

## A comprehensive assessment of factors related to smoking and other cardiovascular disease risk factors among people

## experiencing severe mental illness

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BSc (Hons)

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## **TABLE OF CONTENTS**

ABSTRACT	viii
PUBLICATIONS DURING ENROLMENT	Х
DECLARATIONS	xiv
ACKNOWLEDGEMENTS	xvii
GLOSSARY OF ABBREVIATIONS	XX
SETTING THE SCENE	xxiii

CHA	APTER ONE: INTRODUCTION	1
1.1	Increased smoking in severe mental illness	2
1.2	Poor physical health in severe mental illness	3
1.3	Impact of smoking in severe mental illness	5
1.4	Smoking myths related to people experiencing severe mental illness	6
1.5	Reasons for increased smoking in severe mental illness	7
1.6	Motivation and confidence in relation to quitting smoking in people experiencing	
	psychosis	9
1.7	Targeting multiple CVD risk factors among smokers experiencing psychosis	11
1.8	Gender differences in smoking	13
1.9	Smoking interventions in severe mental illness	14
1.10	Smoking reduction and cessation in severe mental illness	15
1.11	Impact of smoking reduction/cessation on severe mental illness and medication	17
1.12	Smoking in psychiatry	19
1.13	Smokefree psychiatric facilities	20
1.14	SUMMARY OF INTRODUCTION	23
1.15	STUDY AIMS	24

## CHAPTER TWO: CHARACTERISTICS OF SMOKERS EXPERIENCING

	PSYCHOSIS	28
2.1	PREAMBLE	28
	Health behaviour risk factors for coronary heart disease (CHD) in smokers with	
	a psychotic disorder: baseline results	30
2.2	OVERVIEW OF RESULTS	44

## CHAPTER THREE: GENDER DIFFERENCES IN SMOKERS DIAGNOSED

	WITH PSYCHOSIS	45
3.1	PREAMBLE	45
	Gender differences in characteristics and outcomes of smokers diagnosed with	
	psychosis participating in a smoking cessation intervention	47

## CHAPTER FOUR: TREATMENT OPTIONS FOR SMOKING CESSATION

	AMONG PEOPLE EXPERIENCING PSYCHOSIS	65
4.1	PREAMBLE	65
	Sequential behavioral treatment of smoking and weight control in bipolar	
	disorder	70

	Response to Anandarajan et al.: Manic exacerbation induced by nicotine patch	76
4.2	OVERVIEW OF RESULTS	78
CH	APTER FIVE: IMPLEMENTING A TOTALLY SMOKEFREE POLICY	
	IN THE ACUTE PSYCHIATRY SETTING: THE INPATIENT	
	EXPERIENCE	80
5.1	PREAMBLE	80
	Inpatient views and experiences before and after implementing a totally	
	smoke-free policy in the acute psychiatry hospital setting	82
	An inpatient group to support the implementation of a Totally Smokefree Policy	
	in the acute psychiatry setting: The role of psychologists	92
5.2	OVERVIEW OF RESULTS	117
CH	APTER SIX: DISCUSSION	119
6.1	SUMMARY OF RESEARCH FINDINGS	119
6.2	COMPARISON WITH PREVIOUS RESEARCH	122
	6.2.1 Previous research in smokers with severe mental illness	122
	6.2.2 Previous research in smokers from the general population	128
6.3	THEORETICAL IMPLICATIONS OF FINDINGS	134
6.4	CLINICAL IMPLICATIONS OF FINDINGS	136
	6.4.1 Motivation and confidence	137
	6.4.2 Smoking cessation pharmacotherapy	138
	6.4.3 Psychosocial interventions for smoking cessation among people with	
	severe mental illness	139

	6.4.4 Multi-component interventions for CVD risk reduction	140
	6.4.5 Gender sensitive approaches to smoking cessation	140
6.5	STRENGTHS OF THE RESEARCH	141
6.6	LIMITATIONS OF THE RESEARCH	142
6.7	FUTURE RESEARCH	143
	6.7.1 Direct extension of the study	143
	6.7.2 Broader issues to be covered in future work	144
6.8	CONCLUSION	146
REFERENCES		148
API	PENDICES	167
APF	PENDIX 1:	167
	A prospective study of the impact of smoking on outcomes in bipolar and	

schizoaffective disorder	168
APPENDIX 2:	174

## Coronary heart disease risk reduction intervention among overweight smokers

with a psychotic disorder: pilot trial	175
APPENDIX 3:	182

Healthy lifestyle intervention for people with severe mental disorders	183
APPENDIX 4:	197

Study protocol: a randomised controlled trial investigating the effect of a healthy	
lifestyle intervention for people with severe mental disorders	198
APPENDIX 5:	206
Varenicline plus healthy lifestyle intervention for smoking cessation in psychotic	
disorders	207

APPENDIX 6:	214
Randomized controlled trial of a healthy lifestyle intervention among smokers	
with psychotic disorders	215
APPENDIX 7:	232
Manic exacerbation induced by nicotine patch	233

#### ABSTRACT

The prevalence of smoking and the resultant impact on the health and well-being of people experiencing severe mental illness, is significantly disproportionate to smokers in the general population. Smokers experiencing severe mental illness are more likely to die, and at an earlier age, from smoking-related conditions, predominantly cardiovascular disease (CVD). Further, smoking among people experiencing severe mental illness is associated with a poorer clinical picture, and increases the financial stress already experienced by this group of smokers. The overall aim of this thesis was to explore various aspects of smoking behaviour among people experiencing severe mental illness.

The first study explored CVD risk factors and associated variables among 43 smokers diagnosed with psychosis. Results indicated that smokers experiencing psychosis were generally overweight, physically inactive and had a poor diet. Participants reported smoking because they were addicted and to manage stress. They were motivated to quit smoking, improve their diet and increase their physical activity, but lacked confidence in their ability to make these changes.

The next two studies explored gender differences in smokers diagnosed with psychosis. One study investigated gender differences among 298 smokers participating in a smoking cessation intervention. The other study examined the perceived risks and benefits of quitting in 200 people experiencing psychosis. Findings indicated that females were more likely than males to report smoking to prevent weight gain, and were particularly concerned that quitting would cause them to gain weight and experience negative emotions. Females reported more reasons for quitting and were more likely to be driven by extrinsic motivators to quit. Overall

these studies revealed that smokers experiencing psychosis demonstrated fewer gender differences compared to smokers without mental illness.

The next section focused on interventions addressing smoking and other CVD risk factors. One paper presented a case study of a female smoker diagnosed with bipolar disorder describing the experience, relevant literature and clinical challenges encountered during her involvement in a multi-component CVD risk factor intervention. Another paper demonstrated how the theoretical knowledge and clinical experience gained during this thesis could dispel some common myths regarding smoking cessation among people with severe mental illness.

The final studies explored the patient perspective of being admitted to a psychiatric ward where smoking is banned. One study examined the views and experiences of 46 inpatients before, and 52 inpatients after, the implementation of a Totally Smokefree Policy in the psychiatry ward. Another study detailed the design, implementation, experience and evaluation of an inpatient group supporting a total smoking ban in the acute psychiatry setting, including data from 22 groups with 71 participants. Findings indicated that while smokers had the most negative views about the smoking ban, they smoked much less once admitted and were interested in quitting in the future. Following the smoking ban, patients described experiencing increased negative emotions, and struggled with losing smoking as their main coping strategy for stress.

The results of this thesis provide new and important insights into smoking among people experiencing severe mental illness and can be directly translated into clinical practice.

## PUBLICATIONS DURING ENROLMENT

## Papers published during enrolment

- Baker, A., Kay-Lambkin, F. J., Richmond, R., Filia, S., Castle, D., Williams, J., & Lewin, T.
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- Filia, S. L., Gurvich, C. T., Horvat, A., Shelton, C. L., Katona, L. J., Baker, A. L., Stafrace, S., Keppich-Arnold, S., & Kulkarni, J. (2015). Inpatient views and experiences before and after implementing a totally smoke-free policy in the acute psychiatry hospital setting. *International Journal of Mental Health Nursing*, 24(4), 350-359.

#### Papers submitted and returned for revision during enrolment

Filia, S.L., Shelton, C.L., Katona, L.J., Horvat, A., Gurvich, C.T., Baker, A.L., Stafrace, S., Keppich-Arnold, S., & Kulkarni, J. (2015). An inpatient group to support the implementation of a Totally Smokefree Policy in the acute psychiatry setting: The role of psychology.

#### Abstracts published during enrolment

- Castle, D., Hocking, B., Filia, S., & Organ, B. (2008). The physical health of people with a serious mental illness. *Australian and New Zealand Journal of Psychiatry*, 42(Suppl. 1), A12.
- Filia, S., Baker, A., Richmond, R., Castle, D., Kay-Lambkin, F., Sakrouge, R., Taylor, R., Harris, D., de Castella, A., & Kulkarni, J. (2008). The healthy lifestyles project: pilot data from a multicomponent risk factor intervention for people with severe mental illness. *Australian and New Zealand Journal of Psychiatry*, 41(Suppl. 2), A456.
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## DECLARATIONS

## Thesis including published works General Declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma 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, except where due reference is made in the text of the thesis.

This thesis includes 6 original papers published in peer reviewed journals and 1 unpublished publication. The core theme of the thesis is the exploration of factors related to smoking and other cardiovascular disease risk factors among people experiencing severe mental illness. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within the Monash Alfred Psychiatry research centre (MAPrc), Central Clinical School under the supervision of Professor Jayashri Kulkarni, Professor Amanda Baker and Dr Caroline Gurvich.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

Thesis	Publication title	Publication	Nature and extent (%) of
chapter		status*	students contribution
2	Health behaviour risk factors for coronary heart disease (CHD) in smokers with a psychotic disorder: baseline results	Published	Assisted with study design and protocol; completed ethics application and annual reports; recruitment of participants; data collection; data analysis; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs
			Contribution = 80%
3	Gender differences in characteristics and outcomes of smokers diagnosed with psychosis participating in a smoking cessation intervention	Published	Conceptualisation of the study; literature review; obtained ethics approval; data analysis; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs Contribution = 80%
3	The perceived risks and benefits	Published	Conceptualisation of the
	of quitting in smokers diagnosed		study; literature review;

In the case of Chapters 2, 3, 4 and 5 my contribution to the work involved the following:

	with severe mental illness participating in a smoking cessation intervention: gender differences and comparison to smokers without mental illness		completed ethics application and annual reports; recruitment of participants; data collection; data analysis; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs
4	Sequential behavioral treatment of smoking and weight control in bipolar disorder	Published	Contribution = 80% Formulated concept for the paper; review of relevant literature; completed ethics application and annual reports; contributed to development of the study treatment manual; research therapist; selection and write up of case study; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs
4	Response to Anandarajan et al.: Manic exacerbation induced by nicotine patch	Published	Contribution = 90% Development of concepts in the paper; review of relevant literature; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs Contribution = 90%
5	Inpatient views and experiences before and after implementing a totally smoke-free policy in the acute psychiatry hospital setting	Published	Study design and protocol; literature review; obtained ethics approval; recruitment of participants; data collection; data analysis; preparation of manuscript; submission of manuscript including preparation of revisions and correction of proofs Contribution = 85%

-		5 10	<u> </u>
5	An inpatient group to support the	Returned for	Study design and protocol
	implementation of a Totally	revision	including the development
	Smokefree Policy in the acute		of the content and materials
	psychiatry setting: The role of		for the group sessions;
	psychology		literature review; obtained
			ethics approval; recruitment
			of participants; facilitating
			group sessions; data
			collection; data analysis;
			preparation of manuscript;
			submission of manuscript;
			preparing revised
			manuscript
			1
			Contribution = 85%

\* e.g. 'published'/ 'in press'/ 'accepted'/ 'returned for revision'

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

## **Student signature:**

## Date: 3<sup>rd</sup> DEC 2015

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the student and co-authors' contributions to this work.

Main Supervisor signature:

Date: 3<sup>rd</sup> DEC 2015

## **GLOSSARY OF ABBREVIATIONS**

А	action
AIHW	Australian Institute of Health and Welfare
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
AOD	alcohol and other drug
BCOS	Bipolar Comprehensive Outcomes Study
BDI-II	Beck Depression Inventory II
BMI	body mass index
BPAD	bipolar affective disorder
BPRS	Brief Psychiatric Rating Scale
С	contemplation
CBT	cognitive behavioural therapy
CGI-BP	Clinical Global Impression scale for bipolar disorder
CHD	coronary heart disease
СМ	case manager
СМ	contingency management
СМНТ	community mental health team
СО	carbon monoxide
CONSORT	Consolidated Standards of Reporting Trials
COPD	chronic obstructive pulmonary disease
CPD	cigarettes per day
CVD	cardiovascular disease
СҮР	cytochrome P450 enzyme system
DIP	Diagnostic Interview for Psychosis

DSM	Diagnostic and Statistical Manual of Mental Disorders
DSP	Disability Support Pension
ENDS	electronic nicotine delivery systems
EQ-5D	EuroQol health related quality of life 5-dimension questionnaire
FTND	Fagerstrom test of nicotine dependence
GP	general practitioner
HAMD-21	21 item Hamilton Depression Rating Scale
HDL	high-density lipoprotein
HDU	high dependency unit
ICD-10	International Classification of Diseases, 10 <sup>th</sup> Revision
IWQOL-lite	Impact of Weight on Quality of Life scale
LDU	low dependency unit
М	maintenance
m	mean
MAPrc	Monash Alfred Psychiatry research centre
MI	motivational interviewing
MINI	Mini International Neuropsychiatric Interview
MNWS-R	Minnesota Nicotine Withdrawal Scale – Revised
n	number
NA	not applicable
NHMRC	National Health and Medical Research Council
NRT	nicotine replacement therapy
NS	no significant difference
NSW	New South Wales
OTI	Opiate Treatment Index

PA	preparation for action
PBS	Pharmaceutical Benefits Scheme
PC	precontemplation
PRBQ	Perceived Risks and Benefits Questionnaire
RCT	randomised controlled trial
RDI	recommended daily intake
RFQ	Reasons For Quitting scale
RMQ	Readiness and Motivation to Quit Smoking Questionnaire
RSQ	Reasons for Smoking Questionnaire
SD	standard deviation
SE	standard error
SF-12 (MCS)	12-item Short Form survey Mental health Component Score
SF-12 (PCS)	12-item Short Form survey Physical health Component Score
SF-12	12-item Short Form survey
SF-36	36-item Short Form survey
SLICE/LIFE	Streamlined Longitudinal Interview Clinical Evaluation from the
	Longitudinal Interval Follow-up Evaluation
SPSS	Statistical Package for the Social Sciences
STAI	State-Trait Anxiety Inventory
tDCS	transcranial direct current stimulation
WHO	World Health Organisation
YMRS	Young Mania Rating Scale

#### SETTING THE SCENE

This PhD candidature has progressed across an extended duration of time, mainly due to the personal and family circumstances of the candidate. The PhD confirmation of candidature was completed in late 2008, the same year that this literature review was prepared. The literature review lays the foundation for the studies undertaken as part of this thesis, describing the relevant research that was current at that particular time and highlighting how the proposed research would significantly add to this. For this reason, the work described in the literature review does not go beyond 2008. Advances in knowledge and research in this area are accounted for within this thesis in the introductory sections to each chapter, within the publications themselves, and throughout the integrative discussion.

During this PhD, the candidate has been part of a larger research team and as such has made important contributions to other related research beyond that included in the first author publications. Consequently, this has resulted in the candidate being included as a co-author on several other publications. Specifically, the candidate has contributed to formulating the study designs; developing the interventions involved including the treatment manuals; recruited study participants; collected data for the studies; acted as a therapist delivering the interventions; supervised other staff and therapists working on this research; and been involved in the preparation and revision of the manuscripts. Clearly, as the candidate is not wholly responsible for the intellectual property involved in these studies, the resultant publications have been included as appendices, but mentioned throughout this thesis as they form an integral part of the story of this research.

xxvii

#### **CHAPTER ONE: INTRODUCTION**

Smoking contributes to the development and exacerbation of a range of recognised medical conditions. The Australian Institute of Health and Welfare (AIHW) have identified that smoking has the greatest impact of the 14 major health risks (lifestyle, physiological, social and environmental), and accounts for 1 in every 9 deaths in Australia (Begg et al., 2007). More broadly, the World Health Organisation (WHO) estimated in 2006 that 5 million deaths worldwide occurred as a result of smoking tobacco. This figure is expected to double by the year 2020, with 70% of the deaths occurring in low and middle-income countries (WHO, 2006).

The prevalence of smoking is elevated in certain groups within society. A linear relationship between smoking and socioeconomic status has been established, with only half as many regular smokers in the most affluent category than in the most disadvantaged category (AIHW, 2006). Related to this, are the findings that people experiencing any form of mental illness smoke in greater numbers than those unaffected. Psychosis is a general term used to describe a range of psychiatric conditions characterised by a loss of contact with reality and this includes conditions such as schizophrenia, schizoaffective disorder, bipolar affective disorder (BPAD) and depression with features of psychosis. The term "severe mental illness" is also commonly used, and this includes each of these conditions just described as "psychosis" together with major depression and borderline personality disorder. The conditions encompassed under these terms, psychosis and severe mental illness, are the focus of this thesis.

1

#### 1.1 Increased smoking in severe mental illness

Studies report that people experiencing severe mental illness, when compared to the general population, have significantly increased rates of smoking (AccessEconomics, 2007; de Leon & Diaz, 2005). Australian data indicates that the prevalence rate of smoking among people with mental illness is 31.8% compared to 17.7% of people without a mental illness (AccessEconomics, 2007). The difference is even greater in different settings and for specific types of mental illness.

People with a severe mental illness who are admitted to a psychiatric hospital tend to increase the amount they smoke. Jochelson and Majrowski (2006) found that up to 70% of inpatients in a psychiatric ward smoked, with 50% smoking heavily. These rates were considerably increased compared to the amount they smoked at home. Being admitted to a psychiatric ward can also result in non-smokers becoming smokers (Lawn, Pols, & Barber, 2002).

A meta-analysis of 42 studies across 20 countries including 7593 people experiencing schizophrenia concluded that people with this condition are 5.3 times more likely to be current smokers than people from the general population (de Leon & Diaz, 2005). In fact, this meta-analysis demonstrated prevalence rates of smoking among people diagnosed with schizophrenia of up to 90%.

Not only do people experiencing severe mental illness smoke more than the general population, but they also smoke differently. Research has demonstrated that people experiencing severe mental illness smoke more heavily than people in the general population. One study has described that people experiencing a mental illness smoke at least 16% more heavily than people without (Compton, 2005). This study, reported that the average smoker

2

with a mental illness has 26.2 cigarettes per day, compared to the average person who smokes 22.6 per day. Other work has confirmed this finding, in addition to concluding that people with severe mental illness smoke for longer periods, and have higher levels of nicotine dependence than smokers in the general population (Kumari & Postma, 2005). Studies of smoking behaviour have further demonstrated that people experiencing schizophrenia smoke more puffs per cigarette than people without mental illness, consequently increasing their nicotine intake (Williams et al., 2008). People with a mental illness are twice as likely to smoke chop-chop tobacco than the general population. It has been estimated that chop-chop accounts for about 15% of tobacco use by people with a mental illness (Moeller-Saxone, Tobias, & Helyer, 2005). Chop-chop tobacco is illegally grown or produced tobacco. Because chop-chop escapes the strict regulation and production that legal tobacco is subjected to, it contains different potentially harmful substances (e.g. mould and grass clippings), which can result in serious respiratory illness, even death. This poses an extra significant health risk for smokers with a mental illness.

The prevalence of smoking in Australia has steadily been declining since the 1950s (AIHW, 2006). However, this is not the case for people with mental illness. Research from the United States has indicated that smoking rates in people experiencing mental illness have not fallen significantly in the past 40 years (Lamberg, 2004).

## 1.2 Poor physical health in severe mental illness

The impact of mental illness on a person can be significant and broad. Unfortunately, not only do people experiencing severe mental illness have difficulty with their thinking, emotions and relationships, but their physical health is often poor. People experiencing severe mental illness have a shortened lifespan compared to the general population. In fact, it has been reported that people experiencing severe mental illness lose about 20 years of normal life span compared to the general population (Colton & Manderscheid, 2006; Newman & Bland, 1991). Rates of death for people with schizophrenia are about 2-3 times higher than those expected or observed in the general population (Auquier, Lancon, Rouillon, Lader, & Holmes, 2006; Osby, Correia, Brandt, Ekbom, & Sparen, 2000). The main reason for the increased mortality among people with a mental illness is deaths caused by comorbid medical conditions, not suicide (Aguilar, Gurpegui, Diaz, & de Leon, 2005; Auquier et al., 2006; Brown, Inskip, & Barraclough, 2000).

The biggest physical health problem and major cause of death for people experiencing severe mental illness is coronary heart disease (CHD) (Harris & Barraclough, 1998; Lawrence, Holman, Jablensky, & Hobbs, 2003; Osby et al., 2000). It has been estimated that between 50-75% of people with schizophrenia will develop CHD (Hennekans, Hennekans, Hollar, & Casey, 2005). Studies have consistently demonstrated that the prevalence rate of CHD amongst people experiencing psychosis is significantly higher than that seen in the general population (Cohn, Prod'homme, Streiner, Kameh, & Remington, 2004; Goff, Henderson, & Amico, 1992; Hennekans et al., 2005). Furthermore, people experiencing schizophrenia are less likely to receive appropriate treatment for CHD (Kisely et al., 2007; Young & Foster, 2000) and are about twice as likely as the general population to die from heart disease (Brown et al., 2000; Harris & Barraclough, 1998).

The Australian Institute of Health and Welfare (AIHW, 2006) report that the major risk factors for CHD are tobacco smoking, high cholesterol, high blood pressure, physical inactivity and being overweight. Each of these risk factors are seen in elevated rates in

people experiencing severe mental illness. It has been suggested that the majority of the excess natural mortality recorded in people experiencing severe mental illness is due to cigarette smoking (Brown et al., 2000).

Smoking results in nicotine dependence which is characterised by both tolerance and withdrawal symptoms in relation to nicotine use. Nicotine dependence is specifically recognised as a psychiatric condition in the Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association, 2000). Therefore, it is fair to conclude that smoking is the most prevalent and deadly of all psychiatric disorders (Campion, McNeill & Checinski, 2006).

## 1.3 Impact of smoking in severe mental illness

In addition to the well documented increased rate of CHD in people experiencing severe mental illness, smoking contributes to other physical health conditions that also affect this population of smokers. These include various cancers, stroke, hypertension and other cardiovascular conditions, and chronic obstructive airway disease (COPD). In an extensive review of the literature on physical illness in schizophrenia, it was concluded that the rate of respiratory disease, particularly impaired lung function, was increased in this group of people (Leucht, Burkard, Henderson, Maj, & Sartorius, 2007). Another study found that a diagnosis of schizophrenia increased the risk of death from respiratory disease by 10 times compared to the general population (Joukamaa et al., 2001).

The financial cost of smoking is also significant for people experiencing severe mental illness. An Australian researcher calculated the cost of smoking for people treated within a mental health service (Lawn, 2001). Based on estimates in 2001, people with a mental illness

spent about 37% of their income from the Disability Support Pension (DSP) per week on purchasing cigarettes. A significant proportion of this (28%) was paid to the government in the form of cigarette excise tax. People experiencing mental illness receive about \$2.2 billion in DSP per year, whilst they pay \$2.8 billion per year in cigarette excise tax (AccessEconomics, 2007). Therefore, people experiencing mental illness are contributing significantly to the cost of their own care via their smoking behaviour (Lawn, 2001). Further, people experiencing severe mental illness often sacrifice a healthier diet or social activities to be able to afford smoking (Steinberg, Williams, & Ziedonis, 2004)

Studies have demonstrated an independent effect of smoking on poorer clinical outcome and treatment response in depression, bipolar disorder and schizophrenia (Berk, 2007). Our own work compared the clinical characteristics of people experiencing bipolar and schizoaffective disorder according to smoking status and this publication is included as Appendix 1 (Dodd et al., 2010). Smokers experiencing bipolar and schizoaffective disorder had a significantly poorer quality of life and more severe symptoms than non-smokers with these conditions. In schizophrenia, smoking is associated with longer duration of illness, more severe symptoms of psychosis, higher doses of medication, and more frequent hospital admissions (Aguilar et al., 2005; Goff et al., 1992; Salokangas, Honkonen, Stengard, Koivisto, & Hietala, 2006).

## 1.4 Smoking myths related to people experiencing severe mental illness

A number of myths prevail in relation to smokers that experience severe mental illness. These include that people with severe mental illness are not interested in or able to quit smoking; that their mental health will decline if they try to quit smoking; and that they could not or should not tolerate a psychiatric hospital admission without smoking (Pisinger, 2007). Often, these views are particularly prevalent among the health care professionals involved in the care and management of these smokers with severe mental illness. Further, these myths can serve as significant barriers to accessing appropriate smoking cessation treatment for people experiencing severe mental illness. The literature surrounding some of these ideas will be explored in the following sections.

#### 1.5 Reasons for increased smoking in severe mental illness

There is no one reason to explain why people experiencing severe mental illness smoke more than people in the general population. Rather, the explanation is probably found in the complex interaction of several factors (Pisinger, 2007). A range of biological, psychological and social factors have been postulated to contribute to the increased prevalence of smoking in people with severe mental illness (Ziedonis & Williams, 2003). These include genetics; neurobiological vulnerability; high levels of nicotine dependence; self-medication of psychiatric symptoms; reducing side-effects of medication; improving cognition; poor coping abilities; to alleviate boredom and loneliness; as a consequence of the values and practices within the treating system; and due to a lack of access to suitable smoking cessation programs, support and products (Pisinger, 2007; Ziedonis & Williams, 2003).

Few studies have examined self-reported reasons for smoking among people experiencing mental illness (Reichler, Baker, Lewin, & Carr, 2001). Perhaps self-reported reasons are the most relevant to the individual as these personally drive the behaviour, and awareness of these reasons provides the focus for addressing the gaps created when smoking is no longer the desired behaviour. One study asked 59 people experiencing schizophrenia to state the reason why they smoked (Glynn & Sussman, 1990). The two main reasons for smoking, both endorsed by 20% of the sample, were to reduce the side-effects of medication and in response to the symptoms of psychosis. Similarly, a study of 100 people diagnosed with schizophrenia

described the main self-reported reasons for smoking to be relief from negative symptoms and medication side-effects (Forchuk et al., 2002). Another study of 147 people admitted to a psychiatric hospital with coexisting alcohol and other drug problems, found the most commonly cited reason for smoking was "I am addicted" (39%), followed by reasons related to the calming effects of smoking (17%) (Reichler et al., 2001). Other common self-reported reasons for smoking were to relieve boredom (14%) and due to habit (13%). Baker et al. (2007) asked 298 smokers with psychosis to complete the Reasons for Smoking Questionnaire (Pederson, Bull, Ashley, & MacDonald, 1996). The most common reasons for smoking reported related to stress reduction and addiction. When compared to the responses of smokers from the general population, the people experiencing psychosis were more likely to report that they smoked due to reasons related to stress reduction, stimulation and addiction. Around the same time, Gurpegui et al. (2007) asked 173 smokers diagnosed with schizophrenia, and 100 smokers without mental illness their main reason for smoking. Participants experiencing schizophrenia reported smoking to assist with their mood, agility, alertness, concentration and anxiety. When compared to those without mental illness, desire for calmness was the main reason for smoking reported by participants experiencing schizophrenia. Most recently, a study compared the self-reported reasons for smoking of 61 inpatients diagnosed with schizophrenia to those of 33 people without mental illness (Barr, Procyshyn, Hui, Johnson, & Honer, 2008). This study reported that people experiencing schizophrenia were more likely than the control group to report smoking for stimulation, and pleasure from the ritual of smoking. The most consistent finding from these studies is that when compared to the general population, people who experience mental illness report that they smoke for reasons related to addiction, stress management and stimulation.

# 1.6 Motivation and confidence in relation to quitting smoking in people experiencing psychosis

Motivation for smoking cessation relates both to why smokers want to quit and to the strength of their desire to do so (Curry, Grothaus, & McBride, 1997). Little is known about the characteristics of motivation to quit smoking in people experiencing psychosis (Baker et al., 2007).

Curry, Wagner, and Grothaus (1990) devised the Reasons for Quitting Scale (RFQ) based on their model of intrinsic and extrinsic motivations for smoking cessation. Intrinsic motivation for behaviour relates to rewards internal to the person, e.g. health concerns. Extrinsic motivation describes behaviour that relates to external reward such as financial incentives or peer approval. Items of the RFG relating to health concerns and self-control comprise the intrinsic motivation scale, and those relating to immediate reinforcement and social influence comprise the extrinsic motivation scale. Curry et al. (1990) examined these dimensions of motivation in smokers from the general population. They reported that higher levels of extrinsic motivation were associated with failure to quit smoking. The successful quitter was a person who was able to differentiate between intrinsic and extrinsic motivation, and had significantly higher levels of intrinsic motivation and lower levels of extrinsic motivation.

The first study to formally assess the type of motivation to quit smoking in people experiencing psychosis was reported by Baker et al. (2007). They asked 298 smokers experiencing psychosis to complete the RFQ, and then compared the responses to those of a sample of smokers from the general population (Curry et al., 1997). Both samples had presented for assistance with smoking cessation. People experiencing psychosis demonstrated significantly higher overall motivation scores to quit smoking than people in

9

the general population. People experiencing psychosis were more likely to endorse selfcontrol, immediate reinforcement and social influences as reasons for quitting smoking than the general population, while health concerns were equal between the two samples. Participants experiencing psychosis were significantly more likely to report extrinsic factors as reasons for quitting compared to the general population. This demonstrates that people experiencing psychosis are just as concerned about the health consequences of smoking as the general population. In addition, people experiencing psychosis may be more motivated to quit smoking than the general population, but be driven by the desire to attain external rewards as a consequence of quitting.

A model describing the strength of a person's motivation to change their smoking behaviour has been proposed by Prochaska and DiClemente (DiClemente et al., 1991). The Stages of Change Model describes how individuals move through a series of stages (Precontemplation, Contemplation, Preparation, Action, Maintenance) in the adoption of a healthy behaviour or cessation of an unhealthy one (Prochaska & Velicer, 1997). Research has demonstrated that people in the general population in the precontemplation and contemplation stages were significantly less likely to attempt to quit smoking over 6 months compared to those in the preparation stage (DiClemente et al., 1991). Several studies have assessed the stages of change for smokers with a mental illness who were not seeking assistance to reduce or quit (Carosella, Ossip-Klein, & Owens, 1999; Reichler et al., 2001) and have found the pattern to be similar to that of the general population (Etter, Mohr, Garin, & Etter, 2004). To our knowledge, only one study (Baker et al., 2007) has evaluated the stages of change among smokers experiencing psychosis who presented for assistance to change their smoking behaviour. In this sample, 13.1% were categorised in the precontemplation stage.

10

Simply being motivated to change behaviour is not a guarantee of success. Another variable can mitigate the relationship between motivation and outcome. Self-efficacy, or confidence, is a person's belief in their ability to make a change (Bandura, 1977). Research among smokers in the general population has revealed a relationship between high levels of confidence and smoking abstinence, and low levels of confidence and smoking relapse (Cooney et al., 2007; Shiffman et al., 2000). There have been no studies examining the levels of confidence that smokers experiencing psychosis have in relation to quitting smoking. Knowledge of such information may guide smoking cessation interventions, providing smokers experiencing psychosis with the best opportunities to maximise successful smoking abstinence.

#### 1.7 Targeting multiple CVD risk factors among smokers experiencing psychosis

Smoking is not a unitary problem for people with severe mental illness. As has been previously mentioned, multiple CVD risk factors are seen among people experiencing severe mental illness. As one example, people experiencing severe mental illness are at significant risk of obesity due to the illness itself and partly as a consequence of their psychiatric treatment (Osborn, Nazareth, & King, 2007; McElroy et al., 2004; Virk, Schwartz, Jindal, Nihalani, & Jones, 2004). Like smoking, obesity has been associated with poorer clinical presentations and outcomes in people experiencing severe mental illness, in addition to the obvious physical health consequences that obesity results in (Fagiolini, Kupfer, Houck, Novick, & Frank, 2003; Fagiolini et al., 2004). Smokers already increase their risk of CVD in multiple ways as the physiological impact of smoking serves to increase their blood pressure, cholesterol and overall risk of stroke. But it seems that smokers may also have elevated rates of behavioural CVD risk factors that result as a consequence of their smoking behaviour. One study has found a significant difference in dietary patterns between smoking

and non-smoking patients, as non-smokers showed healthier eating habits than smokers (McCreadie, 2003).

The presence of multiple CVD risk factors makes for a more deadly combination, as this has been associated with greater risk for disease and overall risk of ill health due to their interactive effects (AIHW, 2005). Therefore, interventions designed to reduce CVD risk would ideally address more than one CVD risk factor at a time. Research has demonstrated that this multi-component approach can further have an impact of improving smoking cessation outcomes. A recent Cochrane review of studies undertaken among people from the general population concluded that an increased focus on improving several lifestyle activities can assist a person to stop smoking (Ussher, Taylor, & Faulkner, 2008). There are very few studies of interventions that target specific CVD risk factors individually among people experiencing psychosis. The research literature is still focused on gathering evidence that demonstrates that CVD risk factors are elevated among this population, and clinical practice in this area lags far behind, with CVD risk factors not being routinely assessed or addressed in people experiencing severe mental illness (Kumar, 2004). Given the huge impact that CVD has on the morbidity and mortality of people experiencing psychosis, it seems logical to offer a multi-component CVD risk factor intervention to this population. To date, no such study has been published targeting several CVD risk factors among people experiencing severe mental illness, and smokers as a more specific group within this population seem particularly worthy of such an intervention. Firstly, it is important to determine if smokers experiencing psychosis are interested in and confident that they could make changes to several health behaviours, and such a study has not yet been undertaken.

12
### 1.8 Gender differences in smoking

In the Australian general population, males are more likely to be daily smokers than females (18.6% vs 16.3%) (AIHW, 2006). This statistic is reflected worldwide, with research further indicating that smoking rates are decreasing far more for males than females (Schnoll, Patterson, & Lerman, 2007). Both males and females that smoke are at risk of developing cancer, CVD and respiratory disease, but there are gender differences in smoking related morbidity and mortality (Schnoll et al., 2007). There has been a 600% increase in the incidence of lung cancer related deaths in female smokers in the United States over the past 50 years, while this rate has been decreasing for male smokers since the 1980s (Patel, Bach, & Kris, 2004). Smoking causes unique health problems specifically for females, such as the additional risks it poses in relation to certain cancers (e.g. cervical, ovarian), and the impact that it has on reproductive health and pregnancy (Perkins, 2001).

Research examining gender differences in smoking variables and outcomes in the general population have found clear differences between males and females. Studies have demonstrated that females have poorer smoking cessation treatment outcomes than males (Blake et al., 1989; McKee, O'Malley, Salovey, Krishnan-Sarin, & Mazure, 2005). Further, it has been suggested that female smokers are less interested, committed and/or confident in relation to quitting (Blake et al., 1989). One study found that females reported significantly lower motivation to quit related to health concerns and higher motivation related to immediate reinforcement than males (Curry et al., 1997). Another study demonstrated that female smokers anticipated more negative outcomes associated with quitting (e.g. weight gain, increase in negative emotions) than males (McKee et al., 2005).

13

To date, there has been no research reported that describes potential gender differences in smoking behaviour, motives, cessation or outcomes among people experiencing severe mental illness. Identifying potential gender differences in smokers diagnosed with psychosis is important to ensure that smoking cessation interventions can be gender sensitive to enhance smoking outcomes for this particular population of smokers. There are clear gender differences between males and females in terms of the presentation, course and outcomes related to severe mental illness. Research has demonstrated that when compared to males, females experiencing schizophrenia tend to have better premorbid functioning, a later age of onset, a distinct symptom profile characterised by a less severe course of illness, and different structural brain abnormalities and cognitive deficits (Canuso & Pandina, 2007; Hafner, 2003; Kulkarni et al., 2002, 2008). It might be expected that some of these gender differences in clinical variables among males and females experiencing severe mental illness may translate to gender differences in smoking variables, but to date, the studies required to examine this potential relationship have not yet been undertaken in this population.

#### 1.9 Smoking interventions in severe mental illness

A range of interventions have been applied in the general population to assist people to reduce or quit smoking. These include pharmacotherapy (e.g. nicotine replacement therapy (NRT), bupropion (zyban) and more recently varenicline (champix). Other approaches include brief advice, counselling and behavioural therapies, promotion campaigns, and environmental and regulatory interventions (e.g. smoking bans and cigarette packet labelling) (AccessEconomics, 2007). Some of these obviously apply to people experiencing severe mental illness. More specifically though, smoking interventions that have been delivered to people experiencing severe mental illness include NRT (patches, gum, lozenges, inhaler and nasal spray), bupropion, psychological approaches (e.g. counselling, cognitive behavioural

14

therapy (CBT), and lifestyle changes (e.g. exercise) (Campion, Checinski, & Nurse, 2008; el-Guebaly, Cathcart, Currie, Brown, & Gloster, 2002). The majority of these interventions were individually delivered, fewer in group format, but often a combination of intervention types were utilised (e.g NRT and CBT).

The efficacy of a smoking cessation intervention is determined in a number of ways. The number of cigarettes per day is recorded. Using an objective measure such as the expired carbon monoxide (CO) test further validates this self-reported abstinence. Research evaluating the success of a smoking intervention often reports on continuous abstinence (which means that the person maintains complete and continuous abstinence from smoking since the intervention) and point prevalence abstinence (which ignores periods of smoking relapse if the person is currently abstinent at the time of the assessment) (AccessEconomics, 2007).

## 1.10 Smoking reduction and cessation in severe mental illness

It has been reported that smokers with severe mental illness face additional barriers to seeking treatment for their smoking behaviour. These include a lack of smoking interventions tailored to their particular needs; the fear of becoming unwell due to the stress of quitting; the reinforcement of smoking within their social group and treating system; a lack of encouragement and support from peers, family and health professionals; concentration and motivation impairments throughout the therapy sessions; and decreased opportunity or availability of alternate activities to smoking (AccessEconomics, 2007). Some of these factors also serve as barriers to successful quitting among people experiencing severe mental illness. Others include the absence of well-developed alternative coping strategies for stress and other emotions (e.g. anger, sadness); the high incidence of smoking in co-clients around

them; the cost of NRT; potential changes in symptoms, mood and medication side-effects; weight gain; and co-occurring drug and alcohol problems.

However, the reality is that many of these potential barriers can be addressed and overcome, and people experiencing severe mental illness can successfully quit smoking. A comprehensive review of studies investigating smoking cessation interventions for people experiencing severe mental illness, concluded that people diagnosed with psychiatric disorders have similar quit rates for smoking cessation interventions to people in the general population (el-Guebaly et al., 2002). The most common smoking cessation intervention for this sample of smokers was a combination of individual counselling and medication (i.e. NRT).

The largest randomised controlled trial (RCT) of a smoking cessation intervention among people experiencing psychosis was conducted in Australia and reported by Baker et al. (2006). A total of 298 smokers experiencing psychosis, were randomly assigned to treatment as usual or individually administered smoking intervention, including NRT, motivational interviewing (MI) and CBT. Significantly more people who attended all treatment sessions had quit smoking at each of the follow-up occasions compared to those assigned to the control condition (e.g total abstinence at 12 month follow-up = 19% vs 7%). These results are comparable to those from the general population, where the use of NRT plus counselling as a smoking cessation intervention resulted in a quit rate of 16-18% (Shearer & Shanahan, 2006).

If complete abstinence cannot be achieved, smoking reduction is a good alternative. Smoking reduction may provide important health and financial benefits for smokers

16

experiencing mental illness (Evins et al., 2004). Importantly, smoking reduction may increase the likelihood of quitting in the future (Hughes, 2000). Baker et al. (2006) found that over one-third of people experiencing psychosis who had reduced their smoking by at least 50% at the 12 month follow-up, were completely abstinent at the 3 year follow-up. This was in comparison to just over 10% of the control condition.

The research related to smoking cessation interventions specifically for people experiencing severe mental illness remains very limited. Further studies are urgently required that involve the implementation and evaluation of different types of interventions that can assist people experiencing severe mental illness to quit smoking, as well as target other CVD risk factors. Ideally, such research would include both psychological and pharmacological interventions designed for this group of smokers. In addition, there have been no published case studies of changes in smoking behaviour in people experiencing severe mental illness. A more detailed account of the challenges faced, the intricacies of what changes were made and how, description of useful coping strategies, the successes, and the personal experience would make for interesting reading, and provide useful additional insights.

## 1.11 Impact of smoking reduction/cessation on severe mental illness and medication

It is important to understand, and prepare for possible changes to symptoms, medication and side-effects that may occur as a result of reducing or quitting cigarette smoking. Awareness of these factors will assist to make the quit attempt more successful for all involved.

Smoking reduction or cessation will inevitably lead to nicotine withdrawal symptoms. These can be quite significant, unpleasant and distressing. Nicotine withdrawal symptoms include cravings, lowered mood, sleep disturbance, concentration difficulties, restlessness, anxiety,

irritability, frustration, increased appetite and weight gain. There is considerable overlap between nicotine withdrawal symptoms and those experienced as part of a mental illness, and it is sometimes difficult to differentiate between the two. In the acute inpatient psychiatric facility, nicotine withdrawal symptoms are often misattributed to a worsening of the person's mental illness, and are seen as an increased potential for violence, and so are often responded to by ensuring the ongoing supply of cigarettes (Lawn & Pols, 2003). Nicotine withdrawal symptoms can be effectively reduced and managed through the use of appropriate smoking cessation pharmacotherapy such as NRT.

In a review of the literature regarding depression during smoking abstinence, evidence indicated that a minority of people experienced an increase in depressive symptoms when they quit smoking (Hughes, 2007). In particular, smokers with a past history of depression, or those with protracted nicotine withdrawal symptoms, were more likely to experience a relapse of depression when they quit smoking. Therefore, it is particularly important that people with a history of depression are closely monitored when they attempt to change their smoking behaviour.

There is even less evidence to suggest that symptoms of psychosis are exacerbated as a consequence of reducing or quitting smoking. Two recent studies did not find any deterioration in symptoms or functioning when a smoking cessation intervention was implemented for people experiencing psychosis (Baker et al., 2006; Currie et al., 2008). Symptom exacerbation, if it occurs, may be more related to the pressures and changes associated with quitting smoking, rather than quitting per se.

One area that smoking reduction/cessation has a definite impact on is psychiatric medication. The hydrocarbons in cigarette smoke, not the nicotine, cause particular enzymes in the liver to be more active, consequently metabolising and clearing medications from the bloodstream more effectively. The enzymes that are induced by compounds in cigarettes are responsible for the metabolism of many psychiatric medications, especially clozapine, olanzapine, haloperidol, fluvoxamine and some benzodiazepines (Bazire, 2005). This is consistent with clinical findings that people who smoke require higher doses of medication (Goff et al., 1992). Consequently, if a person taking psychiatric medication is to reduce or quit smoking, then the blood levels of some medications will increase, causing the emergence or exacerbation of side-effects. Similarly, blood levels of medication will reduce again if smoking is resumed. People experiencing severe mental illness, and those involved in their care, need to be aware and mindful of the possibility of potential dose and medication side-effect changes with smoking changes. This is an area that requires close monitoring.

## 1.12 Smoking in psychiatry

Smoking has been an accepted part of the culture in psychiatric services for many years (Cormac & McNally, 2008). In an evaluation of the views held by psychiatric nurses towards smoking, Lawn and Condon (2006) described the following. Smoking within the inpatient and community psychiatric service was condoned by psychiatric nurses. In fact, it was reported that smoking was significantly relied on as a means of facilitating interaction with their clients, to the point that when staff quit themselves, they noticed the loss of this perceived care option. Smoking was used in the psychiatric setting to reinforce and condition client behaviour. Nursing staff considered smoking to be a tool to help clients manage their symptoms and related distress, and they described smoking with clients to offer a sense of comfort and support. Similarly, in another study evaluating the views of staff working in a

19

large psychiatric hospital (Stubbs, Haw, & Garner, 2004), more than 50% thought that smoking was important in creating therapeutic relationships with their clients, 60% thought that they should be allowed to smoke with their clients, and over 20% believed that cigarettes should be given to their clients to achieve therapeutic goals. The high rate of smoking by psychiatric nurses, compared to other nurses and health professionals (Rowe & Clark, 2000) further contributes to, and complicates these views. Such views within psychiatry also contribute to the perception that people experiencing a mental illness should not, cannot, and do not want to attempt to reduce or quit smoking. Of course, this has been shown to be incorrect (AccessEconomics, 2007; Baker et al., 2006; el-Guebaly et al., 2002).

The issue of smoking is rarely discussed with clients in a psychiatric service, and the diagnosis of nicotine dependence is not routinely recorded in their medical notes (Olivier, Lubman, & Fraser, 2007). Furthermore, attempts at assisting people experiencing severe mental illness to reduce or quit smoking, such as advising clients to cease smoking, referring them to appropriate smoking cessation services or providing NRT, are rarely made by mental health staff (Olivier et al., 2007).

## 1.13 Smokefree psychiatric facilities

Smoking bans in society continue to broaden. Smoking is commonly banned in work places, public spaces including restaurants and pubs, and when traveling by car with children in some states in Australia. The bans are also extending to health settings such as hospitals, including inpatient psychiatric facilities.

Implementing smoking bans in mental health settings presents a significant challenge for all involved (Jochelson, 2006). A recent survey of the attitudes of staff in health settings found

that about 1 in 10 staff from general healthcare opposed a smoking ban in their service, whilst 1 in 3 staff members from psychiatry were against a ban in their setting (McNally et al., 2006). The role of smoking within psychiatry has been described above. In becoming a smokefree psychiatric facility, staff and inpatients lose all the perceived benefits associated with smoking. Staff fear how clients will react to the smoking ban, feel uneasy and unsure how they can support their patients who are smokers, and think that there will be negative outcomes as a result of the ban, such as increased aggression and violence (Cormac & McNally, 2008). However these concerns are unsubstantiated by the research. In a review of 26 international studies of smoking bans in mental health settings, it was concluded that the introduction of the ban did not result in increased aggression, seclusion use, use of as-needed medication, or discharge against medical advice (Lawn & Pols, 2005). It is important to note that staff and inpatient attitudes towards the smokefree inpatient psychiatric unit can improve after the ban. Resnick and Bosworth (1989) found that 24% of staff and 7% of inpatients initially supported the introduction of a total smoking ban in a psychiatric crisis unit before it was implemented, while 22% of inpatients and 90% of staff supported it postimplementation.

To this point, research regarding the implementation of total smoking bans in the inpatient psychiatric setting has focused on staff attitudes and has largely ignored the patient perspective. Staff views are very important, as these are likely to have a direct impact on the success of the implementation of the total smoking ban and determine whether theoretically effective interventions work in everyday practice (McNally et al., 2006). However, inpatient views are equally as important. There has been no published study that specifically examines the views and experiences of inpatients admitted to an acute psychiatry ward both before and after the implementation of a total smoking ban. For inpatients entering a

21

smokefree psychiatric facility, this represents a time of enforced temporary smoking abstinence or an opportunity to attempt to reduce or quit, and make the most of NRT provided. An awareness and understanding of the particular challenges and experiences faced by smokers with severe mental illness who are admitted to a smokefree psychiatric inpatient ward is both necessary and important, in order to assist inpatients to best cope with the constraints of the setting.

### **1.14 SUMMARY OF INTRODUCTION**

Smoking is a particularly significant and serious problem for people affected by mental illness. Smoking influences many aspects of the smoker's life including their physical health, psychological well-being, financial situation, quality of life, and it increasingly restricts their behaviour. Most importantly though, smoking contributes to the poor health and reduced lifespan of people experiencing severe mental illness, particularly by increasing their risk of CVD. Additional CVD risk factors apart from smoking are present in higher rates among people experiencing severe mental illness. Despite the detrimental impact smoking has on many facets of the lives of people experiencing severe mental illness, knowledge in this area remains limited, and the translation into clinical practice is seriously lacking. Greater emphasis needs to be placed on determining the characteristics of smokers experiencing severe mental illness, tailoring and implementing smoking cessation interventions in this group, and the assessment of relevant smoking outcomes. The research undertaken within this thesis will broadly explore the nature of smoking among people experiencing severe mental illness. Through a number of novel studies, the results of this thesis will significantly contribute to the limited body of research in this area, and further provide substantial clinical and theoretical implications.

## 1.15 STUDY AIMS

This thesis will investigate smoking and severe mental illness according to 3 main themes, and will include sub-studies within each area. The specific aims of the studies undertaken within this thesis are stated in the publications included in each chapter. The 3 main areas encompassed in this thesis and the broader study aims are as follows:

## Characteristics of smokers experiencing psychosis

- To establish the risk factors for coronary heart disease (CHD) in smokers diagnosed with psychosis (Chapter 2)
- To examine the reasons for smoking, reasons for quitting, stages of change and motivational characteristics in people experiencing psychosis (Chapter 2)
- To explore potential gender differences in smoking behaviour, motivational characteristics and smoking cessation outcomes among smokers diagnosed with psychosis (Chapter 3)

Interventions addressing smoking and other CVD risk factors in smokers diagnosed with psychosis

- To design, implement and evaluate treatments that address smoking and other CVD risk factors among people experiencing psychosis (Chapter 4)
- To present the relevant literature and clinical challenges in the context of a case study detailing the experience of a person diagnosed with psychosis participating in an intervention addressing smoking and other CVD risk factors (Chapter 4)

Implementing a Totally Smokefree Policy in the acute inpatient psychiatry ward: The inpatient experience

- To explore the views and experiences of inpatients admitted to an acute psychiatry ward before and after the implementation of a Totally Smokefree Policy (Chapter 5)
- To design, implement and evaluate an inpatient group to support the implementation of a Totally Smokefree Policy in the acute psychiatry setting (Chapter 5)

## 1.16 BRIEF DESCRIPTION OF THE RESEARCH WITHIN THIS THESIS

There are a total of 7 first author publications included in the body of this thesis, and a further 6 publications included as Appendices.

The first publication describes a study that explored the level of specific risk factors for CHD among 43 smokers diagnosed with psychosis before they participated in a multi-component intervention designed to reduce these risk factors, including the reasons for engaging in these health behaviours and motivation and confidence to change.

The second publication describes a study that explored potential gender differences in characteristics and outcomes of 298 smokers diagnosed with psychosis who were participating in a smoking cessation intervention, with follow-up at 3, 6 and 12 months.

The third publication details a study that examined the perceived risks and benefits of quitting smoking in 200 people experiencing psychosis before they participated in a multi-component risk factor intervention for CVD.

The fourth publication presents a case study of a female smoker diagnosed with BPAD and describes the experience, relevant literature and clinical challenges encountered during her involvement in a multi-component CVD risk factor intervention.

The fifth publication demonstrates an application of the theoretical knowledge and clinical experience gained during this thesis to provide accurate information and dispel some common myths in relation to smoking cessation among people with severe mental illness.

The sixth publication describes a study that examined the views and experiences of 46 inpatients before the implementation of a Totally Smokefree Policy in the acute psychiatry setting and 52 inpatients following the implementation of this policy.

The seventh publication describes the design, implementation and evaluation of an inpatient group to support the introduction of a total smoking ban in the acute psychiatry setting based on 22 groups with a total of 71 participants.

## CHAPTER TWO: CHARACTERISTICS OF SMOKERS EXPERIENCING PSYCHOSIS

## **2.1 PREAMBLE**

The paper in this chapter presents the baseline results of the first ever study to offer an intervention targeting several risk factors for cardiovascular disease (CVD) specifically in smokers diagnosed with psychosis. This was the first experimental study undertaken as part of this thesis.

The aim of this chapter was to 1) establish risk factors for coronary heart disease (CHD) in smokers with psychosis and 2) examine the reasons for smoking/quitting, and the levels of motivation and confidence to change. The research described in this chapter addressed a number of gaps in the literature as previous research in this area had been limited. Only three studies had calculated the risk for CHD among people with psychosis using a specific algorithm, and found the level of risk to be increased compared to the general population (Cohn et al., 2004; Goff et al., 2005; McCreadie, 2003). Several studies had examined selfreported reasons for smoking in people with mental illness, mainly indicating that this population smoked to relieve symptom and medication side-effects, because they are addicted, to manage stress, and to provide mental stimulation (Baker et al., 2007; Barr et al., 2008; Forchuk et al., 2002; Glynn & Sussman, 1990; Gurpegui et al., 2007). A review including 14 studies concluded that people diagnosed with mental illness are as motivated to quit smoking as those in the general population (Siru, Hulse, & Tait, 2009). The dietary intake of people diagnosed with psychosis was found to be poor compared to the general population (Brown et al., 1999; McCreadie, 2003; Osborn et al., 2006), and only one study assessed motivation to improve diet in people with psychosis (Archie et al., 2007). Two

29

studies looked at motivation to increase physical activity in people with psychosis (Archie et al., 2007; Ussher, Stanbury, Cheeseman, & Faulkner, 2007).

The paper presented in this chapter, "Health behaviour risk factors for coronary heart disease (CHD) in smokers with a psychotic disorder: baseline results" has been published in a Special Issue titled Smoking and Mental Health within the journal *Mental Health and Substance Use* in 2011. This paper describes the first research to explore self-reported reasons for smoking and quitting in people experiencing psychosis before they participated in a multi-component intervention designed to reduce their risk for CHD. It was also the first study to examine the levels of motivation and confidence to change multiple health behaviours in smokers diagnosed with psychosis. The paper provides the platform for the remaining studies that were undertaken in the group of smokers with psychosis either before or during their involvement in the multi-component intervention for CVD risk factors.

