*Foot Care*

**29. On how many of the last 7 days did you check your feet?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**30. On how many of the last 7 days did you inspect the inside of your shoes?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

*Smoking*

**31. Have you smoked or taken a puff of a cigarette in the last 7 days?**

☐ No → Skip to Q 32

☐ Yes → **31.1 How many cigarettes did you smoke on an average day?** ☐☐☐

*Medications*

**32. On how many of the last 7 days did you take your recommended diabetes medication?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**33. On how many of the last 7 days did you take your recommended insulin injections?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

**34. On how many of the last 7 days did you take your recommended number of diabetes pills?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

# DRP: Diabetes Renal Project (Doctors Survey - Health Indicators)

Thank-you for participating in this large multi-centre research project, called the Diabetes Renal Project (DRP). This National Health and Medical Research Council (NHMRC) partnership project is being conducted by Monash University, in partnership with Monash Health, Alfred Health, Royal North Shore Hospital, Concord Repatriation General Hospital, The George Institute for Global Health, Diabetes Australia, and Kidney Health Australia.

## INSTRUCTIONS

**PLEASE:**
Use a black **BIRO**, (DO NOT use a pencil or a fountain or felt tip pen)

Please **PRINT** in **CAPITAL** letters and stay within the box provided for text.

If you make a **mistake when writing**, cross it out with one thick line and write your correct answer above the box.

To answer a multiple choice question place a **CROSS INSIDE** the box like this: ☒

If you make a **mistake**, place a diagonal line through the incorrect answer like this: ☒ and then put a cross in the box of your preferred response.

Write dates using leading zeros (e.g. **6th April 2011 = 06/04/2011**)

**DO NOT USE** liquid paper to correct mistakes.

**AVOID** folding the form.

Please complete every page of the questionnaire. Sometimes questions may seem very similar or repetitious but they are all a little different, so please answer each question.

**THANK YOU**

Hospital ID: ☐ Site Staff ID: ☐☐☐☐☐ Participant ID: ☐☐☐☐

**Date** ☐☐ / ☐☐ / ☐☐☐☐
day month year

# Health Indicators (Doctors Survey)

## Section 1: Demographic of Patient Participant

**1. Age** *(years)* ☐☐

**2. Gender** ☐ Male ☐ Female

**3. Participant Post-code** ☐☐☐☐

**4. Aboriginal background** ☐ No ☐ Yes

**5.Torres Strait Islander background** ☐ No ☐ Yes

**6. Maori/Pacific Strait Islander background** ☐ No ☐ Yes

**7. Is the participant a current smoker ?**

☐ No → Skip to Q 8

☐ Yes → **7.1. Average number of cigarettes smoked per day?** ☐☐

**8. Has the participant previously smoked ?**

☐ No → Skip to Q 9

☐ Yes → **8.1. Average number of cigarettes smoked per day?** ☐☐

**9. Does the participant currently drink alcohol?**

☐ No → Skip to Q 10

☐ Yes → **9.1. Average number of standard drinks per week?** ☐☐

## Section 2: Examination Findings

**Please complete with the most recent examination findings and date of examination**

**10. Blood Pressure -** *(the average of 3 readings measured after 5 minutes sitting)*

☐☐☐ / ☐☐☐ mmHg → **10.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

**11. Heart Rate** ☐☐☐ Bpm → **11.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

**12. Weight** ☐☐☐.☐ Kg → **12.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

**13. Height** ☐.☐☐ Metres → **13.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

**At the most recent examination, does the participant have the following conditions:**

**14a. New loss of vibratory sensation (both feet)**

☐ No ☐ Yes → Date of examination **14a.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

☐ Not examined/unknown

**14b. New loss of ankle reflexes (both legs)**

☐ No ☐ Yes → Date of examination **14b.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

☐ Not examined/unknown

**14c. New loss of light touch (eg. loss of pressure sensation with 10gm force monofilament)**

☐ No ☐ Yes → Date of examination **14c.1** ☐☐ / ☐☐ / ☐☐☐☐
day month year

☐ Not examined/unknown

## Section 2: Examination Findings (cont)

**15. Foot ulcers**

☐ No ☐ Yes → Date of examination **15.1** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

☐ Not examined/unknown

**16. Foot deformity**

☐ No ☐ Yes → Date of examination **16.1** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