Following this paper, and the related publication describing the outcomes of the pilot study (discussed in Chapter 4 and included as Appendix 2), the research team refined our terminology based upon advice from leading researchers in the field. A shift was made from using the term "coronary heart disease" to using "cardiovascular disease" instead. This is because CVD encompasses cerebrovascular disease (stroke), vascular disease, and hypertension, in addition to CHD (heart attack and angina), all of which are more prevalent in people with mental illness than in the general population.

This chapter will conclude with a brief overview of the results from this study.

# Health behaviour risk factors for coronary heart disease (CHD) in smokers with a psychotic disorder: baseline results

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*Background*. People with psychotic disorders are more likely to develop and die from coronary heart disease (CHD) than the general population.

*Aims*. This study aimed to explore the level of CHD risk factors (smoking, diet and physical activity) in smokers with psychosis. The second aim was to examine the reasons for smoking/quitting, and the levels of motivation and confidence to change.

*Method.* Forty-three smokers diagnosed with psychosis were assessed using semistructured interviews and standardised self-report instruments. Carbon monoxide levels, blood pressure, height, weight and hip/waist measurements were assessed. Blood samples were taken for cholesterol and blood sugar levels. CHD risk percentiles were calculated using the Framingham algorithm.

*Results.* Participants smoked heavily (mean 30.8 cigarettes per day  $\pm 12.5$ ). The majority reported smoking due to addiction and for stress management and many contemplated quitting, mainly due to health concerns. Participants were on average moderately obese and had a poor diet. While being physically underactive, the majority wanted to improve their fitness levels. Participants were motivated to quit smoking, improve their diet and increase their physical activity, but had little confidence in their ability to make these changes. The average calculated CHD risk percentile for the sample was 74.3  $\pm 23.6$ .

*Conclusions.* This sample of smokers with a psychotic disorder had multiple risk factors for CHD. They were interested and willing to make changes to their health behaviours, but lacked confidence. Shared care between psychiatrists and GP's could effectively manage these serious health issues for people with mental illness.

Keywords: smoking; psychosis; coronary heart disease; risk factors; motivation

#### Introduction

People diagnosed with psychosis have shorter lives, by about 20 years, compared to the general population (Colton & Manderscheid, 2006; Newman & Bland, 1991).

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The biggest physical health problem and major cause of death for people with psychosis is coronary heart disease (CHD) (Cohn, Prod'homme, Streiner, Kameh, & Remington, 2004; Hennekens C.H., Hennekens A.R., Hollar, & Casey, 2005; McCreadie, 2003; Osby, Correia, Brandt, Ekbom, & Sparen, 2000). Between 50–75% of people with schizophrenia will develop CHD (Hennekens et al., 2005). People with psychosis are less likely to receive appropriate treatment for CHD (Druss, Bradford, & Rosenheck, 2000; Kisely et al., 2007) and are about twice as likely as the general population to die from heart disease (Brown, Inskip, & Barraclough, 2000; Harris & Barraclough, 1998). The major risk factors for CHD are tobacco smoking, high cholesterol, high blood pressure, physical inactivity and being overweight (Australian Institute for Health and Welfare, 2006, 2010). These risk factors are all elevated in people diagnosed with psychosis (Beebe, 2008; Brown, Birtwistle, Roe, & Thompson, 1999; de Leon & Diaz, 2005; McCreadie, 2003; Osborn, Nazareth, & King, 2006; Ussher, Stanbury, Cheeseman, & Faulkner, 2007).

Several studies have quantified the risk of developing CHD in people diagnosed with psychosis, utilising Framingham estimates that take into consideration risk factors such as age, gender, smoking, blood pressure and cholesterol. Two studies found CHD risk was significantly increased for both males and females with psychosis compared to the general population (Goff et al., 2005a,b) and only for males with mental illness in the remaining studies (Cohn et al., 2004; McCreadie, 2003).

There is a great need for interventions specifically targeted at simultaneously reducing CHD risk factors among people diagnosed with psychosis e.g. (Baker et al., 2009, 2011). Three variables that encapsulate various aspects of CHD risk factors seem especially worthy of focus in people with psychosis: smoking, diet and physical activity. As these factors have a strong behavioural component, they are particularly amenable to psychological treatment. To implement an intervention, it is important to develop an understanding of the level of behaviour; the reasons for the behaviour occurring; the reasons to change the behaviour and the strength of motivation to change. This information guides the development and implementation of a relevant intervention for the target population.

Only five published studies have examined self-reported reasons for smoking among people with mental illness. In two, the main reasons for smoking related to symptom relief and medication side-effects (Forchuk et al., 2002; Glynn & Sussman, 1990). The most consistent finding from the other studies is that people with mental illness smoke for reasons related to addiction, stress management and stimulation (Baker et al., 2007; Barr et al., 2008; Gurpegui et al., 2007). This study aims to replicate and extend these findings, by being the first to explore self-reported reasons for smoking in people with psychosis, before they participate in a multi-component intervention designed to reduce their CHD risk.

A recent review identified 14 studies that have examined motivation to quit smoking in people with mental illness (Siru, Hulse, & Tait, 2009). The review concluded that people with mental illness are as motivated to quit smoking as the general population. To our knowledge, only one study (Baker et al., 2007) has evaluated the stages of change among smokers with psychosis presenting for assistance to change their smoking behavior. In this sample, 13.1% were in the precontemplation (PC) stage, 49.7% in the contemplation stage and 37.2% in the preparation stage (Baker et al., 2007).

Several studies have examined the dietary intake of people with psychosis and found this to be poor compared to the general population (Brown et al., 1999;

McCreadie, 2003; Osborn et al., 2006). There has only been one study to assess motivation to improve diet in people with psychosis. Archie and colleagues assessed the stages of change to engage in healthier eating habits among 101 people diagnosed with psychosis and found 10% to be in the PC stage, 69% in the contemplation-preparation stage and 21% in the action stage (Archie et al., 2007).

Few studies have investigated the motivation of people with psychosis to increase their level of physical activity. Archie et al. (2007) found 9% of their sample to be in the PC stage for increasing physical activity, 54% in the contemplation-preparation stage and 37% in the action stage. Ussher et al. (2007) found 48% of people with mental illness wanted to exercise more regularly 'very much so' or 'extremely so.'

This study presents a more detailed look at the baseline results of an intervention trial reported by Baker et al. (2009). Specifically, this study reports on the CHD risk and associated behavioral risk factors (levels of smoking, quality of diet and levels of physical activity) in a sample of smokers with a psychotic disorder, together with the reasons for engaging in these behaviors, and levels of motivation and confidence to change.

#### Method

#### Sample

Sixty people were screened across four sites in Australia (Sydney and Newcastle in NSW and two sites in Melbourne, Victoria). Forty-eight (80%) people met the inclusion criteria. Complete data were available for 43 participants. Inclusion criteria were: aged  $\geq 18$  years; ICD-10 diagnosis of psychosis (International Classification of Diseases, 10th Revision); smoke  $\geq 15$  cigarettes per day and body mass index (BMI)  $\geq 27$ .

#### Procedure

Participants were recruited via referral and notices placed in community mental health settings; general practitioners (GPs) and psychiatric rehabilitation services. Participants gave written informed consent. An assessment taking about 90 minutes was completed. This served as the pre-treatment assessment for the intervention study detailed elsewhere (Baker et al., 2009). The ethics committees at each site approved this study.

#### Measures

#### Diagnosis, demographic and clinical information

The diagnostic interview for psychosis (Castle et al., 2006) provided a psychiatric diagnosis and information regarding demographics, illness course, current symptoms, medication and service use. Current symptoms of psychosis and depression were assessed using the 24-item Brief Psychiatric Rating Scale (BPRS-24) (Ventura et al., 1993) (range: 24–168) and the Beck Depression Inventory II (BDI-II) (Beck et al., 1998) (range: 0–63). Higher scores indicate greater severity of symptoms on both scales. General health was assessed using the 12-item short form (SF-12) survey (Ware et al., 1996), yielding a physical health component score and a mental health component score. Lower scores indicate greater disability.

#### Smoking

Number of cigarettes smoked per day was assessed using the Opiate Treatment Index (OTI) (Darke, Hall, Wodak, Heather, & Ward, 1992). Nicotine dependence was assessed using the Fagerstrom Test for Nicotine Dependence (Fagerstrom et al., 1996) (range 0–10), with higher scores indicating greater dependence. The Micro 11 Smokerlyser assessed breath levels of carbon monoxide.

Participants completed the reasons for smoking questionnaire (Pederson, Bull, Ashley, & MacDonald, 1996). Following Baker et al. (2007) five subscale scores were calculated:

- (1) addiction (habit, craving; range 0–2),
- (2) stress reduction (relaxation, to take a break, reduce stress; range 0-3),
- (3) arousal (peps me up, weight control, enjoyment, to help concentration; range 0–4),
- (4) mental illness (symptoms of illness, medication side-effects; range 0-2),
- (5) partner smoking (range: 0–1).

The reasons for quitting (RFQ) (Curry, Wagner, & Grothaus, 1990) questionnaire captured motivations to quit smoking, including 10 intrinsic motivation items (five items each relating to health concerns and self-control) and 10 extrinsic items (five items each relating to immediate reinforcement and social influence).

The 11-item Readiness and Motivation to Quit Smoking Questionnaire (RMQ) (Crittenden, Manfredi, Lacey, Warnecke, & Parsons, 1994) provided an elaborate stage of readiness scale. PC defines those not contemplating quitting or cutting down in the near future; contemplation (C) defined as planning to quit in the next 6 months but with no plans to quit in the next month or planning to quit in the next month but not quitting for at least 24 hours in the past year; Preparation for Action (PA) describes those who plan on quitting in the next month and have tried quitting for 24 hours in the past year. An overall Motivation Score was calculated, with higher scores indicating greater motivation (range: 4–16). An overall Confidence Score was calculated, with higher scores indicating greater confidence (range: 2–8).

#### Diet/weight

Participants were weighed, wearing light indoor clothing without shoes. Height was measured (metres) and BMI calculated. Hip and waist circumference was taken (centimetres).

The Impact of Weight on Quality of Life (IWQOL-lite) scale (Abraham, 2003) explores how weight affects specific aspects of quality of life. A total score and five subscale scores were derived:

- (1) Physical function
- (2) Self-esteem
- (3) Sexual life
- (4) Public distress
- (5) Work

Higher scores indicate a greater and more negative IWQOL.

Participants recalled their food intake over the previous 24 hours. Dietary intake was categorised into the main food groups (i.e., fruit, vegetables, bread/cereals, meat/fish/eggs, dairy and high fat/sugar foods). Alcohol consumption in the previous month was assessed using the OTI (Darke et al., 1992). The number of caffeinated and soft drinks consumed per day was recorded.

The RMQ was adapted to assess readiness and motivation to improve diet and lose weight. An overall Motivation Score to improve diet and lose weight was calculated, with higher scores indicating greater motivation (range: 2–8). An overall indication of confidence to improve diet and lose weight was given, with higher scores indicating greater confidence (range: 1–4).

#### Physical activity

Participants reported how many times per week they engaged in 20 minutes of vigorous physical activity (activity causing the person to sweat or puff and pant, e.g. running) and 30 minutes of moderate physical activity (activity increasing the heart and breathing rate, e.g. brisk walking). These questions were taken from the smoking, nutrition, alcohol and physical activity (Royal Australian College of General Practitioners, 2004) guidelines, and responses summed to provide a total activity score. The guidelines specify the following categories:  $\leq 1$  episode of exercise/week = low; 2–4 episodes of exercise/week = nearly there and 5 + episodes of exercise/week = active. The RMQ was adapted to assess readiness and motivation to increase physical activity.

#### **Biological measures**

Blood pressure, cholesterol and sugar levels were assessed. Blood samples were obtained by venipuncture and sent to pathology laboratories at the two Melbourne sites. In Newcastle and Sydney, cholesterol and sugar levels were determined using finger-prick blood tests analysed using the Accutrend Glucose and Cholesterol Testing Machine.

#### CHD risk

An estimate of CHD risk was determined using the modified Framingham risk score (Anderson, Odell, Wilson, & Kannel, 1991) and an age and gender specific percentile score derived from the 1989 Risk Factor Prevalence Survey conducted by the National Heart Foundation (Bennett & Magnus, 1994). A CHD risk percentile > 80 indicates those at highest risk of CHD relative to other Australians of the same age and gender who do not have the risk factors, while a percentile of 50 is considered average.

#### Statistical analysis

Descriptive statistics for demographic, clinical, smoking, diet and physical activity variables were computed. Gender differences for diet/weight variables were examined using independent sample *t*-tests. Daily serves of main food groups were compared to recommended daily intake using one-sample *t*-tests. Procedures were two-tailed, and all statistical analyses were conducted using SPSS (SPSS, Chicago, IL, USA).

#### Results

#### Sample characteristics

Demographic and clinical features of the sample are presented in Table 1. Generally, participants were aged in their mid 30s, Australian born, single and receiving welfare support. The most common diagnosis was schizophrenia, with most experiencing a chronic course of illness, taking atypical anti-psychotic medication regularly and recently seeing a GP. The sample was on average moderately symptomatic (BPRS), mildly depressed (BDI-II) and had mild levels of disability in relation to their mental and physical health functioning (SF-12).

#### Smoking

Table 2 shows participants who were on average heavy smokers with high levels of nicotine dependence, who commenced smoking at a young age, and had made few

Demographic characteristics	
Age in years mean (SD, range)	36.3 (8.42, 21–59)
Male, $\%$ ( <i>n</i> )	58.1 (25)
Australian born, % ( <i>n</i> )	90.7 (39)
Single, never married, $\%$ ( <i>n</i> )	81.4 (35)
Completed highest school year available, $\%$ ( <i>n</i> )	37.2 (16)
Age left school (SD, range)	16.3 (1.6, 13–18)
Employed full or part time, $\%$ ( <i>n</i> )	28.0 (12)
Receiving welfare support, $\%$ ( <i>n</i> )	90.7 (39)
ICD-10 primary diagnosis	
Schizophrenia, $\%(n)$	53.5 (23)
Schizoaffective disorder, $\%$ ( <i>n</i> )	25.6 (11)
Bipolar affective disorder, $\%$ (n)	13.9 (6)
Other non-organic psychotic syndrome. $\%$ ( <i>n</i> )	7.0 (3)
Contact with health services (past 12 months)	
Admission to psychiatric hospital. $\%$ ( <i>n</i> )	34.9 (15)
Community mental health team. $\%(n)$	48.8 (21)
General practitioner. $\%$ ( <i>n</i> )	83.7 (36)
Private psychiatrist, $\%(n)$	44.2 (19)
Illness factors	
Family history of schizophrenia. $\%$ ( <i>n</i> )	46.5 (20)
Age in years of illness onset mean (SD range)	20.8(7.4, 4-49)
Years since illness onset mean (SD, range)	15.5(8.4, 3-51)
Course of psychotic disorder	
Single episode good or unknown recovery $\%(n)$	0
Multiple episodes good recovery $\%(n)$	18 6 (8)
Multiple episodes, good recovery, $\gamma_0(n)$ Multiple episodes, minimal recovery or deterioration % (n)	32.6(14)
Chronic little deterioration $\%(n)$	11.6(5)
Chronic, clear deterioration, $\frac{1}{2}(n)$	37.2 (16)
Taking anti-nsychotic medication $\frac{1}{2}$ ( <i>n</i> )	89.4 (38)
Current psychonethology and functioning	09.4 (50)
BPRS global score mean (SD range)	40.7 (13.2 24-75)
PDL II score mean (SD, range)	14.2 (0.5, 0.21)
SE 12 ( $DCS$ ) mean (SD, range)	1+.2 (9.3, 0-31) 45.5 (0.7, 15.2, 61.5)
$SI^{-12}$ (FCS) illeall (SD, fallge) SE 12 (MCS) mean (SD, range)	43.3 (9.7, 13.2-01.3)
SF-12 (MCS) mean (SD, Tange)	40.8 (11.0, 14.4–37.2)

Table 1. Demographic and clinical characteristics of the sample (n = 43).

Note: ICD, International Classification of Diseases; BPRS, Brief Psychiatric Rating Scale; BDI-II, Beck Depression Inventory; SF, Short Form Survey.

previous attempts to quit. Many participants (81.4%, n = 35) reported that a health professional had advised them to quit smoking. For 80% (n = 28), this advice came from their GP. Only 8.6% (n = 3) and 5.7% (n = 2) of this subgroup were advised to quit smoking by their psychiatrist and case manager, respectively.

The most important self-reported reason for smoking was addiction (53.5%, n = 23). Reasons for smoking and quitting are presented in Table 2 and stage of change, motivation and confidence to quit smoking in Table 3. Most contemplated quitting mainly due to health concerns, and despite being motivated to change their smoking behaviour, they had poor confidence in their ability to do this.

#### Diet/weight

Diet and weight variables are presented in Table 4. Participants were on average moderately obese. They consumed caffeinated beverages and fast food often. Current weight affected various aspects of participants' quality of life, particularly for females, who were significantly more likely than males to report that their weight

Table 2. Smoking characteristics of sample and reasons for smoking and quitting.

Current number of cigarettes per day, mean (SD, range) Current level of nicotine dependence, mean (SD, range) <sup>a</sup> Current expired carbon monoxide level, mean (SD, range) Age smoked first cigarette, mean (SD, range) Age started smoking daily, mean (SD, range)			30.8 (12.5, 15–60) 7.9 (1.7, 4–10) 18.7 (5.6, 11–28) 13.8 (41.6, 5–29) 17.1 (4.7, 8–29) 2.8 (1.5, 0.5)
Tried to give up unsuccessfully, $\%$ ( <i>n</i> )		icali (SD, Talige)	62.8 (27)
Reasons for smoking	Mean (SD)	Reasons for quitting	Mean (SD)
Stress reduction (0–3)	2.54 (0.81)	Intrinsic	2.73 (0.73)
Arousal (0–4)	2.29 (1.02)	Health concerns (0-4)	2.80 (0.73)
Addiction (0–2)	1.88 (0.40)	Self-control (0–4)	2.67 (1.15)
Mental illness (0–2)	0.92 (0.76)	Extrinsic	1.73 (0.74)
Partner smoking (0-1) 0.42 (0.51) Im		Immed reinforcement (0-	4) 2.26 (1.04)
		Social influence (0–4)	1.20 (0.78)
		Intrinsic minus extrinsic	1.01 (0.82)
		Overall scale score (0–4)	2.23 (0.60)

Note: <sup>a</sup>Fagerstrom Test for Nicotine Dependence (FTND), range = 0-10, 8 + = high dependence.

Table 3. Stage of change, motivation and confidence to quit smoking, improve diet and increase physical activity in smokers with psychosis.

Stage of change, motivation and confidence	Quit smoking, % (n)	Improve diet, % (n)	Increase physical activity, % ( <i>n</i> )	
Precontemplation (PC)	7.0 (3)	15.8 (6)	21.4 (9)	
Contemplation (C)	69.8 (30)	42.1 (16)	38.1 (16)	
Preparing for action (PA)	23.3 (10)	34.2 (13)	35.7 (15)	
Action (Å)	NA	5.3 (2)	4.8 (2)	
Maintenance (M)	NA	2.6 (1)	NA	
Motivation mean (SD; range) Confidence mean (SD; range)	13.1 (2.6; 4–16) 4.3 (1.6; 2–8)	6.4 (1.4; 2–8) 2.9 (0.8; 1–4)	6.0 (1.9; 2–8) 2.8 (0.9; 1–4)	

Diet/weight variable	Total sample, mean (SD, range)	Females, mean (SD, range)	Males, mean (SD, range)	
Weight (kg)	101.0 (17.7, 68–153)	94.1 (18.8, 68–138)	106.0 (15.4, 85–153) <sup>a</sup>	
Body Mass Index (BMI)	33.9 (5.2, 27–50)	34.5 (6.2, 27–50)	33.4 (4.5, 27–43)	
Hip circumference (cm)	114.8 (9.7, 99–143)	117.6 (10.5, 99–143)	112.8 (8.8, 103–141)	
Waist circumference	112.7 (12.5, 88–144)	109.8 (14.5, 88–141)	114.8 (10.5, 100–144)	
IWQOL-lite total (31–155)	67.8 (28.5, 31–134)	79.9 (32.0, 31–134)	60.0 (23.6, 31–114) <sup>a</sup>	
Physical function (11–55)	24.5 (10.6, 11–49)	28.0 (11.8, 11–49)	22.2 (9.2, 11–41)	
Self-esteem (7–35)	19.4 (8.6, 7–35)	23.2 (8.7, 7–35)	$16.9 (7.7, 7-33)^{a}$	
Sexual life (4–20)	7.6 (4.6, 4–20)	9.1 (5.7, 4–20)	6.7 (3.4, 4–13)	
Public distress (5–25)	8.5 (4.2, 5–21)	9.9 (4.3, 5–17)	7.7 (3.9, 5–21)	
Work/daily activities (4–20)	7.8 (4.2, 4–18)	9.5 (5.1, 4–18)	$6.6 (3.3, 4-14)^{a}$	
Caffeine drinks/day	7.1 (4.7, 0–22)	6.7 (4.7, 1–20)	7.4 (4.8, 0-22)	
Fast food/week	3.0 (4.3, 0–7)	1.6 (1.3, 0-5)	3.9 (5.3, 1–7)	
Full sugar drinks/day	2.0 (2.6, 0-8)	1.6 (2.4, 0–7)	2.3 (2.7, 0-8)	

Table 4. Diet and weight-related variables for sample.

Note: "Significant difference between males and females at p < 0.05.

impacted on their self-esteem, t(40) = -2.46, p = 0.02, and ability to undertake work and daily activities, t(39) = -2.20, p = 0.03.

Food intake of participants over the previous 24 hours was categorised as shown in Table 5. Both females and males were not eating sufficient daily serves of vegetables (t(16) = -9.0, p < 0.001 and t(24) = -17.6, p < 0.001) and fruit (t(16) = -4.8, p < 0.001 and t(24) = -7.3, p < 0.001). Males were not consuming enough dairy products per day, t(24) = -3.1, p = 0.01, whilst females were not eating enough bread and cereals, t(16) = -2.4, p = 0.028). Males were eating significantly more high fat/sugar foods (including full sugar drinks and alcohol) per day than is recommended, t(23) = 2.6, p = 0.015.

Health professionals had advised 56% (n = 23) of participants to improve their diet and 64% (n = 27) to lose weight. The advice to improve diet was provided by a GP to 18 participants, a case manager to 8 and a psychiatrist to 4. The advice to lose weight was provided by a GP to 25 participants, a psychiatrist to 9 and a case manager to 8.

Information regarding readiness, motivation and confidence to improve diet is in Table 3. Despite being motivated to improve their diet, participants had low confidence in their ability to make the changes. Similarly, they were motivated to lose weight (mean: 6.7, SD = 1.5), but again lacked confidence to do so (mean: 2.4, SD = 1.1).

#### Physical activity

Participants engaged in some form of physical activity, a mean of 3.3 times per week (SD = 2.4, range = 0–8). They undertook 0.8 sessions of vigorous exercise per week (SD = 1.3, range = 0–4) and 2.4 sessions of moderate exercise (SD = 2.3, range = 0–7).

	Number of daily serves				
Food group	Total sample, <i>n</i> (SD, range)	Females, <i>n</i> (SD, range)	RDI females	Males, <i>n</i> (SD, range)	RDI males
Vegetables Fruit Meat/fish/eggs Bread/cereals Dairy Extra foods	$\begin{array}{c} 1.2 \ (1.3, \ 0-6) \\ 0.8 \ (0.9, \ 0-3) \\ 1.3 \ (0.9, \ 0-3) \\ 3.6 \ (4.8, \ 0-30) \\ 1.6 \ (1.3, \ 0-5) \\ 4.8 \ (4.4, \ 0-17) \end{array}$	1.4 (1.6, 0–6) 0.9 (1.0, 0–3) 1.1 (0.7, 0–2) 2.8 (2.0, 1–8) 1.9 (1.5, 0–5) 3.2 (2.4, 0–8)	5 <sup>a</sup> 2 <sup>a</sup> 1 4–9 <sup>a</sup> 2 0–2.5	$\begin{array}{c} 1.1 \ (1.1, \ 0-4) \\ 0.7 \ (0.9, \ 0-3) \\ 1.4 \ (0.9, \ 0-3) \\ 4.1 \ (6.0, \ 0-30) \\ 1.3 \ (1.1, \ 0-4) \\ 5.8 \ (5.2, \ 0-17) \end{array}$	$5^{a} \\ 2^{a} \\ 1 \\ 6-12 \\ 2^{a} \\ 0-3^{a}$

Table 5. Self-reported number of daily serves of main food groups consumed in previous 24 hours compared to the Recommended Daily Intake (RDI).

Note: <sup>a</sup>Significantly different at p < 0.05 from the minimum RDI for vegetables, fruit, meat, bread and dairy food groups and maximum RDI for extra foods group (includes servings of high fat/sugar foods, full sugar drinks and alcohol).

Most participants (88.4%, n = 38) indicated that their fitness levels needed to improve. Almost two-thirds (65.1%, n = 28) had been advised by a health professional that they needed to increase their level of exercise. This advice was most commonly given by GP's (19), case managers (10) and psychiatrists (7).

Readiness, motivation and confidence to increase physical activity are presented in Table 3. Participants were motivated to increase their physical activity, but with less confidence in their ability to do so.

#### **Biological measures**

Mean systolic blood pressure = 127.7 mmHg (SD = 16.0, range: 100-160 mmHg); mean diastolic blood pressure = 82.8 mmHg (SD = 11.2, range: 62-106 mmHg); mean total cholesterol = 4.5 mmol/L (SD = 1.6, range: 1.0-7.3 mmol/L) and mean blood sugar = 4.1 mmol/L (SD = 1.7, range: 1.0-6.4 mmol/L).

#### CHD risk

CHD risk was calculated for 38 participants. The mean CHD risk percentile was 74.3 (SD = 23.6, range: 14–100), with half having a CHD risk percentile greater than 80 (55.3%, n = 21, mean age = 35.9 years, SD = 7.6, range: 23–50) including four people with a percentile of 99 (10.5%, mean age = 32.0 years, SD = 7.5, range: 23–41) and three scoring 100 (7.9%, mean age = 27.7 years, SD = 7.2, range: 23–36).

#### Discussion

We report on the CHD risk and associated health behaviour risk factors in a sample of smokers with psychosis, including reasons for engaging in and changing these behaviours, and motivation and confidence to change. The results have important implications for the clinical management of health behaviours, prevention and treatment of CHD and smoking interventions in smokers with psychosis.

The sample had multiple risk factors for CHD. They were heavy smokers, who were overweight, did insufficient exercise and had a poor diet. The calculated CHD

risk score was very high. They were, however, interested in and motivated to make healthy lifestyle changes.

Participants smoked heavily, had high levels of nicotine dependence and few previous quit attempts. These findings are consistent with previous studies (Baker et al., 2007; Compton, 2005; Kumari & Postma, 2005). Our sample smoked mainly due to addiction and for stress reduction, a finding supported by previous research (Baker et al., 2007; Barr, Procyshyn, Hui, Johnson, & Honer, 2008; Gurpegui et al., 2007). The current results are almost identical to those of Baker et al. (2007) who found that smokers with psychosis were significantly more likely to cite addiction, stress reduction and stimulation as reasons for smoking than the general population. Our participants recognised, and were concerned about, the health implications of being a smoker, and this was their main reason for wanting to quit. Smoking interventions for people diagnosed with psychosis need to specifically address nicotine addiction using both pharmacotherapy (e.g. nicotine replacement therapy) and behavioural approaches. This includes assisting patients to develop and implement alternative coping strategies for stress management other than smoking and facilitating the development of interests to reduce boredom. Highlighting the health benefits of quitting, for example through motivational interviewing, is important.

The inclusion criteria required participants who have a minimum BMI placing them in the overweight category. Therefore, our sample was, on average, moderately obese. Of particular concern though, was that they were mainly young adults, and their weight affected various aspects of their quality of life. This was especially the case for females. Participants reported being motivated to lose weight, and many commented that their weight issues were largely ignored in the mental health setting. There is an urgent need for assistance and support for weight management in this group. Interventions need to be gender sensitive, and particularly address self-esteem issues.

Studies examining the diet of people with mental illness have applied different measures and techniques. Ours is the first to compare the daily intake of the main food groups to the recommended levels according to gender for people with psychosis.

The dietary intake of the current sample was inadequate in some areas. The finding that the sample did not eat enough fruit and vegetables on a daily basis is consistent with previous research (Brown et al., 1999; McCreadie, 2003; Osborn et al., 2006). Participants consumed drinks containing caffeine regularly throughout the day. There were gender differences, with males eating less dairy foods, and more high fat/sugar foods than recommended, and females eating fewer serves of breads/ cereals than recommended. Participants acknowledged their diet deficiencies and were motivated to make improvements. This is consistent with the only other study assessing stage of change to improve diet in people experiencing psychosis (Archie et al., 2007), albeit a lower proportion of our sample were actively improving their diet (5 vs. 21%). Perhaps our study appealed to people who recognised the need to make positive lifestyle changes, but had not yet started. Those already in the action stage may not have thought it was useful or necessary to participate in such a project. As with being overweight, poor nutrition is a significant risk factor for CHD (AIHW, 2006, 2010). Practical information regarding serving sizes, healthy food choices, eating well on a budget, food preparation and cooking skills should be provided to people diagnosed with psychosis and referral to a dietician or occupational therapist considered.

In general, smokers in this study were not engaging in sufficient physical activity, a finding similar to that of other studies (Beebe, 2008; Brown et al., 1999; McCreadie 2003; Osborn et al., 2006; Ussher et al., 2007). Despite this, the majority recognised that they needed to improve their fitness, and over 70% were contemplating or preparing to increase their exercise. Compared to the findings of Archie et al. (2007) more people in this study were in the PC, contemplation and preparation stages, and many fewer in the action stage. Again, the multi-component intervention offered in this study may have appealed to a certain group of patients. Interventions aimed at assisting people with psychosis to undertake physical activity are necessary and important. Such interventions need to focus on assisting the client to determine exercise that fits with their fitness level, interests, budget, and access to facilities. A walking program is often the easiest option for most.

A consistent finding in this study was the discrepancy between strong motivation to change health behaviour and low confidence in being able to do so. Thus, interventions aimed at reducing these CHD risk factors for people with psychosis need to include strategies to assist building confidence and self-efficacy and offer regular long-term support and encouragement. Interventions that include such elements, like the treatment in our multi-component risk factor study (Baker et al., 2009, 2011), assist in participants being successfully able to make positive lifestyle changes.

Another consistent finding was the disappointingly low level of general health advice given to participants by those involved in their usual mental health care. The health promotion message was delivered to most by their GPs. Ideally, all health professionals working with this group of patients need to recognise and address these serious health issues.

GPs seem best placed and most proactive in advising their patients with psychosis to make positive lifestyle changes to reduce their CHD risk. Specific Australian guidelines exist that include recommendations to assist people with a mental illness to quit smoking (Strasser et al., 2002; Zwar et al., 2003), and these can be easily applied by GPs. The ideal model of care would involve shared care by psychiatrists (and other mental health professionals if available) and GPs. Psychiatrists and GPs could regularly communicate regarding the physical impact of psychiatric medication for their patients (e.g. increased appetite, weight gain and sedation), the appropriate choice and use of pharmacotherapy for smoking cessation and discuss possible medication changes needed with smoking reduction/cessation. GPs, together with other staff within their practice (e.g. practice nurse, psychologist), could implement the treatment manually developed for our multi-component risk factor intervention (Baker et al., 2009, 2011).

There are several limitations to this study. The sample was small and perhaps this group of participants were more in tune with their physical health than others with psychosis, as they decided to participate in the intervention. A larger study investigating CHD risk and associated health behaviours in people diagnosed with psychosis, including non-smokers will be worthwhile.

#### Conclusion

This sample of smokers with psychosis demonstrated several significant risk factors for CHD that demand immediate clinical attention. They were motivated to make positive lifestyle changes, but lacked confidence. Shared care between psychiatrists and GPs could effectively address these serious health issues.

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## CHAPTER TWO: CHARACTERISTICS OF SMOKERS EXPERIENCING PSYCHOSIS

## 2.2 OVERVIEW OF RESULTS

The paper presented in this chapter explored the presence of several risk factors for CVD among smokers diagnosed with psychosis before they participated in a multi-component intervention specifically designed to target these health behaviours. This included investigating the reasons for engaging in and changing these behaviours, as well as motivation and confidence to change.

The results of this study indicate that these smokers diagnosed with psychosis were at an increased risk of developing CHD compared to other Australians of the same age and gender, due to the presence of multiple risk factors including smoking heavily, having a poor diet, and not doing enough exercise. This group of people with psychosis reported that they smoked mainly because they were addicted and because smoking helped them to manage stress, while they mainly wanted to quit due to health concerns. While they expressed an interest and willingness to quit smoking, improve their diet and engage in more exercise, this group of smokers with psychosis did not feel confident in themselves that they could possibly change these health behaviours. The relevant clinical implications arising from these results will be addressed in Chapter 6: Discussion.

The following chapter will further focus on the characteristics of smokers diagnosed with psychosis by exploring potential gender differences in this population across a range of variables.

## CHAPTER THREE: GENDER DIFFERENCES IN SMOKERS DIAGNOSED WITH PSYCHOSIS

## **3.1 PREAMBLE**

This chapter will explore gender differences among smokers experiencing psychosis, how the results relate to smokers in the general population, and the specific treatment implications these findings may have.

A range of gender differences have been identified among males and females experiencing mental illness in terms of the incidence, pattern and experience of specific symptoms and psychiatric disorders (Kulkarni, 2010; Kulkarni, Gavrilidis, Hayes, Heaton, & Worsley, 2012). Further, there are clear gender differences in smoking related variables and outcomes among male and female smokers without mental illness (Blake et al., 1989; Curry et al., 1997; Perkins, 2001; Reid, Pipe, Riley, & Sorensen, 2009). There have been a few studies examining gender differences among smokers diagnosed with mental illness more broadly (e.g. mood, anxiety and substance use disorders) (Johnson et al., 2010; Okoli et al., 2011; Torchalla, Okoli, Malchy, & Johnson, 2011) yet a complete lack of research among smokers specifically experiencing psychosis (e.g. schizophrenia, schizoaffective disorder, bipolar disorder and depression with psychosis). Smokers diagnosed with psychosis have some of the highest rates of smoking and nicotine dependence. Therefore, it is particularly pertinent that any potential gender differences among smokers with psychosis are identified in order to appropriately tailor smoking cessation interventions to hopefully maximise successful abstinence in this population.

The first paper presented in this chapter, "Gender differences in characteristics and outcomes of smokers diagnosed with psychosis participating in a smoking cessation intervention" has been published in *Psychiatry Research* in 2014. This paper describes the first research to explore potential gender differences on a range of smoking variables specifically among smokers experiencing psychosis.

The second paper in this chapter "The perceived risks and benefits of quitting in smokers diagnosed with severe mental illness participating in a smoking cessation intervention: Gender differences and comparison to smokers without mental illness" has been published in *Drug and Alcohol Review* in 2014. This paper is the first to investigate smokers' beliefs about quitting by applying the concept of perceived risks and benefits of quitting smoking as defined by McKee et al., (2005) among smokers experiencing psychosis, and to then explore gender differences and relate the pattern of results to those obtained from smokers in the general population.

This chapter will conclude with a brief overview of these results.
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# Gender differences in characteristics and outcomes of smokers diagnosed with psychosis participating in a smoking cessation intervention

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#### ABSTRACT

While research has identified gender differences in characteristics and outcomes of smokers in the general population, no studies have examined this among smokers with psychosis. This study aimed to explore gender differences among 298 smokers with psychosis (schizophrenia, schizoaffective and bipolar affective disorder) participating in a smoking intervention study. Results revealed a general lack of gender differences on a range of variables for smokers with psychosis including reasons for smoking/ quitting, readiness and motivation to quit, use of nicotine replacement therapy, and smoking outcomes including point prevalence or continuous abstinence, and there were no significant predictors of smoking reduction status according to gender at any of the follow-up time-points. The current study did find that female smokers with psychosis were significantly more likely than males to report that they smoking and were more likely to be driven by extrinsic motivators to quit such as immediate reinforcement and social influence, compared to the male smokers with psychosis. Clinical implications include specifically focussing on weight issues and enhancing intrinsic motivation to quit smoking for female smokers with psychosis; and strengthening reasons for quitting among males with psychosis.

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### 1. Introduction

There are differences between smokers diagnosed with psychotic disorders (e.g. schizophrenia, bipolar affective disorder and schizoaffective disorder) and smokers not experiencing mental illness in the general population. The prevalence of smoking is significantly increased in people diagnosed with psychosis compared to those without (up to 90% vs. 16%) (de Leon and Diaz, 2005; AIHW, 2010). Smokers diagnosed with psychosis smoke more cigarettes and illegally grown tobacco ("chop chop" tobacco), smoke for longer periods and have higher levels of nicotine dependence than people in the general population (Compton, 2005; Kumari and Postma, 2005; Moeller-Saxone et al., 2005; Williams et al., 2011). Smokers diagnosed with psychosis are motivated to quit (Siru et al., 2009), but their success rates are more modest than those of people without mental illness

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0165-1781/\$ - see front matter © 2014 Elsevier Ireland Ltd. All rights reserved. http://dx.doi.org/10.1016/j.psychres.2014.01.002 (El-Guebaly et al., 2002; Banham and Gilbody, 2010). Every effort needs to be given to enhancing smoking cessation outcomes for people diagnosed with severe mental illness such as psychosis, as their smoking behaviour is directly contributing to the significantly increased morbidity and mortality related to cardiovascular disease evident in this population (Osby et al., 2000; Cohn et al., 2004; Hennekans et al., 2005).

Research examining gender differences in smoking variables and outcomes in the general population have found clear differences between males and females. While females are more likely to seek assistance to quit smoking and engage in more quitting strategies, they tend to have more difficulty quitting (Perkins, 2001; Reid et al., 2009) and poorer smoking cessation treatment outcomes than males (Blake et al., 1989; Perkins, 2001). Female smokers in the general population are less likely to use nicotine replacement therapy (NRT), and are more likely to report subjective distress related to nicotine withdrawal symptoms than male smokers (Perkins, 2001). Research has indicated that females are less interested, committed and confident in relation to quitting smoking (Blake et al., 1989; Perkins, 2001).







There are also gender differences in reasons for smoking and quitting in the general population. Females were more likely than males to say they smoked to suppress their appetite, to cope with daily life, because other family members smoke, and because they enjoy smoking (Reid et al., 2009). Research has found that females, rather than males, use cigarettes to cope with negative emotions, and are more vulnerable to developing negative affective states (e.g. depression and stress) during a quit attempt (Borelli et al., 1996). Females also reported significantly lower motivation to quit smoking for reasons related to health concerns and higher motivation to quit smoking for reasons related to immediate reinforcement (e.g. save money on cigarettes, won't smell) than males (Curry et al., 1997). Research suggests that attempts to guit smoking by females are likely to be promoted by extrinsic motivators like concern for the health of others, social influences and the cost of smoking (Reid et al., 2009).

While there has been no research reported to date that describes potential gender differences in smoking behaviour, motives, experiences or cessation outcomes among people specifically diagnosed with psychosis, some literature is emerging examining such gender differences in people with mental illness more broadly, usually combining participants with mood and anxiety disorders together with those with psychosis (Johnson et al., 2010; Torchalla et al., 2011; Okoli et al., 2011). One study found no significant differences between male and female smokers diagnosed with mental illness in number of cigarettes per day, level of nicotine dependence and readiness to change (Torchalla et al., 2011). Predictors of smoking in males with severe mental illness included being less educated, separated or divorced or aged 50-59 years and in females being younger (17-29 years) and living in residential facilities (Johnson et al., 2010). Predictors of smoking cessation among both males and females with a substance use disorder and/or mental illness were baseline carbon monoxide level and greater attendance at the smoking clinic, and a history of alcohol dependence (Okoli et al., 2011). Heroin and marijuana use were predictive of unsuccessful smoking cessation only in males (Okoli et al., 2011).

Identifying potential gender differences in smokers diagnosed with psychosis is important to ensure that smoking cessation interventions are gender sensitive to enhance smoking outcomes in this population. The current study is the first to examine gender differences on a range of smoking variables among people specifically diagnosed with psychosis. The current study aims to

- examine gender differences in smoking variables for people diagnosed with psychosis before and after they participate in a smoking cessation treatment, and
- determine what factors are predictive of smoking reduction and cessation in people diagnosed with psychosis, according to gender.

#### 2. Methods

#### 2.1. Sample

A total of 298 people diagnosed with psychosis (including schizophrenia, schizoaffective disorder, bipolar affective disorder, severe depression with psychosis and other psychotic disorders) were recruited from Sydney and the Newcastle region of NSW, Australia to participate in a randomised controlled trial of a smoking intervention among individuals diagnosed with psychosis (see Baker et al., 2006, 2007). This paper presents the results of a gender analysis of these data. Inclusion criteria included: aged  $\geq$  18 years; smoking at least 15 cigarettes per day; and an ICD-10 diagnosis of psychosis as described above (International Classification of Diseases, 10th Revision). Exclusion criteria included having a medical condition that would preclude the use of NRT; being currently acutely psychotic (if this was the case, these potential participants were screened 1 month later to reassess study suitability), and having an acquired cognitive impairment.

#### 2.2. Procedure

All participants were in a non-acute phase of psychosis when they commenced in this study, and provided written informed consent. A baseline assessment was completed and then participants were randomly allocated to either: (1) treatment group: received eight individual sessions of 1 h duration consisting of motivational interviewing and cognitive behavioural therapy (CBT) plus NRT and smoking cessation self-help booklets or (2) comparison group: received the same smoking cessation self-help booklets together with treatment as usual. Further information about the procedure and therapeutic interventions delivered in this study are described in Baker et al. (2006), but briefly, participants in the treatment group received NRT as follows: 21 mg nicotine patches for 6 weeks; 14 mg nicotine patches for 2 weeks and 7 mg nicotine patches for 2 weeks. All participants completed follow-up assessments at 3 months (15 weeks after baseline), 6 months and 12 months. These follow-up assessments were conducted by a researcher blinded to the treatment condition. The research was approved by relevant regional and university ethics committees.

#### 2.3. Measures

#### 2.3.1. Demographic and clinical variables

The Diagnostic Interview for Psychosis (DIP) (Castle et al., 2006) provided a psychiatric diagnosis according to ICD-10. The DIP also provided information regarding demographics, illness course and service use. Current symptoms of psychosis were assessed using the 24-item Brief Psychiatric Rating Scale (BPRS-24) (Ventura et al., 1993), a clinician administered and rated tool that is scored based on a semi-structured interview, with higher scores indicating greater severity of symptoms (range: 24-68). Current symptoms of depression were assessed using the self-report Beck Depression Inventory II (BDI-II) (Beck et al., 1998) with higher scores indicating more severe depression (range: 0-63). Anxiety symptoms were measured using the State-Trait Anxiety Inventory (STAI) (Spielberger, 1983), with higher scores indicating more severe anxiety (range: 20-80). The STAI differentiates anxiety as a state, based on responses to 20 statements about how the person feels "right at this moment" and as a trait, based on responses to statements about how they feel "in general." The 12-item Short Form Survey (SF-12) (Ware et al., 1996) was used to assess general health functioning, producing a physical health component score and a mental health component score with lower scores indicating greater disability. Substance use over the previous month was assessed using the Drug Use domain of the Opiate Treatment Index (OTI) (Darke et al., 1991), and this was specifically completed for cannabis and alcohol use.

#### 2.3.2. Smoking variables

The number of cigarettes smoked per day was calculated using the Drug Use domain of the OTI. Participants were asked when their 3 most recent days of smoking occurred and how many cigarettes they smoked on each occasion. A simple calculation then provided an average daily number of cigarettes smoked based over a 28 day period. Nicotine dependence was assessed using the Fagerstrom Test for Nicotine Dependence (Fagerstrom et al., 1996), with higher scores indicative of greater nicotine dependence (range: 0–10). A Micro 11 Smokerlyser was used to assess breath levels of carbon monoxide. A carbon monoxide reading of < 10 suggests that the person was unlikely to have smoked in the previous 8 h. Participants were asked about changes to their smoking in the previous 12 months, any changes to their mental state with prior quit attempts and what advice they had received about their smoking from health professionals. The raw data in Table 2 for the following smoking variables, age first cigarette, cigarettes per day, level of nicotine dependence, has been previously reported in Baker et al. (2007) and has been reproduced here for completeness.

Participants completed the Reasons for Smoking Questionnaire (RSQ) (Pederson et al., 1996), by responding "yes" or "no" to statements providing reasons for smoking. Five subscale scores were then calculated: addiction (habit, craving; range 0–2); stress reduction (relaxation, to take a break, reduce stress; range 0–3); arousal (peps me up, weight control, enjoyment, to help concentration; range 0–4); mental illness (symptoms of mental illness, medication side-effects; range 0–2) and partner smoking (range 0–1).

Motivations to quit smoking were captured using the Reasons for Quitting scale (RFQ) (Curry et al., 1990). The RFQ scale includes 10 intrinsic motivation items (five items each relating to health concerns and self-control) and 10 extrinsic motivation items (five items each relating to immediate reinforcement and social influence). Participants responded to each reason for quitting according to 0=not at all; 1=slightly true; 2=somewhat true; 3=mostly true; and 4=extremely true. The raw data in Table 2 relating to gender differences in RFQ has been reported previously (Baker et al., 2007) and has been reproduced here for completeness.

Level of motivation to quit smoking was evaluated using the 11-item Readiness and Motivation to Quit Smoking Questionnaire (RMQ) (Crittenden et al., 1994). Participants responded to a series of statements by selecting yes or no for some questions (e.g. Are you thinking of quitting smoking?) and by selecting 1=not at all determined; 2=a little determined; 3=somewhat determined and 4=very determined for other questions (e.g. How much do you want to quit smoking?). A scoring algorithm was applied and participants were categorised into the following groups based on their final scores: Precontemplation (PC) defines those not contemplating quitting or cutting down smoking in the near future; Contemplation (C) defines those who plan to quit in the next 6 months, but with no plans to quit in the next month or those planning to quit in the next month who have not quit for at least 24 h in the past year; Preparation for Action (PA) describes those who plan on quitting in the next month and have tried quitting for 24 h in the past year.

Smoking outcome measures were defined as continuous abstinence, pointprevalence abstinence and smoking reduction status. Continuous abstinence describes the situation where a person does not smoke at all from their nominated quit date to the assessment point (i.e. 3, 6 or 12 months). Point-prevalence abstinence defines those who do not smoke for the 7 days before the assessment point. Smoking abstinence was determined based on participants responses to the Tobacco Index of the OTI regarding their daily cigarette consumption and this was further biochemically validated by a CO reading of < 10 ppm. Smoking reduction status was based on whether or not the participant had reduced their daily consumption of cigarettes by 50% or greater (including abstinence) compared to baseline.

#### 2.4. Statistical analysis

Gender differences in demographic, clinical and general smoking variables at baseline were analysed using the  $\chi^2$  test of independence for categorical responses and one-way Analysis of Variance (ANOVA) for continuous variables. Age, marital status and education served as covariates in the subsequent analyses (ANCOVAS) used to examine gender differences in the remaining smoking variables. A series of logistic regression analyses were performed to explore the relationship between smoking outcome variables, treatment group and gender at each assessment timepoint. As there were no significant gender by treatment differences over time, subsequent analysis in this study did not separate the sample by treatment group. A two-step model building procedure was used to determine which variables to include in a logistic model assessing predictors of smoking reduction status ( < 50% reduction or  $\geq$  50% reduction including abstinence) at the three assessment points (3, 6 and 12 months). Smoking reduction status was chosen as the dependent variable rather than continuous or point-prevalence abstinence alone to allow sufficient cases per cell. In the first step, bivariate correlations were calculated between smoking reduction status and a range of demographic and smoking related variables, psychiatric diagnosis, current psychopathology, and substance use. In the second step, only those variables significantly correlated with smoking reduction status at p < 0.05 were included in the final multivariate model. The final logistic regression analysis was stratified by sex to explore gender differences in smoking reduction status. The threshold for statistical significance for all analyses was set at p < 0.01 as a partial control for the number of statistical tests.

#### 3. Results

3.1. Gender differences in demographic and clinical variables at baseline

Table 1 presents demographic and clinical variables according to gender. There were 156 males (52.3%) and 142 females (47.7%). Male smokers diagnosed with psychosis were significantly younger, more likely to be single, unemployed, living with their parents or friends and to have left school and completed a trade, than female smokers. Female smokers diagnosed with psychosis were significantly older when their psychiatric condition developed, and had more psychiatric hospitalisations and visits to the GP in the previous 12 months than male smokers. There were no gender differences in primary psychiatric diagnosis, recent substance use or level of current psychopathology or functioning.

#### 3.2. Gender differences in smoking variables at baseline

#### 3.2.1. General smoking variables

There were no significant gender differences on a range of smoking related variables at baseline (see Table 2). Both male and female smokers experiencing psychosis started smoking in their early teens and were currently heavy smokers. Females had higher ratings of nicotine dependence than males, a difference that was approaching statistical significance [F(1,293)=5.77, p=0.017]. The majority of smokers diagnosed with psychosis had tried to quit smoking in the previous year, and some were able to quit for at

least a month. Most of these smokers had been advised to quit by a health professional, mainly their GP. Few smokers diagnosed with psychosis were advised to quit by their mental health workers, such as their case manager or psychiatrist.

#### 3.2.2. Reasons for smoking

Generally male and female smokers with psychosis did not differ in their reasons for smoking. However, as can be seen in Table 2, females were more likely to report that they smoked to increase arousal (weight control, enjoyment, to help concentration and to pep them up), a difference that was approaching statistical significance [F(1,293)=6.14, p=0.014]. Responses to the individual scale items revealed that females were significantly more likely than males to report that they smoked to prevent weight gain [F(1,293)=14.1, p < 0.001].

#### 3.2.3. Reasons for quitting

As previously reported (Baker et al., 2007), female smokers diagnosed with psychosis reported significantly more reasons for quitting than males. While males and females reported quitting for health concerns and self-control equally, females were significantly more likely to say that they want to quit for reasons related to immediate reinforcement (e.g. won't smell; won't burn holes; won't have to clean as often) and social influence (e.g. people are upset with me). There were no significant gender differences in readiness and motivation to quit smoking (Precontemplation: 15.4% males/10.6% females; Contemplation: 43.6% males/56.3% females; Preparation for Action: 41.0% males/33.1% females).

#### 3.3. Gender differences in smoking outcome variables

There were no significant gender or gender by treatment differences over time on a range of smoking outcome variables, including point prevalence or continuous abstinence (see Table 3). Male and female smokers diagnosed with psychosis did not differ in their use of NRT, quit attempts or number of treatment sessions attended. Males smoked significantly stronger cigarettes than females at 6 [F(1,201)=18.62, p < 0.001] and 12 months [F(1,209)=16.01, p < 0.001], while females smoked significantly more cigarettes at 6 months than males [F(1,219)=9.02, p=0.003].

#### 3.4. Predictors of smoking reduction status by gender

Variables that were significantly correlated with smoking reduction status at p < 0.05 at the three assessment time-points (3, 6 and 12 months) are presented in Table 4 and these were entered into the logistic regression analyses. There were no significant predictors of smoking reduction status according to gender at any of the follow-up time-points at the p < 0.01 level. However, trends were emerging at the 3 month assessment time-point for females that were predictive of unsuccessful smoking reduction status: having a DSM-IV diagnosis of schizophrenia (p=0.014), an ICD-10 diagnosis of other psychosis (p=0.014).

#### 4. Discussion

This study explored gender differences on a range of smoking variables in the largest published study to date of a randomised controlled trial of a smoking intervention among people diagnosed with psychosis. Although important gender differences were evident among smokers with psychosis, there were fewer differences compared to previously conducted research examining gender differences among smokers in the general population (Blake et al., 1989; Perkins, 2001; Reid et al., 2009). The application

#### Table 1

Demographic and clinical variables at baseline by gender.

	Males $n = 156$	Females $n = 142$	p value
Age mean (S.D., range)	35.15 (9.65,18-60)	40.01 (12.08, 18-64)	< 0.001
Australian born (%)	82.7	87.3	NS
Marital status (%) Single, never married Married Defacto Separated/Divorced Widowed	78.2 7.1 6.4 8.3 0	52.1 7.0 8.5 28.9 3.5	< 0.001
Education (%) Some high school Completed high school Trade/apprenticeship Diploma certificate Completed tertiary	34.6 23.1 17.9 18.6 5.8	23.9 17.6 1.4 36.6 20.4	< 0.001
Receiving welfare support Employment (%) No work at present Work part- or full-time Student	91.0 75.0 20.5 3.9	84.5 60.6 26.1 9.2	NS < 0.05
Living arrangements % Alone Parents Family (partner, other relatives) Friends Children, without partner Other	37.2 19.9 14.7 15.4 2.6 10.3	39.4 16.2 19.0 6.3 12.7 6.3	< 0.05
Illness factors Primary diagnosis (%) Schizoaffective disorder Bipolar disorder Severe dep with psychosis Other psychosis Age illness onset m (S.D., range)	46.8 12.2 9.6 6.4 25.0 21.51 (5.90,5-42)	37.3 16.9 8.5 6.3 31.0 24.40 (8.46,9–50)	NS < 0.01
Substance use in past month Alcohol OTI mean (S.D., range) Cannabis OTI mean (S.D., range)	0.71 (1.47,0-10) 0.71 (4.30,0-40)	0.73 (3.02,0–29) 0.44 (2.09,0–15)	NS NS
Service use over past 12 months mean (S.D., range) No. psychiatric hospitalisations Visits to GP Visits to CMHT	0.58 (0.86,0–4) 10.14 (13.40,0–100) 15.04 (40.74,0–365)	0.82 (1.14,0-5) 14.51 (19.06,0-104) 19.50 (38.68,0-365)	< 0.05 < 0.05 NS
Current psychopathology and functioning mean (S.D., range) BPRS BDI-II STAI State STAI Trait SF 12 (PCS) SF 12 (MCS)	33.32 (8.75,24–74) 15.31 (11.87,0–53) 40.64 (11.94,20–72) 46.82 (11.89,20–79) 47.63 (7.45,27–61) 46.78 (8.51,22–62)	34.87 (11.11,24–94) 17.28 (15.28,0–60) 42.22 (12.75,20–74) 48.74 (12.55,20–74) 46.40 (7.58,27–59) 45.49 (8.11,26–62)	NS NS NS NS NS

S.D.=standard deviation; NS=no significant difference; Defacto=a relationship where two people who are not married live together as a couple; OTI=Opiate Treatment Index; GP=General Practitioner; CMHT=Community Mental Health Team; BPRS=Brief Psychiatric Rating Scale; BDI=Beck Depression Inventory; STAI=State-Trait Anxiety Inventory; SF-12 (PCS)=12-item Short Form Survey Physical health Component Score; SF-12 (MCS)=12-item Short Form Survey Mental health Component Score

of tailored smoking cessation interventions for people experiencing psychosis is crucial in order to address the significant morbidity and mortality they experience as a consequence of their smoking. The results of the current study have important clinical application as they may enable smoking cessation interventions for people with psychosis to be gender sensitive and potentially improve smoking outcomes.