☐ Not examined/unknown

## Section 3: Medical History

**17. Diabetes Type** ☐ Type 1 ☐ Type 2 **18. Duration of diabetes** ☐☐ *years* ☐☐ *months*

**OR** ☐ Unknown/not documented

---

**Has the participant experienced any of the following complications/comorbidities?**

| | | | | | |
|---|---|---|---|---|---|
| **19. Ischemic Heart Disease?** | ☐ No | ☐ Yes | **23. Peripheral Neuropathy?** | ☐ No | ☐ Yes |
| **20. Stroke?** | ☐ No | ☐ Yes | **24. Diabetic Nephropathy?** | ☐ No | ☐ Yes |
| **21. Peripheral Vascular disease?** | ☐ No | ☐ Yes | **25. Hypertension** | ☐ No | ☐ Yes |
| **22. Diabetic Retinopathy?** | ☐ No | ☐ Yes | **26. Dyslipidemia** | ☐ No | ☐ Yes |

**27. Does the participant have a family history of heart disease?** ☐ No ☐ Yes

**OR** ☐ Unknown/not documented

---

**28. Duration of nephrological care** ☐☐ *years* ☐☐ *months* **OR** ☐ Unknown/not documented

**29. Kidney disease stage** *(select one option)* ☐ Stage 3a ☐ Stage 3b ☐ Stage 4 ☐ Stage 5

**30. Is the patient currently on dialysis?**

☐ No → Skip to Q 31

☐ Yes → **30.1 Haemodialysis** ☐ No ☐ Yes → **30.2** Number of months on dialysis ☐☐☐

**30.3 Peritoneal** ☐ No ☐ Yes → **30.4** Number of months on dialysis ☐☐☐

## Section 3: Medical History (cont)

**31. Prior to their current dialysis, has the patient been on any other form of dialysis?**

☐ No → Skip to Q 32

☐ Yes→ **31.1 Haemodialysis?**

☐ No ☐ Yes

Date commenced **31.2** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Date ceased **31.3** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**31.4 Peritoneal dialysis?**

☐ No ☐ Yes

Date commenced **31.5** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Date ceased **31.6** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**32. Has the patient had a kidney transplant?**

☐ No → Skip to Q 33

☐ Yes→ **32.1 Date of transplant** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**OR** ☐ Unknown/not documented

## Section 4: Medical Care of Diabetes and Chronic Kidney Disease

**33. How often does the participant monitor his/her diabetes with a blood glucose monitor?** *(select one option)*

☐ ≥ 3 times per day ☐ Once per day (daily) ☐ Once per week (weekly) ☐ Uncertain

☐ 2 times per day ☐ A few times per week ☐ Rarely ☐ Not documented

**34. Please indicate when the participant was last referred/seen by the following health professionals.** *(Select the appropriate response for each health professional).*

| | Not referred/reviewed by this health professional | 3 months or less | 4-12 months ago | 13-24 months ago | As required | Uncertain |
|---|---|---|---|---|---|---|
| **a.** Endocrinologist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **b.** Nephrologist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **c.** Diabetes Nurse Educator | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **d.** Renal Nurse Practitioner | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **e.** Optometrist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **f.** Ophthalmologist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **g.** Podiatrist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **h.** Dentist | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **i.** Dietician | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| **j.** Social Worker | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

## Section 5: Medications

**35. Is the participant on Insulin?**

☐ No → Skip to Q 36

☐ Yes→ **35.1 Is the participant on an Insulin pump?** ☐ No ☐ Yes

**35.2 What type of insulin?** *(select all that apply)*

☐ Long acting ☐ Short acting ☐ Rapid acting ☐ Basal

**36. Is the participant on diabetes tablets?**

☐ No → Skip to Q 34

☐ Yes→ **Does the participant take:**

| | | |
|---|---|---|
| **36.1 Metformin?** | ☐ No | ☐ Yes |
| **36.2 Sulphonylurea?** | ☐ No | ☐ Yes |
| **36.3 Glitazone?** | ☐ No | ☐ Yes |
| **36.4 Acarbose?** | ☐ No | ☐ Yes |
| **36.5 Gliptin (DPP4 inhibitor)?** | ☐ No | ☐ Yes |
| **36.6 GLP1 agonist?** **(e.g exenatide or liraglutide)** | ☐ No | ☐ Yes |
| **36.7 SGLT2 inhibitors?** | ☐ No | ☐ Yes |

**36.8 Other diabetes medication** *(please list below)*

**37. Other medications - is the participant taking:**

| | | |
|---|---|---|
| **37.1 ACE inhibitor?** | ☐ No | ☐ Yes |
| **37.2 Angiotensin2 Receptor Blocker?** | ☐ No | ☐ Yes |
| **37.3 Other Antihypertensives?** | ☐ No | ☐ Yes |
| **37.4 Statin?** | ☐ No | ☐ Yes |
| **37.5Fibrate?** | ☐ No | ☐ Yes |
| **37.6 Erythropoieting Stimulating Agent?** | ☐ No | ☐ Yes |
| **37.7 Phosphate binder?** | ☐ No | ☐ Yes |
| **37.8 Iron Supplementation (IV or Oral)?** | ☐ No | ☐ Yes |

## Section 6: Investigations

**38. Has a HbA1c test been performed in the last 3 months?** ☐ No ☐ Yes

*Please record the most recent HbA1c result*

**38.1 HbA1c** ☐☐☐ mmol/mol ***and*** **38.2** ☐☐.☐ % → **38.3** Date of test ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**39. Please enter details below of the most recent lipid profile results:**

**39.1 Total Cholesterol** ☐☐.☐ mmol/L

**39.2 LDL Cholesterol** ☐.☐☐ mmol/L

**39.3 HDL Cholesterol** ☐☐.☐☐ mmol/L

**39.4 Triglycerides** ☐.☐☐ mmol/L

**39.5 Date of test** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**OR** ☐ Not tested

**40. Please enter details below of the most recent serum biochemistry profile results:**

**40.1 Potassium** ☐.☐ mmol/L

**40.2 Creatinine** ☐☐☐☐ µmol/L

**40.3 Calcium** ☐.☐☐ mmol/L

**40.4 Phosphate** ☐.☐☐ mmol/L

**40.5 Parathyroid hormone (PTH)** ☐☐☐.☐
(result within last 6 months)

**40.5.1 Units** ☐ pmol/L ☐ ng/L

**OR** ☐ Not done within the past 6 months

**40.6 eGFR** ☐☐☐ mL/min per 1.73m$^2$

**40.7 Albumin** ☐☐☐ g/L

**40.8 Date of test** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

(For PTH, please record result from within the past 6 months of this date)

**OR** ☐ Not tested

**41. Please record the most recent spot urine albumin / creatinine ratio (ACR):**

☐☐☐☐.☐☐ mg/mmol **40.1 Date of test** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) **OR** ☐ Not tested

**42. If you have used another method to measure microalbumin / proteinuria please record details below:**

☐☐☐☐.☐☐ **42.1 Units** ☐ mg/L ☐ mg/24hr ☐ µg/min ☐ g/mmol ☐ g/L

**42.2 Date of test** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year) **OR** ☐ Not tested

**43. Please enter the most recent Haemoglobin test result:** ☐☐☐ g/L **43.1 Date of test** ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

**OR** ☐ Not tested

**The Summary of Diabetes Self- Care Activities for Diabetes and Kidney Disease**

*The questions below ask you about your diabetes and kidney disease self-care activities during the past **7 days**. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.*

**Diet**

How many of the last SEVEN DAYS have you followed a healthful eating plan?

0 1 2 3 4 5 6 7

On average, **over the past month**, how many DAYS PER WEEK have you followed your eating plan?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

0 1 2 3 4 5 6 7

**Exercise**

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

**Blood Sugar Testing**

On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

# Your Health
## *– and –*
# Well-Being

**Kidney Disease and Quality of Life (KDQOL™-36)**

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

***Thank you for completing these questions!***


Copyright © 2000 by RAND and the University of Arizona

# Study of Quality of Life
# For Patients on Dialysis

## What is the purpose of the study?

This study is being carried out in cooperation with physicians and their patients. The purpose is to assess the quality of life of patients with kidney disease.

## What will I be asked to do?

For this study, we want you to complete a survey today about your health, how you feel and your background.

## Confidentiality of information?

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

## How will participation benefit me?

The information you provide will tell us how you feel about your care and further understanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

## Do I have to take part?

You do not have to fill out the survey and you can refuse to answer any question. Your decision to participate will not affect your opportunity to receive care.

# Your Health

**This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.**

**1. In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]**

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**The following items are about activities you might do during a typical day. <u>Does your health now limit</u> you in these activities? If so, how much? [Mark an ☒ in a box on each line.]**

| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|
| **2.** <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf ..... | ☐ 1 | ☐ 2 | ☐ 3 |
| **3.** Climbing <u>several</u> flights of stairs ..... | ☐ 1 | ☐ 2 | ☐ 3 |

**During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

| | Yes | No |
|---|---|---|
| **4.** <u>Accomplished less</u> than you would like..... | ☐ 1 | ☐ 2 |
| **5.** Were limited in the <u>kind</u> of work or other activities..... | ☐ 1 | ☐ 2 |