It is puzzling why our study found fewer gender differences in smokers with psychosis compared to those in the general population. People experiencing psychosis have significantly higher rates of smoking and nicotine dependence than smokers in the general population, and will as a consequence experience greater nicotine withdrawal symptoms during cessation attempts. For example, mean FTND scores for smokers in the general population range from 3.0–4.3 (Fagerstrom et al., 1996), compared to 7.72 for males and 8.43 for females in the current study of smokers with psychosis. This may make smokers with psychosis a more homogenous group, whereby the level of nicotine dependence is elevated to the point that it could possibly serve to override the effects of gender. Similarly, the influence that stress has on smoking behaviour among people with psychosis may obliterate the effects of gender. A potent relationship between smoking and stress exists for people with psychosis. In line with previous studies among smokers with mental illness, male and female smokers with psychosis in this study nominated stress reduction as a reason for smoking (Gurpegui et al., 2007; Barr et al., 2008; Filia et al., 2011). People experiencing psychosis often perceive that smoking has a positive impact on their stress levels, a view that is

#### Table 2

Smoking variables at baseline by gender.

14.54 (4.78,3-40) 29.03 (11.50,10-80) 7.72 (2.16,2-10) 21.92 (11.28,0-68) 14.7 59.6 46.8	15.45 (5.65,4–47) 32.05 (14.79;10–120) 8.43 (1.94,4–10) 21.35 (13.09,0–82) 9.9 57.8 40.1	NS NS 0.017 NS NS NS
14.7 59.6 46.8 4.3 34.8	9.9 57.8 40.1 7.8	NS NS NS
4.3 34.8	7.8	
50.4	31.3 48.4	NS NS NS
71.2 85.6 21.6 33.3	69.0 91.8 18.4 43.9	NS NS NS NS
2.51 (0.81) 1.85 (1.05) 1.85 (0.41) 0.33 (0.55) 0.08 (0.28)	2.61 (0.69) 2.19 (1.15) 1.91 (0.33) 0.39 (0.59) 0.14 (0.35)	NS 0.014 NS NS NS
2.50 (1.18) 2.45 (1.29) 2.08 (1.18) 0.95 (0.97) 0.96 (0.93)	2.74 (1.08) 2.85 (0.99) 2.71 (1.05) 1.30 (1.10) 0.80 (0.88)	NS NS < 0.001 < 0.01 NS
	34.8 50.4 71.2 85.6 21.6 33.3 2.51 (0.81) 1.85 (1.05) 1.85 (0.41) 0.33 (0.55) 0.08 (0.28) 2.50 (1.18) 2.45 (1.29) 2.08 (1.18) 0.95 (0.97) 0.96 (0.93) 1.99 (0.85)	34.8       31.3         50.4       48.4         71.2       69.0         85.6       91.8         21.6       18.4         33.3       43.9         2.51 (0.81)       2.61 (0.69)         1.85 (1.05)       2.19 (1.15)         1.85 (0.41)       1.91 (0.33)         0.33 (0.55)       0.39 (0.59)         0.08 (0.28)       0.14 (0.35)         2.50 (1.18)       2.74 (1.08)         2.45 (1.29)       2.85 (0.99)         2.08 (1.18)       2.71 (1.05)         0.95 (0.97)       1.30 (1.10)         0.96 (0.93)       0.80 (0.88)         1.99 (0.85)       2.40 (0.78)

m=mean; S.D.=standard deviation; NS=no significant difference; GP=General Practitioner; CM=case manager.

<sup>a</sup> These variables have been previously reported in Baker et al. (2007) and have been reproduced here for completeness.

Table 3	
Smoking outcome variables by g	gender.

	3 months		6 months		12 months	
	Male	Female	Male	Female	Male	Female
Cigs per day mean (S.D.)	19.43 (13.00)	23.29 (18.19)	20.30 (12.31)	24.64** (17.78)	21.26 (13.93)	23.94 (16.35)
Cont abstinence, %	6.4	8.5	3.2	4.2	1.9	2.1
Point prev. abstinence, %	9.0	12.0	5.1	8.5	7.7	9.2
$\geq$ 50% Reduction, %	30.8	28.9	24.3	23.9	23.7	24.6
Mean change in CPD from baseline	-9.60	- 8.76	- 8.73	- 7.41	- 7.77	- 8.11

S.D.=standard deviation; CPD=cigarettes per day.

\*\* Significant difference at *p* < 0.01.

also often held and reinforced by mental health professionals (Lawn and Pols, 2005). However, the most plausible explanation is that people experiencing psychosis continue to smoke in order to avoid the discomfort of nicotine withdrawal symptoms such as stress and anxiety that are associated with their significant levels of nicotine dependence. Finally, there are other additional barriers to quitting smoking that people with psychosis experience compared to smokers in the general population, which may account for the different pattern of smoking outcome results. These include low levels of confidence and self-efficacy in relation to quitting among smokers with psychosis (Filia et al., 2011), smokers with psychosis not being routinely offered smoking cessation interventions (Baker et al., 2010), the reinforcement of smoking among their social and treatment networks (Lawn and Pols, 2005), the reduced impact of anti-smoking campaigns for people with psychosis (Thornton et al., 2011), and that nicotine can transiently improve some of the cognitive deficits evident in psychosis (Dolan et al., 2004).

Some of the gender differences identified in this study are consistent with those previously identified among smokers in the general population. Female smokers diagnosed with psychosis were more likely than males to report they smoked to prevent weight gain, a finding also reported in the general population (Reid et al., 2009). For female smokers with psychosis, issues around weight need to be specifically targeted to improve smoking cessation outcomes for this group, as we know from the general population that smokers concerned about weight gain are less motivated to quit, have poorer abstinence outcomes and are more likely to drop out of treatment (Perkins, 2001). Cognitivebehavioural therapy (CBT) has been successfully applied to reduce weight concerns in female smokers, consequently improving their smoking cessation outcomes (Perkins, 2001). Research indicates

#### Table 4

Correlations with smoking reduction status across time by gender.

	3 months Correlation co	efficient	6 months Correlation co	efficient	12 months Correlation co	efficient
	Male	Female	Male	Female	Male	Female
Experimental group No. sessions attended	0.26 <b>**</b> 0.33 <b>**</b>	0.34 <b>**</b> 0.42 <b>**</b>	0.02 0.09	0.26 <b>**</b> 0.33 <b>**</b>	0.07 0.16*	0.24 <b>**</b> 0.34 <b>**</b>
Clinical/demographic variables: DSM schizophrenia ICD-10 BPAD ICD-10 other psychosis Qualifications STAI trait score No. hospital admissions OTI cannabis Cups coffee day Nurse advised to quit	$-0.18^{*}$ -0.06 0.13 0.12 -0.14 0.00 -0.002 -0.05 -0.02 0.05	$\begin{array}{c} 0.09\\ 0.14\\ -0.19^*\\ -0.11\\ -0.05\\ 0.07\\ -0.06\\ -0.06\\ 0.10\\ 0.04\end{array}$	$\begin{array}{c} 0.02\\ 0.03\\ 0.04\\ -\ 0.004\\ -\ 0.05\\ -\ 0.11\\ 0.20^*\\ 0.13\\ -\ 0.22^*\\ 0.2\end{array}$	$\begin{array}{c} 0.05\\ 0.13\\ -0.10\\ -0.01\\ -0.22^{*}\\ 0.07\\ -0.02\\ -0.17\\ 0.05\\ 0.10^{*}\end{array}$	-0.12 0.04 0.08 $0.16^*$ 0.08 $-0.17^*$ -0.07 -0.10 -0.14	$\begin{array}{c} 0.000\\ 0.24^{***}\\ -0.07\\ 0.01\\ -0.09\\ 0.03\\ -0.01\\ -0.19^{*}\\ 0.13\\ 0.04\end{array}$
Smoking dependency: FTND CO reading	- 0.09 - 0.05	-0.18* -0.13	- 0.03 0.05 - 0.06	-0.19 <sup>*</sup> -0.18* -0.23*	0.04 0.04 - 0.09	-0.04 -0.12
Reasons for Smoking: Smoking helps symptoms mental illness Smoking helps you to handle stress Smoking is a habit	0.16* 0.02 0.03	- 0.05 - 0.22** - 0.02	0.10 0.05 - 0.008	0.03 - 0.20* - 0.05	- 0.02 0.14 0.16*	0.03 - 0.12 - 0.05
Reasons for Quitting: Like yourself better Want people to stop nagging Will get a financial reward Prove not addicted Received an ultimatum Show can quit Accomplish other things Will save money Self-control Social influence	$0.18^*$ $0.19^*$ 0.04 -0.02 0.12 0.10 0.08 0.13 0.09	-0.003 -0.03 0.06 0.11 0.16 0.05 0.03 -0.09 0.07 0.09	$\begin{array}{c} 0.08\\ 0.05\\ 0.18^{*}\\ -0.01\\ -0.12\\ 0.03\\ 0.05\\ 0.02\\ 0.05\\ 0.05\\ 0.05\\ \end{array}$	-0.05 -0.03 0.05 0.17* 0.21* 0.06 0.12 -0.15 0.10 0.08	0.24** 0.12 0.18* 0.23** -0.01 0.19* 0.19* 0.087 0.25** 0.16*	-0.04 -0.06 -0.06 0.10 $0.19^*$ 0.04 0.07 $-0.18^*$ 0.05 -0.003
Motivation: Current plan to quit smoking Five stages of motivation Stage of change	0.07 0.05 0.05	0.22** 0.19* 0.19*	0.10 - 0.002 0.03	0.15 0.10 0.06	0.13 0.06 0.03	0.13 0.11 0.08

STAI=State-Trait Anxiety Inventory; OTI=Opiate Treatment Index; FTND=Fagerstrom Test of Nicotine Dependence; CO=Carbon monoxide.

\* Significant difference at p < 0.05.

\*\* Significant difference at p < 0.01.

that interventions combining smoking cessation and weight control treatment, compared to smoking cessation alone, enhanced abstinence and reduced weight gain following quitting (Spring et al., 2004). Furthermore, the best outcomes were achieved for female smokers using a sequential approach, where smoking cessation was addressed before weight control treatment. If interventions are designed to minimise weight gain, this may increase the appeal of smoking cessation treatments, particularly for female smokers with psychosis. We have found the sequential approach useful for a female smoker with bipolar disorder whereby smoking was tackled first, and then issues around weight, diet and exercise were targeted (Filia et al., 2012).

Male and female smokers with psychosis were equally concerned about the health implications of being a smoker, and this was one of their main reasons for quitting, a finding consistent with smokers in the general population (Curry et al., 1997; Reid et al., 2009). Additionally, we found that female smokers with psychosis reported more reasons for quitting smoking and were more likely to be driven by extrinsic motivators to quit (immediate reinforcement and social influence), which is consistent with results from smokers in the general population (Curry et al., 1997; Reid et al., 2009). Higher levels of extrinsic motivation have been associated with failure to quit smoking in smokers in the general population (Curry et al., 1990). Smoking interventions for people with psychosis should attempt to strengthen reasons for quitting, especially for males, and enhance intrinsic motivators for quitting (e.g. health concerns and self-control), especially for females, via motivational interviewing. However, as suggested by Lynagh et al. (2011), certain populations may not be as responsive to efforts at increasing intrinsic motivation, and in this case, extrinsic motivators such as the use of financial incentives (e.g. contingency management) to promote behaviour change may be particularly useful, especially for female smokers with psychosis.

There are other findings that are inconsistent with those in smokers in the general population but consistent with findings among people with mental illness. As recently reported among a sample of smokers experiencing mental illness more broadly (Torchalla et al., 2011), there was no difference in readiness and motivation to quit smoking according to gender in the current sample. In the general population it has more usually been found that women are less interested in or committed to quitting (Blake et al., 1989; Perkins, 2001; McKee et al., 2005; Reid et al., 2009). Again, this lack of difference among smokers with psychosis compared to those in the general population may be due to the overriding impact of the higher levels of nicotine dependence seen among people with psychosis.

Furthermore, in the general population, female smokers are more likely than males to smoke to cope with stress and negative emotions (Borelli et al., 1996; Reid et al., 2009), a result not replicated here among smokers with psychosis. Interesting though, an association between female smokers with psychosis in this study who reported that they smoked in order to handle stress and unsuccessful smoking reduction status at 3 months was emerging. Generally though, as previously mentioned, smokers with psychosis in this study nominated stress reduction as a reason for smoking, consistent with other studies among smokers with mental illness. Smoking cessation interventions for people experiencing psychosis must acknowledge and address the role smoking has in stress management. Patients may require assistance to develop and implement alternative coping strategies for stress management apart from smoking (Filia et al., 2011). Assisting patients to try strategies such as progressive muscle relaxation, deep breathing, positive imagery, distraction and emotion regulation will be useful (Prochaska, 2010). If smokers with psychosis are armed with effective stress management strategies, together with effective pharmacotherapy that serves to reduce their level of nicotine dependence, they will have a better chance of success when they attempt to quit smoking.

An interesting finding is the absence of significant gender differences in smoking cessation treatment outcomes in people diagnosed with psychosis in the current study. This finding is inconsistent with results from smokers in the general population where female smokers typically do more poorly than males (Blake et al., 1989; Perkins, 2001; McKee et al., 2005; Reid et al., 2009). However, these results are consistent with the only other published study that examined smoking cessation outcomes by gender in people with a substance use and/or mental illness (Okoli et al., 2011). Efforts aimed at assessing and treating nicotine dependence in all smokers with mental illness need to be maximised to improve smoking cessation outcomes for this population as a whole.

Finally, we have some unique results that are neither consistent with those among smokers in the general population nor those with mental illness based on research to date. We found no significant predictors of smoking reduction status, including abstinence, according to gender in the current study, a finding inconsistent with that of Okoli et al. (2011) in smokers with substance use and/or mental illness, and a range of studies as reported by Perkins (2001) among the general population. However, for females only, having a DSM-IV diagnosis of schizophrenia; an ICD-10 diagnosis of other psychosis; and smoking in order to handle stress were emerging as trends that predicted unsuccessful smoking reduction status at 3 months. This pattern of results needs to be replicated in future research before any conclusions can be made.

There are some limitations to the present study. This was a gender analysis of a smoking intervention study for people experiencing psychosis. Consequently, the results relate to a group of people diagnosed with psychosis from Australia, in a non-acute phase of the illness, who expressed some interest in quitting smoking. This may limit the generalisability of the results to all smokers diagnosed with psychosis. We have made qualitative comparisons between our pattern of results among smokers with psychosis to those in the general population without mental illness, but acknowledge that we have not controlled for potential differences between these two groups of smokers that may otherwise account for the pattern of results. Future research is required to further explore potential gender differences in smokers with mental illness and to replicate and extend the pattern of results in other smokers experiencing psychosis. Specific research comparing smoking variables and outcomes between smokers with psychosis and those without is needed in an attempt to understand the aetiology of differences between the groups.

In conclusion, the findings of the present study significantly add to the growing research examining gender differences in smoking among people experiencing mental illness. Our findings offer useful information that will contribute to understanding differences and similarities in smoking behaviour, motives and cessation outcomes among males and females with psychosis, and those in the general population. Smoking needs to be tackled as a matter of urgency for all smokers experiencing mental illness to prevent medical co-morbidity and premature death. Smoking cessation interventions for people diagnosed with psychosis need to be more intensive and longer term than for smokers in the general population, and the gender sensitive modifications suggested in this paper will hopefully improve smoking cessation outcomes for people experiencing psychosis.

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# The perceived risks and benefits of quitting in smokers diagnosed with severe mental illness participating in a smoking cessation intervention: Gender differences and comparison to smokers without mental illness

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## Abstract

Introduction and Aims. This study aimed to examine the perceived risks and benefits of quitting in smokers diagnosed with psychosis, including potential gender differences and comparisons to smokers in the general population. Design and Methods. Data were collected from 200 people diagnosed with psychosis participating in a randomised controlled trial testing the effectiveness of a multi-component intervention for smoking cessation and cardiovascular disease risk reduction in people with severe mental illness. Results were compared with both treatment and non-treatment seeking smokers in the general population. **Results.** Male and female smokers with psychosis generally had similar perceived risks and benefits of quitting. Females rated it significantly more likely that they would experience weight gain and negative affect upon quitting than males diagnosed with psychosis. Compared with smokers in the general population also seeking smoking cessation treatment, this sample of smokers with psychosis demonstrated fewer gender differences and lower ratings of perceived risks and benefits of quitting. The pattern of risk and benefit ratings in smokers diagnosed with psychosis was similar to those of non-treatment seeking smokers in the general population. Discussion and Conclusions. These results increase our understanding of smoking in people with severe mental illness, and can directly inform smoking interventions to maximise successful abstinence for this group of smokers. For female smokers with psychosis, smoking cessation interventions need to address concerns regarding weight gain and negative affect. Intervention strategies aimed at enhancing beliefs about the benefits of quitting smoking for both male and female smokers with psychosis are necessary. [Filia S L, Baker A L, Gurvich C T, Richmond R, Kulkarni J. The perceived risks and benefits of quitting in smokers diagnosed with severe mental illness participating in a smoking cessation intervention: Gender differences and comparison to smokers without mental illness. Drug Alcohol Rev 2014;33:78-85]

Key words: smoking, smoking cessation, severe mental illness, perceived risk and benefits, gender differences.

# Introduction

Worldwide, the prevalence of tobacco smoking and the resultant impact on the health, well-being and lifespan of people who experience severe mental illness, such as schizophrenia and bipolar affective disorder (BPAD), is significantly disproportionate to smokers in the general population. For example, in Australia, 15.1% of the general population smokes daily [1], whereas recent smoking rates for Australians diagnosed with psychosis are 66.6% [2]. Smokers who experience severe mental illness are more likely to die from smoking-related conditions, predominantly cardiovascular disease (CVD), than from the mental illness per se [3,4]. Further, smokers with severe mental illness die at significantly greater rates and much younger ages than people

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without mental illness [5,6]. Quitting smoking will not only improve the health of people experiencing severe mental illness, it will also have important benefits on their financial situation, clinical presentation and overall quality of life.

Smokers experiencing severe mental illness want to quit [7] but find it harder and have less success overall compared with smokers in the general population [8,9]. We wanted to explore the beliefs that smokers diagnosed with psychosis have about the risks (e.g. craving) and benefits (e.g. improved health) of quitting smoking, research that had not previously been conducted in this population. Knowing what smokers with severe mental illness consider to be the risks and benefits of stopping smoking would enable us to further tailor smoking cessation interventions to hopefully improve the chance of successful abstinence for this group of typically challenging to treat smokers.

McKee et al. developed the perceived risks and benefits questionnaire (PRBO) to assess smokers' beliefs about quitting [10]. Research using the PRBQ has examined gender differences and the overall pattern of responses in people without mental illness seeking smoking cessation treatment [10,11] and in nontreatment seekers [12]. McKee et al. found female smokers seeking treatment anticipated significantly more risks (weight gain, increased negative affect, social ostracism and decreased concentration) associated with smoking cessation than males [10]. This gender difference was replicated by Toll et al. who found female smokers had significantly higher perceived risk scores (increased weight and negative affect and reduced enjoyment) than males [11]. McKee et al. further found female smokers rated numerous benefits of quitting smoking significantly higher than males (improved health, well-being, self-esteem, finances, physical appeal and social approval) [10]. In the general population of smokers not seeking assistance with quitting, these gender differences were almost absent. Males and females in this group had similar perceived risks and benefits of quitting, except for weight gain risks, where females had significantly higher beliefs about this occurring than males [12]. Overall, the non-treatment seeking smokers in the general population had lower ratings of perceived risks and benefits of quitting compared with the treatment seeking sample in the McKee et al. study [10].

The current study is the first to explore the perceived risks and benefits of quitting in smokers with severe mental illness. Using data from a large randomised controlled trial (RCT) testing the effectiveness of a multi-component intervention for smoking cessation and CVD risk reduction in people diagnosed with psychosis [13,14], we aimed to:

- Examine the perceived risks and benefits of quitting in smokers diagnosed with psychosis presenting for treatment in a smoking intervention study.
- Explore potential gender differences in the perceived risks and benefits of quitting.
- Compare the pattern of risks and benefits of quitting in smokers with psychosis with smokers in the general population.

# Method

## Sample

A total of 236 smokers were recruited from Melbourne, Victoria and Sydney and Newcastle, New South Wales, Australia to participate in an RCT testing the effectiveness of a multi-component intervention for smoking cessation and CVD risk reduction among people with psychosis [13,14]. The RCT followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The inclusion criteria were as follows: aged  $\geq$ 18 years, has a diagnosis of psychosis and smoke  $\geq$ 15 cigarettes per day. This paper presents the data from 200 participants that had completed the PRBQ at the baseline assessment of the RCT, as 36 participants were missing all data from the PRBQ.

## Procedure

Potential participants were identified from community mental health services, outpatient hospital clinics, psychiatric rehabilitation services, psychology and general practitioner practices, and by self-referral from the general community. The research team contacted the potential participant, and a brief screening interview was conducted to ensure all inclusion criteria were met. All participants provided written informed consent and completed a comprehensive baseline assessment for the RCT [13,14]. The study was approved by the relevant hospital and university ethics committees at each site.

# Measures

Demographic and clinical variables. Demographic variables were collected using the Diagnostic Interview for Psychosis [15]. Psychiatric diagnosis was determined using the Mini International Neuropsychiatric Interview [16] and categorised according to schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder, schizophreniform disorder), BPAD (type 1 and 2) and other non-organic psychotic disorder (mood disorder with psychotic features; psychotic disorder not otherwise specified).

*Smoking variables.* The number of cigarettes smoked per day was calculated using the drug use domain of the

Variable	Total $n = 200$	Female $n = 79$	Male $n = 121$
Age (m, SD)	41.38 (11.10)	42.67 (9.93)	40.53 (11.76)
Race (percentage of Australian born)	83.0	83.5	83.3
Years school education (m, SD)	11.30 (2.21)	11.33 (2.49)	11.28 (2.02)
Cigarettes per day (m, SD)	28.11 (14.88)	26.75 (11.65)	29.00 (16.64)
Age daily smoking (m, SD)	18.11 (5.42)	18.54 (5.84)	17.82 (5.12)
FTND score (m, SD)	6.96 (1.83)	7.08 (1.73)	6.89 (1.89)
Lifetime quit attempts (m, SD)	6.02 (12.92)	5.73 (8.90)	6.22 (15.13)
Length (weeks) longest quit attempt (m, SD)	262.67 (553.30)	334.48 (726.96)	215.39 (396.62)
Psychiatric diagnosis $(n, \%)^*$			
Schizophrenia spectrum disorder	115 (57.5)	34 (43.0)	81 (66.9)
Bipolar affective disorder	46 (23.0)	26 (32.9)	20 (16.5)
Other non-organic psychotic disorder	39 (19.5)	19 (24.1)	20 (16.5)

 Table 1. Characteristics of baseline sample by gender

\*Significant gender difference in psychiatric diagnosis at P < 0.01. FTND, fagerstrom test for nicotine dependence; m, mean, SD, standard deviation.

Opiate Treatment Index [17]. Participants were asked when their three most recent days of smoking occurred and how many cigarettes they smoked on each occasion. A simple calculation then provided an average daily number of cigarettes smoked based over a 28 day period. Nicotine dependence was assessed using the Fagerstrom Test for Nicotine Dependence [18] with higher scores indicative of greater nicotine dependence (range: 0-10). Participants were asked at what age they started smoking daily, how many times they had attempted to quit and about their longest quit attempt.

PRBO. Participants completed the 39-item selfreport PRBQ by responding to the stem question 'Use the scale below to rate how likely each item would be if you were to stop smoking' using 1 = no chance, 2 = very unlikely, 3 = unlikely, 4 = moderate chance, 5 = likely, 6 = very likely, and 7 = certain to happen. Items were grouped into 12 scales following McKee et al. [10]. Perceived risks include: (i) weight gain; (ii) negative affect; (iii) attend/concentrate; (iv) social ostracism; (v) loss of enjoyment; and (vi) craving. Perceived benefits include the following: (i) health; (ii) well-being; (iii) self-esteem; (iv) finances; (v) physical appeal; and (vi) social approval. Individual item responses were averaged to create the 12 scale scores, and the overall Perceived Risks and Perceived Benefits scales were calculated by averaging the risk and benefit items respectively.

Statistical analysis. Gender differences in demographic, clinical and general smoking variables were analysed using the  $\chi^2$ -test of independence for categorical responses and one-way analysis of variance for continuous variables. Gender differences on the PRBQ were examined using multivariate analysis of variance controlling for diagnosis which significantly differed according to gender. Within-subject differences comparing overall ratings of perceived benefits versus risks were examined using paired sample statistics. Comparison of PRBQ scores from our results to those of smokers in the general population also seeking smoking cessation treatment in the McKee *et al.* study and non-treatment seekers in the Weinberger *et al.* study was made using single sample *t*-tests [10,12].

## Results

## Demographic, clinical and smoking variables

Of the 200 participants, 60.5% were males and 39.5% females. Table 1 presents the characteristics of this sample by gender. Generally, participants were aged in their early 40's, Australian born, and despite being heavy smokers with high levels of nicotine dependence, they had made several quit attempts and had been abstinent for lengthy periods in the past. There was a significant gender difference for psychiatric diagnosis [ $\chi^2$  (2200), P = 0.003], with more males being diagnosed with schizophrenia spectrum disorders than females and a greater proportion of females with BPAD and other forms of psychosis.

## Gender differences on the PRBQ

Multivariate analysis of variance examining mean differences in perceived risks and benefits of smoking cessation, controlling for psychiatric diagnosis, revealed a significant effect of gender [F(12,186) = 2.72, P = 0.002]. Female smokers with psychosis reported significantly greater perceived risks of quitting (m = 4.53)than males (m = 4.17). The comparison of individual

Scale	Total $n = 200$	Female $n = 79$	Male $n = 121$
Perceived risk	4.31 (0.08)	4.53 (0.13)*	4.17 (0.10)
Weight gain	4.46 (0.10)	4.70 (0.16)*	4.30 (0.13)
Negative affect	4.63 (0.11)	5.11 (0.16)***	4.33 (0.13)
Attend/concentrate	3.52 (0.11)	3.78 (0.20)	3.34 (0.13)
Social ostracism	3.55 (0.12)	3.63 (0.19)	3.50 (0.15)
Loss of enjoyment	4.53 (0.13)	4.53 (0.19)	4.53 (0.17)
Craving	5.54 (0.11)	5.65 (0.18)	5.47 (0.14)
Perceived benefit	6.02 (0.07)	6.18 (0.11)	5.91 (0.08)
Health	6.01 (0.08)	6.08 (0.14)	5.97 (0.10)
Well-being	5.97 (0.08)	6.16 (0.13)	5.86 (0.10)
Self-esteem	6.06 (0.08)	6.29 (0.13)*	5.91 (0.10)
Finances	6.32 (0.07)	6.46 (0.12)	6.22 (0.10)
Physical appeal	6.31 (0.08)	6.37 (0.14)	6.26 (0.10)
Social approval	5.74 (0.09)	5.99 (0.14)	5.57 (0.12)

Table 2. Mean (SE) scale scores of PRBQ by gender

\*P < 0.05; \*\*P < 0.01; \*\*\* $P \le 0.001$ . PRBQ, perceived risks and benefits questionnaire. SE, standard error.

scale means according to gender is presented in Table 2. There were very few gender differences on the PRBQ scales among our sample of smokers with psychosis. Female smokers did report significantly stronger beliefs in terms of weight gain and negative affect risks of quitting smoking than males. Specifically, within the negative affect scale, females were significantly more concerned than males about being more irritable (females m = 5.23; males m = 4.43) and less calm (females m = 5.14; males m = 4.15) upon quitting. Further, females had significantly higher belief ratings about the benefits of smoking cessation on their self-esteem than males.

Within-subject differences revealed that females perceived significantly more benefits of quitting smoking than risks, t(78) = -9.62, P < 0.001. Males also rated the perceived benefits of smoking cessation significantly greater than the perceived risks, t(120) = -14.29, P < 0.001.

# Comparison with treatment seeking smokers in the general population

Table 3 shows the comparison of PRBQ ratings from our sample of smokers with psychosis to those of smokers without mental illness in the general population also seeking smoking cessation treatment in the McKee *et al.* study [10]. Both females and males in our study had significantly lower belief ratings on all, but one, of the perceived risk and benefit scales of the PRBQ than smokers from the general population. Female smokers from our study rated their beliefs about the perceived risk of experiencing negative affect upon quitting similarly to the female smokers in the McKee *et al.* study (P = 0.73) [10].

# Comparison with non-treatment seeking smokers in the general population

Table 4 shows the comparison of our sample of smokers with psychosis to the sample from the Weinberger et al. study exploring PRBQ responses in smokers from the general population not seeking smoking cessation treatment [12]. It was not possible to make a gender comparison, as the Weinberger et al. study only presented results for their sample overall [12]. Our smokers with psychosis rated their beliefs about the perceived risks and benefits of quitting smoking very similarly to those of non-treatment seeking smokers in the general population. Our smokers were significantly more concerned about experiencing negative affect and less concerned about the loss of enjoyment after quitting than the smokers from the Weinberger et al. study [12]. Further, our sample rated the general well-being, self-esteem and physical appeal benefits of smoking cessation significantly higher than the general population sample.

# Discussion

The present study is the first to use the PRBQ in people with mental illness, and the findings offer important insights, particularly given the limited research in this group of smokers. For female smokers with psychosis, smoking cessation interventions need to target issues related to weight and negative affect. Intervention strategies aimed at enhancing beliefs about the benefits of quitting smoking for both male and female smokers with psychosis are necessary.

We found few gender differences in the beliefs that males and females with psychosis anticipated as risks

	:	Female	Male		nale N	
Scale	Current study $n = 79$	General population <sup>a</sup> n = 273	Current study $n = 121$	General population <sup>a</sup> n = 300		
Perceived risk (m, SE)	4.53 (0.13)	5.11 (0.06)***	4.17 (0.10)	4.76 (0.05)***		
Weight gain	4.70 (0.16)	5.60 (0.08)***	4.30 (0.13)	4.77 (0.08)**		
Negative affect	5.11 (0.16)	5.05 (0.08)	4.33 (0.13)	4.72 (0.08)**		
Attend/concentrate	3.78 (0.20)	4.29 (0.08)*	3.34 (0.13)	4.01 (0.08)***		
Social ostracism	3.63 (0.19)	4.69 (0.09)***	3.50 (0.15)	4.29 (0.08)***		
Loss of enjoyment	4.53 (0.19)	5.49 (0.09)***	4.53 (0.17)	5.35 (0.09)***		
Craving	5.65 (0.18)	6.08 (0.07)*	5.47 (0.14)	6.01 (0.07)***		
Perceived benefit (m, SE)	6.18 (0.11)	6.62 (0.03)***	5.91 (0.08)	6.47 (0.03)***		
Health	6.08 (0.14)	6.77 (0.04)***	5.97 (0.10)	6.64 (0.03)***		
Well-being	6.16 (0.13)	6.56 (0.04)**	5.86 (0.10)	6.42 (0.04)***		
Self-esteem	6.29 (0.13)	6.65 (0.04)**	5.91 (0.10)	6.43 (0.04)***		
Finances	6.46 (0.12)	6.77 (0.04)**	6.22 (0.10)	6.58 (0.04)***		
Physical appeal	6.37 (0.14)	6.87 (0.03)***	6.26 (0.10)	6.76 (0.03)***		
Social approval	5.99 (0.14)	6.51 (0.04)***	5.57 (0.12)	6.36 (0.04)***		

Table 3. Comparison of PRBQ by gender in smokers with psychosis and a general population sample

\*P < 0.05; \*\*P < 0.01; \*\*\* $P \le 0.001$ . \*Comparison sample of smokers in the general population from [10] McKee *et al.* m, mean; PRBQ, perceived risks and benefits questionnaire; SE, standard error.

Table 4.	Comparison of	f PRBQ in .	smokers wit	h psychosis	and a
non-tr	eatment seeking	g sample fro	om the gener	ral population	<i>on</i>

Scale	Current study n = 200	General population <sup>a</sup> $n = 188$
Perceived risk (m, SE)	4.31 (0.08)	4.2
Weight gain	4.46 (0.10)	4.4
Negative affect	4.63 (0.11)**	4.3
Attend/concentrate	3.52 (0.11)	3.4
Social ostracism	3.55 (0.12)	3.7
Loss of enjoyment	4.53 (0.13)	4.8*
Craving	5.54 (0.11)	5.4
Perceived benefit (m, SE)	6.02 (0.07)	n/a
Health	6.01 (0.08)	5.9
Well-being	5.97 (0.08)***	5.5
Self-esteem	6.06 (0.08)***	5.4
Finances	6.32 (0.07)	6.2
Physical appeal	6.31 (0.08)***	5.5
Social approval	5.74 (0.09)	5.6

\*P < 0.05; \*\*P < 0.01; \*\*\* $P \le 0.001$ . <sup>a</sup>Comparison sample of smokers in the general population from [12] Weinberger *et al.* m, mean; PRBQ, perceived risks and benefits questionnaire; SE, standard error.

and benefits of quitting smoking. Females with psychosis more strongly endorsed overall perceived risks of smoking cessation. Additionally, the expectation of increased self-esteem after quitting smoking, and concerns about weight gain and negative affect were beliefs more strongly endorsed by the female smokers in our study. In keeping with the current findings, we previously found few gender differences in the characteristics and outcomes of smokers diagnosed with psychosis, and that females were significantly more likely than males to report they smoked to prevent weight gain [19]. Perhaps contrary to the beliefs of many health professionals, carers and even patients, both the males and females in the current study rate the benefits of quitting significantly higher than the risks. The expectation that smokers with psychosis will endure many negative experiences (e.g. increased stress, poor concentration, social exclusion) when trying to quit is a powerful barrier to being routinely offered appropriate smoking cessation treatments. It seems that smokers with psychosis are possibly not as concerned about these potential risks of quitting.

When the current results are compared with those from smokers in the general population also seeking treatment for smoking cessation, there are two main differences. Firstly, there is a lack of gender differences. In the general population, female smokers motivated to quit anticipate significantly more negative outcomes [10,11] and are significantly more likely to acknowledge the benefits associated with quitting than males [10]. The current study generally failed to replicate this pattern of results in smokers with psychosis. The only findings consistent with research in the general population were that female smokers with psychosis have significantly higher overall risk perceptions associated with quitting than males, specifically in terms of weight gain and negative affect, and significantly anticipated improved self-esteem as a benefit of smoking cessation. As in our previous research, the current sample of smokers with psychosis did not demonstrate other gender differences in general smoking variables (e.g. nicotine dependence; cigarettes per day) that are typically seen in smokers without mental illness [19]. The current study provides further evidence that smokers with psychosis are a more homogeneous group than male and female smokers in the general population.

The reasons for the lack of gender differences between our sample and smokers in the general population are unclear, but perhaps as we have previously postulated, the higher rates of smoking and nicotine dependence among smokers with severe mental illness may serve to override the effects of gender [19]. Another possibility relates to differing psychosocial roles and level of functioning among people with, and without, severe mental illness. Compared with the general population, fewer people experiencing severe mental illness engage in traditional gender roles that may typically influence a smoker's perceptions about quitting (e.g. as main caregiver of children or ill family members) [20]. Additionally, people who experience severe mental illness often lack structured activities in their everyday lives [21]. Together, these factors may translate to a lack of gender differences in smoking behaviours. Another contributing factor to the link between smoking, gender and mental illness may involve neurobiological mechanisms. For example, estrogen exerts an effect on nicotine-evoked dopamine release, which may explain the gender differences in response to nicotine and smoking behaviour evident in the general population of smokers [22]. However, people with psychosis are often hypoestrogenic which may in some way influence the homogeneity in smoking variables seen in our sample of smokers with severe mental illness [23].

The second key difference is that smokers diagnosed with psychosis in the current study are less concerned about the perceived risks of quitting than smokers in the general population. Although it is ideal to have low risk perception ratings, as prior research in the general population has found perceived risks to be negatively related to quit motivation and treatment outcome, this finding in the current study sample seems counterintuitive [10,11]. Smokers with severe mental illness have higher rates of smoking and nicotine dependence, and together with the additional barriers to smoking cessation they face, they will consequently experience more of these risks and generally have greater difficulty quitting than the general population. Despite increasing knowledge and awareness of the health effects of smoking, anti-smoking campaigns were less effective for people with psychosis, who tended to detach their smoking behaviour from its consequences [24]. The current sample of smokers with psychosis may have been aware of, but did not fully acknowledge,

the potential risks associated with quitting. Furthermore, this sample of smokers with severe mental illness did not rate the benefits of quitting as highly as smokers in the general population. It could be possible that the low levels of confidence and self-efficacy in relation to quitting among smokers with psychosis may serve to dampen the expectation of positive outcomes upon quitting [25]. Further, it is possible that information delivered about the benefits of quitting via education, media and other influences may not have the same impact on smokers with psychosis, potentially as a consequence of the cognitive impairments they experience as part of the mental illness.

The belief ratings that smokers with severe mental illness in the current study have about the risks and benefits they may experience upon quitting appear to lie between those of smokers in the general population wanting assistance with quitting and those not seeking treatment. When compared with smokers in the general population not seeking assistance with quitting, our smokers with severe mental illness did not have significantly different ratings on the majority of the PRBQ scales. There were a few differences though, with our sample being more likely to anticipate improvements in their general well-being, self-esteem and physical appeal, and being more concerned about experiencing negative affect yet less concerned about the loss of enjoyment upon quitting than smokers in the general population not seeking treatment [12]. This pattern of findings is reassuring, as the beliefs that smokers with mental illness have about the risks and perceptions of quitting are not entirely different from those of smokers in the general population, which further increases our understanding of smoking in this population and can inform relevant treatment options.

Evidence-based smoking cessation interventions designed for smokers in the general population should routinely be offered to smokers with severe mental illness, and such interventions need to be more intensive and longer term. Smoking cessation treatments can be further tailored for smokers with severe mental illness based on the findings from the current study. Interventions need to address the specific risk perceptions that female smokers with mental illness anticipate when quitting such as weight gain and negative affect (e.g. irritability, feeling less calm). These variables are significant barriers to quitting and are related to lower motivation and poorer outcomes in terms of smoking abstinence and relapse in female smokers in the general population [10,11,26]. Acknowledging and addressing weight concerns is important, and providing additional treatment related to healthy eating and exercise will be helpful, such as the multi-component intervention delivered to smokers with psychosis [13,14]. Further, it is important to assist female smokers with

strategies to manage negative affect they may experience during a quit attempt. It would be ideal for both male and female smokers with severe mental illness to have stronger beliefs regarding the benefits of quitting, as perceived benefits are positively related to quit motivation and treatment outcome in smokers in the general population [10]. Appropriate education about the benefits of smoking cessation should be delivered to all smokers with severe mental illness at every possible opportunity, and motivational interviewing techniques can be utilised to further enhance these beliefs.

A limitation of the current study relates to the ability to generalise these findings to all smokers with severe mental illness. This study was conducted with a sample of smokers with psychosis in the community in a nonacute phase of the illness, who had expressed some interest in quitting and were participating in a multicomponent study for smoking cessation and CVD risk reduction. Therefore, these results are not completely representative of all smokers with psychosis. Future research replicating this study in other samples of smokers with severe mental illness is required to further explore the pattern of results, lack of gender differences and comparisons with smokers in the general population. The relationship between the perceived risks and benefits of quitting and pre-treatment motivation and treatment outcomes needs to be explored in this population of smokers. It would also be interesting to examine the pattern of risks and benefits of quitting in a sample of smokers with severe mental illness not seeking treatment for smoking cessation.

## Conclusion

The results of the current study make an important contribution to understanding the similarities and differences in the perceived risks and benefits of quitting among smokers with severe mental illness and those in the general population. The male and female smokers with severe mental illness in this study who were seeking smoking cessation treatment generally had similar perceptions of the risks and benefits associated with quitting. Further, the perception ratings of the risks and benefits associated with quitting in smokers with severe mental illness sit somewhere between those of smokers in the general population wanting assistance with quitting and those not seeking treatment. The results of the present study provide three important suggestions to target in smoking cessation interventions with people experiencing mental illness that will hopefully increase their chances of successful abstinence; the need to address concerns regarding weight gain and negative affect upon quitting for females; and the need to strengthen the benefits of quitting for all smokers with mental illness.

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# CHAPTER THREE: GENDER DIFFERENCES IN SMOKERS DIAGNOSED WITH PSYCHOSIS

# **3.2 OVERVIEW OF RESULTS**

The papers presented in this chapter explored potential gender differences on a range of smoking variables specifically among people experiencing psychosis. A consistent finding across the two papers was that smokers experiencing psychosis demonstrated fewer gender differences on a range of smoking variables when compared to smokers without mental illness. In contrast to smokers in the general population, male and female smokers with psychosis generally had similar: reasons for smoking/quitting; perceived risks and benefits of quitting; levels of readiness and motivation to quit; patterns of NRT use and smoking outcomes in terms of point-prevalence and continuous abstinence. There were some gender differences identified among smokers experiencing psychosis that replicate the pattern of results among male and female smokers without mental illness in the general population. These include that females were more likely than males to report they smoked to prevent weight gain, and that they anticipated experiencing weight gain and negative affect as risks of smoking cessation. Further, females overall had more reasons for quitting smoking and were more likely to be driven by extrinsic motivators to quit such as immediate reinforcement and social influence, than males.

Taken together, these findings highlight some interesting similarities and differences between male and female smokers experiencing psychosis and smokers in the general population. The findings in this chapter offer important implications for the treatment of smoking cessation among people experiencing psychosis, which will be further explored in the Discussion section.

65

The following chapter presents a series of papers related to a range of smoking cessation treatment approaches for people experiencing psychosis.

# CHAPTER FOUR: TREATMENT OPTIONS FOR SMOKING CESSATION AMONG PEOPLE EXPERIENCING PSYCHOSIS

# 4.1 PREAMBLE

This chapter includes a series of papers describing the progression of work undertaken by a team of clinical researchers working collectively to design, implement and evaluate treatments that address CVD risk factors among people experiencing psychosis, with a particular emphasis on smoking cessation. The studies described below differ according to the type of intervention offered (face-to-face vs telephone); type of smoking cessation pharmacotherapy used (NRT vs varenicline); duration of treatment (3 months vs 9 months); and the number of participants involved (from a case study up to 235 participants). By way of introducing the two first author publications included in this chapter, an overview of the papers included as appendices will first be provided.

At the time when the work described below was commencing, smoking and other CVD risk factors among people experiencing mental illness were generally neglected in both the research and clinical arenas. This is despite the emerging literature at the time indicating that smoking had very clear adverse physical, clinical, financial and social consequences for people experiencing psychosis. The following publications relate to an extension and refinement of the initial work by Baker et al., (2006; 2007), which included members from this current research group, that was then the largest RCT of a smoking cessation intervention among people with psychosis (n=298).

The paper "Coronary heart disease risk reduction intervention among overweight smokers with a psychotic disorder: pilot trial" was published in the *Australian and New Zealand* 

67

*Journal of Psychiatry* in 2009, and is included in Appendix 2. This paper presents the results of the first ever study to develop and implement a multi-component healthy lifestyles intervention targeting several CVD risk factors among smokers diagnosed with psychosis. The intervention was manual based and consisted of MI, CBT and NRT offered over 9 individual face-to-face sessions across 3 months, with assessments at baseline and posttreatment. Findings demonstrated that that the multi-component intervention was both feasible and effective in significantly reducing overall CVD risk, smoking and weight in the short-term in people experiencing psychosis. Smoking results indicated that 11.6% of the sample was continuously abstinent at the follow-up assessment, while 18.6% met criteria for point-prevalence abstinence. There was also a significant increase in the level of moderate physical activity undertaken by participants, and while an improvement in diet was also noted, this result was not statistically significant. These results were achieved in the absence of any significant changes in levels of depression, functioning or symptoms of psychosis among participants.

Following on from this pilot study, the research team extended this work and designed and implemented a RCT. The next two papers describe the rationale, development and design of the RCT, and are included as Appendices. The paper titled "Healthy Lifestyle intervention for people with severe mental disorders" has been published in a Special Issue titled Smoking and Mental Health within the journal *Mental Health and Substance Use* in 2011 (see Appendix 3). This paper reviews the background literature relevant to the study and provides a general overview of the individual session content of the intervention, including the NRT protocol used. In brief, the protocol recommends that people smoking 30 or more cigarettes per day use 2 x 21mg nicotine patches in addition to up to 12 x 2mg nicotine lozenges per day for the first 12 weeks, with the NRT dose being gradually tapered over the next 12 weeks

68

(i.e. a total of 24 weeks of NRT). For those smoking less than 30 cigarettes per day, 1 x 21mg nicotine patch is recommended together with the lozenges for the first 20 weeks, then tapering over the remaining 4 weeks.

The paper "Study protocol: a randomised controlled trial investigating the effect of a healthy lifestyle intervention for people with severe mental disorders" published in BMC Public Health in 2011 (see Appendix 4) provides greater detail about the specifics of the RCT study design and intervention content. In this RCT, the intervention was delivered over a greater length of time and across two treatment conditions as follows. All participants received individual face-to-face feedback and MI regarding their smoking and other CVD risk factors following the assessment phase. Participants were then randomised to one of two 17 session manual guided interventions delivered over a 9 month period. Participants randomised to the Healthy Lifestyles intervention received individual face-to-face sessions of 1 hour duration that focused on encouraging smoking cessation and improvements in diet and physical activity, using a combination of MI, CBT and contingency management (CM). Participants randomised to the Telephone control condition received individual phone-calls of about 10 minutes duration that focused on smoking, NRT and brief monitoring of their diet and activity levels. All participants were provided with a 24 week supply of NRT as described earlier. Outcome measures performed at baseline were repeated at weeks 15, then 12, 18, 24, 30 and 36 months after baseline by independent assessors blind to treatment condition. The outcome measures used in this study included a range of scales assessing tobacco use, physical activity, dietary habits, other CVD risk factors (e.g. alcohol use, weight, blood pressure, cholesterol and blood sugar levels), psychiatric symptom scales and measures of quality of life and general functioning. This manuscript also highlights some of the challenges faced when implementing such a study, for example the intensity of staff

supervision required to ensure treatment fidelity, and recruiting and retaining participants experiencing severe mental illness into a program of such duration.

The paper titled "Varenicline plus healthy lifestyle intervention for smoking cessation in psychotic disorders" published in the *Annals of Clinical Psychiatry* in 2012 can be found in Appendix 5. This paper describes an open study combining the smoking cessation medication varenicline (Champix) with the multi-component healthy lifestyle intervention used in the pilot study (Baker et al., 2009) for smokers diagnosed with psychosis. Results indicated that the study intervention was associated with a significant decrease in the number of cigarettes smoked per day, without significant changes in the symptoms of depression, mania or psychosis. Specifically, 36% of the sample had quit smoking at 3 months, and 42% at 6 months. The reported side-effects of varenicline were similar to those experienced by people without mental illness (e.g. nausea and sleep disturbance).

The paper titled "Randomized controlled trial of a healthy lifestyle intervention among smokers with psychotic disorders" can be found in Appendix 6. This paper was published in *Nicotine and Tobacco Research* in 2015 within the Special Edition on Interventions to Reduce Tobacco-Related Health Disparities. It presents the outcomes from The Healthy Lifestyles RCT described above at the 15 week and 12 month assessment timepoints. Results indicate that both the Healthy Lifestyles face-to-face intervention and the Telephone based control condition were associated with significant reductions in CVD risk scores and smoking in people with psychosis. Point prevalence smoking abstinence rates were 11% for the Healthy Lifestyles face-to-face intervention and 13% for the Telephone intervention at 15 weeks, and 6.6% and 8.0% respectively at 12 months. There were no significant changes

70

across time in symptoms of psychosis for either treatment group, with significant improvements in overall functioning and symptoms of depression.

The first paper specifically included in this chapter, "Sequential behavioral treatment of smoking and weight control in bipolar disorder" has been published in *Translational Behavioral Medicine* in 2012. At that time, there had been no published studies evaluating smoking cessation interventions solely in people diagnosed with BPAD. This was despite the emerging research indicating that people with BPAD are as much at risk of CVD as those diagnosed with schizophrenia. This paper presents the relevant literature in the context of a specific case study of a female participant in The Healthy Lifestyles RCT that highlights some of the clinical challenges that may be encountered when working specifically with people with BPAD to quit smoking.

The second paper included in this chapter is a Letter to the Editor of *The Australian and New Zealand Journal of Psychiatry* that was published in 2012. This letter was prepared in response to an earlier letter published in the same journal by Anandarajan, Tibrewal, and Dhillon (2012) titled "Manic exacerbation induced by nicotine patch" (see Appendix 7). Our paper demonstrates an application of the theoretical knowledge and clinical experience I have developed during my PhD studies to provide accurate information and to dispel some common myths that serve to act as significant barriers preventing people with severe mental illness from accessing smoking cessation treatments.

This chapter will conclude with a brief overview of these results.

# **CASE STUDY**

# TBM

# Sequential behavioral treatment of smoking and weight control in bipolar disorder

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## ABSTRACT

People with severe mental illnesses like schizophrenia and bipolar disorder (BPAD) live significantly shorter lives than people in the general population and most commonly die of cardiovascular disease (CVD). CVD risk behaviors such as smoking are not routinely assessed or assertively treated among people with a severe mental illness. This article provides an illustrative case example of a woman with BPAD who is motivated to quit smoking, despite concerns about weight gain and relapse to depression. It outlines key considerations and describes the patient's experience of participating in a behavioral intervention focussing first on smoking, then diet and physical activity. Clinical challenges encountered during treatment are discussed in the context of relevant literature. These include motivational issues, relapse to depression, medication interactions, weight gain, addressing multiple health behavior change, focussing on a behavioral rather than cognitive approach, collaborating with other health care providers, and

#### **KEYWORDS**

gender issues.

Smoking, Smoking cessation, Bipolar disorder, Sequential behavioral treatment, Weight gain, Physical activity

Patients with severe mental illnesses such as schizophrenia and bipolar disorder (BPAD) have an increased prevalence of metabolic syndrome and its component risk factors for cardiovascular disease (CVD) and diabetes [1, 2]. CVD is the leading cause of death in the mentally ill, with recent studies indicating premature death estimates of 25 years of life lost in this population [3, 4]. People with BPAD are as much at risk of CVD as those diagnosed with schizophrenia [5-10]. The typical CVD risk profile of a person with BPAD is characterized by high rates of cigarette smoking, obesity, metabolic syndrome, diabetes, hypertension, and elevated total cholesterol and low levels of high-density lipoprotein (HDL) [7-10]. The physical health needs of people with mental illness are often neglected, meaning that behavioral and biomedical risk factors for CVD are not routinely assessed or assertively treated in this population.

## Implications

**Practice**: Multiple health behavior interventions in smokers with severe mental illness are feasible and can be effective.

**Policy**: A behavioral approach developed to help smokers without severe mental illness to quit and manage weight may also have applicability for people with bipolar disorder who smoke and share similar concerns about gaining weight.

**Research**: Further studies in bipolar disorder are required to determine if established treatments for smoking cessation are effective and feasible in this population.

Although treatment with psychiatric medications is a contributing factor, access to primary health care is often poor and complicated by socioeconomic factors that negatively impact care [11, 12].

Researchers recently have called for specific programs to be implemented for people with BPAD that focus on reducing cigarette smoking, increasing physical activity, and improving dietary habits to reduce their risk of CVD and ameliorate the health inequalities they experience [9]. The case below demonstrates one such approach and highlights some of the clinical challenges that may be encountered when working with people with BPAD to quit smoking (Table 1).

#### **SMOKING PREVALENCE**

Compared to the general population, people with mental illness have significantly increased rates of smoking. Few studies have reported smoking prevalence rates specifically for those with BPAD. Of those that have, the smoking rates are very similar to those in schizophrenia. A large study (n=2774) conducted in the USA found the prevalence of smoking to be 67% in people with schizoaffective disorder, 66% for BPAD, and 61% for schizophrenia, all of which were much higher than in the general population (24%) [13]. Another found the prevalence of smoking to be 57% for major

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Cite this as: *TBM* 2012;2:290–295 doi: 10.1007/s13142-012-0111-1 Table 1 | Case study of a woman with bipolar disorder who wanted to give up smoking but was concerned about weight gain and relapse to depression

Ms. A was a 63-year old woman, with a diagnosis of bipolar affective disorder. Her current condition was stable. Her medication included a mood stabilizer (sodium valproate), an antidepressant (fluvoxamine), and simvastatin for hypercholesterolemia. Ms. A saw a psychiatrist monthly and a community mental health service case manager fortnightly. She smoked 25 cigarettes a day, and had made three serious quit attempts in 48 years of smoking, the longest-lasting 2 weeks. Relapses to smoking were precipitated by stress and lowered mood. Ms. A had not previously used pharmacotherapy for smoking cessation. Although she was motivated to guit smoking, she was preoccupied with the possibility of gaining weight, and experiencing a relapse to depression. She was overweight and her diet lacked fruit/vegetables. Ms. A was sedentary and wanted to increase her level of physical activity. Ms. A participated in a multi-component CVD risk reduction intervention over a 38-week period that provided an intensive psychosocial intervention together with combination nicotine replacement therapy (NRT). In session 1, motivational interviewing techniques examined Ms. A's unhealthy behaviors and goals for change were set. The intervention then sequentially targeted smoking (from week 1), physical activity (from week 4), and diet (from week 7). Ms. A made her first quit attempt 2 weeks into treatment. She used one 21 mg nicotine patch daily and tried one 2 mg nicotine lozenge but disliked the taste. Within a week of commencing the 21 mg patches, she began experiencing nightmares and sleep disturbance, and reported feeling mildly depressed, with initial insomnia, amotivation, and anhedonia. Ms. A smoked 1/2-1 cigarette per day for the next 4 weeks. She was encouraged to persist with the lozenges and used up to five per day. She persisted with the patches, and the sleep disturbance and vivid dreams dissipated. After 6 1/2 weeks, Ms. A had ceased smoking. Ms. A resisted working within a cognitive therapeutic framework and the focus was placed on behavioral strategies such as avoiding coffee first thing in the morning, not smoking inside her home, distraction activities (e.g., knitting, crosswords, cards), and using sugar-free mints. Seven weeks into treatment Ms. A reported the depression had worsened and she was increasingly anxious and irritable. She was less reactive, had difficulty concentrating, and was slowed in her speech and movements. She described feelings of worthlessness and hopelessness, but did not express any suicidal ideation. Increased support options were arranged and Ms. A saw her case manager and psychiatrist more frequently during this time. Her valproate levels were checked and found to be sub-therapeutic, and medication adjustments were made. Ms. A remained abstinent from cigarettes during this time, and the moderate depression resolved by week 14. However from weeks 22-34, she experienced mild depression. During week 22 Ms. A had two cigarettes on two separate days. This smoking relapse coincided with a return of the depressive symptoms. She struggled over the next month, smoking one to four cigarettes per day. However, by week 30, she had stopped smoking, and remained abstinent from cigarettes at the final therapy session at week 38. Following session 1, Ms. A self-initiated some healthy behaviors based on her existing knowledge of healthy eating.

After session 1, she started eating breakfast. By week 3, Ms. A was eating two pieces of fruit a day and cooking a main meal for dinner. She struggled to maintain these positive changes to her diet between weeks 7–12 when her depressive symptoms were at their most severe. By week 26, Ms. A was again eating fresh fruit/vegetables regularly and having three balanced meals a day. She gained 2.7 kg over the first 15 weeks. One year following commencement of treatment, Ms. A's weight remained constant, and by 18 months she was 1.2 kg lighter than her starting weight.

At the commencement of the program, Ms. A was walking only short distances. From weeks 4–14, she was inactive due to the depression. By week 18, Ms. A commenced a walking program. She started by walking 20 min a day four times a week, and increased this to 40 min a day six times a week by the end of the intervention.

depression, 66% for BPAD, and 74% for schizophrenia, compared to 25% in controls [14]. The prevalence of smoking was higher for those with BPAD (68.8%) than any other psychiatric diagnosis in another large study (n=4411) [15]. In Australia, 16.6% of people in the general community are daily smokers [16], as compared to 51% of people with BPAD [17].

#### **SMOKING HARMS**

In addition to significantly contributing to the poor physical health and premature mortality of people with BPAD, smoking adversely affects the clinical presentation, course, treatment response, and outcomes in BPAD. A large study in BPAD (n=1904) found that smoking was associated with greater symptom and episode severity, rapid cycling, more lifetime depressive and manic episodes, comorbid psychiatric disorders, being currently symptomatic, greater alcohol and illicit substance use, and a history of suicide attempts [18]. Another study found that smokers with BPAD had significantly poorer outcomes in terms of depression and overall BPAD symptoms, longer hospitalizations, greater substance use, and poorer health-related quality of life [17]. Smokers with BPAD involved in a clinical trial investigating olanzapine as a treatment for acute mania had poorer treatment outcomes with greater manic symptoms and overall episode severity [19].

#### **SMOKING TREATMENT**

A range of approaches have been implemented to assist people with severe mental illness to quit smoking, including pharmacotherapy (e.g., nicotine replacement therapy (NRT), bupropion and varenicline) and psychological approaches (e.g., counseling, education, motivational interviewing (MI), cognitivebehavioral therapy (CBT), and contingency managepage 291 of 295 ment). A combination approach, adding psychosocial interventions to an appropriate smoking cessation pharmacotherapy over a sustained period works best in helping people with severe mental illness to quit smoking [20]. Three reviews of smoking cessation interventions for people with severe mental illness reported that this population are able to quit or reduce smoking, and that standard approaches to smoking cessation have comparable success with the general population and people with severe mental illness [21–23].

To our knowledge, there have been no published studies to date that evaluate smoking cessation interventions solely in people with BPAD. In one of the largest smoking cessation intervention studies among people with severe mental illness, 298 participants were randomly assigned to treatment as usual or an individually administered smoking intervention that included NRT + CBT + MI [24]. Significantly more people who attended all treatment sessions had quit smoking at each follow-up point compared to those assigned to the control condition (e.g., total abstinence at 12-month followup=19% vs. 7%). While this study did not analyze outcomes according to diagnosis, 9.1% of the sample comprised people with BPAD. Similarly, in the first study to implement and evaluate a multi-component CVD risk factor intervention targeting smoking, diet, and physical activity in people with psychosis, 13.9% of the sample had BPAD [25]. In a current study, in which Ms. A was enrolled as a participant, 30.2% of the sample have a diagnosis of BPAD [26]. Early smoking results for the total sample are promising, with participants significantly reducing their daily cigarette intake at the first assessment point (15 weeks). While the current evidence is limited, it seems likely that people with BPAD can quit smoking.

Pharmacological interventions for smoking cessation in BPAD require some additional considerations. Combination NRT seems the most suitable first-line option for people with BPAD. Combination NRT is indicated for heavy smokers with high levels of nicotine dependence and involves combining one medication that allows for passive nicotine delivery (i.e., transdermal nicotine patch) with another that allows ad lib nicotine delivery to manage cravings (e.g., nicotine gum, lozenges, or inhaler) [27, 28]. The use of combination NRT has been recommended for people with severe mental illness to effectively manage their higher levels of nicotine dependence [25, 29-34], and is effective for smoking reduction and cessation in people with BPAD [25, 26]. The dose and mode of NRT needs to be modified according to individual nicotine withdrawal symptoms, and a combination of patch and titratable ad lib forms of NRT (e.g., lozenges, gum) up to 42 mg/day has been recommended for people with severe mental illness [31, 32]. Bupropion, an antidepressant, should be used with caution in people with BPAD due to the propensity for precipitating a manic episode [33]. Although varenicline may offer another plausible alternative smoking cessation pharmacotherapy for use in BPAD, thus far no trials have been reported in samples with BPAD.

# CLINICAL CHALLENGES IN SMOKING CESSATION TREATMENT IN BPAD

# Motivation

People with a severe mental illness are as motivated to quit smoking as the general population [35] and motivation to quit smoking waxes and wanes throughout ongoing treatment for smoking cessation. Although people with severe mental illness do recognize the serious consequences of smoking, and want to guit mainly for health reasons [36, 37], they commonly lack confidence in their ability to successfully quit [37]. Smoking cessation interventions for people with severe mental illness, such as BPAD, thus need to target motivational and self-efficacy issues [38]. Several studies have found MI to be an effective and feasible treatment option for tackling comorbid substance use (mainly cannabis and alcohol) among people with psychosis [39-42] and smoking cessation in people with psychosis [24, 25]. MI techniques [43] involving the discussion of the positive and less positive aspects of smoking and smoking cessation should be employed as required during the course of intervention.

#### Risk of relapse to depression

While available evidence from studies in schizophrenia and schizoaffective disorder do not suggest a deterioration in mental state during smoking cessation [21, 24, 25, 44], evidence suggests that smokers with a previous history of depression may experience a recurrence of depression during smoking cessation [45]. This is more likely for those depressed at baseline and those who experience protracted nicotine withdrawal symptoms. Nicotine withdrawal symptoms can act as stressors for people experiencing mental illness, in turn triggering or exacerbating other mental illness symptoms [38]. Ideally, people with BPAD embarking on a smoking cessation attempt should be stable in terms of their mood. Before and during any smoking cessation attempt, mood symptoms need to be closely and regularly monitored in people with BPAD. Any depressive symptoms that may emerge during a smoking cessation attempt must be addressed immediately, as these can have a detrimental impact on motivation to quit. Additionally, an assertive approach to managing nicotine withdrawal symptoms in people with BPAD is crucial. Ms. A experienced a depressive relapse during her smoking cessation attempt and this impacted on her motivation to quit and the amount she smoked. Prompt and effective management of these symptoms by her treating team enabled Ms. A to recover and continue with her quit attempt.

## Smoking and medication

Smoking reduction or cessation can alter the doses of some psychiatric medications. Toxic products

released during tobacco consumption, not nicotine, increase the metabolism of some psychiatric medications in the liver by inducing the cytochrome P450 (CYP) enzyme system, primarily CYP1A2 [46]. As smoking reduces, this metabolism will slow, subsequently increasing the doses of some medications in the body, possibly resulting in the emergence or exacerbation of medication side effects. Alternatively, patients may experience an increased therapeutic benefit upon smoking reduction or cessation with increased doses of medication available in their system. Psychiatric medications frequently used in the treatment of BPAD that are affected by changes in smoking and liver metabolism include olanzapine, chlorpromazine, fluvoxamine, mirtazapine, and diazepam. It is important to advise patients of these potential interactions at the outset of smoking cessation treatment, to regularly monitor possible changes to medication side effects and to adjust dosage of medications as required.

Risk of weight gain: need for multi-component intervention People with severe mental illnesses are at significant risk of obesity due to the illness itself and partly as a consequence of their psychiatric treatment [47–49]. Medications commonly used to treat the symptoms of BPAD such as mood stabilizers (e.g., lithium, sodium valproate), atypical antipsychotics (olanzapine and risperidone) and some antidepressants (e.g., paroxetine and mirtazapine) have been associated with significant weight gain [50]. Like smoking, obesity has been associated with poorer clinical presentation and outcomes in BPAD [51, 52]. It thus seems sensible to offer interventions that target a number of CVD risk factors in people with BPAD.

Evidence indicates that changing multiple health behaviors is feasible [53]. A recent meta-analysis of randomized controlled trials (RCTs) was conducted comparing combined smoking treatment and behavioral weight control to smoking treatment alone for smokers in the general population [54]. Results indicated that combined smoking cessation and weight control treatment, compared to smoking cessation treatment alone, enhanced tobacco abstinence and also reduced post-cessation weight gain significantly in the short term. Specifically, the best results for weight gain associated with smoking cessation in female smokers were achieved by offering a sequential approach, whereby smoking cessation was addressed *before* initiating weight control treatment [55].

We developed, implemented, and evaluated a multi-component intervention targeting smoking, diet, and physical activity in overweight smokers with psychosis [25], finding this to be both feasible and effective in decreasing CVD risk scores, smoking, and weight. We have since commenced a larger and longer duration multi-component study in people with severe mental illness, again sequentially targeting smoking, diet, and physical activity [26, 56]. The first session employs MI to examine the person's unhealthy behaviors and goals for change

are set. Smoking is specifically addressed first, with the intervention for physical activity starting in week 4, and diet in week 7. Ms. A benefited from our sequential, multi-component intervention. Although she gained 2.7 kg in the first 15 weeks, she weighed 1.2 kg less than she weighed before treatment after 18 months. Weight gain with smoking cessation has been clearly documented [57], and the amount gained usually varies between 3 and 6 kg, with women being more likely to gain more. In this context, Ms. A's initial weight gain was comparatively small. Weight gain can seriously undermine a successful quit attempt, particularly in female smokers [58]. Interventions designed to minimize weight gain may increase the appeal of smoking cessation treatments, especially for female smokers. Smoking interventions for people with BPAD will benefit from being multi-component and sequential, firstly addressing smoking and then targeting issues around weight, diet, and exercise.

#### Behavioral interventions for smoking cessation

Evidence strongly supports the use of both counseling and pharmacotherapy for smoking cessation [21, 24, 25, 34, 59]. Furthermore, as people with severe mental illness may experience cognitive and/or other difficulties, behavioral interventions may be a preferred approach in smoking cessation treatment, as was the case for Ms. A. Behavioral interventions targeted at the high risk situations for smoking are warranted, e.g., first thing in the morning, drinking coffee/alcohol, socializing with other smokers, stress/ depression, and boredom.

Unique additional high risk situations exist for smokers with severe mental illness like BPAD, e.g., smokers increase their consumption of cigarettes during manic episodes [19] and smoking behavior is reinforced in the psychiatric treating system [60]. Given the decreased opportunity or availability of alternate activities to smoking, absence of well-developed alternative coping strategies for stress and other emotions, and associated motivation and cognitive difficulties seen in severe mental illness, smokers with BPAD will require additional support in identifying and implementing suitable behavioral interventions for smoking cessation. This may include assisting patients to problem solve in order to formulate methods to change patterns of behavior associated with smoking, as well as determining suitable distraction techniques. Role playing these strategies with patients is helpful.

#### Close collaboration with health care providers

Given that smoking cessation efforts in people with severe mental illness need to address issues related to mental state, medication, weight, physical health, and daily functioning, mustering support and expertise from all available health care providers is worthwhile. Establishing contact with other health care providers involved in the patient's treatment at page 293 of 295

the outset is a good practice, as is providing regular feedback regarding their patient's smoking cessation efforts. Harmonious working relationships between health care providers can contribute towards the success of smoking cessation treatment. A united and consistent message regarding smoking cessation from all health care providers to patients is necessary. This was a key factor that contributed to Ms. A's successful quit attempt. The provision of relevant education to health care providers may neutralize unhelpful staff attitudes such as people with mental illness do not want to and cannot quit smoking, the patient's psychiatric condition will deteriorate if they don't smoke, patients need to smoke due to their mental illness symptoms, and smoking is the only coping strategy people with mental illness have [60, 61].

#### Gender differences

The risks of several of the most serious smokingrelated illnesses appear to be higher in women than men who smoke [58]. Additionally, smoking poses unique health risks for women (e.g., obstetric and perinatal complications, breast and cervical cancer). All smokers with BPAD should be offered smoking cessation treatment, but efforts aimed at females may be particularly worthwhile in reducing the overall morbidity, mortality, and health care costs associated with smoking in BPAD.

There have been no published studies examining gender differences in smoking variables specifically among people with BPAD. In the general population, women are more likely to smoke to suppress their appetite and cope with the stresses of daily life, and be more concerned about weight gain during a quit attempt than men [62]. We found that women with severe mental illness reported being more likely to smoke to prevent weight gain, and had significantly more reasons for quitting than men [63]. Smoking cessation approaches for people with BPAD need to be gender sensitive, addressing weight issues for women, and strengthening reasons for quitting for males via MI.

#### Summary

The prevalence of smoking and its associated harms are significant problems among people with BPAD, and contribute to increased medical comorbidity and mortality. While there is a wealth of scientific evidence to justify and guide smoking cessation treatment in BPAD, clinical practice has still to catch up. All smokers with BPAD should routinely be offered smoking interventions. Optimal smoking cessation treatment in BPAD involves the combination of appropriate pharmacotherapy with an extended duration psychosocial intervention. Specific attention needs to be directed to issues of motivation, risk of relapse to depression and medication. Interventions need to be gender sensitive, addressing weight gain after smoking cessation, and a close collaboration with other health care providers needs to be established. Smoking cessation attempts should not be abandoned in the event of a smoking relapse or with mental health symptoms provided the patient wishes to continue.

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# Response to Anandarajan et al.: Manic exacerbation induced by nicotine patch

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## To the Editor

In their letter to you, Anandarajan et al. (2012) purport that the daily use of a single 21 mg 24-hour nicotine patch for a 3-week period induced a manic episode in a 35-year-old man with a past history of bipolar disorder (BPAD). Anandarajan et al. (2012) suggest two possible explanations to account for their observation. The first relates to a disruption of the sleep/wake cycle induced by nicotine patches acting as a stimulant. The second proposed mechanism suggests that the patches stimulated nicotinic cholinergic receptors on mesolimbic dopaminergic neurons resulting in increased dopaminergic activity, and that this patient was particularly susceptible to this hyperdopaminergic activity due to "a vulnerable brain" and not being on maintenance mood stabiliser treatment. We believe that this association between the use of nicotine patches and manic relapse is largely unfounded, and is in fact a dangerous claim to make. To suggest that the very treatment which has the potential of saving the lives of many smokers that experience mental illness is doing harm is inaccurate and paternalistic.

Nicotine replacement therapy (NRT) first became available in the 1980s and since then millions of smokers worldwide have used some form of NRT during a smoking cessation attempt, with the majority purchasing these products over the counter (i.e. without a prescription) (Ferguson et al., 2011). There is well-substantiated evidence that all forms of NRT are safe, well tolerated and effective in quitting smoking (Ferguson et al., 2011). Anandarajan et al. (2012) are correct in saying that there is a paucity of literature exploring the relationship between 'excessive' nicotine levels and the precipitation of a manic episode. To the best of our knowledge, there has been no reported evidence that use of nicotine patches, or other forms of NRT generally, results in the experience of a manic episode. Our own work and that of others, among thousands of people experiencing psychosis, including hundreds with BPAD, demonstrates that people experiencing severe mental illness do not experience deterioration in their mental state, either in the form of a relapse to psychosis, depression or mania during smoking cessation, including those using NRT (Baker et al., 2006, 2009, 2011; Banham and Gilbody, 2010; Williams et al., 2011). However, smokers with a previous history of depression may experience a recurrence of depression during a quit attempt (Hughes, 2007), and this is more likely for those who experience protracted nicotine withdrawal symptoms. Nicotine withdrawal symptoms such as cravings, irritability, anxiety, restlessness, sleep disturbance, difficulty concentrating and lowered mood can act as stressors for people experiencing mental illness, in turn triggering or exacerbating other symptoms of mental illness (Fagerstrom and Aubin, 2009).

We propose that the manic episode may have been triggered by nicotine withdrawal symptoms experienced by this heavy smoker as a consequence of being *underdosed* with NRT. Contrary to the claims of Anandarajan et al. (2012), this patient would not have had excessive nicotine levels. The dose of nicotine delivered by the transdermal patch, and the speed at which the nicotine is delivered, is substantially lower than that achieved by smoking cigarettes (Sweeney et al., 2001), which disputes the claim made by Anandarajan et al. (2012) that the nicotine patches caused hyperdopaminergic activity. Furthermore, if this was in fact the case, we would expect to see the emergence of symptoms of psychosis, particularly in a patient such as the one described, who had previously required 6 mg of risperidone to remain asymptomatic. People with severe mental illness typically smoke heavily (> 20 cigarettes per day) and have high levels of nicotine dependence, and it has been recommended that combinations of NRT such as the nicotine patch, together with titratable forms of NRT (e.g. gum, lozenges) be used in this population (Hughes et al., 1999; Williams and Foulds, 2007). If this patient was referred to our Healthy Lifestyles Project for smoking cessation (Baker et al., 2011), we would recommend that he commence using  $2 \times 21$  mg nicotine patches daily together with up to  $12 \times 2$  mg nicotine lozenges, and the NRT would be titrated down over an extended period of time.

Finally we are very concerned that linking the use of NRT and smoking cessation to a manic relapse will frighten clinicians and give them yet another reason why people with mental illness should not quit smoking. The leading cause of premature death and morbidity in people with mental illness is cardiovascular disease, and smoking is the most significant contributing risk factor in this population (Colton and Manderscheid, 2006). We must take a common sense approach and remind ourselves that the use of nicotine through NRT products is far safer than smoking in and of itself. All smokers with mental illness should be advised, encouraged and supported to quit smoking as a matter of priority, and this should be done under the supervision of their treating team to ensure that nicotine withdrawal symptoms, mental illness symptoms and medication side effects are closely monitored.

## **Declaration of interest**

Glaxo Smith Kline (GSK) provided the authors with the nicotine replacement therapy (NRT) for the authors Healthy Lifestyles study mentioned in the letter. GSK did not have any role in the design of the study, nor did they contribute to the dosage regime and they do not have access to any of the study data or have any role in the analysis of it.

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# CHAPTER FOUR: TREATMENT OPTIONS FOR SMOKING CESSATION AMONG PEOPLE EXPERIENCING PSYCHOSIS

# 4.2 OVERVIEW OF RESULTS

The papers presented in this chapter were largely theoretical in nature and explored various aspects of interventions that address multiple CVD risk factors specifically in smokers diagnosed with psychosis. Taken together, these papers were able to present the rationale, procedure and evidence for offering people experiencing psychosis with a range of different interventions that will assist them to reduce or quit smoking, as well as reduce other CVD risk factors they may have.

In terms of the two first author publications included in this chapter, similar themes emerged. Firstly, these two papers demonstrate how the research in this area can be directly translated into clinical practice. Secondly, these two papers highlight several clinical challenges that may be faced when working with people experiencing psychosis addressing their smoking behaviour, and provide suggestions on how to respond to these in practice. These include targeting motivational and self-efficacy issues; the need to closely monitor mental illness symptoms and medication side-effects during any quit attempt; proactively identifying and treating nicotine withdrawal symptoms with sufficient doses of smoking cessation pharmacotherapy; the interaction between smoking and some psychiatric medications; offering a range of behavioural interventions; and the possibility of weight gain during a smoking cessation attempt, particularly for female smokers with psychosis.

81

Overall, the papers in this chapter offer direct clinical implications for the treatment of smoking and other CVD risk factors in people with psychosis that will be explored in detail in the Discussion chapter.

The next chapter will shift focus to a different situation faced by smokers diagnosed with severe mental illness, that is, admission to a psychiatric ward that prohibits smoking on site, and will explore the patient experience.

# CHAPTER FIVE: IMPLEMENTING A TOTALLY SMOKEFREE POLICY IN THE ACUTE PSYCHIATRY SETTING: THE INPATIENT EXPERIENCE

# **5.1 PREAMBLE**

This chapter will explore the patient experience of a Totally Smokefree Policy in the acute psychiatry hospital setting, and how these results can be used to directly inform clinical practice surrounding total smoking bans in the psychiatry ward.

Previous research described in this thesis largely stems from smokers experiencing psychosis before or during their voluntary participation in a smoking cessation intervention. This chapter presents research from smokers with severe mental illness who are mandated by a hospital policy to temporarily cease smoking while being an inpatient of the acute psychiatry hospital ward, often involuntarily. As healthcare services continue to implement policies prohibiting smoking, people experiencing severe mental illness will inevitably be faced with this scenario and the subsequent challenge of suddenly stopping smoking at least while they are admitted to hospital. Generally, the research to date about the implementation of hospital smokefree policies has largely ignored the perspectives and experiences of patients (Shopik, Schultz, Nykiforuk, Finegan, & Kvern, 2012). There have been a few studies that have considered the views of inpatients of psychiatric services with total smoking bans (Hehir, Indig, Prosser, & Archer, 2012; Ratschen, Britton, Doody, & McNeill, 2010; Resnick & Bosworth, 1989; Shmueli, Fletcher, Hall, Hall, & Prochaska, 2008; Smith et al., 2013). However, the results of such research have not been comprehensive enough to sufficiently guide staff and services in the best way to prepare, manage and support smokers experiencing severe mental illness that are admitted to units with Totally Smokefree Policies. Therefore,

in the absence of such research, the studies detailed in this chapter were designed and undertaken.

The first paper presented in this chapter, "Inpatient views and experiences before and after implementing a Totally Smokefree Policy in the acute psychiatry hospital setting" has been published in the *International Journal of Mental Health Nursing* in 2015. As the title suggests, this paper provides the first in depth analysis of what inpatients think about a total smoking ban in the psychiatric ward, how they cope not smoking on the ward, and how the Totally Smokefree Policy has influenced their own smoking behaviour and the ward in general.

The second paper in this chapter "An inpatient group to support the implementation of a Totally Smokefree Policy in the acute psychiatry setting: The role of psychologists" has been reviewed by the *Australian Journal of Psychology*, and has been returned for revision. This is the first paper to describe the design, implementation, experience and evaluation of a specific group to support inpatients following the implementation of a total smoking ban in the acute psychiatry setting.

This chapter will conclude with a brief overview of these results.
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## FEATURE ARTICLE Inpatient views and experiences before and after implementing a totally smoke-free policy in the acute psychiatry hospital setting

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**ABSTRACT:** In the present study, we examined the views and experiences of patients admitted to an acute psychiatry unit before and after the implementation of a totally smoke-free policy. Forty-six inpatients completed a questionnaire assessing their views before the smoking ban. Another 52 inpatients completed a questionnaire assessing their views and experiences after the smoking ban. Before the totally smoke-free policy, 69.6% smoked, with 67.7% smoking more when admitted to the psychiatry ward. Before the smoking ban, 54.4% reported that the totally smoke-free policy would be 'negative' or 'very negative,' and 30.5% said it would be 'positive' or 'very positive.' After the totally smoke-free policy, 57.7% smoked heavily before hospital (mean cigarettes/day = 24.9), with consumption dramatically reducing following admission to a totally smoke-free psychiatric unit (mean cigarettes/day = 8.3). After the totally smoke-free policy, 36.5% reported that it was 'negative' or 'very negative,' and 50% reported that it was 'negative' or 'very negative,' and 50% reported that it was 'positive' or 'very positive.' Overall, inpatients reported improved acceptance of the policy following implementation. Inpatients stated that the most difficult thing about the smoking ban was experiencing increased negative emotions, while the most positive aspect was the improved physical environment of the ward. Inpatients who smoke must be appropriately supported using a range of strategies, and in the present study, we suggest relevant clinical implications.

**KEY WORDS:** inpatient psychiatry, inpatient view, patient experience, smoking, smoking ban.

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## INTRODUCTION

It has only been within the past 10 years that health-care services in Australia have implemented policies prohibiting smoking, and these range from partial to total smoking bans. The main objectives for implementing a totally smoke-free policy in a health-care service are to reduce the health impacts associated with smoking and the exposure to environmental tobacco smoke for all individuals, and to provide a safer, healthier, and more pleasant environment for all. The introduction of such a policy poses a challenge for all health-care services, but particularly for acute inpatient psychiatry services for two main reasons. First, people with mental illness have very high rates of smoking and nicotine dependence (Cooper *et al.* 2012).

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Second, smoking historically plays a role in the day-to-day running of the psychiatry ward (Cormac & McNally 2008). Exempting mental health units from smoke-free policies is not the answer to this challenging scenario (Lawn & Campion 2013). We argue that this will only serve to further increase the health inequalities that this patient group experiences as a consequence of their smoking, and it would deprive all individuals in that environment of the important benefits of such a policy.

A significant disparity exists between people who do and do not have mental illness in terms of smoking prevalence and the impact it has on their health, well-being, and lifespan. People with mental illness smoke more and for longer periods, and have higher levels of nicotine dependence than the general population (Compton 2005; Kumari & Postma 2005). Recent smoking rates in Australia are 12.8% (AIHW 2014), while rates among participants of the Australian Survey of High Impact Psychosis (SHIP) study are 66.6% (Cooper et al. 2012). These rates are even higher in certain settings. For example, smoking rates among inpatients of psychiatric units are between 70% and 80% (Hehir et al. 2012; Jochelson & Majrowski 2006). Once admitted to a psychiatric hospital, the majority of smokers increase the amount they smoke (Jochelson & Majrowski 2006; Olivier et al. 2007), and non-smokers risk leaving the ward as smokers (Lawn et al. 2002; Wye et al. 2009).

Smoking has been an accepted part of the culture in psychiatry for many years (Cormac & McNally 2008). The role of smoking in the inpatient psychiatry ward is particularly entrenched. Staff of psychiatry wards describe smoking as a means of establishing and maintaining a therapeutic relationship with patients. Further, some staff use cigarettes as a token economy for reward or punishment, and to reinforce and condition behaviour of inpatients (Lawn & Condon 2006; Olivier et al. 2007; Ratschen et al. 2011). Past research describes how many mental health services support inpatients smoking by either directly supplying cigarettes, purchasing cigarettes for inpatients who do not have leave, or by escorting inpatients to buy cigarettes (Lawn & Pols 2005). The main reasons for smoking reported by people with mental illness are to cope with stress and because they are addicted (Baker et al. 2007; Filia et al. 2011).

The implementation of hospital smoke-free policies significantly changes the health-care context for patients who smoke, yet there is minimal research focused on inpatient perspectives and experiences (Shopik *et al.* 2012). Obtaining the patient perspective is crucial, as this will guide the level and type of support that is required to make the implementation of a total smoking ban both

successful and manageable for all inpatients. There has been no published study to date that specifically examines and compares the views and experiences of inpatients admitted to an acute psychiatry unit, both before and after the implementation of a total smoking ban. However, there are some related investigations among inpatients of psychiatric services with total smoking bans (Hehir *et al.* 2012; Ratschen *et al.* 2010; Resnick & Bosworth 1989; Shmueli *et al.* 2008; Smith *et al.* 2013).

Two recent studies have examined inpatient attitudes following the implementation of a total smoking ban in long-stay psychiatric facilities (Hehir et al. 2012; Smith et al. 2013). In the forensic mental health hospital, the majority of inpatients (80%) were smokers when admitted to the unit, with 42% wanting to quit (Hehir et al. 2012). Some inpatients were angry at being forced to stop smoking, while others described feeling glad that they could not smoke, and many (75%) reported feeling healthier since being admitted to the smoke-free environment (Hehir et al. 2012). In the second study of 100 inpatients admitted to a long-stay psychiatric facility with a total smoking ban, 44% reported being happy with the ban, while 32% were angry (Smith et al. 2013). Approval rates varied according to smoking status, with 70% of non-smokers and 24% of smokers being happy with the smoking ban. While 50% of smokers reported being angry about the ban, none of the non-smokers were. On admission, 60% of inpatients were smokers, and while 67% of these continued to smoke, they significantly decreased their cigarette consumption from approximately 31 cigarettes per day before admission to 12 cigarettes per day after. Of those not smoking, 53% reported not using any smoking cessation treatment, while 29% used nicotine replacement therapy (NRT). Overall, 49% reported that their health had improved as a consequence of the smoking ban.

Another two studies examined the views of smokers after being admitted to acute inpatient psychiatry units with total smoking bans (Ratschen *et al.* 2010; Shmueli *et al.* 2008). An in-depth analysis of 15 inpatient smokers revealed that the majority generally approved of the ban, providing they could go outside to smoke (Ratschen *et al.* 2010). Patients generally changed their smoking behaviour on admission, with 47% reporting they were smoking less than when at home, but none used NRT. Smoking was generally perceived as a way to deal with stress and boredom, and as a habit these inpatients enjoyed. Shmueli *et al.* (2008) reported that hospitalization in a smoke-free acute psychiatry ward is associated with increases in patients' expectancies about quitting and staying smoke free. While they reported that 70% of these inpatients used NRT, this study did not specifically explore the patients' views and experiences of the smoking ban per se.

Finally, there was only one study, conducted 25 years ago, that examined inpatient views both before and after the implementation of a total smoking ban in a psychiatric crisis unit (Resnick & Bosworth 1989). This study found that inpatients views towards the ban significantly improved following implementation, with 7% favouring it before, and 22% afterwards. This study did not explore the inpatients reasons for their views, or provide a description of how they actually coped with such a change.

The current study aims to explore the views and experiences of inpatients admitted to an acute psychiatry unit before and after the implementation of a totally smoke-free policy. This includes providing the first in-depth analysis of the reasons why inpatients agree or disagree with the smoking ban, how they cope without smoking on the ward, and how the smoke-free policy influences their own smoking behaviour and the psychiatry ward in general.

#### MATERIALS AND METHODS

#### Setting and sample

This study was conducted in the acute inpatient psychiatry unit of The Alfred, a public general hospital servicing the inner southeast area of Melbourne, Australia. The Alfred Psychiatry Inpatient Unit has 58 beds divided across two floors by catchment area, including 44 lowdependency beds (LDU), 10 beds in the highdependency units, and four beds in the Alfred Psychiatry Intensive Care Statewide Service (Lee et al. 2013). A multidisciplinary team offers care to the inpatients, including psychiatrists, psychiatric registrars, medical officers, nurses, psychologists, occupational therapists, social workers, and music and art therapists. Patients admitted to this unit are generally diagnosed with schizophrenia or other psychoses, bipolar disorder, depression, alcohol and/or other substance use disorders, and borderline personality disorder.

The Alfred was the first major metropolitan health service in Victoria to implement a totally smoke-free policy. This policy was implemented in The Alfred Psychiatry Inpatient Unit in June 2008. Staff, patients, and visitors are not able to smoke in any areas of the ward, including the outdoor courtyards and outside the front of the building. If patients have leave, they can walk to the perimeter of the building (approximately 200 m) to smoke. A total of 98 inpatients from the LDU of The Alfred Psychiatry Inpatient Unit participated in this study (46 before and 52 following the policy implementation).

#### Procedure

In the 6 weeks before the implementation of the totally smoke-free policy, inpatients of the acute psychiatry unit were asked by the ward occupational therapy staff to complete a brief (1-page), anonymous questionnaire regarding the planned smoking ban.

Subsequently, 7–8 months after the implementation of the smoking ban, a different group of inpatients was approached by a member of the research team to complete the second questionnaire. Inpatients were provided with a cover letter inviting them to complete the brief (2-page), anonymous questionnaire. Once participants read the information letter, consent was implied by completion of the questionnaire. The relevant hospital and university ethics committees approved the study.

#### Materials

## Questionnaire completed before implementing the totally smoke-free policy

A seven-item questionnaire was developed by the ward occupational therapist as an initial quality assurance activity, whereby responses would assist both staff and inpatients to prepare for the smoke-free transition. Participants were asked what they thought about the totally smoke-free policy using 'very positive', 'positive', 'unsure', 'negative', and 'very negative.' Participants were asked to suggest alternatives to smoking when admitted to the psychiatry ward, and about their own smoking behaviour. Participants were asked if they 'agree' or 'disagree' that The Alfred Hospital should be completely smoke free, and to provide reasons for their response.

# Questionnaire completed after implementing the totally smoke-free policy

The questionnaire was devised by the research team, and consisted of 22 structured and open-ended items, including patient demographics, smoking variables, and attitudes towards the smoke-free policy. Participants were asked to describe how the smoking ban has changed the psychiatry ward, what the most difficult things are about not smoking, what the positives are about not smoking, how they have been coping with not smoking, and about their future plans for quitting or reducing smoking.

#### Statistical analysis

Frequency and descriptive statistics were calculated for quantitative data. Inpatient views towards the totally smoke-free policy were compared according to smoking

• • •		
What do you think about the decision to become totally smoke free?	Before totally smoke-free policy $(n = 46)$	After totally smoke-free policy $(n = 52)$
Very positive	19.6%	34.6%
Positive	10.9%	15.4%
Unsure	15.2%	13.5%
Negative	17.4%	9.6%
Very negative	37.0%	26.9%

**TABLE 1:** Inpatient views about implementing the totally smoke-free policy in the acute psychiatry unit before and after it was introduced

status using the  $\chi^2$ -test of independence. Qualitative data derived were analysed using thematic analysis following Braun and Clarke (2006). Responses were systematically analysed by SF and AH, and initial themes were generated. SF later conducted an in-depth review of the data, and further defined and named the themes. Responses were then independently reviewed and coded according to themes by SF and CG. A measure of inter-rater reliability between the two coders was calculated using Cohen's kappa, with levels from 0.61 to 0.80 indicating substantial agreement between raters, and 0.81–0.99 indicating almost perfect agreement (Viera & Garrett 2005). Inter-rater reliability levels achieved through the thematic analysis coding in this study were high, with kappa levels ranging from 0.74 to 0.95.

#### RESULTS

# Questionnaire responses before the totally smoke-free policy was implemented

#### Smoking variables

A total of 46 inpatients completed the questionnaire before the totally smoke-free policy was implemented. The incidence of current smoking in this group was 69.6% (n = 32), with respondents reporting they smoked an average of 18.1 cigarettes per day (standard deviation (SD) = 10.7, range = 2–40). Over two-thirds (67.7%, n = 21) reported smoking more when they are admitted to the acute inpatient psychiatry unit. On average, this group of psychiatric inpatients reported smoking 8.5 cigarettes per day (SD = 9.1, range = 2–40), in addition to their usual daily amount. The remaining inpatients (32.3%, n = 10) reported smoking the same amount on the ward as they do at home, while no patients reported smoking fewer cigarettes when they are admitted to the acute inpatient psychiatry unit.

## Inpatient views before implementing the totally smoke-free policy

Inpatients' views about the acute inpatient psychiatry unit becoming totally smoke free are presented in Table 1.



**FIG. 1:** Inpatient views of the totally smoke-free policy before implementation in acute psychiatry according to smoking status. X axis, Terms used to describe inpatients' views about implementing the totally smoke-free policy; Y axis, Inpatients who endorsed each view (%); ■, smokers; ⊠, non-smokers.

Before the smoking ban, over half (54.4%) reported that implementing the totally smoke-free policy would be 'negative' or 'very negative'. A total of 30.5% reported that the totally smoke-free policy would be 'positive' or 'very positive', and 15.2% were unsure. When inpatient views were compared according to smoking status, a significant difference was revealed ( $\chi^2(4) = 23.7, P < 0.001$ ) (Fig. 1). Half of the smokers reported that implementing the smoking ban would be 'very negative', while half of the non-smokers reported that it would be 'very positive'. A total of 18.8% of smokers reported that the totally smokefree policy would be 'positive' or 'very positive'. A greater proportion of non-smokers than smokers were 'unsure' about implementing the smoking ban (35.7% vs 6.3%).

For the sample overall, 39.1% said that they 'agreed' that the Alfred Hospital should be completely smoke free, while 58.7% 'disagreed', and 2.2% were 'unsure'. The four most commonly stated reasons for agreeing with

implementing a smoking ban, in order from most to least prevalent were: (i) hospitals should promote health; (ii) smoking is bad for your health; (iii) to prevent passive smoking for patients, staff, and visitors; and (iv) to improve the physical environment and safety of the ward. The four most commonly stated reasons for disagreeing with implementing a smoking ban, in order from most to least prevalent were: (i) smoking has a calming/relaxing effect (including smoking as a coping mechanism for stress management); (ii) smoking is addictive, and patients will experience nicotine withdrawal symptoms; (iii) smoking is a free choice (including that the ban would violate a patient's freedom or right to choose to smoke); and (iv) the smoking ban will increase patient and staff agitation.

## Alternatives to smoking when admitted to a totally smoke-free psychiatry unit, as suggested by inpatients before the smoking ban was implemented

Respondents provided suggestions regarding what smokers could do when being admitted to a ward with a smoking ban. The main suggestions, in order from most to least frequent, are described. Inpatients of the acute psychiatry unit suggested that smokers should use NRT, rather than smoke. Smoking when on leave from the psychiatric ward was the next frequent suggestion, and this included both escorted and unescorted leave. Quite a number said that smoking should be allowed to continue (i.e. there should be no smoking ban), with several saving that there are no alternatives to smoking. Keeping occupied and busy was the next most common suggestion, and this included creative activities (e.g. art, music, singing), physical activities (e.g. exercise, yoga), and participating in ward groups and social activities (e.g. speaking to other patients and staff). Finally, respondents suggested that there should be a designated smoking area on the ward (e.g. a smoking room or courtyard).

# Questionnaire responses after the totally smoke-free policy was implemented

#### Demographic and smoking variables

A total of 52 inpatients completed the questionnaire after the totally smoke-free policy was implemented. The demographic and smoking characteristics of participants are presented in Table 2. Generally, participants had been admitted to the inpatient psychiatric unit for several weeks, with the majority being smokers before admission to hospital. Following admission, 5.8% of inpatients who had smoked before admission to hospital reported that they were no longer smokers. Participants had a lengthy

**TABLE 2:** Demographic and smoking characteristics of the sample

 completing the questionnaire after the totally smoke-free policy was

 implemented

	Total $n = 52$
Sex (%)	
Male	57.7
Female	42.3
Age (mean, SD)	39.1 (10.8)
Self-reported length ward stay (days; mean, SD)	23.7(37.1)
Smoking variables	
Smoking prior to admission (n, %)	30(57.7)
Current smoker $(n, \%)$	27(51.9)
Years smoking (mean, SD)	19.5 (9.4)
Cigarettes/day prior to hospital admission (mean, SD)	24.9(18.1)
Cigarettes/day on the ward (mean, SD)	8.3(10.3)
Smoking cessation information	
Ever tried to quit $(n, \%)$	22† (78.6)
No. quit attempts (mean, SD)	4.3(7.1)

 $\dagger$ Total n = 28 for this question. SD, standard deviation.

smoking history, and prior to admission, were on average classified as heavy smokers (smoking >20 cigarettes/day). However, this amount decreased dramatically after admission to a totally smoke-free psychiatric unit, with participants now being generally classified as light smokers (smoking <10 cigarettes/day). Most of the current smokers had tried to quit in the past, with the majority trying several times. The most common previously used quit method reported by 12 participants was 'going cold turkey', followed by nicotine patches (5), inhaler (3), and lozenges (2). Other reported methods included reduction, hypnotherapy, acupuncture, and willpower.

Three-quarters of respondents (75.5%) said they had been exposed to less passive smoking since the totally smoke-free policy was implemented. A total of 75% reported they were still smoking following the implementation of the ban. However, this question did not differentiate between smoking while on leave or direct violation of the ward smoking ban. Among current smokers, 67.9% reported using NRT during their psychiatric admission. Specifically, 15.8% used the nicotine patch, 36.8% used nicotine inhalers, 5.3% used nicotine lozenges, and 42.1% used combination NRT (patch + inhaler). Of those using NRT, 21.1% said it was 'very helpful', 31.6% said 'helpful', and 47.4% reported that NRT use was 'unhelpful'. Of the current smokers, 32.1% reported no plans to quit smoking at all, while 50% indicated that they would like to quit at some point (14.3% said they wanted to quit immediately), and 17.8% reported plans to reduce smoking, rather than quitting (7.1% said they wanted to cut back immediately).



**FIG. 2:** Inpatient views of the totally smoke-free policy after implementation in acute psychiatry according to smoking status. X axis, Terms used to describe inpatients' views about implementing the totally smoke-free policy; Y axis, Inpatients who endorsed each view (%); ■, smokers; , non-smokers.

## Inpatient views following the implementation of the totally smoke-free policy

Following the implementation of the totally smoke-free policy, 50% of inpatients reported that that smoking ban was 'positive' or 'very positive' (Table 1). A total of 36.5% reported that the smoking ban was 'negative' or 'very negative', and 13.5% were 'unsure'. When inpatient views were compared according to smoking status, a significant difference was revealed ( $\chi^2(4) = 21.8, P < 0.001$ ) (Fig. 2). Almost half of the smokers reported that the implementation of the smoking ban has been 'very negative', while most of the non-smokers reported it has been 'very positive'. A total of 29.6% of smokers reported that the totally smoke-free policy has been 'positive' or 'very positive'. A greater proportion of non-smokers than smokers were 'unsure' about the smoking ban (20% vs 7.4%).

#### Impact of the totally smoke-free policy

Inpatients were asked to describe how the smoking ban had changed the psychiatry ward, and the most frequent response was that inpatients were experiencing more negative emotions since the implementation of the policy, including feeling miserable, angry, frustrated, irritable, and anxious. Next were a range of responses fitting the 'other' category, which included inpatients being occupied in different ways now, rather than smoking, and they were saving money by not smoking. Equally frequent responses were that inpatients were unsure how the ward had changed; and secondly, that there was actually no difference as people were still smoking in the courtyard.

Most difficult things about not	Positive things about not being
being able to smoke on the	able to smoke on the psychiatry
psychiatry ward	ward
1. Inpatients are experiencing	1. Physical environment of the
increased negative emotions	ward has improved (i.e.
(e.g. frustration, anxiety,	cleaner, better air quality,
restlessness, anger)	fresh smell, fewer butts)
<ol> <li>Smoking has been removed</li></ol>	2. Physical and mental health
as a coping strategy (for	of the patients, staff, and
stress, tension, to calm down)	visitors has improved
<ol> <li>Inpatients are experiencing cravings and nicotine withdrawal</li> </ol>	3. There are no positives of the smoking ban to report
4. You cannot choose when you want to smoke	4. Passive smoking is reduced
5. There are no difficulties associated with the smoking ban	5. Ban promotes smoking reduction or abstinence

Respondents acknowledged that the physical environment of the ward had improved with descriptions of fresher air to breathe, people no longer smelling of cigarette smoke, and a cleaner ward environment without cigarette butts littering the courtyard.

Responses describing the most difficult, as well as the positive things about not being able to smoke on the psychiatry ward were grouped. The five most common themes in order, from most to least frequent, are presented in Table 3.

### Coping without smoking

Current smokers were asked to report what they had been doing to cope with not smoking on the ward. The five most common responses in order from most to least frequent were: (i) eating/drinking (including tea/coffee); (ii) watching TV or DVDs; (iii) listening to or playing music; (iv) exercise; and (v) using NRT.

### DISCUSSION

This paper provides the first in-depth analysis of inpatient views and experiences before and after the implementation of a smoking ban in the acute psychiatry hospital setting, and offers important insights that have direct clinical relevance. Before the implementation of the totally smoke-free policy, the majority of inpatients in the current study were heavy smokers, and smoked even more when admitted to the psychiatry ward. Over half had negative views about the implementation of the smoking ban, with smokers having the most negative perspectives. The main suggestion given by inpatients as an alternative to smoking, when admitted to a totally smoke-free psychiatry unit, was to use NRT. When questioned after the implementation of the smoking ban, the majority of inpatients were heavy smokers on admission, but were then classified as light smokers once admitted to a totally smoke-free psychiatry ward. Approximately twothirds of smokers used NRT during their admission, but almost half said it was unhelpful. Over half had positive views about the implementation of the smoking ban, while smokers still had negative perspectives. Inpatients reported the most difficult thing about not being able to smoke on the psychiatry ward was that patients were experiencing increased negative emotions, and reported that the most positive aspect was that the smoking ban had improved the physical environment of the ward. Smokers reported that the main way they were coping without being able to smoke on the ward was by eating and drinking.

Consistent with previous research among the psychiatric inpatient population, the smoking rates of the participants in the current study were high (69.6% and 57.7%) (Hehir et al. 2012; Lawrence et al. 2011; Smith et al. 2013). Further, before the implementation of the smoking ban, many smokers reported increasing their daily cigarette intake following admission to the psychiatric ward. This changed for inpatients admitted to a psychiatric unit with a totally smoke-free policy, who on average reported smoking one-third of the amount they usually consumed prior to admission, with three inpatients guitting altogether. If smokers admitted to the acute inpatient psychiatry unit with a total smoking ban are dramatically reducing their daily cigarette intake, than they will experience significant nicotine withdrawal symptoms. This matter needs to be promptly addressed by the treating team, including an assessment of the level of nicotine dependence using a standardized tool, such as the Fagerstrom Test of Nicotine Dependence (FTND) (Fagerstrom et al. 1996), encouraging and facilitating the use of suitable pharmacotherapy, such as NRT, as well as providing inpatients with assistance with behavioural strategies for managing nicotine withdrawal and cravings. Behavioural interventions specifically targeting their high risk situations for smoking are warranted; for example, first thing in the morning, when drinking coffee, socializing, and boredom (Filia et al. 2012). Further, smokers admitted to the acute psychiatry inpatient unit with a total smoking ban will particularly require assistance to identify and implement alternative coping strategies to manage stress in their lives.

Before the implementation of the totally smoke-free policy, the main alternative to smoking suggested by inpatients was to use NRT. However, following the implementation of the policy, inpatients who smoked ranked NRT use as their fifth coping strategy for not smoking on the psychiatry ward. While specific reasons for this were not explored, this discrepancy could be attributed to a number of factors. Following the implementation of the totally smoke-free policy, 68% of inpatients in the current study reported using NRT during their admission, yet the majority described this as unhelpful. Some of our qualitative work in the same setting has found that smokers admitted to a totally smoke-free psychiatry unit were not being routinely offered or instructed correctly in the use of NRT, leading to subtherapeutic dosing, poor efficacy, and subsequently negative attitudes towards NRT (Filia et al. pers. comm., 2014). Further, some inpatients had no plans of quitting, and therefore, outrightly refused to use NRT. The immediate and consistent use of NRT throughout the duration of the psychiatric admission must be promoted to all smokers, especially combination NRT (e.g. patch + inhaler) to combat the high levels of nicotine dependence and prevent the significant nicotine withdrawal typically experienced by this population. In some cases, this might require the use of more than one nicotine patch at a time, in addition to other forms of NRT. The service that this research was undertaken in has developed clinical guidelines for the management of nicotine dependence in the inpatient setting. The guidelines stipulate that every smoker has a FTND completed within 24 hours of admission. Using this FTND score, an algorithm developed by pharmacy staff is followed, recommending the type and strength of NRT to offer the patient. The FTND can be repeated as required during admission, and NRT needs to be tailored accordingly. Uptake of NRT might further be promoted by staff providing accurate information about NRT that might help to disperse some of the negative views that inpatients have about it.

Many smokers in the current study had attempted to quit smoking in the past and were interested in quitting in the future, a finding consistent with other research demonstrating that smokers with mental illness think about, and are motivated to quit smoking (Siru *et al.* 2009). Admission to a psychiatric unit with a smoke-free policy can provide a structured and supportive environment to facilitate inpatients to reduce their smoking, and potentially promote future quit attempts and successful abstinence. For some inpatients, this was their first experience of using NRT, and possibly the longest period they had ever been without a cigarette, an opportunity they would have missed if they were not admitted to a psychiatry ward with a smoking ban. Anecdotally, inpatients reported that the period of smoking abstinence they experienced being admitted to the totally smoke-free psychiatric ward was like a trial quit attempt, which gave them the confidence, knowledge, and skills to use in the future when they were ready to quit altogether.

There was an interesting shift in the views of inpatients towards the totally smoke-free policy before and after implementation, with over 50% saying it was negative beforehand, to over 50% saving it was positive after, a finding consistent with the earlier study by Resnick and Bosworth (1989). However, when we consider the views of smokers alone as in Figures 1 and 2, there is little change in their views, with the majority thinking negatively about the smoking ban before and after its implementation (i.e. 50% of smokers said the ban was very negative before, while 48.1% of smokers said it was negative after). It is inevitable that there will be patients who will not agree with a smoking ban in the psychiatry ward, so it is important to acknowledge and discuss this view with inpatients, as well as preparing staff to work in an environment with this view. The aim of the totally smokefree policy is not to enforce patients to quit smoking altogether, but rather it is about temporary smoking abstinence while being present on the hospital grounds. Promoting this view to smokers could possibly shift the way they conceptualize the smoking ban and hopefully weaken some of the resistance that might be expressed, enabling more smokers to take up the offer of support and use NRT, at least until they have leave from the ward when they might choose to return to smoking.

The main reasons for disagreeing with the ban given by inpatients in the current study were that smoking was their main coping strategy for stress, and they were concerned about experiencing nicotine withdrawal symptoms. These views are further reflected in what inpatients described as the most difficult things about the smoking ban. Further, before the totally smoke-free policy was implemented, inpatients suggested that the main alternative to smoking was to use NRT. These patients are able to recognize and express their needs, and staff should respond accordingly. Patients seem to be saving that they need urgent assistance to adequately treat nicotine withdrawal symptoms and to find alternative methods for coping with stress while they are inpatients on the psychiatry ward and cannot smoke. Further, it is concerning that the participants in the current study report that inpatients are experiencing more negative emotions (e.g. frustration, anxiety, restlessness) following implementation of the smoking ban. These negative emotions can also be classified as nicotine withdrawal symptoms. Research in the psychiatric setting found that staff often failed to recognize the symptoms of nicotine withdrawal in patients, and misattributed these as signs of impending violence or illness relapse (Lawn & Pols 2003). If nicotine withdrawal symptoms are proactively assessed and treated, and inpatients are provided with the skills and resources to develop or utilize alternative coping strategies for stress management other than smoking, then perhaps inpatient views about a totally smoke-free policy in the acute psychiatry unit would shift more positively.