**During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

| | Yes | No |
|---|---|---|
| **6.** <u>Accomplished less</u> than you would like..... | ☐ 1 | ☐ 2 |
| **7.** Didn't do work or other activities as <u>carefully</u> as usual..... | ☐ 1 | ☐ 2 |

**8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.**

**How much of the time during the <u>past 4 weeks</u>…**

| | All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| **9.** Have you felt calm and peaceful? ..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |
| **10.** Did you have a lot of energy? ..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |
| **11.** Have you felt downhearted and blue? . | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

**12. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

# Your Kidney Disease

**How <u>true</u> or <u>false</u> is each of the following statements for you?**

| | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|
| **13.** My kidney disease interferes too much with my life ..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **14.** Too much of my time is spent dealing with my kidney disease..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **15.** I feel frustrated dealing with my kidney disease..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **16.** I feel like a burden on my family ..... | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**During the <u>past 4 weeks</u>, to what extent were you bothered by each of the following?**

| | Not at all bothered | Somewhat bothered | Moderately bothered | Very much bothered | Extremely bothered |
|---|---|---|---|---|---|
| | ▼ | ▼ | ▼ | ▼ | ▼ |
| **17.** Soreness in your muscles? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **18.** Chest pain? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **19.** Cramps? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **20.** Itchy skin? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **21.** Dry skin? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **22.** Shortness of breath? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **23.** Faintness or dizziness? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **24.** Lack of appetite? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **25.** Washed out or drained? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **26.** Numbness in hands or feet? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **27.** Nausea or upset stomach? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **28[a].** (Hemodialysis patient only) Problems with your access site? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **28[b].** (Peritoneal dialysis patient only) Problems with your catheter site? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

# Effects of Kidney Disease on Your Daily Life

**Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease <u>bother</u> you in each of the following areas?**

| | | Not at all bothered | Somewhat bothered | Moderately bothered | Very much bothered | Extremely bothered |
|---|---|---|---|---|---|---|
| | | ▼ | ▼ | ▼ | ▼ | ▼ |
| **29.** | Fluid restriction? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **30.** | Dietary restriction? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **31.** | Your ability to work around the house? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **32.** | Your ability to travel? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **33.** | Being dependent on doctors and other medical staff? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **34.** | Stress or worries caused by kidney disease? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **35.** | Your sex life? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| **36.** | Your personal appearance? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

***Thank you for completing these questions!***

38371

Hospital ID: Site Staff ID: Participant ID:

**Date** day / month / year

## Patient Activation Measure (PAM) 13™ ©Insignia Health, LLC 2013

*Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by crossing your answer. Your answers should be what is true for you and not just what you think others want you to say. If the statement does not apply to you, cross N/A. (Please choose only one response for each statement).*

| | Disagree Strongly | Disagree | Agree | Agree Strongly | N/A |
|---|---|---|---|---|---|
| **1.** When all is said and done, I am the person who is responsible for taking care of my health | ☐ | ☐ | ☐ | ☐ | ☐ |
| **2.** Taking an active role in my own health care is the most important thing that affects my health | ☐ | ☐ | ☐ | ☐ | ☐ |
| **3.** I am confident that I can help prevent or reduce problems associated with my health | ☐ | ☐ | ☐ | ☐ | ☐ |
| **4.** I know what each of my prescribed medications do | ☐ | ☐ | ☐ | ☐ | ☐ |
| **5.** I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself | ☐ | ☐ | ☐ | ☐ | ☐ |
| **6.** I am confident that I can tell a doctor concerns I have even when he or she does not ask | ☐ | ☐ | ☐ | ☐ | ☐ |
| **7.** I am confident that I can follow through on medical treatments I may need to do at home | ☐ | ☐ | ☐ | ☐ | ☐ |
| **8.** I understand my health problems and what causes them | ☐ | ☐ | ☐ | ☐ | ☐ |
| **9.** I know what treatments are available for my health problems | ☐ | ☐ | ☐ | ☐ | ☐ |
| **10.** I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising | ☐ | ☐ | ☐ | ☐ | ☐ |
| **11.** I know how to prevent problems with my health | ☐ | ☐ | ☐ | ☐ | ☐ |
| **12.** I am confident I can figure out solutions when new problems arise with my health | ☐ | ☐ | ☐ | ☐ | ☐ |
| **13.** I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress | ☐ | ☐ | ☐ | ☐ | ☐ |

Insignia Health. "Patient Activation Measure; Copyright © 2003-2010, University of Oregon. All rights reserved.
Contact Insignia Health at www.insigniahealth.com