The most common strategy reported by smokers to cope with not smoking on the ward was eating and drinking, including drinks such as tea and coffee. While it is unclear in the current study exactly what the inpatients are eating, it is important that totally smoke-free psychiatry units provide healthy snack options that are accessible to patients, such as fresh fruit and vegetables and reducedfat yoghurt. Inpatients might substitute smoking with cups of tea or coffee on the psychiatric unit, thereby significantly increasing their caffeine consumption. It is important for both staff and patients to understand the relationship between caffeine and smoking. Toxic products from cigarettes, such as hydrocarbons and tars, are released into the body during smoking, which increase the metabolism of some psychiatric medications, alcohol, and caffeine in the liver by inducing the cytochrome P450 (CYP) enzyme system, primarily CYP1A2 (Zevin & Benowitz 1999). Nicotine alone does not induce these liver enzymes. As smoking reduces, caffeine levels will increase, and even more so if the person consumes more caffeine via tea, coffee, cola, and energy drinks. The increasing levels of caffeine will result in feelings of restlessness, irritability, anxiety, and insomnia, all of which mimic the symptoms of nicotine withdrawal. This will be both unpleasant and confusing for patients and staff, and is generally perceived as a need for a cigarette, rather than recognizing that it is the effects of caffeine. Inpatients should be encouraged to reduce their caffeine intake and have access to alternative drinks, such as water, lowkilojoule cordial, herbal tea, or decaffeinated coffee. Further, participating in ward activities/groups and having access to input from occupational therapists on the ward might combat increased eating and drinking, and offer inpatients alternative coping mechanisms to smoking.

A limitation of the current study relates to the ability to generalize these findings to all inpatients of psychiatry units with a totally smoke-free policy. The current results represent the specific views and experiences of inpatients admitted to our service at a particular point in time. Since this study was conducted, The Alfred has continued to review and refine practice, and currently has a very comprehensive system in place for the assessment and management of nicotine dependence among all inpatients admitted to the hospital. It would be interesting to see how such organizational practice changes influence inpatients' views. Further, the current study cannot account for the potential impact that staff attitudes and experiences have on inpatients views and behaviour. Ideally, it would be useful to assess inpatients' views about the totally smoke-free policy regularly (e.g. annually) in order to inform best practice.

#### CONCLUSION

The current study provides important insights into the thoughts and experiences of inpatients admitted to the acute psychiatry unit before and after the implementation of a totally smoke-free policy. While not all patients agreed with the implementation of a total smoking ban, they were able to acknowledge that they were smoking less, the air and the ward was much cleaner, and many were interested in quitting smoking in the future. Patients described an increase in negative emotions following the implementation of the totally smoke-free policy, and this can most likely be attributed to nicotine withdrawal.

Two main research publications provide a number of evidence based suggestions to consider for the effective introduction of smoking bans in psychiatry from a staff, organizational, and patient management perspective (Lawn & Campion 2010; Lawn & Pols 2005). The results of the current study offer further suggestions to support inpatients admitted to psychiatry units with a smoking ban, directly based on the patient experience:

- Acknowledge the views of inpatients regarding the totally smoke-free policy, and provide opportunities to share and discuss these views
- Assess and treat nicotine withdrawal symptoms proactively, consistently, and regularly throughout the admission
- Offer inpatients support and resources to develop alternative strategies for coping with stress that are practical for the ward setting
- Maintain an active group/ward activities programme to keep inpatients engaged, and provide opportunities for patients to participate in activities that relate to their interests and volition
- Provide a range of alternative activities (e.g. music, art, exercise) on the ward that can serve as distractions for coping with cravings for cigarettes
- Offer healthy snack options that inpatients can access as required, including decaffeinated beverages

Addressing smoking in the acute inpatient psychiatry setting is part of a continuum of care that needs to be routinely offered to all consumers of mental health services in order to reduce the high rates of smoking and associated morbidity and mortality in this population. The results of the present study contribute to our knowledge about the inpatient perspective and experience of a totally smoke-free policy, and offer some useful suggestions for clinical practice.

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## An inpatient group to support the implementation of a Totally Smokefree Policy in the acute psychiatry setting: The role of psychologists

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### ABSTRACT

**Objective:** This paper describes the design, implementation, experience and evaluation of an inpatient group to support the introduction of a total smoking ban in the acute psychiatry setting.

**Method:** The Smokefree Support Group was designed and facilitated by psychology staff within the psychiatry department. The group was held weekly on the inpatient psychiatry unit. At the conclusion of each group, staff recorded information including the general content covered; patient interactions; and main themes that emerged. Qualitative data was analysed using thematic analysis. A sample of inpatients completed a questionnaire evaluating the group.

**Results:** Qualitative data was analysed from 22 groups with a total of 71 participants (mean number of group attendees=3.2; range=2-7). The main themes discussed during the group were nicotine replacement therapy; smoking as the main coping strategy for stress; inpatient views about the Totally Smokefree Policy; smoking as an unwanted addiction; boredom and experiencing nicotine withdrawal symptoms. Positive aspects noted about the Smokefree Support Group included the importance of peer support; the chance for inpatients to ventilate about the policy; patients receiving accurate information about smoking and staff facilitating access to nicotine replacement therapy. Inpatients rated the Smokefree Support Group as interesting and useful, and most said they would attend another session.

**Conclusions:** The Smokefree Support Group was an important initiative of psychology staff to support inpatients following the introduction of a total smoking ban in the acute psychiatry

unit. These results have direct clinical implications and can assist other services in their transition to becoming Totally Smokefree.

**Keywords:** inpatient psychiatry, patient group, psychologists, smoking, smoking ban, Totally Smokefree Policy

## **KEY POINTS**

## What is already known about this topic

- 1. Healthcare services around Australia are implementing Smokefree Policies and this poses certain challenges for the acute inpatient psychiatry setting
- 2. Patients admitted to inpatient psychiatry wards have very high rates of smoking and nicotine dependence
- Smoking is much a part of the psychiatry ward with staff using smoking in patient rapport and management, and patients relying on smoking as their main way to cope with stress

## What this paper adds

- 1. A structure to facilitate a group that supports inpatients to cope when they are admitted to a psychiatry ward with a total smoking ban
- 2. A rich array of information about the experience of smokers admitted to a psychiatry ward with a total smoking ban that can be used to inform ward practices around such a policy
- Evidence of the important and valuable role that psychologists can play in supporting the psychiatry ward and inpatients following the introduction of a Totally Smokefree Policy

## **Introduction:**

Over recent years a number of strategies have been implemented specifically aimed at lowering the smoking prevalence in Australia, and reducing the health impacts associated with smoking and exposure to environmental tobacco smoke. One such example is the implementation of smokefree policies in healthcare services around Australia. The introduction of a policy requiring staff, patients and visitors not to smoke on site can be particularly challenging for the acute psychiatry hospital setting. This is mainly because people experiencing mental illness have very high rates of smoking and nicotine dependence (Cooper et al., 2012) and that smoking has been an accepted part of the culture in psychiatry for many years (Cormac & McNally, 2008).

Recent smoking rates in the general population in Australia are 12.8% (AIHW, 2014), while rates among people experiencing psychosis living in the community in Australia are 66.6% (Cooper et al., 2012) and 69.6% among inpatients admitted to an acute psychiatry unit (Filia et al., 2015). Traditionally, smoking has played a significant role in the day-to-day functioning of the psychiatry ward. In the inpatient psychiatry setting, smoking has been described as an important tool to facilitate therapeutic relationships between staff and inpatients and as a token economy used by staff to reward or punish behaviour of inpatients (Lawn & Condon, 2006; Olivier, Lubman, & Fraser, 2007; Ratschen, Britton, & McNeill, 2011).

Research regarding the introduction of smokefree policies in the inpatient psychiatry setting has largely focused on the implementation of such a change from a staff, organisational and patient management perspective (Cormac & McNally, 2008; Lawn & Campion, 2010; 2013; Lawn & Pols, 2005; McNally et al., 2006). There is minimal research examining the

perspectives and experiences of patients admitted to a hospital that has implemented a smokefree policy (Shopik, Schultz, Nykiforuk, Finegan, & Kvern, 2012) and even less specifically in the setting of an acute inpatient psychiatry unit with a total smoking ban.

The Alfred was the first major metropolitan hospital in Victoria to implement a complete smoking ban, and unlike other healthcare services in the state, an exemption for the inpatient psychiatry unit was not made. The Totally Smokefree Policy was implemented in The Alfred Psychiatry Inpatient Unit in June 2008, stipulating that staff, patients and visitors could not smoke in any areas of the wards, including the outdoor courtyards, balconies and outside the front of the building. At this time, we could not find any published research that investigated the views and experiences of smokers either before or after they were admitted to an acute psychiatry inpatient unit that enforced a total smoking ban. Similarly, while there were several group based programs designed to assist people experiencing mental illness to quit smoking in the community (e.g. SANE Australia, 2004; Williams et al., 2005), to the best of our knowledge there was no group program specifically devised for smokers admitted to an acute psychiatry ward where they are required to abstain completely from smoking regardless of their desire to quit. Therefore, as part of a multi-tiered approach to the implementation of The Totally Smokefree Policy in the acute psychiatry setting, the psychology staff of Alfred Psychiatry decided to provide an inpatient group to support patients with this major service change. This paper describes the design, implementation, experience and evaluation of an inpatient group to support the implementation of a total smoking ban in the acute psychiatry setting.

### Method:

#### Setting

The Alfred Psychiatry Inpatient unit is located within The Alfred, a public general hospital servicing the Inner South East Area of Melbourne, Australia. The Alfred Psychiatry Inpatient Unit has 58 beds divided across two wards according to geographical catchment area. Patients admitted to this service are generally diagnosed with schizophrenia or other psychotic disorders, bipolar disorder, depression, alcohol and/or other substance use disorders; and borderline personality disorder. The smoking prevalence among patients admitted to this acute psychiatry setting is high, with one study in this setting identifying smoking rates of 69.6% and 57.7% at two separate timepoints (Filia et al., 2015). As previously mentioned, a total smoking ban was introduced in The Alfred Psychiatry Inpatient Unit in June 2008.

#### Procedure

#### Group format

The Smokefree Support Group was designed as an open group so that inpatients could choose to attend anytime during their admission. The group was held weekly for about 45 minutes to 1 hour from June 2008 – December 2009. While the group was predominantly designed for smokers, past smokers and non-smokers were welcome to attend. The Smokefree Support Group was integrated into the overall ward group program and the time, day and location of the group was listed on the weekly group timetable on a white board in the communal area of each psychiatry ward. The Smokefree Support Group was further promoted to inpatients in the weekly ward meeting and by flyers posted around the ward. Staff of the acute inpatient psychiatry unit were informed about the Smokefree Support Group in usual team meetings

and through the use of flyers in staff areas. Staff were asked to encourage suitable patients to attend the group.

## Group facilitation

The Smokefree Support Group was designed and facilitated by members of the psychology staff of Alfred Psychiatry who had some expertise in the area of smoking cessation for people with mental illness. It was recognised that the discipline of psychology has a specific and unique skill set to offer to the running and evaluation of such a group; particularly the training and expertise in interventions such as motivational interviewing, cognitive behavioural therapy (CBT), psychosocial treatments, and relaxation training, as well as extensive research skills. The Smokefree Support Group was always led by author SF, generally together with the ward psychologist (CS). At that time, SF was registered as a provisional psychologist. There were occasions when the group was co-facilitated by the occupational therapists and/or allied health assistants working on the ward, depending on staff availability and the number of group attendees.

### Group content

The aim of the Smokefree Support Group was to:

- Provide patients with an opportunity to talk about the Totally Smokefree Policy
- Enable patients to share their experiences of being an inpatient in a Smokefree ward
- Educate patients about nicotine withdrawal symptoms
- Provide information about nicotine replacement therapy (NRT) and encourage patients to use NRT
- Offer patients a range of strategies they could use on the ward to cope with cravings for cigarettes

• Allow patients to receive group support and encouragement

Based on these aims, a plan for the Smokefree Support Group was devised by SF and CS (see Table 1). This plan was not rigidly adhered to, rather it offered a range of potential topics for discussion and resources to use. This included several patient handouts that were prepared by SF and CS. Some of the handouts were specifically designed for this group, while others were adapted to suit the context and setting of the inpatient unit from a Healthy Lifestyles Treatment Manual developed for smokers experiencing severe mental illness (Baker et al., 2009). A patient-centered approach was taken, with the content of each Smokefree Support Group being guided by participant discussion. The handouts were useful in focusing patient attention and providing resources that they could review and use at a later point.

## Insert Table 1 about here

#### Evaluation of the group

### Staff evaluation of the Smokefree Support Group

A specific Group Record Sheet was devised and completed at the end of each Smokefree Support Group by the group facilitators. The following information was collected: date; who attended (staff and patients); general content covered; summary of patient interactions and general group dynamics; main themes that emerged; and the personal experience of the facilitators running the group. Each Group Record Sheet served as a basis for clinical supervision of SF by authors LK and AB.

Qualitative data derived from the Group Record Sheet were analysed using thematic analysis following Braun and Clarke (2006). Authors SF and CS met after each session and analysed

the group content and generated initial themes (i.e. main group discussion themes; main challenges of running the group; positive aspects of the group). Author SF later conducted an in depth review of the data and further defined and named themes.

### Patient evaluation of the Smokefree Support Group

A sample of group participants completed the Smokefree Support Group Evaluation Client Questionnaire. This questionnaire was devised by the research team and consisted of 11 structured and open-ended items. Participants were asked why they attended the Smokefree Support Group; how interesting and useful they found the group; what was most/least helpful about the group; whether they would attend the group again; and about their plans for quitting or reducing smoking.

This research was approved by the relevant hospital and university ethics committees.

### **Results:**

### Staff evaluation of the Smokefree Support Group

The Smokefree Support Group Record Sheet was specifically analysed for 22 groups with a total of 71 participants (mean number of group attendees=3.2; range=2-7). While there were many more sessions held, this was the number of groups that were facilitated together by SF and CS and then thematically coded by these authors.

#### Group themes

The main themes discussed by group participants during each Smokefree Support Group were coded and the frequency rated. The most common theme discussed was NRT, which was raised in 17 of the 22 groups (77.3%). The discussions ranged from NRT not being used

frequently; using a sub-therapeutic dose of NRT; poor education/support around NRT use; to NRT use being a positive experience and being very helpful. Smoking as the main coping strategy used for stress management was discussed in 16 groups (72.7%), as were a range of views about the Totally Smokefree Policy (72.7%). Views expressed about the Totally Smokefree Policy included patients being unhappy about it (e.g. it being a negative thing, feeling angry and frustrated about it), while others were happy with the policy (e.g. it is a positive thing and a good opportunity to reduce/quit smoking), and others were confused as they reported that smoking still occurred on the ward. Group participants described smoking as an unwanted addiction in 14 groups (63.6%), and this included comments about wanting to quit, not being able to manage the cost of smoking, as well as the negative physical health consequences of smoking. Boredom was raised in 11 groups (50%), in terms of smoking to relieve boredom, as well as it being difficult not to smoke due to boredom on the ward. Group participants discussed experiencing nicotine withdrawal symptoms in 9 of the groups (40.9%).

## Main challenges

There were three main challenges experienced by staff facilitating the Smokefree Support Group. The first challenge related to the acute disturbance experienced by some patients attending the group. This included patients experiencing elevated mood (e.g. increased rate and volume of speech); thought disorder (e.g. going off the topic of discussion); being restless, agitated and irritable; and decreased concentration/attention span. The second main challenge experienced by the group facilitators was about being able to engage patients with negative and/or depressive symptoms into the group discussion. The final challenge related to the actual timing of the Smokefree Support Group, which coincided with the ward "Walking Group." Some patients with suitable leave entitlements would either choose not to

attend the Smokefree Support Group, or would leave early, so that they could go out on the Walking Group, which at that time was an opportunity to smoke off the hospital site.

#### *Positive aspects*

Group facilitators noted a number of positive aspects related to the running of the Smokefree Support Group. Not only did the group offer patients support from staff, but it enabled peer support, with patients praising and encouraging each other in terms of their change in smoking behaviour. It was noted that 12 patients (16.9%) were totally abstinent from smoking since their admission to hospital, and in one group the participants applauded the patients that were not smoking. This peer support continued beyond the group. The Smokefree Support Group gave patients the opportunity to ventilate about the Totally Smokefree Policy and often group facilitators noted that initial resistance and frustration diminished as participants were provided with knowledge and a range of skills to assist them to cope with cravings for cigarettes. Patients attending the group were often provided with information about smoking that was new to them, and the group facilitators commonly assisted patients to access NRT at the end of each Smokefree Support Group.

### Patient evaluation of the Smokefree Support Group

A total of 13 participants completed the Smokefree Support Group Evaluation Client Questionnaire (i.e. 18.3% of attendees). The mean age of respondents was 36.9 years (SD=6.0; range=29-51) and on average they had been admitted to the psychiatry ward for 3.1 weeks (SD=2.0; range=0.7-8.0). The four main reasons cited for attending the Smokefree Support Group in order were 1) I wanted to talk about the smoking ban on the ward; 2) I was interested in learning ways to cope with not being able to smoke on the ward; 3) I want to quit smoking and 4) I want to cut back the amount that I smoke. Over three quarters of respondents (n=10; 76.9%) reported that the Smokefree Support Group was "completely" or "very" interesting. The same number (n=10; 76.9%) also reported that the group was "completely" or "very" useful. Respondents were further asked what was most helpful about attending the Smokefree Support Group, and the main responses in order of frequency are described. Patients attending the group reported that they found it helpful being able to talk about the smoking ban and discussing strategies to cope with not being able to smoke on the ward. The next most frequent response was that it was useful to attend the group to be able to listen to the experience of other patients. Receiving staff support was the next most helpful thing cited by group attendees. In terms of what group attendees found least helpful about attending the Smokefree Support Group, the responses in order were: the mental state of other patients affected the group; participants experiencing cravings for cigarettes during the group; and the discrepancy between some staff and patient views of the Totally Smokefree Policy. The majority of respondents (n=10; 76.9%) said that they would attend another Smokefree Support Group. When asked about future plans for smoking, over half of respondents (n=7; 53.8%) reported that they would like to quit smoking at some point, with 15.4% (n=2) stating that they would like to cut back the amount they smoke. Only one participant had no intention of quitting smoking in the future.

## **Discussion:**

The development and facilitation of a group to support inpatients following the implementation of a total smoking ban in the acute psychiatry setting was an important and worthwhile initiative of the psychology staff within The Alfred Hospital Department of Psychiatry. The Smokefree Support Group fostered valuable group discussion, self-help and peer support amongst patients, and provided education and information on managing cravings, withdrawal symptoms and ongoing smoking cessation services available in the

community upon discharge. Other services wanting to implement a similar patient support group within their own setting can benefit from the group structure offered in this paper, and take from the insights gained through our experiences.

Psychologists are important members of the treatment team within the inpatient psychiatry setting. In addition to the individual patient work they provide, psychologists can play an integral role in the ward group program, offering unique expertise and perspectives. This was demonstrated in the context of the Smokefree Support Group. The psychology staff within The Alfred Psychiatry department were able to successfully design, facilitate and evaluate this group to support inpatients following the implementation of The Totally Smokefree Policy in the acute psychiatry setting. Specifically, psychology trained staff facilitating the Smokefree Support Group were able to implement their skills in patient engagement, group therapy practices, psychoeducation, symptom assessment and management, motivational interviewing, CBT, and through a range of behavioural interventions which are further described below. For the psychology staff, facilitating the Smokefree Support Group provided them with an opportunity to play a greater role in the ward group program, and a chance to further develop their professional skills in group therapy. Recent research among Australian psychologists has found that despite being ideal providers of smoking cessation interventions, psychologists were generally not asking their patients about smoking status, advising cessation or offering any type of smoking cessation intervention in their practice (Bowman et al., 2013). By facilitating a group supporting inpatients following the introduction of a total smoking ban, psychologists based in the acute psychiatry ward can contribute to increasing the potential of their discipline as a profession in the provision of care surrounding smoking.

The topic of NRT was frequently discussed during the Smokefree Support Groups, with similar themes mentioned to those in our previous work in the same setting (Filia et al., 2015). Initial views about NRT expressed by group participants were generally negative, with inpatients describing intermittent and sub-therapeutic use of NRT, with some outright refusing to use NRT as they stated they had no intention of quitting. The Smokefree Support Group was the ideal opportunity for the group facilitators to appropriately challenge some of these views through the provision of accurate information about NRT, and alternative ways of thinking. For example, one view frequently posed to attendees of the Smokefree Support Group was that they had nothing to lose in trying NRT (it was free and it would relieve their uncomfortable symptoms of nicotine withdrawal), at least while they did not have any leave from the ward and were unable to smoke freely. Group facilitators highlighted the importance of combining NRT use with cognitive and behavioural strategies for managing nicotine withdrawal and cravings.

Many inpatients described smoking as their main coping strategy for stress, a finding consistent with other research (Filia et al., 2015) and reports that people experiencing severe mental illness cite stress reduction as their main reason for smoking (Barr, Procyshyn, Hui, Johnson, & Honer, 2008; Filia et al., 2011; Gurpegui et al., 2007). The removal of this coping strategy for inpatients when they are admitted to the Totally Smokefree psychiatry unit is a significant challenge for patients and staff alike. Smokers admitted to the Totally Smokefree psychiatry ward will require assistance developing and implementing alternative coping strategies for stress management other than smoking, and the Smokefree Support Group provided this opportunity through the facilitation by psychology trained staff. Psychologists are trained in a range of strategies suitable for stress management such as CBT, deep breathing, progressive muscle relaxation, distraction, emotion regulation, positive

imagery and mindfulness techniques. Facilitators of the Smokefree Support Group were able to offer patients information, instruction and support in trying a range of these strategies as alternatives to smoking when they were stressed on the psychiatry ward.

The Smokefree Support Group provided a structured setting for patients to be able to ventilate their views and experiences of being admitted to a Totally Smokefree psychiatry ward, and to receive group support. Patients recognised and appreciated this function of the group. Their views about the smoking ban may have been unheard or dismissed in the context of the everyday functioning of the psychiatry ward. Further, the group facilitated the power of peer support, whereby patients were able to benefit from hearing others' experiences and receive mutual trust, respect and support that continued beyond the structure of the group.

Despite some patients disagreeing with the Totally Smokefree Policy, smoking was considered to be an unwanted addiction by many patients. Group participants expressed concerns over the financial and health implications of smoking, and many were interested in quitting in the future, findings consistent with other research among smokers experiencing severe mental illness (Filia et al., 2011; Filia et al., 2015; Siru, Hulse, & Tait, 2009). The Smokefree Support Group provided patients with a range of valuable information and skills that they could implement in future quit attempts, which is possibly something they may have never gained if they did not attend this group.

Both group facilitators and attendees of the Smokefree Support Group noted difficulties related to the mental state of some patients during group sessions. This challenge is not unique to the Smokefree Support Group, rather it is simply part of the experience of running

groups within the acute inpatient psychiatry setting. It is important to recognise this and implement strategies accordingly. It is worthwhile having an experienced and confident group facilitator who can redirect the discussion respectfully and appropriately, and using handouts as a means of focusing attention may be helpful.

The main limitation of the current study relates to the quantitative aspect of the patient evaluation of the group. Only a small number of participants completed the Smokefree Support Group Evaluation Client Questionnaire (13 of the 71; 18.3%). There were two main reasons for this. Firstly, we decided to start collecting patient evaluations after the Smokefree Support Group had already commenced, and the need to obtain ethics approval meant that this was delayed further. Secondly, we found that many patients were not willing to stay around after the group to complete the questionnaire, as they either had to see their doctor, attend another group, or they wanted to utilise their leave off the ward to have a cigarette. While it would have been ideal that a greater number of patients completed this questionnaire, this does not adversely affect the general message from this study, as the majority of the results discussed in this paper are taken from the staff evaluation of the Smokefree Support Group. These results represent the experience and views of staff and patients at that particular time, from one acute inpatient psychiatry unit. The findings are still likely to be of interest and relevance to other inpatient psychiatry services that also have, or are implementing, a total smoking ban.

The Smokefree Support Group was successfully introduced into the acute psychiatry inpatient unit of The Alfred Hospital and each of the intended group aims were achieved. Further, the group provided a rich array of information about the experience of smokers admitted to the Totally Smokefree psychiatry unit that could be used to inform ward practices

around this policy. The Smokefree Support Group demonstrated the valuable role psychologists can play both in the ward group program and during the implementation of a total smoking ban in acute psychiatry. The current results can help inform clinical practice and assist similar services in the transition to becoming a Totally Smokefree acute psychiatry inpatient unit.

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## TABLES

General topic	Detail	Suggested
		resources
Group welcome	Welcome all group members	Provide healthy
•	All staff to introduce themselves and briefly	snacks; sugar
	explain their role	free lollies; water
		or herbal tea
Breaking the Ice	Ask patients to introduce themselves	
Activity	Ask patients to briefly talk about their	
	smoking, e.g. how many cigarettes they	
	were smoking per day before coming to	
	hospital; or what their future plans are for	
	their smoking; or if they have tried to quit in	
	the past	
Group purpose	Explain that this group is an opportunity to	
	talk about what it means for the ward to be	
	Totally Smokefree, to discuss how patients	
	are experiencing this and to provide	
	information about ways that patients can	
	cope with the situation and the experiences	
	they may be having (e.g. cravings, nicotine	
	withdrawal)	
Open discussion	Ask patients to share their views and	
	experiences of being admitted to a Totally	

**Table 1:** Plan for the Smokefree Support Group in the acute inpatient psychiatry setting

		Smokefree psychiatry unit	
Nicotine withdrawal	٠	Ask patients to describe the experience of	Review and
symptoms		being without a cigarette for several hours	provide handout
	•	Break the experiences down into the	about
		thoughts, feelings, physical sensations or	NICOTINE
		behaviours people might notice when they	WITHDRAWAL
		have not smoked for a while (could use a	
		whiteboard or poster paper and textas to	
		assist with this activity)	
	•	Provide information on nicotine withdrawal	
		symptoms	
Cravings – Facts and	•	Discuss cravings for cigarettes	Review and
coping	•	Provide information on the nature of	provide handout
		cravings, e.g. duration, common triggers	titled: FACTS
	•	Have patients share what they have been	ABOUT
		doing to cope with cravings on the ward	CRAVINGS and
	•	Provide information about a range of	COPING WITH
		behavioural and cognitive strategies that	CRAVINGS
		patients can specifically try within the	
		psychiatry ward to cope with cravings for	
		cigarettes	
	•	If possible, demonstrate or guide patients	
		through some of these strategies during the	
		group (e.g. progressive muscle relaxation;	

		mindfulness exercise)	
	•	Direct patients to other groups that may be	
		relevant on the ward for coping with	
		cravings, e.g. a relaxation group	
Nicotine replacement	٠	Discuss NRT use, including what forms of	Written material
therapy		NRT patients have tried and their	about NRT
		experience of using NRT	products e.g.
	•	Provide information about what NRT	QUIT brochures
		products are available and how to use these	
Smoking and	•	Provide information on the interaction	Review and
medication		between smoking and some psychiatric	provide handout
		medications (e.g. olanzapine and clozapine)	titled:
		including the way that reducing or quitting	SMOKING and
		smoking can alter some medication doses,	MEDICATION
		and increase some side-effects	
	•	Encourage patients to discuss this with their	
		doctor and/or the ward pharmacist	
Beyond the ward	•	Ask patients what they plan to do about	Written material
		their smoking post discharge	from local and/or
	•	Provide relevant information to patients	national smoking
		about resources/services available upon	cessation
		discharge from the ward if they wish to	services such as
		reduce or quit smoking	QUIT
# CHAPTER FIVE: IMPLEMENTING A TOTALLY SMOKEFREE POLICY IN THE ACUTE PSYCHIATRY SETTING: THE INPATIENT EXPERIENCE

# **5.2 OVERVIEW OF RESULTS**

The papers presented in this chapter explored aspects related to the patient experience of a total smoking ban in the acute psychiatry inpatient setting, and together these two studies provide a rich array of information that can be used to prepare, manage and support smokers admitted to the Totally Smokefree psychiatry unit.

There were several consistent findings across the two papers. While smokers had the most negative views about the Totally Smokefree Policy, they were smoking much less once they were admitted, and recognised that smoking was an unwanted addiction, with many expressing an interest in quitting in the future. Patients described an increase in negative emotions following the implementation of the Totally Smokefree Policy, and this can most likely be attributed to nicotine withdrawal, which they were concerned about experiencing. Inpatients required assistance to identify and develop alternative coping strategies other than smoking to manage the stress and boredom they experienced on the psychiatry ward. A range of views and experiences surrounding NRT were discussed by inpatients, highlighting the important role staff can play in providing accurate information about NRT and facilitating patient access to it. Inpatients of a psychiatric unit with a total smoking ban benefit from the opportunity to share their views and experiences of the Totally Smokefree Policy, and to receive peer support. Despite the significant challenges a total smoking ban poses for inpatients of an acute psychiatry unit, patients were able to recognise how the policy had improved the physical environment of the ward, and most were willing to accept assistance to be supported with this major change.

There are a range of important clinical implications arising from the findings in this chapter that can support patients, staff and services during the implementation of a Totally Smokefree Policy in the acute inpatient psychiatry setting. These will be explored in detail in the following Discussion chapter.

# **CHAPTER SIX: DISCUSSION**

The broad aim of this thesis was to explore various aspects of smoking behaviour among people who experience severe mental illness, considering a range of variables across different settings. This thesis presents experimental, clinical and theoretical research that explores key areas directly relevant to smokers diagnosed with severe mental illness. This work has been undertaken in over 700 different people across Australia who experience severe mental illness. Most of the research is novel, and the results offer important clinical implications for the management and treatment of smoking and other CVD risk factors among people with severe mental illness. The main findings from this thesis will now be summarised, followed by a comparison of the results to previous research, a discussion of the theoretical and clinical implications of the findings, consideration of the strengths and limitations of the thesis, and areas for future research.

## 6.1 SUMMARY OF RESEARCH FINDINGS

In Chapter 2, the level of specific risk factors for CHD were explored among 43 smokers diagnosed with psychosis before they participated in a multi-component intervention designed to reduce these risk factors, including the reasons for engaging in these health behaviours and motivation and confidence to change. Results indicated that smokers diagnosed with psychosis were generally overweight, physically inactive and had a poor diet, which further increased their risk of developing CVD. Being overweight affected the quality of life of these smokers with psychosis. Their poor diet was characterised by a lack of fruit and vegetables, and frequent consumption of caffeinated beverages and take-away meals. A consistent finding throughout this thesis was that smokers with psychosis reported that they continued to smoke because they were addicted and because smoking assisted them to manage stress. They recognised and were concerned about the effects of smoking on their

health, and this was their main reason for quitting. These smokers with psychosis were motivated to quit smoking, but lacked confidence in themselves that they could achieve this. They were also motivated to change other unhealthy behaviours (e.g. poor diet, lack of exercise), but again lacked confidence.

Gender differences in smokers diagnosed with psychosis were explored in Chapter 3, culminating in two publications. The first paper in this chapter investigated potential gender differences in characteristics and outcomes of 298 smokers diagnosed with psychosis who were participating in a smoking cessation intervention, with follow-up at 3, 6 and 12 months. The second paper examined the perceived risks and benefits of quitting smoking in 200 people experiencing psychosis before they participated in a multi-component risk factor intervention for CVD. Across these papers, there were some gender differences identified among these smokers diagnosed with psychosis. Compared to males, females reported smoking to prevent weight gain. Further, females were particularly concerned that quitting would cause them to gain weight and experience negative emotions such as irritability and agitation. Female smokers with psychosis were more likely than males to believe that quitting would improve their self-esteem, and overall they reported more reasons for quitting than the males. Female smokers with psychosis in this research were more likely to be driven by extrinsic motivators to quit such as immediate reinforcement and social influence, than were males.

Chapter 4 presented a series of papers investigating treatment options for smoking cessation among people experiencing psychosis. Collectively, the research undertaken as part of this chapter has demonstrated that a range of treatment options can assist smokers with psychosis to reduce or quit smoking, while also addressing other CVD risk factors. These include a

multi-component healthy lifestyles intervention delivered face-to-face or a briefer version delivered via telephone; high dose, combination, extended duration NRT coupled with a healthy lifestyles intervention; and standard dosing of varenicline together with a healthy lifestyles intervention. The two publications within this chapter demonstrate how the research findings and theoretical knowledge arising from this thesis directly assisted in the management of several clinical challenges that arose while addressing smoking and other CVD risk factors in people experiencing psychosis. Further, the research findings and knowledge were used to dispel some common myths within the literature surrounding the treatment of smoking in people with mental illness.

The research exploring the patient perspective of being admitted to a psychiatric ward prohibiting smoking on site has been presented across two papers in Chapter 5. The first paper in this chapter examined the views and experiences of 46 inpatients before, and 52 inpatients after, the implementation of a Totally Smokefree Policy in the acute psychiatry setting. The second paper detailed the design, implementation, experience and evaluation of an inpatient group that supported the introduction of a total smoking ban in the acute psychiatry setting. This included qualitative data obtained from 22 groups with 71 participants, and quantitative data from a further 13 inpatients. The research within this chapter uncovered very high rates of smoking among patients admitted to the acute psychiatry unit. While smokers tended to have the most negative views about the implementation of a Totally Smokefree Policy in this setting, they dramatically reduced their daily cigarette consumption once the smoking ban was implemented, and further recognised that smoking was an unwanted addiction and were interested in quitting in the future. Following the introduction of the Totally Smokefree Policy, patients reported an increase in the experience of negative emotions on the ward, and they were concerned about the loss of

smoking as their main coping strategy for stress. While patients were using NRT, many found it unhelpful, often as they were not using it optimally. Patients identified that the physical environment of the ward had improved following the implementation of the total smoking ban. The Smokefree Support group was a successful initiative of the psychology staff, with patients appreciating the opportunity to ventilate about the policy, and acknowledging the mutual benefits of peer and staff support.

# 6.2 COMPARISON WITH PREVIOUS RESEARCH

The research undertaken within this thesis will now be compared to previous research, highlighting major parallels and important differences, both among smokers experiencing severe mental illness and smokers in the general population.

# 6.2.1 Previous research in smokers with severe mental illness

The results described in Chapter 2 "Characteristics of smokers experiencing psychosis" are consistent with a number of other studies, recalling however, that this paper was the first to explore self-reported reasons for smoking and quitting in people experiencing psychosis before they participated in a multi-component CVD risk factor intervention, not simply a smoking cessation intervention.

The finding that this group of smokers diagnosed with psychosis were heavy smokers with high levels of nicotine dependence, as well as elevated levels of other CVD risk factors, is consistent with previous research among people with psychosis (Ashton, Rigby, & Galletly, 2013; Baker et al., 2007; Beebe, 2008; Brown et al., 1999; Chuang, Mansell, & Patten, 2008; Compton, 2005; de Leon & Diaz, 2005; Kumari & Postma, 2005; McCreadie, 2003; Osborn et al., 2006; Ussher et al., 2007). Similarly, the finding that this group of smokers with

psychosis reported that their main reasons for smoking related to addiction and stress reduction is also supported by previous research (Baker et al., 2007; Barr et al., 2008; Gurpegui et al., 2007). One of the main reasons for quitting smoking reported by this sample was due to health concerns, a finding supported by research among other smokers with psychosis prior to participating in a smoking cessation intervention (Ashton et al., 2013; Baker et al., 2007; Mann-Wrobel, Bennett, Weiner, Buchanan, & Ball, 2011), and research among non-treatment seeking smokers with psychosis (Kelly et al., 2012), and inpatient of an acute psychiatry unit (Stockings et al., 2013). This sample of people diagnosed with psychosis reported being quite motivated to quit smoking, a finding consistent with the studies included in the review by Siru et al. (2009). Additionally, 69.8% rated themselves in the "Contemplation" stage of change in terms of quitting smoking, which is higher than the result reported (49.7%) in the only other study to evaluate the stages of change among smokers with psychosis presenting for assistance to change their smoking behaviour (Baker et al., 2007). When this sample was compared to the sample in the Baker et al. (2007) study, they are very similar in terms of the number of cigarettes smoked per day, level of nicotine dependence and overall pattern of results. Perhaps the fact that this study offered a multicomponent intervention targeting several CVD risk factors, rather than just a smoking cessation treatment as in Baker et al. (2007), somehow attracted a greater proportion of people with psychosis that were contemplating quitting smoking. The finding that smokers with psychosis were motivated to quit but lacked confidence, is supported by another study that was published at almost the same time as the paper in this chapter. In their study, Mann-Wrobel et al. (2011) found that prior to participating in a smoking cessation intervention, most smokers diagnosed with schizophrenia or schizoaffective disorder wanted to quit, but generally reported low levels of confidence in their ability to stop smoking.

Other findings described in Chapter 2 are consistent with previous research among people with psychosis, including that this sample of smokers: consumed a poor diet characterised by insufficient fruit and vegetable intake and frequent consumption of caffeine and take-away foods typically high in saturated fats; were physically inactive; and were motivated to improve their diet and undertake more exercise (Archie et al., 2007; Beebe, 2008; Bobes, Arango, Garcia-Garcia, & Rejas, 2010; Brown et al., 1999; Galletly et al., 2012; Hahn et al., 2014; McCreadie, 2003; Nenke, Hahn, Thompson, Liu, & Galletly, 2015; Osborn et al., 2006; Ussher et al., 2007).

There is an absence of other research that the results of the papers described in Chapter 3 "Gender differences in smokers diagnosed with psychosis" can be directly compared to, given that this research was the first to explore these concepts specifically in this population of smokers. However, some of the results can be compared to those emanating from a group of researchers in Canada who have published 3 papers examining gender differences in smoking related variables in people diagnosed more broadly with severe mental illness, i.e. these studies combined participants with psychotic (schizophrenia and schizoaffective disorder) and non-psychotic disorders (mood, anxiety and substance use disorders) (Johnson et al., 2010; Okoli et al., 2011; Torchalla et al., 2011). The finding in this thesis that there were no gender differences between smokers diagnosed with psychosis in terms of their level of readiness or motivation to quit smoking is consistent with the work of Torchalla et al. (2011). While the finding that there were no gender differences in smoking cessation treatment outcomes among people diagnosed with psychosis is consistent with the results obtained by Okoli et al. (2011). However, the finding that there were no significant predictors of smoking reduction status, including abstinence, according to gender in this sample of smokers with psychosis, is inconsistent with the results obtained by Okoli et al.

(2011). They found that having a lower expired CO level at baseline and a greater number of visits to the tobacco treatment program significantly predicted smoking cessation for both males and females, and further that having a history of alcohol, heroin/opioid and marijuana use was predictive of unsuccessful smoking cessation only among the males. The most plausible explanation would be that the sample in the Okoli et al. (2011) study comprised of smokers diagnosed with mental illness more broadly (psychotic and non-psychotic disorders) and/or substance use, rather than smokers diagnosed with psychosis only as in this research. The different diagnostic categories and associated symptoms of these smokers may have an impact on smoking related variables, in turn affecting the influence of gender on smoking outcomes. Replication of these findings is required before further conclusions can be drawn.

Again, there is an absence of research that the results from the papers in Chapter 4 "Treatment options for smoking cessation among people experiencing psychosis" can be directly compared to as they arise from the implementation of the first multi-component intervention addressing smoking and other CVD risk factors. Generally though, comparison of smoking cessation outcomes (abstinence and reduction) from the studies included in this thesis and others among smokers with mental illness reveal similar outcomes. For example, the point prevalence abstinence rate at 3 months in the Baker et al. (2009) study was 18.6% and 11.9% in the Baker et al. (2015) study, which are comparable to, or better than, the rate achieved (10.4%) in the largest RCT evaluating a smoking cessation intervention including NRT in smokers with psychosis (Baker et al., 2006). This may be because compared to the Baker et al. (2006) study, the other two studies offered participants individually tailored flexible, combination NRT dosing, across a longer period of time. Similarly, the smoking abstinence rate reported in the paper included in this thesis combining varenicline with a multi-component healthy lifestyle intervention was 36% at 3 months (Castle et al., 2012)

which is similar to that reported by Pachas et al. (2012) that offered varenicline together with a group CBT program for smoking cessation to smokers with schizophrenia or schizoaffective disorder (34% at 3 months), and Evins et al. (2014) who provided varenicline with group CBT to smokers diagnosed with schizophrenia and BPAD (42% at 3 months). However, the smoking abstinence results reported in the Castle et al. (2012) study are much better than those reported by Williams et al. (2012) among smokers with schizophrenia (19% at 3 months). The most plausible explanation for the higher abstinence rates reported by Castle et al. (2012), Evins et al. (2014) and Pachas et al. (2012) when compared to those of Williams et al. (2012), is that the former studies combined varenicline with an additional psychosocial intervention, that may have assisted to improve the smoking cessation outcomes over varenicline alone in smokers with severe mental illness. The two papers included as part of this thesis that describe the rationale and protocol of the RCT for the multi-component CVD risk factor intervention designed for smokers with psychosis (Baker et al., 2011a and 2011b) were the first in the field and results from this RCT are now emerging (i.e. Baker et al., 2015 presents results up to the 12 month assessment point). There is now one comparable paper by Gaughran et al. (2013) that describes the protocol of their RCT designed to target one or more health behaviours among people with severe mental illness including smoking, exercise, diet, substance use (including cannabis and alcohol) and diabetic control. The baseline results from this study were recently published (Gardner-Sood et al., 2015) and they provide further evidence of the presence of significant risk factors for CVD in people experiencing severe mental illness, specifically high rates of smoking, obesity, Type 2 diabetes, and elevated cholesterol and blood pressure.

At the time when the research detailed in Chapter 5 "Implementing a Totally Smokefree Policy in the acute psychiatry setting: the inpatient experience" was undertaken, there was

only one other study that considered the views of inpatients of psychiatric services before and after the implementation of a total smoking ban (Resnick & Bosworth, 1989). While the general direction of results was similar between these studies, in that inpatients views about the smoking ban improved following implementation, the rates were quite different. In the Resnick and Bosworth (1989) study, 7% of inpatients supported the ban before it was implemented and 22% after, while in our study 30.5% of inpatients reported that implementing a totally smokefree policy would be "positive" or "very positive" beforehand and 50% reported the ban was "positive" or "very positive" after it was implemented. The temporal difference between these studies may account for these findings, more specifically though, the studies were conducted in different settings which could influence inpatients views. The study conducted in 1989 was within a small psychiatric crisis unit where patients were admitted for an average length of stay of 4 days for assessment, containment, stabilisation and referral (Resnick & Bosworth, 1989). It seems this equates to a High Dependency Unit (HDU) within an acute inpatient psychiatry ward. The research undertaken in this part of the thesis was within the low dependency unit (LDU) of a large acute inpatient unit, where the average length of stay was 3 weeks. It seems fair to assume that patients admitted to the psychiatric crisis unit would be at their most unwell, distressed and disorganised, and perhaps were less keen on supporting a smoking ban compared to those inpatients in the acute psychiatry unit who possibly anticipated receiving assistance not to smoke, or opportunities to smoke with increasing leave entitlements, as they would be there for several weeks.

Four other comparable studies have been published since the research in this thesis was undertaken, but each of these studies only considered inpatients views *after* the implementation of the total smoking ban, without providing the level of rich qualitative data

obtained in this research. Two studies were conducted in long-stay psychiatric facilities (Hehir et al., 2012; Smith et al., 2013), which is a different setting to this research that was undertaken in the acute psychiatry inpatient unit. Yet the general pattern of results from these studies was similar to ours, with high rates of smoking among patients admitted to these units, with about one third expressing anger or very negative views towards the implementation of the smoking ban, and smokers having the most negative perspectives about the Totally Smokefree Policy. The third study was undertaken in an acute psychiatric inpatient unit like the research described in Filia et al. (2015a and 2015b) and provided some similar results, in that inpatients were aware of the health risks of smoking and indicated that they were interested in quitting in the future, and further that smoking was their main way to deal with stress and boredom experienced on the ward (Ratschen et al., 2010). The fourth comparable study is by Stockings et al. (2015) which was published in the same journal issue as Filia et al. (2015a) and presents the results of an Australian study conducted the year after our work in an acute inpatient psychiatry setting with a total smoking ban, with strikingly similar results. After the implementation of a no smoking policy in the acute psychiatry ward, 29.6% of smokers in the Filia et al. (2015a) study and 29.9% of smokers in the Stockings et al. (2015) study reported that the smoking ban was positive. Further, while 67.9% of smokers in the Filia et al. (2015a) study and 75.3% in the Stockings et al. (2015) study used NRT during their admission, the majority reported that it was not very effective (47.4% and 56.1% respectively), suggesting significant underdosing of NRT in this setting.

# 6.2.2 Previous research in smokers from the general population

While there are distinct differences between smokers diagnosed with severe mental illness and smokers in the general population on some variables (e.g. smoking rates; the impact of smoking on physical, psychosocial, financial and clinical domains; prevalence of other CVD risk factors) some results are similar across these two different populations of smokers. This section will now compare the results obtained in this thesis to relevant findings that may exist among smokers without mental illness. This is important as it will better inform the tailoring of smoking cessation treatments specifically for people experiencing severe mental illness.

The participants within this thesis diagnosed with severe mental illness generally smoked a greater number of cigarettes per day and had higher levels of nicotine dependence compared to samples of smokers from the general population from a range of studies, a finding consistent with previous research (Compton, 2005; de Leon, Tracy, McCann, McGrory, & Diaz, 2002; Kelly et al., 2012; Kumari & Postma, 2005; Lasser et al., 2000; McKee et al., 2005; Rigotti et al., 2000). Despite presenting as a group of "hardcore smokers" the people diagnosed with severe mental illness studied as part of this thesis were just as motivated to quit as smokers from the general population without mental illness, again a finding consistent with other research (Baker et al., 2007; Curry et al., 1997; Siru et al., 2009).

In terms of reasons for smoking, overall the participants in this thesis were more likely to report that they smoke in order to manage stress and because they are addicted, than smokers without mental illness in the general population (Baker et al., 2007; Pederson et al., 1996). Smokers diagnosed with psychosis in this thesis that were seeking smoking cessation treatment, were just as likely to report wanting to quit due to health concerns as smokers from the general population (Baker et al., 2007; Curry et al., 1997; Kelly et al., 2012). However, they were more likely to report reasons for quitting related to self-control (e.g. to show I can quit), immediate reinforcement (e.g. save money on cigarettes) and social influences (e.g. want people to stop nagging me to quit) than treatment seeking smokers from the general population (Curry et al., 1997) and non-treatment seeking smokers from the general

population (Kelly et al., 2012). Overall, the smokers with psychosis studied in this thesis indicated that they were driven more by extrinsic motivators (immediate reinforcement and social influence) rather than intrinsic motivators (health concerns and self-control) to quit smoking, a pattern opposite to that typically seen among smokers in the general population (Curry et al., 1997; Kelly et al., 2012). While it is not entirely clear why this is the case, the significant financial impact that smoking has specifically for people with psychosis, coupled with the lack of confidence and self-efficacy in relation to quitting smoking, may help to account for this pattern of results.

When gender differences were explored among the smokers studied in this thesis experiencing psychosis, a different pattern of results emerged compared to those obtained from smokers in the general population. Overall, a lack of gender differences among smokers with psychosis was revealed, meaning that unlike smokers in the general population, the male and female smokers in the current research had similar reasons for smoking/quitting; perceived risks and benefits of quitting; levels of readiness and motivation to quit; patterns of NRT use and smoking outcomes in terms of continuous and point-prevalence abstinence. Potential explanations for this pattern of results have been previously explored in the papers found in Chapter 3 and include factors related to differing: levels of nicotine dependence; influences of stress; psychosocial roles; level of functioning; and neurobiological mechanisms among smokers with psychosis compared to those without mental illness. The few gender differences that were revealed among smokers with psychosis were consistent with smokers in the general population. These included females being more likely than males to report smoking to prevent weight gain, and anticipating more risks associated with quitting, specifically in terms of experiencing weight gain and negative affect (McKee et al., 2005; McKee & Weinberger, 2015; Reid et al., 2009). Females also reported more reasons

for quitting smoking and were more likely to be driven by extrinsic motivators to quit than males (Curry et al., 1997; Reid et al., 2009).

In relation to treatment options for smoking cessation among smokers diagnosed with psychosis, the current available evidence in the general population cannot be directly compared to the results of the research undertaken within this thesis. While there are currently no directly comparable studies employing the same study design, intervention and dosing of smoking cessation pharmacotherapy, new research in this field continues to emerge updating previous findings. For example, there is currently a randomised double blind active and placebo controlled multicentre study underway funded by Pfizer that directly compares NRT, varenicline, bupropion and placebo in smokers with and without mental illness, and the results of this research will be informative (ClinicalTrials.gov Identifier NCT01456936). Some studies report that smokers with mental illness can successfully quit, but generally have lower quit rates than smokers without mental illness (de Leon & Diaz, 2005; Lasser et al., 2000; Mendelsohn & Montebello, 2013). While three reviews of smoking cessation interventions for people with mental illness conclude that standard approaches to smoking cessation have comparable success with the general population and people with severe mental illness (Banham & Gilbody, 2010; el-Guebaly et al., 2002; Morrison & Naegle, 2010). The smoking abstinence rates achieved in the current thesis in the study using varenicline among smokers with psychosis are comparable to those achieved in studies among smokers without mental illness (Aubin et al., 2008; Cahill, Stead, & Lancaster, 2012), but this is not the case for the results achieved using NRT (Aubin et al., 2008; Stead et al., 2012). It can be concluded though, from the research in this thesis, that smokers with mental illness face specific barriers and challenges related to smoking cessation that smokers without mental illness in the general population will never encounter. These include significantly higher

rates of smoking and nicotine dependence; the role of smoking in the psychiatric treatment system; the interaction between smoking and psychiatric medication; weight gain issues related to psychiatric medication treatment and physical inactivity; reduced confidence and self-efficacy in relation to successfully quitting; decreased opportunity or availability of alternate activities to smoking; absence of well-developed alternative coping strategies for stress; motivation and cognitive difficulties inherent in severe mental illness; reduced social support; the potential influence of mental state on quit attempts; and increased co-morbidity of drug and alcohol use. Each of these challenges has direct consequences for the clinical management of a person diagnosed with psychosis making a smoking cessation attempt, and these will be covered in the section discussing the clinical implications of the findings from this thesis.

Being admitted to an acute inpatient psychiatric unit with a total smoking ban is quite a different experience for a smoker compared to being admitted to a general medical ward. Apart from the differences in characteristics between smokers with and without mental illness already outlined in this thesis, the acute inpatient psychiatry ward imposes specific restrictions. For example, the smoker may be admitted against his/her will involuntarily under the Mental Health Act, and even if admitted as a voluntary patient, the smoker may not be able to leave the ward freely to smoke as the doors of the ward may be locked, or due to restricted leave entitlements. Despite the vast differences between being admitted as a smoker to a psychiatry ward compared to a general medical ward, there are some parallels from the research among smokers in the general population admitted to a general hospital with a total smoking ban. As with smokers diagnosed with severe mental illness, there is a paucity of research examining the inpatient perspective of Totally Smokefree policies among smokers in the general population (Shopik et al., 2012). An investigation of views and

experiences of smokers in the general population admitted to surgical and medical wards following a total smoking ban revealed that these inpatients smoked during hospital admissions for stress relief, socialisation, to get a break from hospital and due to boredom (Shopik et al., 2012). These results are not dissimilar to the reports made by the inpatients admitted to the acute psychiatry inpatient ward following implementation of a total smoking ban as presented in this thesis. Another study among smokers admitted to a smokefree general hospital found that those who experienced cravings and other nicotine withdrawal symptoms were more likely to continue smoking during their hospitalisation (Rigotti et al., 2000), a finding that reflects some of the experiences reported by the inpatients admitted to the acute psychiatry ward as described in this thesis. A study among patients of a cancer hospital found that smokers had more negative views in relation to the planned total smoking ban compared to the non-smokers (Unrod, Oliver, Heckman, Simmons, & Brandon, 2012). Nonetheless, the smokers could anticipate some of the benefits of the cancer hospital becoming totally smokefree, and many expressed an interest in obtaining support in relation to smoking cessation. While the actual figures in relation to views about the smoking ban differed substantially between patients of the cancer hospital and those admitted to the acute psychiatry inpatient ward, the overall pattern of results was similar between these two different patient populations. For example, in the cancer hospital 56.9% of smokers favoured the planned implementation of the Totally Smokefree Policy, while only 18.8% of smokers surveyed in the acute inpatient psychiatry unit thought it would be a positive initiative. There could be a number of potential explanations for this discrepancy, but perhaps the most likely suggestions would relate to the differences in smoking amounts and nicotine dependency between these two samples, and factors inherent in being treated for cancer, a health condition that can be directly related to smoking.

### 6.3 THEORETICAL IMPLICATIONS OF FINDINGS

The results of the research arising from this thesis have stemmed from a number of novel studies among smokers experiencing severe mental illness. Consequently, the theoretical implications of these findings are quite significant and offer unique contributions to the field. The findings from this thesis that replicate those based on previous research among smokers with severe mental illness make an important theoretical contribution as well, by adding further weight to what has already been found in a limited field of research. The findings from this thesis that are novel and add to the knowledge related to smoking and other CVD risk factors among people with severe mental illness will now be summarised. As most of these findings are new, replication is required to give strength to the meaning of these results, but they provide a solid platform to base future research on.

This thesis was the first body of research to find that smokers diagnosed with psychosis were motivated to change multiple health behaviours (i.e. smoking, diet and exercise) by participating in a multi-component CVD risk factor intervention. Further, this research was the first to demonstrate that despite high levels of motivation to change multiple health behaviours, these smokers with psychosis were not confident that they could make such changes. This is an important finding that warrants further attention. It is anticipated that low levels of confidence among smokers with psychosis could pose as an additional barrier to accessing smoking cessation treatments, and may further contribute to the lower smoking abstinence rates reported by some studies among smokers with severe mental illness compared to those in the general population.

By conducting the first exploration of gender differences on a range of smoking variables specifically among smokers diagnosed with psychosis, the work in this thesis suggests that

generally male and female smokers diagnosed with psychosis are a more homogenous group compared to male and female smokers in the general population. Further, the thesis provides evidence that some of the gender differences identified among smokers in the general population are also present in smokers diagnosed with psychosis, specifically in terms of the concerns that female smokers have in relation to smoking, weight gain and negative affect. This knowledge was not present in the literature prior to the publications arising from this thesis.

Of significant theoretical implication in this field is the finding that smokers diagnosed with psychosis are able to change several health behaviours in response to a multi-component CVD risk factor intervention. The impact of this finding is great, as it not only serves to dispel a range of common myths surrounding people with severe mental illness, but it offers a solid base for future studies to extend this work. Importantly, the findings also demonstrate that this research can be directly translated into clinical practice. The publications from this thesis describe a range of interventions that can be offered to people experiencing psychosis to assist them to reduce or quit smoking, as well as targeting other CVD risk factors. These papers offer a significant contribution to the theory in this area as they specifically describe how to implement the interventions, together with a discussion of potential clinical challenges that may be encountered, and provide suggestions for practical solutions to these.

The work undertaken in this thesis provides important insights into the patient experience of being admitted to an acute psychiatry inpatient unit with a total smoking ban and this significantly adds to the very limited knowledge base in this area. Further, it offers the first theoretical and practical framework for an inpatient support group following the implementation of a total smoking ban in acute psychiatry. A range of new knowledge

emanated from this part of the research. Before the smoking ban, inpatients agreed that it should be implemented as hospitals should promote health, and that smoking is bad for health. However, they were concerned about losing smoking as a coping mechanism for stress and experiencing nicotine withdrawal symptoms. Following the smoking ban, inpatients dramatically reduced their daily smoking amount irrespective of their views regarding the Totally Smokefree Policy. Inpatients described difficulties arising from the smoking ban such as experiencing increased negative emotions, not having smoking as a coping strategy and experiencing ongoing cravings and nicotine withdrawal. They could also describe some positives about the change including that the physical ward environment had improved, together with the physical and mental health of the patients, staff and visitors. The most frequent coping strategy for not smoking on the ward reported by inpatients was eating and/or drinking. Inpatients valued the opportunity to share their views and experiences of being admitted to a Totally Smokefree psychiatry ward in the group setting, and to receive peer and staff support. Inpatients most commonly spoke about NRT, and smoking being their main coping strategy for stress. Prior to this current research, the literature simply described what inpatients thought about the implementation of a total smoking ban in acute psychiatry in terms of agreeing or disagreeing with it. The current findings have real implications for the clinical management of a smoker in the acute inpatient psychiatry unit and these will be explored in the next section.

# 6.4 CLINICAL IMPLICATIONS OF FINDINGS

A major strength of the work undertaken as part of this thesis is that the results have direct treatment implications. Importantly, not only have the majority of the papers arising from this thesis already been published in relevant journals, but research from this thesis has also been directly translated into clinical practice surrounding the treatment of smoking and other

CVD risk factors in people with severe mental illness. Smoking cessation interventions need to be routinely offered to every smoker that experiences mental illness, regardless of their stage of change. Evidence-based smoking cessation interventions designed for smokers in the general population provide a good starting point, but the findings from this thesis can guide some modifications specifically for this particular population. The main clinical implications that stem from this thesis will now be summarised.

# 6.4.1 Motivation and confidence

To reduce the discrepancy between being motivated to quit while having low confidence, smoking cessation interventions for people experiencing severe mental illness will benefit from including strategies that boost self-efficacy and offer regular and long-term support and encouragement. Assisting smokers with severe mental illness to believe that they can quit may be an important component of smoking cessation treatment for this group (Mann-Wrobel et al., 2011). The following strategies may assist in building confidence to quit among smokers with severe mental illness: reinforcing smoking reduction attempts; rewarding all attendance and participation at treatment sessions; responding to smoking relapses in a non-judgmental supportive manner; and assisting the smoker to set a variety of realistic treatment goals and providing praise and encouragement for any small steps that are made towards these goals (Baker et al., 2011a; Mann-Wrobel 2011).

Reasons for quitting smoking among people with severe mental illness, particularly males, require strengthening and motivational interviewing exercises that include a discussion of the positive and less positive aspects of smoking and smoking cessation may be particularly helpful. Such MI exercises can assist to strengthen intrinsic motivators for quitting (e.g. health concerns and self-control), which is particularly pertinent for female smokers with

psychosis. However, it is important to know that some groups of smokers are not as responsive to efforts at increasing intrinsic motivation (Lynagh et al., 2012). If this is the case for smokers with psychosis, then strategies aimed at enhancing extrinsic motivation to promote behaviour change such as the use of financial incentives via contingency management may be particularly useful (Tidey, 2012), especially for female smokers with psychosis.

### 6.4.2 Smoking cessation pharmacotherapy

Optimal smoking cessation treatment for smokers with severe mental illness involves the combination of an appropriate pharmacotherapy with an extended duration psychosocial intervention. Whether as part of a smoking cessation attempt in the community, or for temporary smoking abstinence following admission to a totally smokefree psychiatric ward, smokers with severe mental illness require prompt and easy access to appropriate smoking cessation pharmacotherapy that is tailored to their individual needs (i.e. level of nicotine dependence; experience of nicotine withdrawal symptoms; personal preference). The smoking cessation pharmacotherapy must be adequately dosed, and used over an extended period of treatment. The health professional plays a vital role in supporting their clients that smoke, whether as an inpatient or outpatient, which may involve one or all of the following tasks: regularly assessing the smoker regarding their smoking behaviour, level of nicotine dependence and experience of nicotine withdrawal symptoms; assisting the smoker with severe mental illness to gain access to the smoking cessation pharmacotherapy (this might include providing information about which products are available on the Pharmaceutical Benefits Scheme (PBS) at a heavily reduced cost); providing education on how to use the smoking cessation treatment; and encouraging the smoker to regularly and optimally use the pharmacotherapy.

# 6.4.3 Psychosocial interventions for smoking cessation among people with severe mental illness

For a number of reasons, smokers with severe mental illness will require additional support in identifying and implementing suitable behavioural interventions that target their high risk situations for smoking, whether that be in their home environment or in the totally smokefree acute psychiatry inpatient unit. Smokers experiencing severe mental illness may require assistance with problem solving to formulate methods to change behaviours associated with smoking, as well as determining suitable distraction techniques. Engaging in activities such as role playing these strategies will be particularly helpful.

Smoking cessation interventions for people experiencing severe mental illness must acknowledge and specifically address the significant role that smoking plays in coping with stress, other difficult emotions and boredom for this group of smokers. As described above, it is crucial to assist smokers with severe mental illness to develop and implement a range of alternative coping strategies other than smoking, by providing appropriate support, guidance and resources that are relevant to both the in- and out-patient psychiatry setting. There is a risk that smokers experiencing severe mental illness may replace smoking with eating when faced with their high risk situations for smoking. Assisting and supporting smokers to identify and choose healthy snack options is important, particularly for females experiencing severe mental illness due to their concerns regarding weight gain.

Providing smokers with severe mental illness the opportunity to discuss the impact of their smoking on various aspects of their day-to-day life is a worthwhile option, for example, being admitted involuntarily to an acute psychiatry inpatient unit that prohibits smoking.

Facilitating opportunities for smokers to receive peer and staff support surrounding these issues is important.

# 6.4.4 Multi-component interventions for CVD risk reduction

Not only do smokers with severe mental illness have elevated levels of other CVD risk factors, but they are motivated and able to make multiple health behaviour changes. Therefore, they should be routinely offered interventions that are multi-component and target other CVD risk factors in addition to smoking. One option is to offer smokers the opportunity to participate in a program such as The Healthy Lifestyles Project that delivers a multi-component CVD risk factors intervention either face-to-face or via telephone. However, there are other practical options that can be easily incorporated into the overall management of smokers with severe mental illness, some of which make use of existing resources. This includes options such as arranging a referral to a dietician or diabetes educator; providing healthy snack options and opportunities for exercise on the acute psychiatry inpatient unit; running a walking group or a healthy eating/cooking group; taking a shopping trip to the supermarket or local market; facilitating access to a service that offers healthy prepackaged meal options; and identifying activities within the local community that are free or low-cost and providing clients with a handout of options, e.g. reduced gym membership at certain times of certain days.

# 6.4.5 Gender sensitive approaches to smoking cessation

Further to the comments provided regarding gender differences in motivation among smokers with severe mental illness, the following gender sensitive clinical implications are suggested based on the findings from this thesis. Concerns around weight gain need to be specifically identified, acknowledged and addressed for female smokers that experience severe mental illness. Providing female smokers with severe mental illness additional treatment related to healthy eating and exercise may be helpful. Further, female smokers with psychosis may require focused attention on identifying and implementing suitable strategies to cope with potential feelings of negative affect such as irritability or feeling less calm that they may experience during a quit attempt.

# 6.5 STRENGTHS OF THE RESEARCH

There are a number of significant strengths regarding the body of research within this thesis. Data were collected from over 700 different people experiencing severe mental illness, ensuring that a range of views, experiences and variables were represented. Smoking and related variables were investigated across a range of settings which further increases the comprehensive nature of the information collected, i.e. among smokers in both the inpatient and outpatient environments; from both the public and private psychiatry sector; and capturing smokers during both the acute and non-acute phase of their illness. Data in this thesis were obtained using a variety of techniques, affording the benefit of the richness provided by combining quantitative and qualitative data collection techniques. This research has produced a number of novel findings, which increases the theoretical impact of this work in the field. Adding to this, to date all but one of the papers arising from this thesis have been fully published and are already circulating in the academic world. Most of the results from this thesis have direct clinical relevance and can easily be translated into practice around the treatment of smoking and other CVD risk factors among people experiencing severe mental illness. The candidate has been supervised by, and has collaborated with, highly regarded, successful researchers and some of the data have been collected within projects funded by highly competitive grants (e.g. NHMRC funding), which adds further strength to the quality of the research conducted.

# 6.6 LIMITATIONS OF THE RESEARCH

Several limitations of the research within this thesis can be identified. While specific limitations have already been discussed in the individual papers within this thesis, the more general limitations will be reviewed here. The main limitation relates to the fact that the majority of the data were obtained from people diagnosed with psychosis that were presenting for assistance with smoking cessation treatment. Perhaps such a group of smokers are more in tune with their physical health needs compared to other smokers with severe mental illness as they had decided to participate in such an intervention. While this may mean that some of the results from this thesis are not completely representative of all smokers with mental illness, it does not completely discredit the significance of the theoretical and clinical implications arising from this work. Similarly, while the participants of the studies undertaken among inpatients of the acute psychiatry inpatient unit before and after the implementation of a total smoking ban were not specifically seeking smoking cessation treatment, the results represented the specific views and experiences of those inpatients admitted to that service at that particular point in time. Not only does this limit the generalisability of these results to all inpatients of psychiatry units with a Totally Smokefree Policy, but it means that these views may not be representative of current inpatients of The Alfred Inpatient Psychiatry ward. Most of the analyses undertaken within this thesis did not separate participants by diagnostic group. While this offers no assistance in determining the characteristics of smokers with specific diagnoses (e.g. schizophrenia vs BPAD), or identifying what smoking cessation treatments may be better suited to certain psychiatric diagnoses, it does reflect the public health approach. In terms of the new findings arising from this research, it is difficult to determine how much weight to assign to these, given the lack of other similar research available with which to make comparisons. The impact of each

of these limitations mentioned here can be reduced following replication of these findings in future research.

# 6.7 FUTURE RESEARCH

# 6.7.1 Direct extension of the study

There are a range of potential future projects that logically follow on from the research undertaken as part of this thesis. As has been previously mentioned, there have been a number of novel findings arising from this research that certainly require replication through future research. It would be interesting to explore the relationship between motivation and confidence to quit smoking and smoking cessation outcomes among smokers experiencing severe mental illness. Similarly, it would be worthwhile investigating the relationship between the perceived risks and benefits of quitting smoking, pre-treatment motivation and treatment outcomes in smokers with severe mental illness, and to compare the pattern of these findings to those that already exist among smokers in the general population. Further, exploring the pattern of perceived risks and benefits of quitting smoking reported by people with severe mental illness not seeking treatment for smoking cessation is warranted. It would be interesting to further explore potential gender differences in smokers with mental illness and to attempt to replicate and extend the pattern of results from the current research. Evaluating if potential gender differences exist in the outcomes of the multi-component CVD risk factor study (i.e. Baker et al., 2015) will provide valuable information. Further, determining if methods used to enhance extrinsic motivation to quit smoking such as contingency management are effective in smokers with psychosis, and if any gender differences are apparent, is an important future study. Examining the use of incentives to improve other health behaviours in people experiencing severe mental illness is worthy of investigation (Evins & Cather, 2015). Some of the larger datasets from this thesis could be

re-analysed according to diagnostic group, and further studies could focus on one diagnostic category in greater detail. Undertaking some of these potential future studies will help to compare and contrast smokers with and without mental illness, and this will hopefully provide further treatment and clinical implications that may assist in improving outcomes for this group of smokers.

In terms of the impact of a Totally Smokefree Policy in the acute inpatient psychiatry setting, there is a need to regularly assess inpatients' views about the total smoking ban in order to capture the range of perspectives and experiences of different inpatients admitted at different times. The availability of such information will better inform clinical practice surrounding the assessment, management and support of smokers within this setting. To complete the picture, the attitudes and experiences of staff working within this setting need to be captured, and an attempt made to determine the impact that these have on the views and experiences of inpatients.

#### 6.7.2 Broader issues to be covered in future work

More broadly, a range of future studies are required to ensure that all smokers experiencing severe mental illness are routinely offered the best support and assistance to reduce their overall risk of CVD. Future work needs to continually focus on developing, implementing and evaluating a range of different interventions designed to reduce CVD risk factors among people with severe mental illness. Undertaking well-designed RCTs involving newer forms of smoking cessation pharmacotherapy (e.g. varenicline; oral nicotine spray) combined with relevant psychosocial interventions is crucial, without excluding smokers on the basis that they have experienced severe mental illness. Exploring potential gender differences in such studies is important, as in the general population a recent meta-analysis has demonstrated that

varenicline was significantly more efficacious for female smokers than males (McKee, Smith, Kaufman, Mazure & Weinberger, 2015). Innovative psychosocial interventions for smoking cessation among people experiencing severe mental illness are called for. In the general population, a behavioural smoking treatment based on individual perceived risks of quitting offered to female smokers resulted in higher smoking reduction and abstinence rates than the control condition (Weinberger, Pittman, Mazure, & McKee, 2015). This approach is worthy of investigation in smokers experiencing severe mental illness.

There are even more marginalised groups of smokers that experience mental illness that urgently require assistance to reduce their overall risk of developing CVD. Smoking and other CVD risk factors need to be addressed among more specific groups of people experiencing severe mental illness, e.g. pregnant smokers with mental illness; indigenous smokers with mental illness.

There are new treatment avenues other than pharmacological or psychosocial interventions that need to be explored and potentially pursued for smokers experiencing mental illness. For example, recent neurotechnology advances offer techniques such as transcranial direct current stimulation (tDCS) that has successfully been applied to reduce cravings for cigarettes and number of cigarettes smoked among the general population (Boggio et al., 2009), yet has not been specifically tested in smokers with severe mental illness. With the emergence of electronic nicotine delivery systems (ENDS) such as electronic cigarettes, there is a need to investigate the uptake, role, impact, and effectiveness they have for smokers experiencing severe mental illness (Tidey & Miller, 2015).

### 6.8 CONCLUSION

This thesis makes an important and significant contribution to the body of research regarding smoking and other CVD risk factors among people that experience severe mental illness. The research has been conducted comprehensively, across different settings and with a large number of different participants. The results from this thesis have filled several gaps within the literature, and most of the work has already been published. The findings have definite and direct theoretical and clinical implications, and offer a solid platform to base future research on.

Through a range of studies this research provides evidence that smokers experiencing severe mental illness are interested in and able to make multiple positive lifestyle changes to effectively reduce their risk of developing CVD. However, they may require ongoing assistance to maintain their motivation and level of confidence. Generally, male and female smokers with psychosis do not differ across a range of smoking related variables, however, female smokers are particularly concerned about experiencing weight gain and negative affect during a quit attempt. Smoking is predominantly the main coping strategy used by smokers with severe mental illness to manage feelings of stress, depression, and anxiety, together with boredom in both the inpatient and outpatient settings. Consequently, these smokers require assistance to develop and implement alternative coping strategies other than smoking that are relevant to different settings. Whether during a planned smoking cessation attempt or enforced smoking abstinence, all smokers with severe mental illness need to be proactively assessed in terms of their level of nicotine dependence and experience of nicotine withdrawal symptoms and then promptly offered suitable treatments. Smoking cessation pharmacotherapies such as combination NRT and varenicline can be effective and safe options for smokers with severe mental illness, particularly when combined with a

psychosocial intervention that includes regular monitoring of their mental state and potential changes to their medication side-effects. Smokers admitted to an acute inpatient psychiatry ward with a total smoking ban will find this challenging and they will benefit from the opportunity to discuss their views and experiences surrounding such a policy in an environment supported by staff and peers. If some of the knowledge, experience and clinical implications arising from this thesis are applied to every smoker experiencing severe mental illness, then this will make a good start to tackling the high rates of smoking and other CVD risk factors typically seen in this population of smokers, and effectively reduce the health inequalities and associated morbidity and mortality that this patient group experience.

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# **APPENDIX 1**

A prospective study of the impact of smoking on outcomes in bipolar and schizoaffective

disorder



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# A prospective study of the impact of smoking on outcomes in bipolar and schizoaffective disorder

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# Abstract

**Background:** Tobacco smoking is more prevalent among people with mental illnesses, including bipolar disorder, than in the general community. Most data are cross-sectional, and there are no prospective trials examining the relationship of smoking to outcome in bipolar disorder. The impact of tobacco smoking on mental health outcomes was investigated in a 24-month, naturalistic, longitudinal study of 240 people with bipolar disorder or schizoaffective disorder.

Method: Participants were interviewed and data recorded by trained study clinicians at 9 interviews during the study period.

**Results:** Comparisons were made between participants who smoked daily (n = 122) and the remaining study participants (n = 117). During the 24-month study period, the daily smokers had poorer scores on the Clinical Global Impressions–Depression (P = .034) and Clinical Global Impressions–Overall Bipolar (P = .026) scales and had lengthier stays in hospital (P = .012), compared with nonsmokers.

Limitations: Smoking status was determined by self-report. Nicotine dependence was not measured.

**Conclusion:** These findings suggest that smoking is associated with poorer mental health outcomes in bipolar and schizoaffective disorder. © 2010 Elsevier Inc. All rights reserved.

# 1. Introduction

The prevalence of smoking in psychiatric illness is greater than that observed in the general community. A study of psychiatric outpatients (N = 2774) in the United States found that the prevalence of smoking was highest for schizoaffective disorder (67%), followed by bipolar disorder (66%), which was greater than schizophrenia (63%) and all patients (61%), and was higher than the prevalence of smoking in the general population (24%) [1]. In a study of 424 patients, Diaz et al [2] found that the prevalence of current daily smoking was 57% for major depression (n = 67), 66% for bipolar disorder (n = 99), and 74% for schizophrenia (n = 258), compared with 25% in a cohort of volunteer controls (n = 402). In the 2004-2005 National Health Survey in Australia, 32% of adults self-reporting mental or behavioral problems were current daily smokers compared with 20% of adults without mental or behavioral problems [3]. Figures from the National Drug Strategy Household Survey suggested that in 2007, 22.1% of Australian men and 18% of women aged 20+ years were current smokers. Prevalence was greatest in the 25- to 29-year-old-age stratum, 29.3% being men and 26.7% being women, and lowest in the 70-year-or-older-age stratum, 8.1% being men and 6.0% being women [4].

Cross-sectional studies suggest an association between worse course and outcomes of bipolar disorder and schizoaffective disorder with tobacco use. In the Systematic

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Treatment Enhancement Program, tobacco use was associated with greater rapid cycling, comorbid psychiatric disorders, substance use, being currently episodic, more lifetime depressive and manic episodes, and greater episode severity [5]. Smoking may also adversely impact treatment response. Berk et al [6] compared smokers with nonsmokers in pooled data from 3 large clinical trials examining olanzapine treatment of acute mania and found that smoking was associated with worse treatment outcomes on the Young Mania Rating Scale (YMRS; P = .002) and the Clinical Global Impressions scale for bipolar disorder (CGI-BP; P < .001). The rate of suicide attempts in smokers (49%) was greater than in that in nonsmokers (25%) with bipolar disorder [7].

Association have been identified between tobacco smoking in bipolar disorder and risks to physical health. In a study comparing people with serious mental illness (N = 46 136) with controls (N = 300 426), Osborn et al [8] found a significant association between mental illness and chronic heart disease, explained in part, but not entirely, by tobacco smoking. Birkenaes et al [9] investigated cardiovascular risk factors in people in Olso with bipolar disorder (N = 110) and found that 55 (50%) smoked daily and 25 (22.6%) had a body mass index of 30 kg/m<sup>2</sup> or higher. Gonzalez-Pinto et al [10] found that alcohol abuse or dependence was more prevalent in bipolar patient who smoke or used to smoke compared with those who have never smoked (P = .0012).

To clarify the potential role of reverse causality, prospective studies are required to define the impact of an exposure variable on outcome. To our knowledge, there have been no prospective studies that relate smoking to mental health outcomes for people experiencing bipolar disorder. The aim of this study was therefore to prospectively investigate the effect of tobacco use on the course and outcomes of bipolar disorder and schizoaffective disorder in a 24-month, longitudinal, observational study. The hypothesis of the study was that smoking status at baseline would predict poorer scores in mental health and quality-of-life rating scales in participants who smoke daily compared with those who do not.

# 2. Method

The Bipolar Comprehensive Outcomes Study (BCOS) is a 2-year, prospective, noninterventional observational study of 239 participants with a diagnosis of either bipolar I disorder (n = 175) or schizoaffective disorder, bipolar type (n = 64). Full details of the study methodology have been published elsewhere [11,12]. The studies aims were to investigate clinical, functional, and economic outcomes associated with naturalistic treatment. Data on tobacco smoking were collected; however, assessing the impact of smoking in bipolar disorder was not the primary purpose of the study.

The study commenced recruitment in October 2003 with recruitment at 2 sites, Melbourne (n = 150) and Geelong (n = 150)90), in Australia. Participants were included if they had a diagnosis of bipolar I disorder or schizoaffective disorder, were older than 18 years, and were prescribed a mood stabilizer at the baseline visit. Participants with a diagnosis of schizophrenia, organic psychosis, or dementia were excluded. To capture a diverse clinical population, participants were recruited through the public hospital system, from private specialist clinical settings and primary care, and also by placing advertisements in the local print media. The final participant interview was completed in November 2007. Prospective longitudinal clinical, functional, social, pharmacologic treatment, and economic data were collected from 240 participants at 3-monthly intervals (visits 1 to 9). Treatment decisions were made independently of the study by the participant's primary treating clinicians. Participants used a broad range of medications; however, participants were required to be currently treated with a mood stabilizer at baseline including lithium, sodium valproate, carbamazepine, and olanzapine.

Diagnosis was confirmed by the Mini-International Neuropsychiatric Interview (MINI) [13]. The MINI was also used to diagnose psychiatric comorbidities including alcohol and substance use disorders. Clinical measures included the YMRS, the 21-item Hamilton Depression Rating Scale (HAM-D<sub>21</sub>), CGI-BP, and Current Major Depressive/Mania Checklist, which were all clinician administered. Participant self-rated measures included the EuroQol health-related quality of life 5-dimension questionnaire (EQ-5D) using the UK-standardized population, the 36-item Short Form Health Survey (SF-36), and the Streamlined Longitudinal Interview Clinical Evaluation from the Longitudinal Interval Follow-up Evaluation (SLICE/LIFE). Comprehensive health care resource use information was captured from electronic service usage records and from participant self-reports. Participants were questioned about tobacco use at visit 1 using the Habits form [14]. The Habits form collects data about current smoking status with 5 options: "I smoke daily," "I smoke occasionally," "I don't smoke now but I used to," "I tried it a few times but never smoked regularly," and "I've never smoked." Participants in the BCOS study were dichotomized into those who smoked daily and those who did not. Ethical approval was obtained from the Barwon Health Research and Ethics Advisory Committee (Project no. 03/ 69) and the Alfred Hospital Ethics Committee (Project no. 108/03). All participants gave written informed consent.

Comparisons between daily smokers and nonsmokers were made for medication use, length of hospitalization, and scores measured on the EQ-5D, SF-36, HAM-D<sub>21</sub>, YMRS, CGI-Mania, CGI-Depression, CGI-Overall Bipolar, and SLICE/LIFE scales. Study entry comparisons were assessed using Fisher exact test for categorical measures and analysis of variance (ANOVA) or the 2-sample medians test for continuous measures. All longitudinal profiles were assessed

Table I				

Demographic an	d baseline	characteristics	for daily	smokers	and nonsmoke	s from 239	participants	of BCOS
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	Daily smokers $(n = 122)$	Nonsmokers $(n = 117)$	Р
Age in years (mean ± SD; 95% CI)	38.17 ± 10.99; 36.22-40.12	45.67 ± 13.26; 43.27-48.07	<.0001 F
Diagnosis	36 schizoaffective, 86 bipolar	28 schizoaffective, 89 bipolar	NS
Have partner	42 (34.4%), Yes	57 (48.7%), Yes	.036 f
Have children	56 (45.9%), Yes	61 (52.1%), Yes	NS
Alcoholic drinks consumed daily (mean $\pm$ SD; 95% CI)	$1.26 \pm 2.15; 0.88 - 1.64$	$0.926 \pm 2.17; 0.53 - 1.32$	NS
Alcohol dependence in the past 12 mo	30 (24.6%)	11 (9.4%)	.002 f
EuroQoL: EQ-5D score (mean $\pm$ SD; 95% CI)	$0.718 \pm 0.308;  0.66  0.77$	$0.773 \pm 0.217; 0.73 - 0.81$	NS
EuroQoL: Health state score (mean $\pm$ SD; 95% CI)	$64.7 \pm 22.95; 60.63-68.77$	$68.2 \pm 16.52; 65.21-71.19$	NS
SF-36 mental component scale (mean $\pm$ SD; 95% CI)	$36.33 \pm 13.50; 33.92-38.73$	$37.32 \pm 12.28; 35.08-39.57$	NS
SF-36 physical component scale (mean $\pm$ SD; 95% CI)	$46.62 \pm 10.58;  44.73\text{-}48.50$	$46.82 \pm 10.30;  44.94\text{-}48.71$	NS
Total YMRS score (mean $\pm$ SD; 95% CI)	$9.4 \pm 9.27; 7.76 - 11.04$	$7.0 \pm 7.49; 5.64$ -8.36	.0298 F*
CGI mania score (mean $\pm$ SD; 95% CI)	$3.2 \pm 1.65; 2.91 - 3.49$	$2.7 \pm 1.54$ ; 2.42-2.98	.0327 F
CGI depression score (mean $\pm$ SD; 95% CI)	$3.3 \pm 1.24$ ; 3.08-3.52	$3.1 \pm 1.44; 2.84-3.36$	NS
CGI overall bipolar score (mean $\pm$ SD; 95% CI)	$4.0 \pm 1.16; 3.79-4.21$	$3.6 \pm 1.46; 3.34-3.86$	NS
SLICE/LIFE total score (mean $\pm$ SD; 95% CI)	$2.453 \pm 0.71; 2.33-2.58$	$2.38 \pm 0.64$ ; 2.26-2.49	NS
SLICE/LIFE work score (mean ± SD; 95% CI; 95% CI)	$2.53 \pm 1.12; 2.33-2.73$	$2.56 \pm 1.11; 2.36-2.76$	NS
SLICE/LIFE familial interpersonal relationships score (mean $\pm$ SD; 95% CI)	2.70 ± 1.22; 2.48-2.91	2.49 ± 1.15; 2.28-2.70	NS
Number of hospital admissions in the last 3 months	48 (39.3%)	31 (26.5%)	
Suicide risk in the past month	78 (63.9%)	73 (62.4%)	NS

F indicates overall F test (ANOVA) with smoking (daily/nonsmokers) as independent variable; F\*, overall F test (ANOVA) with smoking (daily/nonsmokers) as independent variable assuming unequal variances; f, Fisher exact test; CI, confidence interval; NS, not significant.

using mixed model repeated measures with random effects for intercept, visit, and visit by visit interaction. The spatial power covariance matrix was used to model the correlation within patients and between visits. Model adequacy was assessed using Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC) criteria along with usual regression diagnostics. Adjustments were made at study entry for the following factors: age, sex, diagnosis, length of hospital stay in previous 3 months, overall CGI-BP, alcohol dependence in the past 12 months (from MINI), smoking status, partner status, employment status, and site. Further adjustments were made for medications taken during the past 24 months: amount of time treated with mood stabilizers, and/or antidepressants, and/or antipsychotics, and/or benzodiazepines or hypnotics. In addition, a visit by smoking interaction term was also considered in the models.

Data were analyzed using SAS Version 9.1 for Windows (SAS Institute, Cary, NC). Missing data were excluded from percentage calculations, and differences were considered statistically significant at the 5% level of significance. Interaction effects were assessed at the 0.1 level.

# 3. Results

One participant withdrew consent. Data from the 239 remaining participants were analyzed; 122 (51%) participants who smoked daily were compared with 117 (49%) participants who did not. The nondaily smokers group (nonsmokers) consisted of 55 (23%) participants who never smoked, 8 (3.4%) who were occasional smokers, 51 (21.3%) who were ex-smokers, and 3 (1.3%) who experimented a few

times but were never regular smokers. Data were obtained using the Habits form administered at baseline. This form was administered at all study visits, and some participants changed their smoking status throughout the 2-year study. Twelve participants who had been daily smokers at baseline were not daily smokers at their last study visit, and 12 participants who were not daily smokers at baseline were daily smokers at their last study visit. Demographic and baseline characteristics for the 2 groups are given in Table 1. Daily smokers were significantly younger (P < .001) and were less likely to have a partner (P = .036) compared with nonsmokers. The mean (SD) age of experiencing first symptoms of mental illness was significantly (P = .002) younger for daily smokers (17.9 ± 7.7 years) than nonsmokers (22.4 ± 12.3 years).

The median number of concurrent medications used by daily smokers and nonsmokers at each study visit was 3 for both groups and ranged from a minimum of 0 for daily smokers and nonsmokers to a maximum of 9 for daily smokers and 10 for nonsmokers.

Outcome measures were analyzed for daily smokers and nonsmokers for each visit and for all visits combined. Across all visits, daily smokers spent less time than nonsmokers on antidepressants (Fig. 1). There was no significant difference between smokers and nonsmokers for treatment with mood stabilizers, antipsychotics, or benzodiazepines and hypnotics. Daily smokers had significantly worse CGI-Depression and CGI-Overall Bipolar scores than did nonsmokers during the 24-month period (mean CGI-D score of 2.87 for daily smokers and 2.63 for nonsmokers [P = .034]; mean CGI-BP score of 3.16 for daily smokers and 2.9 for nonsmokers [P = .0257]). Significant



Fig. 1. Amount of time on antidepressants since the previous visit over 24 months for daily smokers and nonsmokers (expressed as a proportion of the time since the previous visit with error bars showing SD).

differences between daily smokers and nonsmokers were also observed at visits 3 to 6 for CGI-D (Fig. 2) and at visits 2 to 6 for CGI-BP (Fig. 3).

Overall mean scores were similar or numerically worse for daily smokers compared with nonsmokers for the entire 24-month study, but not reaching statistical significance, for SF-36 mental component (42.4 daily smokers versus 42.8 nonsmokers), SF-36 physical component (47.5 daily smokers versus 49.5 nonsmokers), HAM-D<sub>21</sub> (11 daily smokers versus 9.84 nonsmokers), YMRS (8.51 daily smokers versus 8.12 nonsmokers), CGI-Mania (2.37 daily smokers versus 2.32 nonsmokers), SLICE/LIFE total score (2.11 daily smokers versus 2.11 nonsmokers), and EQ-5D utility score (0.78 daily smokers versus 0.82 nonsmokers). Daily smokers had a trend for worse scores than did nonsmokers for EQ-5D



Fig. 2. Least squares means with 95% CIs for CGI-Depression scores over 24 months for daily smokers and nonsmokers.



Fig. 3. Least squares means with 95% CIs for CGI-Overall bipolar scores over 24 months for daily smokers and nonsmokers.

utility score across all visits. However, this was only statistically significant for visits 1 and 2.

Daily smokers spent significantly more days in hospital than did nonsmokers during the 24-month study, with daily smokers staying a median of 4 (range, 0-128) days compared with nonsmokers who stayed a median of 0 (range, 0-345) days (P = .012).

Daily smokers had a higher frequency of substance use in the past 12 months compared with nonsmokers, such as alcohol dependence (30 [23.0%] versus 11 [9.4%]), amphetamine use (15 [12.3%] versus 2 [1.7%]), 3,4-methylenedioxymethamphetamine (MDMA) use (9 [7.4%] versus 3 [2.6%]), and cannabis use (48 [39.3%] versus 7 [6.0%]). A diagnosis of antisocial personality disorder was given for 6 (4.9%) daily smokers and none of the nonsmokers.

# 4. Discussion

High rates of smoking were reported in this cohort, with 51% smoking daily and 54.4% being current smokers (daily + occasional smokers). This is in counterpoint to the 23% local rates of tobacco smoking for adults in Australia (26% men; 20% women) [15] and is concordant with the literature showing that the prevalence of smoking is higher in this cohort than in the general population. In this study, daily smokers experiencing bipolar and schizoaffective disorder had significantly worse outcomes for CGI-Depression and CGI-Overall Bipolar and stayed longer in hospital compared with nonsmokers during the 24-month study. Worse healthrelated quality of life scores were measured for daily smokers using the EQ-5D, and differences in patterns of medication use were found between smokers and nonsmokers.

Mechanisms by which smoking may have an adverse impact on outcomes in bipolar disorder have been proposed. The pathways for the interaction between bipolar disorder and smoking are probably bidirectional, complex, and multifactorial. Biologic, environmental, psychologic, social, and genetic factors are likely to have interacting impacts [16]. In a study of monozygotic and dizygotic twins, Kendler et al [17] concluded that there are probably genetic factors that predispose some people for both depression and tobacco smoking. Studies of schizophrenia have found a downregulation in expression of the  $\alpha$ -7 nicotinic acetylcholine receptor, and a similar characteristic may be shared by people with bipolar disorder [18]. Tobacco smoking may compensate for this deficit. Genetic studies have linked schizophrenia and smoking with the genes coding for the  $\alpha$ -2,  $\beta$ -2, and  $\alpha$ -7 nicotinic receptor subunits and the dinucleotide repeat of the  $\alpha$ -7 gene *CHRNA7*. A chimeric gene of unknown function *CHRFAMA7* was found to be present in fewer copies in both schizophrenia and bipolar disorder [19].

Smoking may aggravate the bipolar cycle, which is suggested by cross-sectional existing evidence linking smoking to more episodic symptoms, increased frequency of both affective poles, and rapid cycling [5]. Smoking may interfere with the efficacy of treatment, resulting in poorer rates of improvement. Smoking has been associated with worse outcomes among patients being treated for acute episodes of bipolar mania [6]. The impact of smoking on the metabolism of psychotropic medications is well documented. This is largely mediated via induction of the hepatic cytochrome P450 enzyme 1A2 by polycyclic aromatic hydrocarbons [20,21], leading to lower serum levels of drugs such as olanzapine, clozapine, haloperidol, benzodiazepines, and some antidepressants [21]. In addition, nicotine induces changes in multiple neurotransmitter systems [22]. Nicotine is a nicotinic cholinergic receptor agonist and causes the release of neurotransmitters such as dopamine, noradrenaline, serotonin, y-aminobutyric acid, and glutamate through the widespread cholinergic innervations of the brain [22]. Compounds in cigarette smoke inhibit the activity of monoamine oxidase, the enzyme responsible for the degradation of biogenic amine neurotransmitters [23]. The dopaminergic pathway may be a particular mechanism linking smoking and bipolar disorder. Dopamine has a shared role in bipolar disorder [24] as well as in the reward pathways that drive the processes of reward and addiction. The mesolimbic dopaminergic pathways mediate reward and reinforcement of smoking via associative learning mechanisms. The sensitization of nicotinic cholinergic, dopaminergic, and other downstream receptors is altered with prolonged nicotine exposure. This may play a role in nicotine tolerance and withdrawal syndromes, in addition to modulating a pathway with a critical role in bipolar disorder [22,25]. Other mutually interacting factors include comorbid illness, substance abuse, and treatment compliance. Smoking was shown to be associated with an increased risk of the development of de novo depression in a 10-year prospective study [26]. It is plausible that overlapping mechanisms may be operative for bipolar and unipolar disorders.

Strengths of this study include the ample sample size, the prospective design, a sampling process that attempted to

capture the diversity of the population, and the low dropout rates. The interaction between smoking and psychopathology is in all probability bidirectional and impacted by many factors. Multiple outcome measures were used; that these showed a consistent direction effect strengthens the likelihood that this is a real effect and reduces the likelihood of type 1 error.

This was a naturalistic study. Limitations due to the study design include selection bias, lack of internal validity, and the fact that results can only examine associations, not causality. All participants were recruited from Melbourne and Geelong in Australia, which is a western, urban environment where the prevalence of tobacco smoking is in decline. Results may have been different if the study was conducted in a location with a different prevalence and/or social acceptability of tobacco smoking. Data were collected using the Habits form and then dichotomized for analysis with current daily smokers as 1 category and all 4 other options grouped as the comparator. These data could have been dichotomized for analysis in other combinations. Another limitation of the study was that smoking might be associated with other adverse lifestyle choices. In this study, the incidence of alcohol dependence and illicit substance use was greater for smokers than for nonsmokers. Tobacco smoking is also associated with poor diet and lower levels of physical activity [27]. These factors may have also contributed to the worse psychiatric outcome among the daily smokers, as exercise has been shown to be useful in bipolar disorder [28]. Smoking may have pharmacokinetic effects relevant to some participants. Smoking has also been associated with low socioeconomic status [5]; however, in this study, there was no significant difference in income between daily smokers and nonsmokers. Finally, given that most participants in both groups were of low income (105 daily smokers and 84 nonsmokers having an income less than \$AUD 500/wk), the results from this study may only be generalized to a subset of people with bipolar disorder or schizoaffective disorder.

Tobacco smoking is highly prevalent among people with bipolar disorder and schizoaffective disorder and is associated with a worse prognosis. There is sufficient evidence to suggest that tobacco smoking should be of concern to clinicians treating patients with bipolar disorder. Many public health educational campaigns have limited impact, as behavioral change is often contingent on the risk factor having personal valence for the individual. Communicating information about the links between the person's illness and their own personal behaviour and risk factors has the potential to catalyze a motivational shift in some individuals. Encouraging smoking cessation among patients with mental illnesses may have additional benefits beyond improvements in physical health [29].

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# **APPENDIX 2**

Coronary heart disease risk reduction intervention among overweight smokers with a

psychotic disorder: pilot trial

# Coronary heart disease risk reduction intervention among overweight smokers with a psychotic disorder: pilot trial

Amanda Baker, Robyn Richmond, David Castle, Jayashri Kulkarni, Frances Kay-Lambkin, Rebecca Sakrouge, Sacha Filia, Terry J. Lewin

**Objective:** The aim of the present pilot study was to test the feasibility and short-term impact of a multi-component risk factor intervention for reducing (i) coronary heart disease (CHD) risk; (ii) smoking; and (iii) weight among smokers with psychosis. Secondary dependent variables included physical activity, unhealthy eating, substance use, psychiatric symptomatology, treatment retention, general functioning, and quality of life. **Method:** This was a feasibility study utilizing a pre-post-treatment design with no control group (n = 43). All participants provided written informed consent and were assessed before treatment and again a mean of 19.6 weeks later. The treatment consisted of nine individual 1 h sessions of motivational interviewing and cognitive behaviour therapy plus nicotine replacement therapy, in addition to treatment as usual. Research assistants who had not been involved in the delivery of the treatment programme conducted post-treatment assessments.

**Results:** The intervention was associated with significant reductions in CHD risk scores, smoking and weight. A significant improvement was also reported in level of moderate physical activity, and a small change in the unhealthy eating index was reported. No improvement in biological measures (cholesterol and blood pressure) was evident.

**Conclusions:** A multi-component CHD risk factor intervention among smokers with psychosis appears to be feasible and effective in the short-term. A randomized controlled trial replicating and extending these findings is warranted.

**Key words:** coronary disease, intervention studies, lifestyle, psychotic disorders, smoking cessation.

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Epidemiological research indicates that the life expectancy for people with schizophrenia and other

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psychotic disorders is approximately 20 years less

than their age-matched counterparts in the general

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population [1]. Mortality rates due to coronary heart disease (CHD) among people with psychotic disorders are around twice that seen in the general population [1]. The leading cause of excess death among people using mental health services in Australia is CHD [2], with at least one-third of people with schizophrenia also experiencing a coronary heart condition [3]. Internationally, CHD occurs more frequently and accounts for more premature deaths than suicide among people with schizophrenia [4]. People with schizophrenia also have much higher rates of CHD risk factors such as obesity, dyslipidaemia, hypertension, diabetes and smoking, and less access to medical care than people without schizophrenia [5]. The use of some antipsychotic medication has a documented association with CHD risk factors, such as weight gain, glucose and lipid abnormalities and cardiac side-effects [1,5]. The exact nature of this interaction is not clear, but given the very high prevalence of high-fat, low-fibre diets, lack of exercise and smoking among people with severe mental disorders, it has been argued that these unhealthy behaviours are the likely causes of the majority of CHD among this group of people, irrespective of medication and socioeconomic deprivation [6]. Unhealthy lifestyles and lower CHD knowledge provide a focus for more comprehensive CHD interventions among people with severe mental disorder [6]. Problematic alcohol and other drug (AOD) use is also highly prevalent among people with severe mental disorders, contributing to overall CHD risk, and it has been recommended that problematic AOD use should be assessed and managed along with other CHD risk behaviours [7].

Given that a large number of these CHD risk factors have an environmental origin [8], it is arguable that they may respond to psychological intervention. Practice guidelines on the management of psychotic disorders recommend that clinicians can play an important role in screening for CHD risk factors, and that attention should be paid to these secondary conditions as well as to treatment for mental health problems [1,5]. Unfortunately, CHD risk factors remain poorly detected and treated among people with psychotic disorders [9]. Lifestyle-type interventions with this group have typically not been as aggressively addressed as their complex psychiatric problems, despite the enormous impact of these factors on health and well-being, long-term morbidity/mortality and treatment compliance [5]. A small body of research, however, is beginning to emerge, suggesting that the psychological treatment of some of these risk factors may be feasible and

effective. For example, interventions for smoking [10–12], weight loss [13–15] and physical activity [16] have been developed and implemented. While some experts argue that trying to stop smoking, change diet and increase the amount of physical activity might result in a patient failing all three [10], a recent Cochrane review concluded that an increased focus on improving several lifestyle activities can assist a person to stop smoking [11].

The present pilot study aimed to test the feasibility and short-term impact of a multi-component risk factor intervention for reducing (i) CHD risk; (ii) smoking; and (iii) weight, among smokers with psychosis. Secondary dependent variables included physical activity, unhealthy eating, substance use, psychiatric symptomatology, treatment retention, general functioning, and quality of life.

# Methods

#### Participants and procedure

This was a feasibility study, utilizing a pre-post-treatment design with no control group. Participants were 43 smokers with a nonacute psychotic disorder who were recruited from Sydney and the Newcastle region of New South Wales, and Melbourne, Victoria, Australia. Referrals were received from community health agencies, general practitioners, and psychiatric rehabilitation services. Inclusion criteria were: (i) aged  $\geq 18$  years; (ii) smoking at least 15 cigarettes per day; (iii) body mass index (BMI)  $\geq 27$ ; and (iv) an ICD-10 diagnosis of a psychotic disorder. Exclusion criteria were (i) medical conditions that would preclude treatment (with nicotine replacement therapy (NRT) or overall; e.g. uncontrolled diabetes) and (ii) brain injury.

All participants provided written informed consent and were assessed before treatment and again a mean of 19.6 weeks later. The treatment consisted of nine individual 1 h sessions of motivational interviewing (MI) and cognitive behaviour therapy (CBT) plus NRT, in addition to treatment as usual. A letter was sent to the participant's general practitioner, case manager and/or treating psychiatrist to notify them of the involvement of their patient. Treatment sessions were conducted at the research centre or, if the subject preferred, at their local community clinic. The pre-treatment assessment session was of 1.5-2 h duration and the post-treatment assessment session lasted approximately 1 h. Research assistants who had not been involved in the delivery of the treatment programme conducted post-treatment assessments. Participants were reimbursed \$AUD20 for their time, travel and participation on each assessment occasion. This research was approved by relevant regional and university ethics committees.

## **Diagnostic measures**

Diagnosis was determined using the Diagnostic Interview for Psychosis (DIP) [12], a semi-structured interview that confirms diagnosis using the Operational Criteria for Psychosis [13] and produces a diagnostic classification in accordance with ICD-10. In addition to providing a clinical diagnosis, the DIP gathered information on sociodemographic characteristics, premorbid adjustment, current symptoms and medication and social functioning.

# Outcome measures: primary dependent variables

# Coronary heart disease risk

Estimated CHD risk scores were derived using the modified Framingham risk score [14] and an age- and sex-specific percentile score derived from the 1989 Risk Factor Prevalence Survey conducted by the National Heart Foundation [15]. Percentile scores >80 indicate higher CHD risk relative to other Australians of a similar age and gender who do not have those risk factors.

# Smoking

Outcome measures were: continuous abstinence; point prevalence abstinence; number of cigarettes smoked per day; and smoking reduction status (whether or not the participant had reduced their daily consumption of cigarettes by  $\geq$  50%, including abstinence) relative to baseline. Continuous abstinence refers to the proportion of participants who reported not smoking at all from the nominated quit date to the post-treatment assessment point. Point prevalence abstinence refers to the proportion of participants who had been abstinent for the 7 days preceding the follow-up assessment [16]. Current abstinence from smoking was confirmed using a Micro 11 Smokerlyser (Air-Met Scientific Pty. Ltd., Melbourne, Victoria, Australia), which assesses breath levels of carbon monoxide (CO). A CO level <10 p.p.m. signified that the participant was unlikely to have smoked in the last 8 h. Nicotine dependence was measured by the Fagerstrom Test for Nicotine Dependence [17], in which scores range from 0 to 10, with scores >3 suggesting dependence. Nicotine withdrawal symptoms were measured using the Minnesota Withdrawal Scale [18], with higher scores indicating greater withdrawal symptoms. Additional questions on smoking history were also included.

# Weight

Measures were: weight in kg (participants wore light indoor clothing, without shoes for measurement, with no adjustment to weight measures for clothing); BMI (calculating weight and height using standard methods); waist and hip circumference and ratio; and the perceived impact of weight, using the Impact of Weight on Quality of Life scale (IWQOL-lite) [19].

# Outcome measures: secondary dependent variables

#### *Physical activity*

Participants were asked two questions about physical activity from the Smoking, Nutrition, Alcohol and Physical Activity guidelines [20]: number of times the person engaged in 20 min of vigorous physical activity and 30 min of moderate physical activity per week. A total activity score for each participant was calculated by adding the number of times per week each participant had exercised according to the categories of vigorous and moderate physical activity. A score of  $\geq$ 5 occasions of exercise per week was categorized as adequate.

# Unhealthy eating

An overall unhealthy eating index was created, with 1 point given for an answer to each question that indicated unhealthy eating habits. The index ranged from 0 to 12, with higher scores indicating more unhealthy eating habits. Unhealthy eating habits included: non-optimal serves per day of each of the five food groups (e.g. fruit, vegetables, breads, lean meats, and dairy); high-fat or highsugar foods; choosing non-wholegrain products; consumption of full-sugar soft drinks or cordials; missing breakfast; adding salt to food; using full-fat dairy products; and consuming meat with visible fat.

# **Biological** measures

Blood pressure, blood cholesterol, and blood sugar levels were measured. In two sites these measures were collected by a pathology laboratory and analysed. In the other two sites the therapists administered these tests using an Omron Automatic Blood Pressure Monitor (Omron electronics, Sydney, New South Wales, Australia), and finger-prick blood tests for blood sugar and cholesterol.

## Alcohol, cannabis and other substance use

Levels of alcohol consumption and cannabis use were assessed in relation to the month prior to interview via the Opiate Treatment Index [21]. Alcohol consumption was classified as 'hazardous' if it exceeded recommended guidelines for drinking (on average no more than four standard drinks for men and two for women per day). The number of caffeinated drinks per day was also recorded.

# Psychiatric symptomatology and quality of life

Psychiatric symptomatology was assessed using the 24-item Brief Psychiatric Rating Scale [22] and the Beck Depression Inventory II [23]. General functioning was measured using the 12-item Short Form survey (SF-12) [24], which produces Mental Component Scores (MCS) and Physical Health Component Scores (PCS), with lower scores indicating greater disability.

# Therapy

The MI, CBT and NRT intervention was delivered individually to participants by a trained therapist, who followed a treatment manual. Regular supervision with a psychologist was provided. Up to 42 mg of NRT was provided per day as per the protocol described by Hughes *et al.* [25]. The intervention consisted of six weekly sessions of 1 h duration followed by three booster sessions at fortnightly intervals (nine sessions in total). An outline of the content of each session is provided in Table 1.

## Statistical analysis

Data were analysed using SPSS for Windows (version 14.0; SPSS, Chicago, IL, USA). Paired t-tests were used to examine the difference from before to after treatment. A small number of regression analyses were also conducted to examine the contribution of treatment and illness factors to change scores on the primary outcome measures. Because this was a small pilot study, no adjustments were made for the number of statistical tests conducted.

# Results

# Subject characteristics

Figure 1 shows the recruitment and attrition profile for the project. There were 60 referrals of whom 48 people (80.0%) were recruited into the study. Five people did not complete the post-treatment assessment and were not included in the analysis. The final sample consisted of 43 participants. The mean age of subjects was 36.3 years, just over half were male (58%), and most were single and had never married (81%). Twenty-eight per cent were employed full time or part-time and 90% received welfare support.

The most common diagnoses were schizophrenia (53.5%) or schizoaffective disorder (25.6%), followed by bipolar disorder (13.9%) and non-organic psychotic syndrome (7%). All participants had experienced more than one episode of psychotic disorder as follows: multiple episodes, good recovery (18.6%); multiple episode, minimal recovery or deterioration (32.6%); chronic course with little deterioration (11.6%); and chronic course with clear deterioration (37.2%).

Differences between the participants who completed all nine sessions of the treatment programme (n = 36) and those who completed fewer sessions (n = 7) were analysed. There were no significant differences between groups on key demographic variables except for gender, with significantly more men (n = 24, 96.0%) completing treatment than women (n = 12, 66.7%;  $\chi^2_{(1)} = 6.61$ , p < 0.01). On average, non-completers had attended two sessions (SD = 2.3, range = 0–5).

#### **Primary outcomes**

#### Coronary heart disease risk

There was a significant reduction in overall CHD risk percentile scores (Table 2).

#### Smoking

The mean age of commencing daily smoking was 17.1 years (SD = 4.7), with an average of 2.8 (SD = 1.5) serious quit attempts. Two participants were using NRT on entry to the study. At post-treatment assessment 11.6% of the sample reported being continuously abstinent from their quit date and 18.6% had been abstinent in the week prior to post-treatment assessment. Table 2 shows significant reductions in smoking in terms of cigarettes per day, level of dependence and expired carbon monoxide. Almost half of the sample (48.8%) reduced their smoking by at least 50%; 34.9% reduced their smoking by <50% and 16.3% showed no

Table 1. Outline of healthy lifestyle intervention

Session	Content				
1	MI with feedback from initial assessment, decisional balance, identification of concerns regarding smoking, goal setting, outline of treatment plan, and self-monitoring homework assignment.				
2	Activity planning, identification of high-risk situations for target behaviours (e.g. smoking, unhealthy eating, lack of exercise), planning a quit date, coping with urges, information about withdrawal symptoms, supply of NRT, homework assignment.				
3	Reinforcement of quit attempt and behaviour changes, review strategies for coping with cravings, engaging support person, education regarding healthy eating and shopping on a budget, supply of NRT.				
4	Identifying unhelpful thoughts, cognitive restructuring, and supply of NRT.				
5	Development of personal skills (i.e. relaxation and problem solving), education on takeaway foods, supply of NRT.				
6	Individual coping skills e.g. coping with psychotic symptoms, stress and anger management, assertiveness skills (cigarette and food refusal), and supply of NRT (2 weeks).				
7	Development of relapse prevention plan, discussion about tapering NRT, supply of NRT (2 weeks).				
8	Review relapse prevention plan, monitor and reward achievement, plan for continued use of NRT and budgeting, foreshadow termination.				
MI, motivational interviewing, NRT, nicotine replacement therapy.					



Figure 1. Recruitment and attrition profiles.

change in their smoking or worse smoking. Self-reported withdrawal symptoms reduced significantly from before treatment (mean = 15.0, SD = 7.8) to after treatment (mean = 12.7, SD = 7.7;  $t_{(42)} = 1.67$ , p =0.02). Likewise, observed withdrawal symptoms also reduced significantly from before treatment (mean = 3.4, SD = 3.3) to after treatment (mean = 2.4, SD = 2.6;  $t_{(40)} = 2.54$ , p = 0.02).

#### Weight

As shown in Table 2 there were significant reductions from before to after treatment in weight, waist circumference, and in scores on the IWQOL-lite. There was no significant change in BMI (Table 2) or in participants' waist/hip ratio (before treatment: mean =0.98, SD =0.08; after treatment: mean =0.97, SD =0.97;  $t_{(40)} = 1.61$ , p = 0.12). Overall, approximately half of the sample achieved some weight loss, with 32.6% achieving a reduction of <5% of their pretreatment weight and 20.9% achieving a reduction of at least 5%.

#### Secondary outcomes

#### Nutrition

There was a small non-significant improvement in the overall unhealthy eating index score (Table 2).

# Physical activity

There was a significant increase in levels of physical activity as measured by the total activity score (before treatment: mean = 3.3, SD = 2.4; after treatment: mean = 4.8, SD = 3.3;  $t_{(42)} = -3.21$ , p <0.01). The increase was evident in levels of moderate physical activity (before treatment: mean = 2.4, SD = 2.3; after treatment:

Table 2. Outcomes on continuous measures $(n = 43)$						
Maaauwa	Before treatment	After treatment				
(n - 35)	Mean (SD, range)	Mean (SD, range)	t-test scores			
Overall CHD risk score	74.3 (23.6, 14.0–100.0)	63.8 (29.1, 10.0–100.0)	$t_{(34)} \!=\! 3.58,  p < \! 0.001$			
Smoking						
Cigarettes day <sup>-1</sup>	30.8 (12.5, 15.0–60.0)	17.2 (14.8, 0.0–55.0)	t <sub>(42)</sub> =7.96, p <0.001			
Cigarettes day <sup><math>-1</math></sup> (n =35)	32.8 (12.7, 15.0–60.0)	21.1 (13.7, 3.0–55.0)	t <sub>(34)</sub> =6.19, p <0.001			
(excluding abstainers at post-treatment assessment)						
Level of dependence (FTND)	7.9 (1.7, 4.0–10.0)	4.7 (3.3, 0.0–10.0)	t <sub>(42)</sub> =6.95, p<0.001			
Carboxymeter (CO p.p.m.) (n = 38)	21.8 (7.9, 5.0-42.0)	17.1 (12.9, 1.0–60.0)	t <sub>(37)</sub> =2.37, p=0.02			
Weight						
Weight (kg)	101.0 (17.7, 68–153)	99.2 (17.4, 60.0–152.0)	t <sub>(42)</sub> =2.57, p=0.01			
Waist circumference (cm)	113.1 (12.6, 88–144)	111.2 (12.5, 86–111.2)	$t_{(40)} = 2.07, p = 0.05$			
BMI	33.9 (26.8–50.1)	33.3 (24.3-48.3)	t <sub>(42)</sub> = 1.39, p = 0.17			
IWQOL-lite (n = 40)	66.7 (28.0, 31–134)	57.8 (22.4, 31.0–111.0)	t <sub>(39)</sub> =3.89, p<0.001			
Physical activity						
Total exercise score	3.3 (2.4, 0.0-8.0)	4.8 (3.3, 0.0–14.0)	t <sub>(42)</sub> =-3.21, p <0.01			
Vigorous exercise per week(n)	0.8 (1.3, 0.0-4.0)	1.3 (2.1, 0.0–7.0)	t <sub>(42)</sub> =-1.17, p =0.25			
Moderate exercise per week(n)	2.4 (2.3, 0.0–7.0)	3.4 (2.4, 0.0–10.0)	t <sub>(42)</sub> =-3.67, p <0.001			
Unhealthy Eating Index	7.5 (2.2, 3.0–12.0)	7.3 (2.2, 2.0–11.0)	t <sub>(42)</sub> =0.60, p=0.55			

BMI, body mass index; CHD, coronary heart disease; FTND, Fagerstram Test for Nicotine Dependence; IWQOL-lite, Impact of Weight on Quality of Life scale; MI, motivational interviewing; NRT, nicotine replacement therapy.

mean = 3.4, SD = 2.4;  $t_{(42)} = -3.67$ , p < 0.001), as opposed to vigorous activity levels (before treatment: mean = 0.84, SD = 1.3; after treatment: mean = 1.3, SD = 2.1;  $t_{(42)} = -1.17$ , p = 0.25).

#### Substance use

There were no significant reductions in alcohol consumption (before treatment: mean = 1.4, SD = 3.5; after treatment: mean = 1.0, SD = 1.9;  $t_{(38)} = 1.25$ , p = 0.22); cannabis use (before treatment: mean = 0.92, SD = 3.0; after treatment: mean = 1.4, SD = 4.4;  $t_{(42)} = 0.16$ , p = 0.159), nor consumption of caffeinated drinks (before treatment: mean = 7.1, SD = 4.7; after treatment: mean = 6.3, SD = 4.2;  $t_{(43)} = 1.08$ , p = 0.29).

# Biological measures (blood sugar and cholesterol)

There were no significant changes in blood sugar from before to after treatment: 32.6% were at <4.4 mmol and 53.5% between 4.4 mmol and 8 mmol before treatment, with corresponding figures of 23.3% and 65.1% after treatment. Likewise, cholesterol levels did not show a significant change: 72.1% had a cholesterol level  $\leq$  5.5 mmol before treatment and 18.6% had a cholesterol level >5.5mmol; and after treatment 65.1% had a cholesterol level of  $\leq$  5.5 mmol and 20.9% had a cholesterol level >5.5 mmol.

#### *Psychopathology*

There were no significant before–after changes in SF-12 general functioning (MCS: from mean =40.8, SD =11.6 to mean =43.6, SD =13.3,  $t_{(42)} = -1.54$ , p =0.13; PCS: from mean =45.5, SD =9.7 to mean =45.4, SD =10.4,  $t_{(42)} = 0.13$ , p =0.89), nor any change in levels of depression (from mean =14.2, SD =9.5 to mean =14.3, SD =12.6,  $t_{(42)} = -0.06$ , p =0.96) or psychotic symptoms (from mean =40.7, SD =13.2 to mean =41.9, SD = 12.2,  $t_{(42)} = -0.67$ , p =0.51).

#### Contribution of treatment and illness factors to change

As a preliminary investigation of the potential factors influencing change, we examined associations between treatment completion, course of illness and the primary outcome measures, while controlling for gender, level of depression and substance abuse. There were no significant associations with change in CHD risk scores or number of cigarettes smoked per day. Two variables were significantly associated with weight loss: treatment completion status (partial correlation = -0.41, p = 0.01) and course of psychotic disorder (partial correlation = 0.38, p = 0.02). Participants who had not completed treatment lost an average of 5.41 kg, compared to an average loss of 1.1 kg among those who completed treatment. Course of psychotic disorder was associated with greater weight loss, averaging 3.23 kg among those with a chronic illness with clear deterioration, 2.1 kg among those with a chronic condition but little deterioration, 1.5 kg among those with multiple episodes and partial recovery between episodes, and an average gain of 0.7 kg among those with good recovery between episodes.

# Discussion

The major finding of the present study was that a multi-component CHD risk factor intervention consisting of MI/CBT and NRT among smokers with a psychotic disorder was associated with significant reductions in CHD risk scores, smoking and weight. A significant improvement was also reported in level of moderate physical activity, and a small change in the unhealthy eating index was reported. These findings are consistent with the view that behaviour change across several domains is possible [11], including among people with psychotic disorders. But no improvement in biological measures (cholesterol and blood pressure) was evident and a longer follow-up period may be needed to gauge changes in these measures.

Smoking results were comparable to or better than our previous smoking cessation treatment [26]. In the present study, at post-treatment assessment 11.6% of the sample reported being continuously abstinent from their quit date, 18.6% had been abstinent in the week prior to post-treatment assessment and 48.8% reported reducing their smoking by at least half. In the previous study, at post-treatment assessment the continuous abstinence rate for the treatment condition was 10.9% whereas for point prevalence abstinence it was 15.0%, while 43.5% of the sample reduced their smoking by at least half [26]. The reduction in the number of cigarettes smoked per day in the present study (from a mean of 31 cigarettes  $day^{-1}$  to a mean of 17 cigarettes day $^{-1}$ ) compares favourably with the previous study (from a mean of 31 cigarettes day<sup>-1</sup> to a mean of 23 cigarettes day<sup>-1</sup> among the treatment condition subjects), and may be associated with the monitoring of nicotine withdrawal symptoms and the flexible delivery of NRT, as well as the more holistic lifestyle focus of the intervention.

The number of participants who completed all intervention sessions (n = 36/43, 83.7%) suggests that the intervention represents a feasible approach to improving lifestyle and reducing CHD among people with psychosis. Further, the absence of any worsening in psychiatric symptomatology suggests that this type of lifestyle intervention and associated behaviour changes is tolerable among people with a psychotic illness. Interestingly, more men completed the interventions may be especially appealing to men. Those who discontinued the intervention prematurely, however, were more likely to have lost weight than those who continued, possibly suggesting that this subgroup gave a higher priority to weight loss

than to broader lifestyle interventions. Chronicity of illness course was also associated with greater weight loss, but not with a greater reduction in smoking, possibly indicating that those with a more chronic course had rarely been targeted for broader lifestyle interventions. Alternatively, a stepped care approach may be more suited to this subgroup, addressing weight first, and building upon this success with other behaviour changes as acceptable to the individual.

Because this was a pilot study of the feasibility of a multi-component CHD risk factor intervention, there are several methodological limitations of the study, including the absence of a control group and no longer-term follow up. To our knowledge, however, this is the first study among people with psychosis with multiple risk factors for CHD, including smoking and weight, to demonstrate the effectiveness of such an intervention. A randomized controlled trial, extending the length of this intervention in order to encourage further dietary changes, and comparing this intervention with a control condition, is warranted.

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# **APPENDIX 3**

Healthy lifestyle intervention for people with severe mental disorders
# Healthy lifestyle intervention for people with severe mental disorders

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Cardiovascular disease (CVD) is the largest single cause of death among people with severe mental disorders, such as schizophrenia and bipolar disorder. Smoking rates are very high among people with severe mental disorders, considerably increasing their risk of CVD. In addition, many people with such disorders also suffer from obesity related to inactivity, unhealthy diets, excessive alcohol consumption and some psychiatric medications. Despite increasing recognition of the widespread impact that smoking and other unhealthy behaviours have on increased morbidity and mortality, treatment of physical health problems is often neglected among people with severe mental disorders. Research evaluating interventions seeking to change multiple health behaviours indicates that these are feasible and effective. In this context, studies evaluating the effectiveness of a multi-component healthy lifestyle intervention for smoking and CVD risk behaviours among people with severe mental disorders are needed. A healthy lifestyles intervention is described.

Keywords: cardiovascular disease; severe mental disorder; randomised controlled trial

#### Cardiovascular disease in the general population and among mental health service users

In Australia in 2007, the most common cause of death for males was cancer and other tumours, followed by cardiovascular disease (CVD) and respiratory system diseases (Australian Institute of Health and Welfare [AIHW], 2010). For females, CVD was the most common cause of death, followed by cancer and other tumours, and respiratory system diseases (AIHW, 2010). Apart from pneumonia and influenza, the group of CVDs accounted for 54% of all male deaths and 59% of all female deaths (AIHW, 2010). The death rate of consumers of mental health services in Australia has been reported as 2.5 times that of the general population, with the greatest number of excess deaths being from CVD (Lawrence, Holman, & Jablensky, 2001). The latter study also noted that people who used mental health

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services had high rates of physical illnesses that are often undiagnosed, leading to lower hospital admission rates and, correspondingly, higher unnecessary deaths (Lawrence et al., 2001).

#### Health determinants of disease

Health determinants of disease can be considered in four broad groups, from 'upstream' background factors encompassing:

- (1) the broad features of society (e.g. culture and systems) and environmental factors
- (2) socioeconomic status (e.g. education and affluence) and knowledge, attitudes and beliefs
- (3) health behaviours (e.g. smoking, alcohol and other drug (AOD) consumption, physical activity, dietary behaviour, sexual behaviours and vaccination behaviours) and psychological and safety factors
- (4) biomedical factors (weight, blood pressure, blood cholesterol, glucose regulation and immune status) (AIHW, 2010).

Often, people have multiple risk factors, associated with greater risk for a particular disease and greater overall risk of ill health (AIHW, 2010) due to their interactive effect (AIHW, 2005a). For example, the presence of multiple risk factors leads to development of atherosclerosis, with more risk factors resulting in a worsening of arteries and reduced life expectancy with greater health care costs (AIHW, 2005a).

Smoking, poor diet, physical inactivity and alcohol misuse are the main behavioural risk factors for CVD (AIHW, 2010). The likelihood of having a cardiovascular event (such as a stroke or coronary event) over a given period of time (referred to as absolute risk) increases with the presence of multiple risk factors (National Heart Foundation of Australia, 2003). A prospective population study of 20,224 men and women aged 45–79 years with no known CVD or cancer at baseline, followed up for an average of 11 years found that these four health behaviours combined predicted a 4-fold difference in mortality, with an estimated impact of reduced life expectancy of 14 years (Khaw et al., 2008).

#### Multiple unhealthy behaviours in people with severe mental disorders

People with schizophrenia and bipolar disorder have much higher rates of CVD risk factors, such as obesity, dyslipidaemia, hypertension, diabetes and smoking, and less access to medical care than people without schizophrenia (Hennekens, 2007; Kilbourne et al., 2008). Additionally, the use of some antipsychotic medication has a documented association with some CVD risk factors, such as weight gain, glucose and lipid abnormalities and cardiac side effects (McDermott et al., 2005; Weiss et al., 2006). The exact nature of these effects is not clear. However, given the very high prevalence of high fat, low-fibre diets, excessive alcohol consumption, lack of exercise and high rates of smoking among people with severe mental disorders, it has been argued that these unhealthy behaviours are the likely causes of the majority of CVD among people with such disorders, irrespective of medication and socio-economic deprivation (Osborn, Nazareth, & King, 2007). This unhealthy lifestyle, compounded by a lower level of knowledge regarding CVD risk factors than in the general population provides a focus

for comprehensive CVD interventions among people with severe mental disorder (Osborn et al., 2007). In addition, AOD abuse is highly prevalent among people with severe mental disorders and contributes to the overall CVD risk. It has been recommended that AOD use should be managed along with other CVD risk behaviours (Barnett et al., 2007; Bobes, Arango, Garcia-Garcia, & Rejas, 2010). We now review the prevalence of these risk behaviours among people with severe mental disorders and detail therapeutic approaches to these problematic behaviours.

#### Smoking among people with severe mental disorders

Smoking is a major CVD risk factor. In a large epidemiological Australian study of people with psychosis (Jablensky et al., 2000), 73% of males and 56% of females were current smokers; rates in the general Australian population are lower than 20% (18% for men and 15% for women) (AIHW, 2010). Higher rates of smoking among people with mental disorders are reported internationally, and remain after controlling for a range of socioeconomic factors (McDermott et al., 2005). Rates of smoking among the general community have declined significantly over the past 20 years, due to successful public awareness campaigns and legislation (AIHW, 2005b). However, people with severe mental disorders do not seem to have benefitted from these general approaches (Baker et al., 2006a). Efforts to encourage people with severe mental disorders not to smoke have been largely rudimentary (Williams & Ziedonis, 2004), and the tobacco industry has targeted marketing to this disadvantaged group (Chapman & Balmain, 2004).

#### Obesity among people with severe mental disorders

Studies indicate that some 60% of those with severe mental disorders are overweight or obese compared to 35% in the general population (Allison, Mackell, & McDonnell, 2003; Taylor & McAskill, 2000). Obesity places people with psychotic disorders at increased risk for adverse cardiovascular events and also impacts negatively on body image and quality of life, which may, in turn, contribute to medication non-adherence and depression (Tham, Jones, Chamberlain, & Castle, 2007). In addition to weight gain, however, the risks of metabolic disturbances in glucose regulation and hyperlipidaemia, especially from the newer atypical antipsychotics, may contribute to metabolic syndrome that greatly increases the risk of developing CVD and diabetes (Newcomer, 2007).

#### Poor diet among people with severe mental disorders

People with severe mental disorders also have been shown often to make ill-informed decisions about their dietary habits (Brown, Birtwistle, Roe, & Thompson, 1999; McCreadie, 2003; Weiss et al., 2006). Typically, people with psychosis have diets that are high in fats and low in fibre, carbohydrates and proteins (Henderson et al., 2006).

#### Physical inactivity among people with severe mental disorders

The adoption of a sedentary lifestyle is also a common feature in the lives of people with psychosis (Henderson et al., 2006). Very few people with psychosis report regular moderate-vigorous physical activity, and many report low levels of mobility

in everyday life (Beebe et al., 2005). People with schizophrenia score significantly lower on physical activity and fitness measures relative to the general community and to people with other mental disorders (Beebe et al., 2005).

#### Excessive alcohol consumption among people with severe mental disorders

Excessive alcohol consumption is a major risk factor for a variety of health problems, such as stroke, coronary heart disease, high blood pressure, some cancers and pancreatitis (Irving, Samokhvalov, & Rehm, 2009; World Health Organization, 2002). Data from the Australian Survey of Low Prevalence Disorders indicate that among people with psychotic disorders, the prevalence of alcohol use disorders is 36% among men and 17% among women. The figures for drug use or dependence are 38% for men and 16% for women (Jablensky et al., 2000).

#### Need to address CVD risk behaviours

Given that a large number of these CVD risk factors have an environmental origin (Brown et al., 1999), it is arguable that they may respond to psychological interventions. Practice guidelines on the management of psychotic disorders (Weiss et al., 2006) recommend that clinicians can play an important role in the screening for CVD risk factors, and that attention should be paid to these 'secondary' conditions as well as to treatment for mental health problems (McDermott et al., 2005). Unfortunately, clinical practice has not kept pace with these recommendations, and CVD risk factors remain poorly detected and treated among people with severe mental disorders (Kumar, 2004), in part at least due to the professional separation of mental and physical health care (Kilbourne et al., 2008). Lifestyle-type interventions with this group have typically not been as aggressively addressed as their complex psychiatric problems, despite the enormous impact of these factors on health and wellbeing, long-term morbidity/ mortality and treatment compliance (McDermott et al., 2005). However, an important body of research is beginning to emerge, suggesting that behavioural interventions for these CVD risk factors may be feasible and effective, singly or together.

#### Smoking cessation interventions among people with severe mental disorder

Recently, Banham and Gilbody (2010) reviewed the evidence for smoking cessation interventions in severe mental disorders, reporting on the primary outcome of smoking cessation as well as secondary outcomes of smoking reduction, change in weight, change in psychiatric symptoms and adverse events. Eight randomised controlled trials of pharmacological and/or psychological interventions were included in the review. The authors concluded that treating tobacco dependence in people with severe mental disorders is effective, with most interventions showing moderate-positive results without worsening of mental state and few adverse events. As only one trial reported change in weight in trial participants, it was recommended that subjects should be assessed for weight change in smoking cessation trials.

#### Weight reduction and dietary intervention among people with severe mental disorders

Although few studies of interventions for obesity have specifically involved people with psychiatric disorders, there is accumulating evidence to suggest that

behavioural interventions can be successful in at least modest weight reduction. For example, a small pilot study of diet and exercise therapy among obese people with schizophrenia showed good participation rates and encouraging benefits in terms of fitness and tolerance to physical activity (Ryan & Thakore, 2002). A randomised controlled trial conducted with older people with schizophrenia and comorbid diabetes (aged 40 or more years) developed and tested a group-based lifestyle intervention comprising education about diabetes and behaviour change strategies associated with healthy food choices and increasing activity levels (McKibbin et al., 2006). Participants showed significant improvements in diabetes knowledge and selfreported physical activity, indicating the potential for this approach among people with psychosis. In Australia, six individual sessions of nutrition education were successful in preventing olanzapine-induced weight gain (Evans, Newton, & Higgins, 2005). Recently, it has been reported that simple behavioural programmes involving teaching of shopping and preparing healthy food can produce lasting weight loss among people with schizophrenia (Jean-Baptiste et al., 2007). Treatment group participants reported significant weight reductions and improvements in physical activity levels, quality of life, health and body image. Kilbourne et al. (2008) recently reported the results of a randomised controlled trial among veterans with bipolar disorder, in which four self-management sessions on behaviour change related to CVD risk factors significantly ameliorated perturbation of physical health-related quality of life compared to usual care.

#### Alcohol intervention among people with severe mental disorders

Recently, Baker, Thornton, Hiles, Hides and Lubman (2010) reviewed the literature on treatment of alcohol misuse among people with psychotic disorders. The review included 10 randomised controlled trials evaluating either service provision or manualised psychological interventions. Collectively, these studies suggested that problem drinking is responsive to high quality service provision with low staff to client ratios and also to specific psychological treatments. An assertive approach was associated with longer stay in residential treatment. Contingency management was related to a significant reduction in alcohol consumption in one study. In terms of psychological interventions, assessment, brief motivational interventions and longer duration cognitive behaviour therapy (up to 10 sessions) were each associated with reductions in alcohol consumption. Additional benefits of longer (10 session) over brief intervention were seen for people with psychosis on ratings of depression, functioning and alcohol outcomes.

#### Smoking and weight-related behavioural interventions

Although some experts have argued that trying to stop smoking, change diet and increase the amount of physical activity might result in a client failing in all three (McEwen, Hajek, McRobbie, & West, 2006), a recent Cochrane review concluded that targeting several lifestyles activities together can assist a person to stop smoking (Ussher, Taylor, & Faulkner, 2008). Recently, Spring et al. (2009) reviewed the efficacy of behavioural weight control interventions also encompassing smoking cessation attempts, on post-cessation weight gain among smokers in the general community. Ten randomised controlled trials were included in the analysis. There was no evidence of any harm through combining smoking treatment and

behavioural weight control procedures and there was evidence of significant shortterm benefit for smoking cessation and weight control. In the longer term, the timelimited interventions evaluated did not appear to be associated with either benefit or harm. Spring et al. suggested that there may be a need to extend the duration of treatment for longer term benefits to be seen.

#### Smoking and alcohol interventions

In a review of tobacco cessation interventions among people with problematic alcohol use, Kalman, Kim, DiGirolamo, Smelson, and Ziedonis (2010) revealed that only a small proportion of smokers (5%) in alcohol treatment programmes considered smoking an important strategy for coping with urges to drink, and that smoking cessation did not increase urges to drink. The authors concluded that a large body of evidence existed to indicate that treatment for smoking cessation did not jeopardise alcohol or other non-nicotine drug outcomes, and in fact improved these outcomes across numerous trials. The need for trials integrating tobacco and alcohol-based strategies was emphasised, along with the need to consider the treatment of tobacco dependence in the same manner as other chronic relapsing conditions such as depression and diabetes, with smokers offered long-term treatment options and extended use of pharmacotherapy (Kalman et al., 2010).

#### Pilot study of healthy lifestyles intervention

Following a randomised controlled trial of smoking cessation treatment among people with severe mental disorders (Baker et al., 2006b), we aimed to develop and evaluate a more holistic approach to smoking cessation and other lifestyle factors related to CVD. The experience we have gained from our pilot programme (described below) showed that setting a variety of goals and assisting clients to make small steps towards these can boost motivation and self-confidence to change unhealthy lifestyle behaviour. In the first study of its kind (see Baker et al., 2009a), we developed and piloted a multi-component healthy lifestyles intervention aimed at CVD risk reduction and smoking cessation among 43 smokers with severe mental disorders. Primary dependent variables were CVD risk score and smoking. Secondary dependent variables included weight, physical activity, unhealthy eating, substance use, psychiatric symptomatology, treatment retention, general functioning and quality of life. Significant improvements in the primary dependent variables, CVD risk and smoking and secondary dependent variables weight and physical activity were found. There was also an improvement in diet although this did not reach statistical significance. The results of this pilot study show that the CVD risk factor intervention is feasible and effective in significantly reducing CVD risk and smoking among people with severe mental disorders. Excellent retention rates (84%) completed all sessions), especially among males, attested to the importance and relevance of the intervention for people with psychosis. Participant reports indicated high levels of satisfaction with the programme content, with access to nicotine replacement therapy (NRT) that is tailored to their needs, and with the opportunity to target a range of lifestyle factors that they considered important, but had hitherto been neglected. Many participants felt that they would have benefited from a longer intervention to provide scope to modify all the lifestyle issues targeted by the treatment. Other research (Hall et al., 2002) has reported that extended counselling can be significantly more effective than standard treatment, among depressed smokers. Consequently, a larger-scale randomised controlled trial, with a longer treatment period is currently underway.

#### A healthy lifestyles intervention

Participants entering the study all undergo an initial face-to-face session and are then randomly assigned either to a face-to-face manual guided intervention (Baker et al., 2009b) or to a manual guided telephone counselling control condition (Baker et al., 2009c) focussing on smoking cessation. Both groups receive, in addition, NRT. The initial session is of 90 min duration. Feedback is given to each participant comparing their behavioural and biomedical risk factors for CVD with recommended levels (e.g. number of fruit and vegetables per day; number of alcoholic drinks per day; level of activity; lipids; blood pressure). Motivational interviewing (Miller & Rollnick, 2002) concerning the person's unhealthy behaviours is conducted and goals are discussed. The content of the face-to-face healthy lifestyles intervention is outlined in Table 1 and the remaining sessions are scheduled for an hour each. Telephone sessions are scheduled for 10 min, except for sessions 4 and 8, which are conducted face to face and are of 30 minutes duration as NRT is supplied, weight is measured and other assessments are conducted. The telephone control condition participants receive the same number of sessions at the same time intervals as the healthy lifestyles intervention.

The healthy lifestyles face-to-face intervention covers smoking, diet, physical activity and alcohol consumption; and it and employs motivational interviewing (Miller & Rollnick, 2002), goal setting, cognitive-behaviour therapy and contingency management techniques. Contingency management provides session-by-session reinforcement for reductions in carbon monoxide readings and sequential reinforcement for continued reduction and reinforcement of abstinence (based on Lamb, Morral, Galbicka, Kirby, & Iguchi, 2005). After the initial session, the telephone control intervention focuses on smoking cessation. Follow-up interviews are conducted by independent interviewers in each site who are blind to intervention allocation.

#### Nicotine replacement therapy

All participants are supplied with NRT at the initial session, at sessions 4 and 8, and on a monthly basis as required. The NRT protocol is outlined in Table 2.

Although NRT product information primarily recommends use in withdrawal versus longer-term maintenance with advice to consult a pharmacist or doctor regarding continued use beyond the withdrawal period, many former smokers successfully maintain abstinence from cigarettes through longer-term use of NRT (Topp, 2008). Given that NRT has no known adverse health effects from long-term use and the clinical need for NRT beyond the withdrawal period, it is sensible to permit smokers who feel they need to use NRT for longer to do so (ASH, 2007). Whilst NRT has been found to increase abstinence rates among people with psychotic disorders (e.g. Baker et al., 2006b), relapse following a typical short course of NRT is very common and study of longer-term treatment with combination NRT and cognitive behaviour therapy has been recommended (e.g. Evins et al., 2007; Kalman et al., 2010). A systematic review and meta-analysis of the effectiveness and

Table 1. Healthy lifestyles intervention outline of sessions.

#### Week 1: Session 1 Assessment feedback and goal setting Engagement and building motivation for change Feedback from assessment Setting goals Randomisation Ground rules and outline of treatment In session assessments Contingency management Supply of NRT Week 2: Session 2 Preparing to quit smoking Review of week and homework activities Planning to quit Introduction to craving monitoring Introduction to coping with urges Devise a craving plan Identify support person Goals and homework In session assessment/Contingency management Telephone session (2-3 days after quit attempt) Monitor and congratulate Reinforcement of changes Review strategies for coping with cravings Monitor use of NRT Adjust dose of NRT if appropriate Week 3: Session 3 Review quit attempt and activity log Review of week and homework activities Review quit attempt or 50% reduction in smoking Review nicotine withdrawal Identify personal triggers and high risk situations Coping with the symptoms of psychosis Monitor use of NRT Goals and homework In session assessment/contingency management Week 4: Session 4 **Becoming more active** Review of week and homework activities Activity log Ways to increase physical activity Prospective planning of exercise Walking program Monitor use of NRT/provide further NRT Goals and homework In session assessments/contingency management Week 5: Session 5 Introduction to thought monitoring Review of week and homework activities Identification of unhelpful thoughts Practice thought monitoring

Progressive muscle relaxation

Table 1. (Continued).

Monitor use of NRT Goals and homework In session assessments/Contingency management

### Week 6: Session 6

**Cognitive restructuring** Review of week and homework activities Identifying negative thoughts Changing negative thought patterns Progressive muscle relaxation Goals and homework Monitor use of NRT In session assessments/Contingency management

#### Week 7: Session 7

#### Cognitive restructuring and healthy eating Review of week and homework activities Managing thoughts Problem solving Healthy eating/food and drink diary Progressive muscle relaxation Goals and homework Review use of NRT In session assessments/contingency management

#### Week 8: Session 8

#### Barriers to healthy eating and food planning

Review of week and homework activities Spotlight food plan Barriers to healthy eating Healthy eating-goal setting Progressive muscle relaxation Goals and homework Review of NRT/Provision of NRT In session assessments/contingency management

### Week 10: Session 9

(Fortnightly) Healthy eating and effective refusal skills Review of week and homework activities Healthy eating-progress towards goals Medication matters Learn and practice refusal skills Progressive muscle relaxation Goals and homework Review of NRT In session assessments/Contingency management

#### Week 12: Session 10 (Fortnightly)

Decision traps and emergency craving plan Review of week and homework activities Decision traps Emergency action plan Progressive muscle relaxation Goals and homework Review NRT In session assessments/contingency management Table 1. (Continued).

#### Week 14: Session 11 (Fortnightly) Relapse prevention and relapse management Review of week and homework activities Relapse prevention Then and now Developing a relapse management plan Ongoing plan for sessions Progressive muscle relaxation Goals and homework Review NRT In session assessments/contingency management 15-week assessment

#### Weeks 18 & 22: Sessions 12 and 13 Monthly booster session

Review of month and homework activities Review progress with quit/reduction or abstinence Provide feedback from 15 week assessment Review progress with increasing activity level Review progress with dietary changes Review relapse prevention/management plan Tapering of NRT/homework In session assessments/contingency management

#### Weeks 26, 30, 34 & 38: Sessions 14–17 Monthly booster session

Review of month and homework activities Review progress with quit/reduction or abstinence Review progress with increasing activity level Review progress with dietary changes Review relapse prevention/management plan Tapering and completion of NRT/homework In session assessments/contingency management

safety of NRT included trials which provided NRT for 9-, 12- and 18-months and reported serious adverse events to have occurred in fewer than 8% of participants (in no cases were these judged likely to be due to NRT) (Moore et al., 2009). Whilst no randomised controlled trials of prolonged NRT among people with psychotic disorders have been published, Williams and Foulds (2007) published a case report of a man with schizophrenia who responded well to intensive and sustained NRT and psychosocial treatment. Thus, the healthy lifestyle randomised controlled trial aims to improve the results of previous studies by providing NRT for a longer period, potentially preventing high rates of early relapse.

People with psychotic disorders tend to smoke heavily and it has been recommended that higher doses using combinations of NRT are preferable and should be combined with cessation support (McNeill, 2001). Double patching  $(2 \times 21 \text{ mg})$  has been employed among people who smoked at least 30 cigarettes a day and was associated with significantly better cessation rates than smaller doses (Hughes et al., 1999); there were no serious adverse events associated with treatment. The authors recommended that double patching be continued longer than 10 weeks as relapse was common. The healthy lifestyles study extends double patching over a 3-month period (within the context of 6 months of NRT) and allows additional use

Weeks	NRT, if smoking $\geq$ 30 cigarettes per day (cpd)
1–12 13–20 21–22 23–24 25+	$2 \times 21$ patch + up to $12 \times 2$ mg lozenges $1 \times 21$ mg patch + up to $12 \times 2$ mg lozenges $1 \times 14$ mg patch + up to $12 \times 2$ mg lozenges $1 \times 7$ mg patch + up to $12 \times 2$ mg lozenges NRT as advised from pharmacist or doctor (If < 30 cpd weeks 1–20 single patch)

Table 2. Nicotine replacement therapy (NRT) protocol for healthy lifestyles randomised controlled trial.

of the lozenge to 'top-up' baseline patch levels of nicotine to enhance the efficacy of combination therapy (Fagerstrom, Schneider, & Lunell, 1993). As reduced smoking can be associated with increased side-effects from medication (McNeill, 2001), these are monitored throughout both face-to-face and telephone interventions.

The potential benefits from this strategy focusing on healthy lifestyles among people with severe mental disorders are that the approach:

- allows sufficient time for change
- addresses multiple behaviours, permitting flexibility in goals and progress
- focuses on healthy behaviour rather than strict or rigid dietary and other regimens.

In addition to outpatient settings, a healthy lifestyles approach may be useful in inpatient, residential and AOD treatment settings.

#### Conclusion

CVD is the largest single cause of death among people with schizophrenia (Von Hausswolff-Juhlin, Bjartveit, Lindström, & Jones, 2009) and bipolar disorder (Osby, Brandt, Correia, Ekbom, & Sparen, 2001). The majority of people with schizophrenia and bipolar disorder smoke (Diaz et al., 2009), thereby increasing their risk of CVD. Many also suffer from obesity, related to inactivity, unhealthy diets and some psychiatric medications (Garcia-Portilla et al., 2009). Despite increasing recognition of the widespread impact that smoking and other unhealthy behaviours have on increased morbidity and mortality, screening for physical/ medical health issues and treatment is often neglected among people with severe mental disorders. The healthy lifestyles intervention is the first of its kind to address these issues by employing a multi-component healthy lifestyle intervention for smoking and CVD risk behaviours among people with severe mental disorders. Results from a pilot study indicate that this approach is feasible and effective in reducing CVD risk and smoking among people with severe mental disorders. Interventions evaluating the longer-term effectiveness of multi-component healthy lifestyle interventions for smoking and CVD risk behaviours among people with severe mental disorders are needed.

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# **APPENDIX 4**

Study protocol: a randomised controlled trial investigating the effect of a healthy lifestyle

intervention for people with severe mental disorders

# STUDY PROTOCOL



**Open Access** 

# Study protocol: a randomised controlled trial investigating the effect of a healthy lifestyle intervention for people with severe mental disorders

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#### Abstract

Background: The largest single cause of death among people with severe mental disorders is cardiovascular disease (CVD). The majority of people with schizophrenia and bipolar disorder smoke and many are also overweight, considerably increasing their risk of CVD. Treatment for smoking and other health risk behaviours is often not prioritized among people with severe mental disorders. This protocol describes a study in which we will assess the effectiveness of a healthy lifestyle intervention on smoking and CVD risk and associated health behaviours among people with severe mental disorders.

Methods/Design: 250 smokers with a severe mental disorder will be recruited. After completion of a baseline assessment and an initial face-to-face intervention session, participants will be randomly assigned to either a multicomponent intervention for smoking cessation and CVD risk reduction or a telephone-based minimal intervention focusing on smoking cessation. Randomisation will be stratified by site (Newcastle, Sydney, Melbourne, Australia), Body Mass Index (BMI) category (normal, overweight, obese) and type of antipsychotic medication (typical, atypical). Participants will receive 8 weekly, 3 fortnightly and 6 monthly sessions delivered face to face (typically 1 hour) or by telephone (typically 10 minutes). Assessments will be conducted by research staff blind to treatment allocation at baseline, 15 weeks, and 12-, 18-, 24-, 30- and 36-months.

Discussion: This study will provide comprehensive data on the effect of a healthy lifestyle intervention on smoking and CVD risk among people with severe mental disorders. If shown to be effective, this intervention can be disseminated to treating clinicians using the treatment manuals.

Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR) identifier: ACTRN12609001039279

#### Background

Cardiovascular disease (CVD) is the largest single cause of death among people with schizophrenia [1] and bipolar disorder [2]. The majority of people with schizophrenia and bipolar disorder smoke [3], considerably increasing their risk of CVD. Many also suffer from obesity, related to inactivity, unhealthy diets and some psychiatric medications [4]. Despite increasing recognition

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of the widespread impact that smoking and other unhealthy behaviours have on increased morbidity and mortality, treatment is often neglected among people with severe mental disorders. This randomised controlled trial of a Healthy Lifestyles intervention is the first of its kind to address these issues by employing a multi-component healthy lifestyle intervention for smoking and CVD risk behaviours among people with severe mental disorders.

The Healthy Lifestyles intervention was evaluated in a pilot program [5] which showed that setting a variety of goals, and assisting clients to make small steps towards



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these, can boost motivation and self-confidence to change unhealthy lifestyle behaviour. In that study we developed and piloted a multi-component Healthy Lifestyles intervention aimed at CVD risk reduction and smoking cessation among 43 smokers with severe mental disorders. Primary dependent variables were CVD risk score and smoking. Secondary dependent variables included weight, physical activity, unhealthy eating, substance use, psychiatric symptomatology, treatment retention, general functioning, and quality of life. Significant improvements in the primary dependent variables, CVD risk and smoking, and secondary dependent variables, weight and physical activity were found. There was also an improvement in diet although this did not reach statistical significance. The results of the pilot study suggested that the CVD risk factor intervention was feasible and effective in significantly reducing CVD risk and smoking among people with severe mental disorders. Excellent retention rates (84% completed all sessions), especially among males, attested to the importance and relevance of the intervention for people with psychosis. Participant reports indicated high levels of satisfaction with the program content, with access to nicotine replacement therapy (NRT) that was tailored to their needs, and with the opportunity to target a range of lifestyle factors that they considered important, but had hitherto been neglected. Many participants felt that they would have benefited from a longer intervention to provide scope to modify all the lifestyle issues targeted by the treatment and to consolidate gains. Other research [6] has reported that extended counselling can be significantly more effective than standard treatment, among depressed smokers. Consequently, we embarked upon the current larger-scale randomised controlled trial, with a longer treatment period; it is funded by competitive research grants from the National Health and Medical Research Council of Australia (project IDs 569210 and APP1009351). This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609001039279).

#### **Methods/Design**

#### Study aims

The purpose of the research described here is to test the effectiveness of a multi-component intervention for smoking cessation and CVD risk reduction among people with severe mental disorders. It is hypothesised that the intervention will produce greater, more sustainable improvements in CVD risk and smoking status relative to the control condition at follow-up.

#### Study design & setting

This is a prospective randomised controlled comparison study. Figure 1 shows the overall design. After completion

of a baseline assessment and an initial face-to-face intervention session, participants will be randomly assigned to either a multi-component intervention for smoking cessation and CVD risk reduction or a telephone-based minimal intervention focusing on smoking cessation. Randomisation will be stratified by site (Newcastle, Sydney, Melbourne, Australia), Body Mass Index (BMI) category (normal, overweight:  $\geq 25$  and < 30; obese:  $\geq$  30) and type of antipsychotic medication (typical, atypical). A permuted block randomisation approach will be used so that the distribution of participants across treatment conditions will be maintained regardless of the final sample size. Following completion of the baseline assessment for each participant, the clinicians will be issued with a sealed randomisation envelope (by an independent person) which displays the participant identification code. The envelope will be opened by the participant at the conclusion of the initial session. This research will be conducted in three sites: Centre for Brain and Mental Health Research, University of Newcastle, New South Wales (NSW); School of Public Health, University of NSW, Sydney, NSW; and the Monash Alfred Psychiatry Research Centre (MAPrc), Monash University and The Alfred, Melbourne, Victoria, Australia. The researchers involved are experienced clinicians and scientists. Ethical approval was obtained for this study through the lead site of Hunter New England Human Ethics Committee and at each site.

#### Patients

Approximately 250 smokers with a severe mental disorder will be identified from community mental health services, outpatient hospital clinics, psychology and general practices or using self-referral from the general community (e.g. via media advertisements). Written, informed consent will be obtained from each potential volunteer before baseline assessment.

#### **Inclusion Criteria**

1) Age 18 years and over (minimum age level recommended for the use of nicotine replacement therapy, NRT);

2) Diagnosis of a severe mental disorder, as confirmed by the Mini International Neuropsychiatric Interview (MINI; [7]) - schizophrenia spectrum or bipolar disorder;

3) Current smoker (at least 15 cigarettes per day); and

4) Taking antipsychotic medication as prescribed for a period of at least two months, with intention to continue for the duration of the study.

#### **Exclusion Criteria**

1) Non-English speakers;

2) Organic brain diseases; and



3) Medical conditions that would preclude treatment (NRT or overall, e.g. uncontrolled diabetes, pregnancy). Participants will be permitted to access additional treatments outside the proposed study, including psychiatric medication: any such treatments will be recorded at each assessment occasion. Any person who indicates suicidal ideation will be assessed using a standard suicide checklist. Only those persons judged as serious risk for suicide will have their participation suspended and be referred to the relevant psychiatric service. The same protocol will be used for people experiencing an acute phase of their psychotic disorder at any stage in the treatment program.

#### Content of the Interventions

Treatment, including NRT, will be provided free to all participants across the face-to-face and phone-based conditions to assist with their attempts at tobacco abstinence and/or reduction. As stated above, all participants will receive an identical first session, after which they will receive four of the 24 weeks supply of NRT. The remaining NRT will be given to participants at weeks 4, 8 and 15. The NRT protocol is flexible and has been described elsewhere [8]. Briefly, participants smoking at least 30 cigarettes per day are eligible to receive double patching in addition to up to  $12 \times 2$  mg lozenges per day, with NRT tapering occurring over the last month of delivery.

Therapists will be psychologists and both the active and control interventions will be guided by manuals (which are available upon request: Baker AL, Kay-Lambkin FJ, Geddes J, Beck A, Sakrouge R, Filia S, Turner A, Clark V: **Healthy Lifestyles intervention therapist manual** and **Healthy Lifestyles intervention telephone manual**. Unpublished manuscripts: University of Newcastle; 2010). Participants will be asked to provide details of their general practitioner (GP), psychiatrist and case worker and to consent to the therapist liaising with these professionals regarding assessment results and treatment progress, management of any acute episodes, and arranging follow-up.

The initial session before randomisation will be conducted face to face with the therapist and will focus on providing feedback to participants regarding their smoking (e.g. level of dependence) and other risk factors for CVD. A case formulation will be developed with the participant regarding their CVD status and unhealthy behaviours, with motivational interviewing (MI) being conducted to help the person consider changes in risk behaviours.

# Healthy Lifestyles Therapist Delivered Intervention (active treatment)

The active treatment protocol focuses on the adoption of more healthy lifestyle choices (see [8] for session by session summary). The initial session will be of 90 minutes duration, followed by seven one hour weekly sessions, three fortnightly hour long sessions and then monthly sessions of one hour duration for six months. A harm reduction focus is an important factor in the engagement and retention of participants, who may present with a range of preparedness to change the lifestyle factors currently impacting on their health and wellbeing. The intervention is designed to encourage smoking cessation and improvements in diet and physical activity, using a combination of MI and cognitive behaviour therapy (CBT) techniques. The initial focus of treatment will be based on the particular CVD risk factor(s), in addition to smoking, considered most problematic by the participant. Therapists will integrate messages and skill development about other CVD risk factors opportunistically. Self-help material will be provided throughout the treatment period, according to the CVD risk factors being discussed in each session.

#### Smoking cessation component

In addition to the provision of NRT that is common to both the Healthy Lifestyle therapist and phone-based conditions, the intervention includes education about the interaction between nicotine and symptomatology, medication and cognition, options for NRT, and examining beliefs regarding the relationship between smoking and symptoms. Despite a harm reduction focus, cessation as the ultimate goal will be encouraged for all participants, and a supportive follow-up telephone call will be made 2-3 days following the initial quit attempt [9]. Nicotine withdrawal symptom severity, cravings to smoke and adverse medication side-effects will be monitored each session.

#### Contingency reinforcement component

In the face-to-face condition, contingent reinforcement will be utilised, as it has been identified as an effective technique for facilitating smoking cessation amongst individuals with severe mental illness [10]. Expired carbon monoxide (CO) will be monitored each week, with positive reinforcement provided in the form of certificates and financial reimbursement (cash and vouchers) when participants meet predetermined criteria for success. The contingency reinforcement schedule will be based on a shaping model. Relative to an abstinent-only model, a shaping model rewards participants for successive reductions in CO readings as well as abstinence. This is in accordance with both abstinence and harm reduction approaches to substance use change. There are several components to this model. Firstly, session-by-session reimbursement is contingent upon demonstrated reductions in expired CO (explained in detail below). Secondly, participants receive a bonus once they meet the CO criterion for a given (set) number of consecutive weeks (e.g. three weeks in a row). Thirdly, an additional 'bonus' is on offer every week for participants who demonstrate abstinence (< 10 ppm expired CO). An advantage of this schedule is that it accounts for individual differences in baseline CO and rates of behaviour change. However, it is anticipated that many participants will be approaching and/or have met the abstinence criterion by the end of the weekly phase of treatment. As such, during the fortnightly and monthly sessions, reinforcement will be contingent upon abstinence only (<10 ppm expired CO). In summary, we will adopt a shaping schedule during the weekly phase of treatment whilst the fortnightly and monthly sessions will provide positive reinforcement only for abstinence.

#### Physical activity component

This component will be integrated with the other components of the Healthy Lifestyles intervention. Specific strategies will be introduced in session 4, with discussion of ways to increase levels of physical activity in everyday life (e.g. taking the stairs rather than the lift) and introduction of a graded walking program with provision of pedometers. Daily pedometer readings have been incorporated into participant monitoring forms, and will also be used to provide objective feedback to treating therapists about the extent of this activity in the day prior to each treatment session. Should participants express a desire to work on their physical activity earlier than session 4, then these strategies will be brought forward in the treatment sequence as required.

#### Dietary and nutrition component

This component will be integrated with the above Healthy Lifestyles strategies with an emphasis on increasing healthy food choices rather than on an 'ideal' caloric intake. Healthy eating habits will initially be discussed in session 7, with food planning and goal setting following in session 8. Specific motivational and CBTrelated techniques will include encouraging participants to eat a variety of foods, eating foods that are high in fibre and low in fat, trying to eat five or more servings of fruits and vegetables a day and drinking plenty of water each day, eating regularly, and drinking alcohol within the recommended guidelines for Australia. Participants will be encouraged to consider issues that prevent them from making healthy choices (such as 'non-hungry eating', eating on a budget, cost effective meal plans and planning a shopping list). Finally,

medication matters will be addressed, including drugnutrient interactions and tips for dealing with medication side effects. As with physical activity, nutritional strategies will be brought forward to earlier sessions in the treatment program should participants wish to focus on these issues prior to session 7.

#### **Booster sessions**

Participants will receive six monthly booster sessions, during which a range of issues can be discussed. These sessions will include relapse prevention, overcoming lapses, review of previous sessions, methods to promote and maintain changes, and NRT tapering.

#### Monitoring

During each treatment session of the Healthy Lifestyle intervention, participants and therapists will complete the following range of formal measurements: side-effects from medication, nicotine withdrawal, weight, cigarettes per day, expired carbon monoxide (CO), NRT use over the past week, and average minutes walking continuously and briskly per week (based on physical activity diary entries).

#### Phone-based Condition (control)

In order to orient participants to possible lifestyle changes and in particular, NRT use, those in the phonebased condition will receive an individual 90 minute face-to-face session a week following baseline assessment, as described above. To control for the number of therapist contacts, brief, manualised telephone calls (around 10 minutes) will be conducted with participants in this condition, to 'check in' about smoking and NRT use. Therapists will complete the following formal assessments for each phone session: adverse symptom checklist (antipsychotic medication), nicotine withdrawal and current symptoms of psychosis and mood. Self-report measurements of cigarettes per day, exercise and dietary intake will be taken each week during the phone-based sessions. These phone-based sessions will be made at the same intervals as therapist visits for the Healthy Lifestyles intervention condition (i.e. weekly for eight weeks, fortnightly for three sessions, followed by monthly calls for six months). In place of the phone-based sessions at weeks 4 and 8, participants will attend face to face sessions of 30 minutes duration where NRT is dispensed, and where any problems with NRT or symptomatology are monitored. Biomedical measures (expired CO and weight) will also be taken at these two sessions.

#### **Treatment Fidelity**

Throughout the treatment period, all staff will receive regular weekly clinical supervision. Treatment fidelity will be monitored by delivering the therapy in a consistent fashion, closely adhering to the Healthy Lifestyles and phone-based (control) manuals. In addition, all treatment sessions will be audio recorded. An independent assessor will randomly select a 20% sample of tapes for each therapist, and rate tapes for treatment fidelity. Therapists will also be asked to bring along taped treatment sessions to clinical supervision sessions for discussion among the group.

#### **Outcome Measures**

Outcome measures will be performed at baseline, during treatment (week 15), and at 12-, 18-, 24-, 30- and 36-months after baseline. Baseline assessments will be conducted prior to notification of randomisation status. Post-treatment and follow-up assessments will be conducted by independent assessors who will remain blind to intervention allocation.

All assessment instruments are widely used in mental health and/or tobacco treatment research and practice (see Table 1), and cover the domains hypothesised to be impacted upon by the treatment. CO measures will be taken one hour after arrival to partially control for effects of travelling in traffic, etc. Each participant will be offered up to \$20AUD for each assessment, as reimbursement for their out of pocket expenses (e.g. travel).

As in the pilot study, the two primary outcome variables will be: (i) overall CVD risk index for participants; and (ii) smoking status; while the secondary dependent variables will include: weight; physical activity; unhealthy eating; substance use; psychiatric symptomatology; treatment retention and treatment alliance; service utilisation; general functioning; and quality of life. The CVD risk index calculation will be performed using the National Vascular Disease Prevention Alliance Absolute Risk Assessment [11] which is based on the Framingham algorithms [12]. Within this index, multiple risk factors of age, gender, systolic blood pressure, cigarette smoking, cholesterol and diabetes are used to predict CVD risk over 5 years [11]. Blood pressure measurements will be taken, as well as a small blood sample by finger prick to measure cholesterol and blood glucose levels. A general health and well-being questionnaire will also be completed by participants to identify lifestyle habits and previous medical history. Smoking status will be determined according to point prevalence abstinence (last 7 days) and continuous abstinence (since quit attempt), both of which will be biochemically validated by a CO reading of  $\leq 10$  ppm. Additionally, we will use 50% reduction in cigarettes per day as an indicator of smoking status [13].

We also plan to report the cost of delivering the intervention in real world settings and the cost impacts of the outcomes achieved by calibration of selected instruments used in the study (e.g. Quality of Life Scale, Global Assessment of Functioning) with those achieved in other costing studies.

#### Table 1 Assessment instruments proposed for the current study

Instrument	Initial	15-wk	12-, 18-, 24-, 30- 36-months
Tobacco Use			
Opiate Treatment Index (OTI, quantity/frequency) [14]		$\checkmark$	$\checkmark$
Point Prevalence and Continuous Abstinence		$\checkmark$	
Readiness to Quit Smoking [15]		-	-
Fagerstrom Test for Nicotine Dependence [16]		$\checkmark$	$\checkmark$
Expired Carbon Monoxide		$\checkmark$	$\checkmark$
Minnesota Nicotine Withdrawal Scale (MNWS-R) [17]		$\checkmark$	$\checkmark$
Physical Activity			
Readiness to change physical activity [18]	$\checkmark$	-	-
Physical activity screen (past week)	$\checkmark$	$\checkmark$	$\checkmark$
Average minutes walking per week	$\checkmark$	$\checkmark$	$\checkmark$
International Physical Activity Questionnaire [19]	$\checkmark$	$\checkmark$	$\checkmark$
Dietary Habits			
Readiness to change eating habits		-	-
24-hour recall of eating patterns		$\checkmark$	$\checkmark$
Other CVD Risk Factors			
OTI- alcohol and cannabis		$\checkmark$	$\checkmark$
Beck Depression Inventory - II [20]		$\checkmark$	$\checkmark$
Brief Symptom Inventory [21]		$\checkmark$	$\checkmark$
Body mass index (height, weight)		$\checkmark$	$\checkmark$
Waist-hip ratio (cms)		$\checkmark$	$\checkmark$
Auscultatory Blood pressure		$\checkmark$	$\checkmark$
Fingerprick Blood Tests (glucose, cholesterol, lipids)		$\checkmark$	$\checkmark$
Treatment and Service Utilisation [22]		$\checkmark$	$\checkmark$
Diagnosis of psychosis and Symptom Measure			
Brief Psychiatric Rating Scale [23]		$\checkmark$	$\checkmark$
Mini International Neuropsychiatric Interview [22]		-	-
Functioning			
Global Assessment of Functioning [24]		$\checkmark$	$\checkmark$
Medical Outcome Survey SF-36 [25]		$\checkmark$	$\checkmark$
Quality of Life Scale [26]		$\checkmark$	$\checkmark$
Impact of Weight on Quality of Life Questionnaire [27]		$\checkmark$	$\checkmark$
Therapeutic Alliance & Intervention Satisfaction [28]	-	$\checkmark$	-

#### Sample size calculation

Prior research conducted by the authors indicates that attrition rates for CBT trials with this sample are, on average, 18% over a 12-month study period following treatment. Thus at 24-month follow-up in the current study (approximately 12 months following the end of treatment), 205 participants will likely remain in the study (102 per treatment condition). Regular contact at every 6 month interval until 36 months post baseline is likely to retain this sample size. This will provide sufficient statistical power (80%) to detect moderate population differences of the order of 0.5 of a standard deviation, using conventional 0.01 level, 2-tailed tests for the primary variables of interest. This is the equivalent of a differential change of approximately 7 cigarettes per day or 13 points on the 100 point CVD risk score, both moderate but clinically useful differences.

#### **Statistical Analysis**

Data coding and analysis will be carried out by the authors using available software packages (e.g. Statistical Package for Social Sciences for Windows). Variables hypothesised to change over time according to treatment allocation will be examined predominantly using generalized linear mixed models, techniques that facilitate management of missing data without imputing values or excluding participants. Chi-square analyses or binary logistic regressions will be performed on categorical outcome variables. Primary outcome measures will typically be analysed in two ways: (1) intention to treat (with study dropouts regarded as continuing smokers and/or with unchanged CVD risk relative to baseline); and (2) analyses performed within the sub-sample of participants who completed the majority of treatment sessions. In addition, comparisons on selected demographic and clinical characteristics will be made between this subsample and those who dropped out of treatment, to help detect any biases in outcome measures. Other potential confounders will also be examined (e.g. involvement in additional treatments) and their potential effects modelled in the major analyses (e.g., controlling and not controlling for these variables). As a partial control for the number of statistical tests, the threshold for significance will be set at p < 0.01.

#### Discussion

There have been several challenging operational issues in mounting the present trial, which fall into two broad categories: delivering the intended interventions; and recruiting and retaining participants.

#### Intervention delivery

The multi-site nature of the trial has required close attention to staff training and supervision. All therapists have prior experience working with people with mental disorders. Manuals for the therapist and telephone delivered conditions are used to guide therapists in each session and detailed protocols have been written for NRT and contingency management components of the intervention. The lead investigator (AB) has trained clinical staff at each site and conducts ongoing weekly group telephone supervision with the therapists. Face to face supervision is also provided separately at each site, with a focus on feedback regarding audiotaped sessions. Therapists usually have to travel to community centres providing mental health treatment, requiring travel time and expenses. While the multi-component nature of the interventions, and our tolerance for additional treatments (outside of the study) are both positive design features, and reflect real-world treatment contexts, they also reduce our capacity to assess the contributions of specific intervention components (or, alternatively, necessitate larger sample sizes, to ensure sufficient numbers of participants who have undertaken particular lifestyle changes).

#### Recruitment and retention

Recruiting participants with a severe mental disorder who are prepared to change aspects of their lifestyle requires persistence and flexibility. On the one hand, recruitment into the study has at times been slower than anticipated, with some services referring relatively few people. On the other hand, the stringent entry criteria (e.g., smoking at least 15 cigarettes per day) has meant that some volunteers were necessarily excluded from the study. The assessment battery for the study has been divided into two one and a half hour sessions, due to its length and the need to complete self-report instruments with participants. Engagement in treatment is enhanced by flexible treatment goals and treatment has occasionally been temporarily suspended whilst participants are admitted to hospital or become too unwell to engage in the interventions. Some participants who have poor literacy skills have also been assisted by modification of self-monitoring sheets to include pictures. As the maintenance of behaviour change is of crucial interest, booster sessions and longer-term assessments are highly desirable. Fortunately, additional funding from the National Health and Medical Research Council of Australia has been successfully sought for follow-up over three years.

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#### Authors' contributions

All authors contributed to the design of the study and developed the protocol. AB gained ethical approval for the lead site of the trial through the Hunter New England Research Ethics Committee. All authors contributed to manuscript preparation. All authors approved the final manuscript for submission.

#### **Competing interests**

The authors declare that they have no competing interests.

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# **APPENDIX 5**

Varenicline plus healthy lifestyle intervention for smoking cessation in psychotic disorders

# **RESEARCH ARTICLE**

# Varenicline plus healthy lifestyle intervention for smoking cessation in psychotic disorders

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CORRESPONDENCE David Castle, MSc, MD, FRCPsych, FRANZCP Chair of Psychiatry St. Vincent's Hospital and The University of Melbourne 46 Nicholson Street Fitzroy, Victoria 3065 Australia E-MAIL **BACKGROUND:** We were interested in exploring the efficacy and safety of varenicline as an adjunct to a healthy lifestyle intervention for smoking cessation among individuals with a severe mental illness.

**METHODS:** We used varenicline as an adjunct to a healthy lifestyle intervention in 14 smokers with a psychotic illness.

**RESULTS:** Overall, smoking cessation rates were 36% at 3 months and 42% at 6 months. The most commonly reported side effects were sleep disturbance and nausea. These tended to occur early in treatment, and patients responded to general measures of support and reassurance. Of the 14 participants, 1 dropped out because of psychiatric problems and 2 because of other side effects.

**CONCLUSIONS:** Varenicline appears to be an effective adjunct to a healthy lifestyle intervention for smokers with a psychotic illness. Although the results of this open study are encouraging, replication in an adequately powered, randomized controlled trial is required before definitive conclusions can be drawn.

**KEYWORDS:** schizophrenia, bipolar disorder, smoking cessation, cognitivebehavioral therapy, varenicline

# INTRODUCTION

Rates of cigarette smoking among the general population in many Western countries have declined significantly over the past 20 years in association with successful public awareness campaigns and antismoking legislation. Individuals with mental illness do not seem to have benefited from these general approaches, because very high rates of smoking persist in those with severe illnesses such as schizophrenia.<sup>1,2</sup> This trend remains after controlling for socioeconomic factors. Smoking is associated with serious morbidity, lower quality of life, and earlier mortality among persons with psychosis compared with the general community. Individuals with psychotic illness who are at significant risk for cardiovascular disease, obesity, and diabetes are particularly in need of effective smoking cessation interventions.<sup>3</sup>

To assist cessation in smokers with psychosis, investigators have evaluated combinations of psychological and pharmacologic interventions,<sup>4</sup> including individualand group-based psychoeducation,<sup>5</sup> nicotine replacement,<sup>6,7</sup> bupropion,<sup>8,9</sup> and bupropion with nicotine replacement.<sup>10-12</sup> Our work in this field set the foundation for the current study.

In a large controlled trial, Baker et al<sup>13,14</sup> randomly assigned 298 heavy smokers with a psychotic disorder to treatment as usual or an 8-session, individually administered intervention (nicotine replacement therapy [NRT] and cognitive-behavioral therapy). Compared with controls, a significantly higher proportion of smokers who completed all treatment sessions had stopped smoking at 12 months (point prevalence abstinence, 19% vs 7%, respectively).

In a subsequent open trial, we<sup>15,16</sup> produced and piloted a more comprehensive treatment program for individuals with psychosis-the "Healthy Lifestyles" program-which addresses diet and exercise as well as cigarette smoking. Treatment sessions over 3 months were offered to all participants after a baseline assessment, with follow-up at 15 weeks. Four sites recruited 43 participants. A statistically significant reduction in smoking occurred between pre- and post-treatment, with 19% point prevalence abstinence at post-treatment assessment. The average number of cigarettes smoked per day was reduced from 31 to 17 (P < .001). These data are encouraging, but abstinence rates of 19% still leave many individuals with schizophrenia with a problematic smoking habit, and new pharmacologic interventions have the potential to enhance abstinence rates.

Varenicline has proven efficacy for smoking cessation in randomized controlled trials (RCTs) when compared with placebo, NRT, and bupropion.<sup>17-21</sup> Varenicline binds with the  $\alpha 4\beta 2$  neuronal nicotinic acetylcholine receptor, where it acts as a partial agonist. Its binding both alleviates symptoms of craving and withdrawal and reduces the rewarding and reinforcing effects of smoking by preventing nicotine binding to  $\alpha 4\beta 2$  receptors. However, serious concerns have been raised about varenicline's potential psychiatric effects, with depression and suicide being the most well-publicized.<sup>22</sup> The perceived risk of these outcomes probably is exaggerated,<sup>23</sup> but a high degree of concern about this agent's use in persons with mental illness remains in the minds of clinicians and patients. Furthermore, single case reports have suggested the potential of varenicline to worsen psychotic symptoms in some individuals with schizophrenia<sup>24</sup> and induce mania in some individuals with bipolar disorder (BD).<sup>25</sup>

The study reported here was aimed at exploring the efficacy and safety of varenicline as an adjunct to a psychosocial intervention in persons with schizophrenia, schizoaffective disorder, or BD. Our hypothesis was that varenicline plus participation in the "Healthy Lifestyles" program would be effective and well tolerated as a smoking cessation intervention among persons with psychotic disorders.

# METHODS

We conducted an open trial of varenicline plus our established "Healthy Lifestyles" intervention among persons with psychotic disorders. Participants were recruited through case managers at the 2 community mental health centers associated with St. Vincent's Mental Health Service, Melbourne, Australia. Our target was 15 participants, based on pragmatics of funding and follow-up; 1 declined to participate after screening, leaving a total of 14.

#### Inclusion criteria

We enrolled individuals age  $\geq 18$  with a diagnosis of a psychotic disorder (schizophrenia, schizoaffective disorder, or BD), based on the Mini International Neuropsychiatric Interview.<sup>26</sup> Enrollees had been on stable psychiatric medication for  $\geq 3$  months and were current heavy smokers ( $\geq 15$  cigarettes per day).

#### **Exclusion criteria**

Exclusion criteria included non-psychotic illness, smoking <15 cigarettes per day, non-English speaking; organic brain disease; an unstable psychiatric condition (eg, actively suicidal as per clinical judgment) or medical condition (eg, uncontrolled diabetes), or any specific contraindication to varenicline (apart from having a mental illness).

# Demographic and illness profile, cigarettes smoked, and main side effects of varenicline in 14 patients with psychotic illness

Age	Sex	Psychiatric diagnosis	Cigarettes smoked per day at entry	Cigarettes smoked per day at 3 months	Cigarettes smoked per day at 6 months	Main reported side effects
25	Male	Mood disorder	20	5	10	Increased appetite, vivid dreams, headache
49	Female	Schizoaffective disorder	40	0	0	Insomnia, vivid dreams, increased appetite
47	Male	Schizophrenia	40	20	20	Blurred vision, dry mouth, fatigue, thirst, dizziness, nausea
65	Male	Schizoaffective disorder	19	0	0	Poor concentration, increased appetite, abnormal dreams, transient depression
30	Male	Schizoaffective disorder	37	12	40	Nausea; stopped varenicline after 3 months
39	Female	Schizophrenia	15	7	6	Nausea, constipation
50	Female	Bipolar I disorder with psychosis	20	7	5	Dry mouth, nausea, sweating
50	Male	Bipolar I disorder with psychosis	20	0	0	Constipation, headache, abnormal dreams
33	Male	Bipolar I disorder with psychosis	40	40	40	Nausea, vomiting; stopped varenicline after 2 weeks
40	Male	Schizoaffective disorder	20	0	0	Abnormal dreams, constipation
51	Female	Bipolar disorder with psychosis	25	_	_	Depression with suicidality; withdrew after a few days
37	Male	Schizoaffective disorder	20	0	0	Fatigue
34	Male	Schizophrenia	25	16	20	Nausea
45	Female	Schizoaffective disorder	25	2	0	Dry mouth, thirst

#### Assessments

All assessment instruments are widely used in mental health and/or tobacco treatment research and practice. Demographic characteristics and previous treatment history were collected from participants at the initial assessment. The following instruments were administered at each weekly visit:

*Tobacco use:* Opiate Treatment Index<sup>27</sup> to estimate average daily use of tobacco; the Fagerström Test for Nicotine Dependence<sup>28</sup>; expired carbon monoxide, using a Bedfont Smokerlyzer; and the Minnesota Nicotine Withdrawal Scale-Revised (self and observer ratings).<sup>29</sup>

*Psychiatric Symptomatology:* Brief Psychiatric Rating Scale (BPRS),<sup>30</sup> a well-validated measure of psy-

chotic symptoms; Beck Depression Inventory (BDI),<sup>31</sup> a well-validated self-report measure of depressed mood, with a specific item on suicidality; and the Young Mania Rating Scale (YMRS),<sup>32</sup> a widely used and validated assessment of manic symptomatology.

*Side effects:* At each visit, participants were asked if they have experienced any symptoms that they considered to be varenicline side effects; they also filled out our standardized side effect checklist (available upon request from the authors).

*Safety checks:* To ensure patient safety, we added specific safety monitoring, including the Columbia Suicide Severity Rating Scale at each weekly visit. In addition, between each study visit the therapist delivering the

intervention (D.H.) made telephone contact with each participant, as a quick wellbeing check.

Formal assessments were conducted at baseline and at 3 and 6 months by trained research assistants who were not involved in delivering the intervention and did not have prior knowledge of the participants. Each participant was offered \$30 for the initial assessment and each post-treatment assessment as reimbursement for time and out-of-pocket expenses (ie, travel, parking fees). All procedures were approved by the St. Vincent's Hospital (Melbourne) Human Research Ethics Committee.

#### Intervention

a) The nonpharmacologic component: The intervention, adapted from our established manual-guided "Healthy Lifestyles" program,15,16 was delivered as 6 weekly, 1-hour sessions, followed by three 1-hour booster sessions at weeks 8, 10, and 12. Therapy components included case formulation and feedback from assessment, psychoeducation, motivation enhancement, mood/craving monitoring, mindfulness training, cognitive restructuring, identifying and managing unhelpful automatic thought patterns, enhancement of non-smoking related activities, pleasant events scheduling, coping with cigarette cravings, problem-solving, refusal skills, and relapse prevention and/or management. During each therapy session, discussion and skills practice focused on unhealthy behaviors the participant identified as most important/problematic. The therapist took the opportunity to integrate messages/skill development about other lifestyle factors as appropriate. Self-help material was provided throughout the treatment period, related to the unhealthy lifestyle behavior discussed in the session. The therapist delivering the intervention (D.H.) was experienced in the "Healthy Lifestyles" program intervention and received training and weekly supervision from Dr. Baker.

*b) The pharmacologic component:* Varenicline was provided to participants at each visit. Dose titration was: 0.5 mg/d for days 1 to 3; 1 mg/d for days 4 to 7; and 2 mg/d (the target dose) from days 8 to 84.

# RESULTS

**TABLE 1** provides a synopsis of the age, sex, and primary psychiatric diagnoses of the intervention group, as well as the most prominent reported side effects. The

most common side effects were sleep disturbance and nausea.

One patient with severe, recurrent BD with psychosis dropped out because of psychiatric issues. She experienced depressed mood, agitation, and irritability along with suicidal ideation and ceased the medication after 4 days. Her psychiatric symptoms stabilized within 1 week, and she continued smoking approximately 25 cigarettes a day. Another patient, who had successfully ceased smoking, stopped varenicline after 3 weeks because of constipation but recommenced it after his urge to smoke worsened and he feared a return to smoking. Two additional patients ceased medication because of ongoing nausea—1 at 3 weeks, and 1 at 3 months.

After 6 months of the intervention, cigarettes smoked per day was significantly reduced, and 6 patients achieved carboxymeter-confirmed abstinence (**TABLE 2**). Analysis of only those who were not abstinent at 6-months followup showed a significant reduction in number of cigarettes smoked per day. Of interest was that, although observerrated nicotine withdrawal increased from baseline to 6-month follow-up (P < .05), patients self-reported a decrease in this rating (P = .02). No significant changes from baseline to follow-up were observed on the BDI (pre: 9.2 [SD 7.0], post: 8.1 [SD 8.1]); YMRS (pre: 3.8 [SD 5.5], post 4.9 [SD 6.0]); or BPRS (pre: 35.6 [SD 5.0], post: 39.8 [SD 8.9]).

### DISCUSSION

This open study demonstrated that varenicline, in association with a comprehensive healthy lifestyle intervention, was associated with a substantial decrease in cigarette smoking among a heterogeneous group of patients with psychotic disorders. Abstinence was achieved in 42% of the participants at the 6-month mark. Side effects were mostly nonpsychiatric (ie, sleep disturbance, nausea) and transient; 1 patient with BD dropped out because of a severe worsening of depression with suicidality.

Some published studies have assessed the use of varenicline in persons with a mental illness. In a preapproval trial by Stapleton et al,<sup>33</sup> varenicline appeared to be effective and well tolerated by patients in a pre-post comparison with NRT. However, that study and its nonpharmacologic intervention were not tailored to persons

	Before treatment			After treatment (6-month follow-up)			Difference			95% CI of difference	
Measure	м	SD	Range	м	SD	Range	t	df	P	Lower	Upper
Cigarettes per day	26.69	9.16	15 to 40	13.08	14.66	0 to 40	4.16	12	.001	6.48	20.75
Cigarettes per day (excluding abstainers post- treatment)	27.44	9.29	15 to 40	18.89	14.10	4 to 40	2.91	8	.02	1.78	15.33
Carboxymeter (CO ppm)	30.08	19.25	10 to 77	20.85	16.27	2 to 60	1.41	12	.18	-5.04	23.51
Dependence (FTND)	6.90	1.91	2 to 10	4.80	3.26	1 to 10	3.11	9	.01	.58	3.62
Withdrawal (other-rated)	.55	.39	.25 to 1.75	.87	.71	0 to 2.25	-2.15	14	.05	63	001
Withdrawal (self-rated)	1.29	.58	0 to 2.33	.96	.57	.11 to 1.78	2.59	13	.02	.06	.61

TABLE 2 Baseline and post-treatment (6-month) ratings

CO: carbon monoxide; df: degrees of freedom; FTND: Fagerström Test for Nicotine Dependence; M: mean; ppm: parts per million; SD: standard deviation.

with a mental illness, and only 7 patients (0.2% of the sample) had a psychotic illness.

Purvis et al<sup>34</sup> performed a retrospective review of 50 military veterans who had received varenicline. Overall, 30% quit smoking, and 70% failed either because of lack of effectiveness or inability to tolerate varenicline. The proportion of those with a mental illness was higher in the failure group vs the success group (57% vs 27%, respectively; P < .001. All 4 of the patients who discontinued because of mood and behavioral problems had an established mental illness.

McClure et al<sup>35</sup> analyzed smoking outcomes and side effects associated with varenicline in attendees at a smoking cessation clinic. Participants with a probable history of major depression were more likely than those without a history to report tension/agitation, irritability/anger, confusion, or depression at 21 days (P < .05) and depression and anxiety at 3 months (P < .01); however, smoking cessation rates did not differ between the groups.

In a study of varenicline in 14 patients with schizophrenia and schizoaffective disorder, Smith et al<sup>36</sup> reported no significant exacerbations in psychopathology ratings. Side effects included nausea, dry mouth, sleepiness, and shaking; 2 patients discontinued treatment, and 9 of the remaining 12 reduced the number of cigarettes smoked, although only 1 was abstinent at the end of the trial. Finally, Weiner et al<sup>37</sup> performed a double-blind, placebo-controlled trial of varenicline in 9 patients with schizophrenia or schizoaffective disorder and found no worsening of psychotic symptoms. Constipation, nausea, and insomnia were reported side effects. Varenicline was associated with a reduction in smoking.

The study presented here demonstrated that the combination of a comprehensive healthy lifestyle/smoking cessation intervention delivered by trained mental health staff can, in conjunction with varenicline, produce smoking abstinence rates of 36% at 3 months (while still on varenicline) and 42% 3 months later, having ceased the medication. This is higher than we reported in our studies with similar patients, using an identical intervention but with NRT (abstinence rate 19%). Furthermore, despite this being a psychiatrically high-risk group, only 1 participant dropped out because of worsening psychiatric symptoms, albeit that it was not clear whether these were directly exacerbated by the varenicline.

The findings regarding psychiatric adverse events are compatible with those reported by McClure et al<sup>35</sup> in patients with depression. Indeed, overall in our study, the side effect profile was similar to that experienced by persons without a mental illness who cease smoking. Two patients ceased medication because of nausea and resumed smoking at baseline rates; 1 patient dropped out because of constipation but restarted varenicline because he feared starting smoking again. It is also worth noting that smoking cessation has been associated with depression, notably in people with a history of depression.<sup>38</sup>

This study has limitations, notably the small number of participants and the fact that we did not control for multiple testing on outcome measures. The heterogeneity of diagnoses also is a drawback, although it allowed a more "real life" clinical sample than would be usual in RCTs. We did not include a control group, but could make some comparisons with the outcomes from previous studies using NRT, as the participant sample was similar and the nonpharmacologic intervention was manualized and has high fidelity. Of course, randomized controlled comparison trials will more definitively determine the superiority or otherwise of varenicline vs NRT in this patient group. Also, longer-term outcome studies are required to determine relapse rates and guide duration of therapy. Including measures of varenicline's effects on neurobiological markers and cognitive functioning would be useful to better characterize the mechanisms that drive so many people with schizophrenia to smoke. A recent randomized placebo-controlled trial<sup>39</sup> showed varenicline to be associated with reduced sensory P50 gating, startle reactivity, and antisaccade errors in persons with schizophrenia.

# CONCLUSIONS

At this stage, we believe it is reasonable to conclude that varenicline can be effective in reducing smoking in individuals with severe mental illness, in conjunction with a comprehensive psychosocial intervention. Most side effects are tolerable and are similar to those experienced by persons without a mental illness. However, because of the potential for worsening of psychiatric symptoms in high-risk patients, we suggest that varenicline be used with careful and comprehensive mental state monitoring, expressly for depressive symptoms and suicidality. Although results of the current open study are encouraging, replication in an adequately powered RCT is required before definitive conclusions can be drawn. ■

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# **APPENDIX 6**

Randomized controlled trial of a healthy lifestyle intervention among smokers with psychotic

disorders
### **Original Investigation**

## Randomized Controlled Trial of a Healthy Lifestyle Intervention Among Smokers With Psychotic Disorders

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#### Abstract

**Introduction:** People with severe mental disorders typically experience a range of health problems; consequently, interventions addressing multiple health behaviors may provide an efficient way to tackle this major public health issue. This two-arm randomized controlled trial among people with psychotic disorders examined the efficacy of nicotine replacement therapy (NRT) plus either a face-to-face or predominantly telephone delivered intervention for smoking cessation and cardiovascular disease (CVD) risk reduction.

**Methods:** Following baseline assessment and completion of a common, individually delivered 90-minute face-to-face intervention, participants (n = 235) were randomized to receive NRT plus: (1) a "Healthy Lifestyles" intervention for smoking cessation and CVD risk behaviors or (2) a predominantly telephone-based intervention (designed to control for NRT provision, session frequency, and other monitoring activities). Research assistants blind to treatment allocation performed assessments at 15 weeks (mid-intervention) and 12 months after baseline.

**Results**: There were no significant differences between intervention conditions in CVD risk or smoking outcomes at 15 weeks or 12 months, with improvements in both conditions (eg, 12 months: 6.4% confirmed point prevalence abstinence rate; 17% experiencing a 50% or greater smoking reduction; mean reduction of 8.6 cigarettes per day; mean improvement in functioning of 9.8 points).

**Conclusions:** The health disparity experienced by people with psychotic disorders is high. Faceto-face Healthy Lifestyle interventions appear to be feasible and somewhat effective. However, given the accessibility of telephone delivered interventions, potentially combined with lower cost, further studies are needed to evaluate telephone delivered smoking cessation and lifestyle interventions for people with psychotic disorders.

#### Introduction

Psychotic disorders (eg, schizophrenia spectrum and bipolar disorders) are severe forms of mental illness characterized by distortions of thinking, perception and emotional response, and are ranked in the top 10 causes of disability worldwide.<sup>1</sup> The life expectancy of people with schizophrenia or bipolar disorder is 12–19 years shorter than that of the general population.<sup>2</sup> Cardiovascular disease (CVD) is the single largest cause of death among this group, accounting for more premature deaths than suicide.<sup>3–6</sup>

Rates of major behavioral risk factors for CVD (smoking, physical inactivity, alcohol use, and low fruit and vegetable intake)<sup>1,7</sup> are higher in people with psychotic disorders,<sup>8,9</sup> and smoking stands as a vitally influential and common risk factor.<sup>10</sup> Recent reports also suggest that all socioeconomic status indicators associated with current smoking are also associated with 12-month mental illness.<sup>11</sup> Smokers with severe mental disorders spend over a quarter of their income on tobacco<sup>12</sup> and, when compared to nonsmokers with severe mental disorders, they are more likely to go without basic necessities such as meals.<sup>13</sup>

A window of opportunity may exist within smoking cessation interventions to address the common clusters of CVD risk behaviors<sup>14</sup> among people with severe mental disorders, as smoking reduces and alternative behaviors and better diet become more affordable. Among the general population, simultaneously addressing multiple health behaviors is increasingly being investigated as a potentially efficient way to tackle CVD risk.<sup>15</sup> Although evidence supports the efficacy of smoking interventions among people with psychotic disorders,<sup>16</sup> as far as we are aware, no randomized controlled trials in this population have been published evaluating interventions targeting smoking and other health risk behaviors.

Given the high prevalence of smoking and other CVD risk behaviors among people with psychotic disorders,<sup>7,17</sup> we compared the efficacy of an intensive face-to-face intervention focused on smoking and other CVD risk behaviors (the "Healthy Lifestyles" intervention) versus a predominantly telephone-delivered intervention (comparison condition), which was designed to control for pharmacotherapy provision (nicotine replacement therapy [NRT]), number of and interval between sessions, and other monitoring (eg, smoking, medication side-effects, diet, and activity). It was hypothesized that the Healthy Lifestyles intervention would produce greater improvements at 12 months following baseline in CVD risk and smoking status relative to the comparison condition.

#### Methods

#### Study Design

We conducted a conventional two-arm randomized controlled trial (ie, primary intervention condition hypothesized to be superior to comparison condition), which is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12609001039279). Study design, sample size estimates, and intervention content have been described elsewhere<sup>18</sup> and intervention manuals are available from the first author.

All participants provided written informed consent and were assessed at baseline, 15 weeks (mid-intervention) and 12 months after baseline; study recruitment occurred between July 2009 and April 2011, with the 12-month follow-up finalized during May 2012. Following baseline assessment, all participants completed an initial, individually-delivered 90-minute face-to-face session, where after they were randomly allocated to receive NRT plus one of

two conditions: (1) a "Healthy Lifestyles" intervention for smoking cessation and CVD risk reduction (comprising an additional 16 face-to-face 1-hour counseling sessions delivered over approximately 9 months—see Supplementary Table S1 for details) or (2) a predominantly telephone delivered intervention, designed to control for administration of NRT, number of and interval between sessions, and other monitoring activities (eg, nicotine withdrawal; anti-psychotic medication side-effects, possibly related to smoking reduction; distress; smoking behavior; diet and physical activity). Telephone sessions were scheduled to be approximately 10 minutes and at weeks 4 and 8 participants attended 30-minute face-to-face sessions, where NRT was dispensed and biomedical measures taken (see Supplementary Table S1 for details).

Assessments at 15 weeks and 12 months were conducted by members of the research team, blind to allocation condition. Participants were reimbursed \$20 for their time, travel, and participation on each assessment occasion, with no reimbursement for treatment session attendance (face-to-face or telephone-based).

#### Participants and Procedure

Participants were 235 smokers with a stable psychotic disorder who were recruited across three sites (in Newcastle, Sydney, and Melbourne, Australia). Ethical approval was obtained through the lead site (from Hunter New England Human Ethics Committee) and at each site. Referral sources included: health services, such as community mental health centers and general practitioners (148, 63%); media campaigns (59, 25%); and other research programs or registers (28, 12%).

Inclusion criteria were: (1) aged at least 18 years; (2) smoking at least 15 cigarettes per day (at any stage of change for quitting smoking); (3) diagnosis of a schizophrenia spectrum or bipolar disorder, as confirmed by the Mini International Neuropsychiatric Interview;<sup>19</sup> and (4) taking antipsychotic medication as prescribed for a period of at least 2 months, with intention to continue for the duration of the study. Exclusion criteria were: (1) inability to speak English; (2) organic brain diseases; and (3) medical conditions that would preclude NRT or other treatment.

Randomization was stratified by study site, body mass index category (normal; overweight:  $\geq 25$  and <30; obese:  $\geq 30$ ) and type of antipsychotic medication (typical; atypical). A permuted block randomization approach was used so that the distribution of these characteristics across conditions was maintained. Following the baseline assessment, study therapists were issued with a sealed randomization envelope (by an independent person) displaying a participant identification code. The envelope was opened by the participant upon conclusion of the initial treatment session. Treatment sessions were preferentially conducted at the local research centre or a nearby community clinic.

#### Measures

Key demographic, clinical and outcome measures are reported here. The assessment instruments have been reported previously<sup>18</sup> and are described only briefly. The two primary outcomes were: (1) overall CVD risk index and (2) smoking status (eg, confirmed 7-day point prevalence abstinence; 50% or greater reduction in cigarettes per day relative to baseline; nicotine dependence). Secondary outcome variables included: psychiatric symptomatology; global functioning; weight and its impact on quality of life; health behaviors (eg, physical activity, unhealthy eating); substance use; biomedical measures; and treatment retention. We also examined the impact of

baseline smoking stage of change on cigarette consumption changes. Supplementary Table S2 provides further information about these measures, including references, and scoring or related details.

#### Therapy

#### Content of Interventions

The interventions have been described elsewhere.<sup>18</sup> They were delivered by psychologists guided by intervention manuals.<sup>20</sup> All participants received an identical first session, after which they received up to 24 week's supply of NRT, delivered at weeks 1, 4, and 8, and thereafter by arrangement. The NRT protocol has also been described elsewhere<sup>21</sup>—see Supplementary Table S1 for details. Consent was sought to liaise with treating health professionals regarding: assessment results and treatment progress; management of any acute episodes; and arranging follow-up. The initial session focused on providing feedback regarding smoking (eg, level of dependence) and other CVD risk factors; a case formulation was also developed with the participant regarding CVD status and unhealthy behaviors, using methods consistent with a motivational interviewing approach.

#### Intensive Face-to-Face Healthy Lifestyles Intervention Condition

The Healthy Lifestyles intervention encouraged smoking cessation and improvements in diet and physical activity, using a combination of motivational interviewing and cognitive behavior therapy techniques. There was an initial focus on smoking, followed by risk behaviors considered most problematic by the participant. The Healthy Lifestyles intervention included education about: the interaction between nicotine and symptomatology; medication and cognition; options for NRT; and examining beliefs regarding the relationship between smoking and symptoms. A supportive follow-up telephone call was made 2-3 days following the initial quit attempt. Nicotine withdrawal severity, cravings to smoke, and adverse medication side-effects were monitored at each session. Contingent reinforcement was utilized, with positive reinforcement provided in the form of certificates and financial reimbursement (cash and vouchers) when participants met predetermined criteria for smoking reduction or abstinence.18

Physical activity strategies were usually introduced in session 4, unless participants expressed a desire to work on these earlier. Ways of increasing levels of physical activity in everyday life were discussed and a graded walking program introduced with provision of pedometers. Healthy eating habits were introduced in session 7, with food planning and goal setting following in session 8. Participants were encouraged to eat a variety of foods, high in fiber and low in fat, to try to eat seven or more servings of fruits and vegetables a day, and to drink plenty of water. Participants were encouraged to address barriers to making healthy choices and to eat regularly.

Booster sessions were scheduled after session 8 (three fortnightly, followed by six monthly sessions), at which a range of issues could be covered (eg, relapse prevention, NRT tapering). During each session, the following were assessed: side-effects from medication; nicotine withdrawal; weight; cigarettes per day; expired carbon monoxide; NRT use; and physical activity.

#### Telephone-Based Intervention Condition

Following baseline assessment and provision of the initial face-toface session, participants received up to 16 further brief, manualguided sessions (14 by telephone and two additional face-to-face sessions—see Supplementary Table S1). Telephone calls were scheduled to be around 10 minutes each. These calls monitored: smoking and NRT use; side-effects from medication; nicotine withdrawal; and current symptoms of psychosis and mood. Self-report measurements of cigarettes per day, exercise, and dietary intake were taken each week. Comparable content areas to the Healthy Lifestyles intervention were discussed in the telephone-based intervention, but less intensively, and without either cognitive behavior therapy or contingent reinforcement. For both conditions, approximately half of the total session time was devoted to discussion about CVD risk behaviors, with smoking related discussion occupying the bulk of that time.

#### Treatment Fidelity

Throughout the treatment period, therapists received weekly clinical supervision. In addition, approximately two-thirds of face-to-face intervention sessions were audio recorded, from which a representative sample was randomly selected and rated by independent clinical psychologists for fidelity and competence, using the Cognitive Therapy Scale.<sup>22</sup> Similarly, approximately half of the telephone-based sessions were audio recorded, with a representative sample randomly selected for rating to ensure treatment session adherence; see Supplementary Table S3 for further details.

#### Statistical Analysis

Data analysis was carried out using SAS 9.2 (SAS Institute Inc., Cary, NC). Change over time and group effects for the continuous outcome measures were examined using generalized linear mixed models to take account of the repeated measurements on individuals and missing data, whilst controlling for study site and baseline scores. The primary binary outcome measures were analyzed according to the intention-to-treat principle, with study dropouts classified as nonabstinent/continuing smokers. Logistic regressions were used for the binary outcome analyses, with study site included as a covariate. Supplementary outcome analyses were based on the amount of treatment actually received (eg, treatment session attendance; any reported NRT usage, but not NRT dosage). The significance level was set at P < .01 to partially control for potential type I errors associated with multiple comparisons; this is the equivalent of a Bonferroni-adjusted family-wise error rate with five members per family (eg, analysis families: CVD risk and smoking measures; psychiatric symptomatology and quality of life measures; and health behavior measures).

#### Results

#### Sample Characteristics

Figure 1 presents recruitment and attrition profiles. Of the 464 people referred, 229 were excluded (49.4%), including 52 (11.2%) who did not meet the inclusion criteria (main reasons: had already quit smoking; smoked less than 15 cigarettes per day; or nonpsychosis) and 118 (25.4%) who declined, leaving a recruited and randomized sample of 235 (Healthy Lifestyles condition: n = 122; telephone condition: n = 113). Mean age of participants was 41.6 (SD = 11.1) years, and just over half were male (138, 59%). Most were: Australian born (194/234, 84%); unemployed (176/217, 81%); receiving welfare support (218, 93%); had not finished secondary school (143/233, 61%); and had never married (157/233, 67%). Diagnoses were: schizophrenia spectrum (138, 59%); bipolar disorder (52, 22%); and nonorganic psychotic syndrome (45, 19%). Average duration of psychosis was 18.6 years (SD = 11.6) and onethird (82, 35%) had been admitted to a psychiatric hospital in the last year.



Figure 1. Recruitment and attrition profiles for the Healthy Lifestyles project (CONSORT diagram).

Most participants had been advised to quit smoking (189/230, 82%) and three-quarters had unsuccessfully tried previously (178/233, 76%). On average, participants reported smoking their first full cigarette at age 15.1 (SD = 5.9) and started smoking daily at age 18.3 (SD = 5.6). The mean body mass index was 30.6 (SD = 6.3) and the majority (184/227, 81%) had a body mass index over 25, placing them in the overweight or obese categories. One-third (73/217, 34%) reported a family history of heart disease and 11% (25/235) had been diagnosed with diabetes.

Table 1 shows mean baseline scores for the key measures; see Supplementary Table S4 for baseline biomedical measures. There were no significant baseline differences between intervention conditions, except for a difference in blood glucose levels. The typical participant reported heavy smoking, a sedentary lifestyle, and consumed well below the recommended servings of two fruits and five vegetables per day.<sup>23</sup> The average 10-year risk of CVD of 7.3% (*SD* = 10.9) fell below the high-risk threshold of 20%, largely due to the age of the sample.

Study recruitment rates were below expectations, relative to the 250 subjects initially planned,<sup>18</sup> as were the retention rates. Overall, 186 individuals (79.1%) completed at least one of the follow-up assessments, however, there were no baseline differences between this subgroup and those who did not complete any follow-up assessments (n = 49).

#### Intervention Attendance

Among those who attended at least one treatment session (n = 211), there was a significant overall difference in session attendance between the Healthy Lifestyles (mean = 9.2, SD = 6.0) and telephone (mean = 12.4, SD = 5.2) conditions (P < .001); see Supplementary Table S1 and Figure 1 for attendance pattern details. Three levels of session completion were generated (Figure 1): Low (1–3 sessions); Midrange (4–8 sessions) and High (9–17 sessions); which largely corresponded with changes in intervention content or timing across sessions (eg, smoking focus; physical activity focus; non-weekly sessions). In the telephone condition, two-thirds (76/113, 67%) had high levels of attendance, compared with 48% (58/122) for the Healthy Lifestyles condition.

#### Session Duration, Fidelity, and Competence

Supplementary Table S3 presents an evaluation of the random subsample of recorded therapy sessions, with respect to overall session duration, minutes discussing CVD risk behaviors, and therapist adherence and competence. Session durations were generally consistent with the session plans in Supplementary Table S1, while therapy adherence rates averaged around 90%. Approximately two-thirds of the discussion about CVD risk behaviors focused on smoking. For the Healthy Lifestyles condition, the mean Cognitive Therapy Scale score was 3.71 (SD = 0.78), indicating that the typical cognitive behavior therapy skills utilized were between "good" and "very good".

#### Patterns of NRT Use

NRT usage patterns are reported in Supplementary Table S1. At the first session, only 17 participants (8.1%) reported using NRT in the previous week. By sessions 2–3, 58% reported using NRT, comprising 49% of the Healthy Lifestyles and 67% of the telephone condition (P = .005). However, at 12 months, comparable NRT rates were reported across the intervention period (85% vs. 88%). A total of 40 participants (Healthy Lifestyles: 16%; telephone: 19%) reduced the number of cigarettes smoked per day by 50% or greater at 12 months relative to baseline and, of these, 93% had used NRT and 83% had high session attendance.

#### Primary Outcomes: CVD Risk and Smoking Status

Mean changes from baseline for the continuous outcome measures by intervention condition are reported in Table 2, while subgroup comparisons for the categorical outcomes are reported in Table 3.

#### CVD Risk

As shown in Table 2, there were no significant differential changes (relative to baseline) in 10-year CVD risk between intervention conditions at 15 weeks or 12 months. However, there was a statistically significant reduction in 10-year CVD risk in both conditions at 15 weeks and at 12 months for the telephone condition.

Measure	Overall ( <i>n</i> = 235)	Healthy Lifestyles condition ( <i>n</i> = 122)	Telephone condition ( <i>n</i> = 113)	Condition comparison <i>P</i> value
10-year CVD risk (ASSIGN score)	7.3 (10.9)	6.6 (8.7)	8.0 (12.6)	.345
Smoking measures				
Cigarettes per day	28.6 (15.3)	29.9 (17.9)	27.2 (11.8)	.187
Expired carbon monoxide (CO)	25.6 (19.0)	24.2 (15.8)	27.1 (21.9)	.240
Fagerstrom Test for Nicotine Dependence (FTND)	6.8 (2.0)	6.8 (2.2)	6.8 (1.8)	.885
Cannabis (use occasions per day)	1.3 (5.8)	1.2 (4.8)	1.3 (6.7)	.868
Psychiatric symptomatology and quality of life				
Brief Psychiatric Rating Scale (BPRS-24)	42.6 (12.9)	42.5 (12.9)	42.7 (12.9)	.917
Beck Depression Inventory (BDI-II)	17.4 (12.8)	17.7 (13.0)	17.0 (12.6)	.729
Global Assessment of Functioning (GAF)	51.2 (10.8)	51.6 (10.9)	50.6 (10.7)	.474
Impact of Weight on Quality of Life (IWOQOL-Lite)	59.1 (28.6)	58.2 (26.5)	60.0 (31.0)	.682
SF-12 Mental Component Scale (MCS)	47.0 (8.4)	46.8 (8.1)	47.2 (8.8)	.706
SF-12 Physical Component Scale (PCS)	45.4 (8.1)	45.8 (7.8)	45.1 (8.4)	.540
Health behaviors				
Walking time (minutes per week)	231 (393)	231 (374)	232 (414)	.988
Sitting time (minutes per week)	2909 (1705)	2855 (1646)	2965 (1768)	.640
Alcohol (standard drinks per day)	1.19 (5.23)	1.39 (6.46)	0.98 (3.49)	.561
Number of daily vegetable servings	1.9 (1.4)	1.9 (1.4)	1.8 (1.4)	.411
Number of daily fruit servings	1.2 (1.1)	1.2 (1.3)	1.1 (1.0)	.616
Combined number of daily fruit and vegetable servings	3.0 (2.0)	3.2 (2.0)	2.9 (1.9)	.337

 Table 1. Mean (SD) for Selected Baseline Measures (Overall and by Treatment Condition): Cardiovascular Disease (CVD) Risk, Smoking,

 Psychiatric Symptomatology and Quality of Life, and Key Health Behaviors

See Supplementary Tables S2 and S4 for further details about the measures and baseline biomedical indices, respectively.

#### Confirmed 7-Day Point Prevalence Abstinence

Point prevalence abstinence was analyzed using self-report confirmed by a carbon monoxide reading of <10 ppm. As detailed in Table 2, there were no differences between the telephone and Healthy Lifestyles conditions in carbon monoxide changes. However, for both conditions there were significant reductions at 15 weeks and for the telephone condition at 12 months. There were no significant overall differences between the conditions in confirmed 7-day pointprevalence abstinence rates at 15 weeks and 12 months (Table 3); in total, 11% of the Healthy Lifestyles condition and 12% of the telephone condition reported abstinence from smoking in the previous week at 15 weeks, falling to 6.6% and 6.2% respectively at 12 months. Notwithstanding, at 15 weeks, participants with high attendance (9-17 sessions) were more likely to report point prevalence abstinence than those who had low to midrange attendance; however, these subgroup differences were not significant at 12 months (Table 3).

#### **Continuous Abstinence**

Only a small number of participants (9/235, 3.8%) reported continuous abstinence across the 12-month follow-up period; consequently, separate analyses are not reported for this outcome, with these participants included among the point prevalence abstinence findings described above.

#### Daily Cigarette Consumption

As detailed in Table 2, no significant differences existed between the conditions with respect to changes in daily cigarette consumption or nicotine dependence, although both conditions reported significant reductions at 15 weeks and 12 months (eg, a mean overall reduction of 8.6 cigarettes per day at 12 months). Furthermore, based on supplementary analyses, there were no significant stage of change by treatment condition interactions (Supplementary Material).

#### **Smoking Reduction Status**

As already noted, there were no significant differences between conditions in smoking reduction status, measured by a 50% or greater reduction in the number of cigarettes smoked per day relative to baseline. However, as shown in Table 3, smoking reduction at both 15 weeks and 12 months was significantly greater in those who attended more treatment sessions. In addition, at 15 weeks, participants who used NRT were significantly more likely to report smoking reduction. Among the subgroup whose consumption fell by 50% or greater at 12 months (n = 40), there was a mean reduction from 27.7 to 5.3 cigarettes per day, with a corresponding mean carbon monoxide reduction from 27.4 to 13.8 ppm.

#### Secondary Outcomes

#### Psychiatric Symptomatology and Quality of Life

Table 2 also shows that there were no significant differences between conditions in the change from baseline for any of the mental health or quality of life indices, with significant improvements on some measures at 12 months (eg, a 9.8 point mean Global Assessment of Functioning improvement) and, importantly, no measures showing significant worsening.

#### Health Behaviors and Other Measures

There were no significant differential changes from baseline in any of the health behaviors (Table 2) or the biomedical measures (Supplementary Table S5). Likewise, neither group showed improvement over time on any of these measures; however, there was a deterioration in total cholesterol in the Healthy Lifestyles condition (Supplementary Table S5). Alcohol, cannabis, and other substance use also remained relatively constant, with no significant differences between conditions.

#### Discussion

A major finding of the present study was that NRT plus a predominantly telephone-based intervention for smoking cessation

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		Healthy Lifestyles conditi	ion	Telephone conditio	и	Difference betwe	en groups
	:		,			Least square mean differenc or <sup>a</sup> ratio (from Poisson	
Measure	Follow-up time	Mean change (99% CI)	Ρ	Mean change (99% CI)	Ρ	analysis) (99% CI)	Group effect P value
10-year CVD risk	15 weeks	-2.0 (-3.6, -0.4)	.002	-2.8 (-4.8, -0.7)	.001	-0.6(-2.5, 1.3)	.420
	12 months	-0.7 (-2.4, 1.0)	.276	-1.6(-3.2,-0.0)	600.	-0.2 (-2.3, 1.9)	.789
Smoking measures							
Cigarettes per day	15 weeks	-14.8 (-21.4, -8.2) <	<.001	-13.7(-17.1, -10.3)	<.001	-1.2 (-6.9, 4.4)	.565
	12 months	-8.5 (-12.8, -4.2) <	<.001	-8.7 (-13.1, -4.4)	<.001	-0.5(-6.1, 5.0)	.796
Expired carbon monoxide (CO)	15 weeks	-5.9(-11.7, -0.2)	.008	-10.3 (-16.4, -4.2)	<.001	-3.1(-9.8, 3.7)	.233
	12 months	-4.9(-10.7, 0.8)	.026	-7.9 (-13.6, -2.1)	<.001	0.4 (-6.3, 7.2)	.864
Fagerstrom Test for Nicotine Dependence (FTND)	15 weeks	-2.0 (-2.8, -1.1) <	<.001	-1.9 (-2.6, -1.2)	<.001	0.3 (-0.9, 1.5)	.486
	12 months	-0.8(-1.7, 0.1)	.015	-1.2(-2.1, -0.3)	<.001	-0.1 (-1.2, 1.0)	.814
Cannabis (use occasions per day)	15 weeks	0.8(-0.9, 2.6)	.218	-0.5(-2.0, 1.0)	.367	-0.3 (-1.3, 0.7)	.439
	12 months	-0.2(-0.7, 0.3)	.265	-0.9(-2.2, 0.4)	.077	-0.7 $(-1.6, 0.2)$	.045
Psychiatric symptomatology and quality of life							
Brief Psychiatric Rating Scale (BPRS-24)	15 weeks	0.6(-2.5, 3.7)	.632	-2.3(-5.0, 0.5)	.032	-1.8(-6.1, 2.4)	.252
	12 months	-0.5(-4.5, 3.5)	.758	-4.6 (-8.8, -0.4)	.005	-2.9(-7.1, 1.2)	.066
Beck Depression Inventory (BDI-II)	15 weeks	-3.0(-7.0, 0.9)	.046	-2.8(-6.0, 0.3)	.018	-0.2(-4.9, 4.5)	.915
	12 months	-3.6(-6.8, -0.3)	.005	-3.8(-8.1, 0.4)	.018	-0.1 $(-4.6, 4.4)$	.940
Global Assessment of Functioning (GAF)	15 weeks	3.9(0.6, 7.1)	.002	5.3(1.6, 9.1)	<.001	$-0.1 \ (-6.0, 5.7)$	.950
	12 months	9.7 (5.3, 14.0) <	<.001	9.9 (4.5, 15.2)	<.001	1.2 (-4.2, 6.6)	.556
Impact of Weight on Quality of Life (IWOQOL-Lite)	15 weeks	-0.6(-5.6, 4.4)	.755	-3.8(-8.0, 0.4)	.018	-3.1 $(-12.4, 6.2)$	.380
	12 months	-2.4(-8.4, 3.6)	.286	-8.4(-18.7, 2.0)	.035	-6.7 $(-15.7, 2.2)$	.051
SF-12 Mental Component Scale (MCS)	15 weeks	0.3 (-2.5, 3.0)	.801	1.1 (-1.6, 3.8)	.290	-0.5(-4.6, 3.6)	.741
	12 months	0.8(-2.9, 4.4)	.571	1.6(-2.4, 5.6)	.287	1.0 (-3.5, 5.5)	.547
SF-12 Physical Component Scale (PCS)	15 weeks	$-0.1 \ (-1.8, 1.7)$	.913	1.5 (-0.4, 3.5)	.042	1.5 (-1.6, 4.6)	.208
	12 months	$1.4 \ (-1.5, 4.3)$	.200	1.0(-2.4, 4.4)	.420	-0.1 (-3.5, 3.4)	.961
Health behaviors							
Walking time (minutes per week)	15 weeks	39.6 (-173, 252)	.624	-10.1 (-159, 139)	.860	-76.3 (-321, 168)	.415
	12 months	96.3 (-113, 306)	.226	-38.9 (-179, 101)	.464	-155.4 (-385, 74.3)	.079
Sitting total (minutes per week)	15 weeks	-294.4 (-843, 254)	.160	-77.0 (-601, 447)	.700	200.5 (-482, 883)	.443
	12 months	-27.3 (-628, 574)	.904	-210.6(-784, 363)	.333	-136.3 (-770, 498)	.574
Alcohol (standard drinks per day)	15 weeks	$0.4 \ (-0.2, 1.1)$	.072	-0.1 (-0.6, 0.4)	.520	$0.1 \ (-1.2, 1.4)$	.901
	12 months	-0.7 $(-3.5, 2.0)$	.495	-0.3 (-1.2, 0.7)	.443	$0.2 \ (-1.1, 1.5)$	.679
Number of daily vegetable servings <sup>a</sup>	15 weeks	0.1 (-0.4, 0.5)	.638	-0.1 (-0.5, 0.3)	.417	$0.82\ (0.60, 1.12)$	.100
	12 months	0.0(-0.5, 0.6)	.908	-0.4(-0.9, 0.1)	.021	$0.78\ (0.54, 1.12)$	.078
Number of daily fruit servings <sup>a</sup>	15 weeks	0.1 (-0.3, 0.5)	.569	-0.0(-0.4, 0.4)	.994	$0.92\ (0.63, 1.34)$	.567
	12 months	-0.1(-0.4, 0.3)	.631	0.0(-0.3, 0.4)	.771	1.11(0.72, 1.70)	.530
Combined number of daily fruit and vegetable	15 weeks	0.2 (-0.5, 0.8)	.494	-0.1(-0.8, 0.5)	.544	$0.86\ (0.66, 1.12)$	.151
servings <sup>a</sup>	12 months	-0.1 (-0.8, 0.7)	.830	-0.4(-1.1, 0.3)	.106	$0.89\ (0.66, 1.21)$	.330
CI = confidence interval: CVD = cardiovascular disease. See S	Supplementary Table	s S2 and S5 for further details a	hour th	- measures and change analy	ses for the	viomedical indices respectively.	aeneralized linear mixed

CI = confidence interval; CVD = cardiovascular disease. See Supplementary 1apus are and baseline scores. models were used to examine change over time and group effects, controlling for study site and baseline scores. \*Comparable Poisson loglinear analyses were used for these outcomes.

Table 3.	Categorical	Smoking	JOutcome Measures b	y Intervention Conditi	on, Level of Attendance	, and Use of NRT
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		15 weeks			12 months		
Measure/group	<i>n</i> (% yes)	Odds ratio (99% CI)	Group effect P value	<i>n</i> (% yes)	Odds ratio (99% CI)	Group effect P value	
Confirmed point prevalence abstinence							
Healthy Lifestyles condition	13 (11%)	0.92 (0.31, 2.70)	.837	8 (6.6%) <sup>a</sup>	1.06 (0.31, 4.35)	.910	
Telephone condition	13 (12%)	referent		$7 (6.2\%)^{a}$	referent		
High attendance (9-17 sessions)	22 (16%)	4.76 (1.11, 20.0)	.006	11 (8.2%)	2.17 (0.46, 10.0)	.199	
Low-midrange attendance (1-8 sessions)	4 (4.0%)	referent		4 (4.0%)	referent		
Any NRT use	25 (14%)	4.55 (0.31, 100)	.142	13 (7.2%)	1.09 (0.14, 8.33)	.919	
No NRT use	1 (3.3%)	referent		2 (6.7%)	referent		
Smoking reduction of 50% or greater relative	e to baseline						
Healthy Lifestyles condition	38 (31%)	0.64 (0.31, 1.30)	.099	19 (16%)	0.81 (0.33, 2.00)	.542	
Telephone condition	47 (42%)	referent		21 (19%)	referent		
High attendance (9–17 sessions)	69 (51%)	5.56 (2.44, 12.5)	<.001	33 (25%)	4.35 (1.39, 14.3)	<.001	
Low-midrange attendance (1-8 sessions)	16 (16%)	referent		7 (6.9%)	referent		
Any NRT use	81 (45%)	7.14 (1.43, 33.3)	.002	37 (20%)	2.33 (0.44, 12.5)	.190	
No NRT use	3 (10%)	referent		3 (10%)	referent		

CI = confidence interval; NRT = nicotine replacement therapy. Binary logistic regressions were used for these analyses, controlling for study site.

<sup>a</sup>Includes those who were continuously abstinent across the 12-month follow-up period (Healthy Lifestyles condition, *n* = 4; telephone condition, *n* = 5).

(monitoring and discussing CVD risk behaviors) was at least as effective as NRT plus an intensive face-to-face Healthy Lifestyles intervention among smokers with a psychotic disorder. Both interventions were associated with significant reductions in CVD risk (predominantly during the intervention phase), cigarette consumption and nicotine dependence, together with associated quality of life improvements. The confirmed 7-day point prevalence smoking abstinence rate of 6.4% at 12 months is consistent with the 3.8%–13.3% range (for 6–13 months) reported by Banham and Gilbody.<sup>16</sup> Likewise, the finding that 17% experienced a 50% or greater reduction in smoking at 12 months is consistent with the 21% rate reported by Morris et al.<sup>24</sup> for a quitline plus group smoking cessation program. Both of these comparator studies were also conducted among smokers with severe mental illness.

Our hypothesis that a Healthy Lifestyles intervention would be more efficacious for smoking cessation was thus not supported in this sample. We had expected the combination of a more intensive face-to-face intervention (comprising motivational interviewing and cognitive behavior therapy), together with contingency management, would be more powerful than a predominantly telephone-delivered intervention consisting mainly of NRT delivery and CVD risk monitoring and discussion.

There are several possible reasons why the interventions were associated with equivalent smoking outcomes. Firstly, potential participants were invited to join a Healthy Lifestyles study among smokers with a psychotic illness. As overall health was the focus, smoking outcomes may have been different if the study had been advertised as focused primarily on smoking cessation (eg, potentially improving the fit between participants' treatment expectations and actual intervention content and delivery, which focused predominantly on smoking in the current trial). Secondly, the scheduled duration of sessions (1 hour vs. 10 minutes) was designed to allow for greater treatment intensity in the face-to-face condition. However, ongoing discussions about CVD risk behaviors occurred in both conditions and attendance was somewhat better in the telephone-based condition, acting to reduce differences in the "dose" of the intervention.

In our pilot Healthy Lifestyles study, 36 of the 43 participants attended all nine face-to-face sessions.<sup>25</sup> Acting on participant

feedback, we extended the duration of interventions in the present study to 17 sessions. However, attendance rates suggest that treatment fatigue may be a factor, with the burden of face-to-face interventions (eg, more time in travel and session attendance; transport issues) being greater than telephonic interventions. However, similar to previous studies,<sup>26-28</sup> greater session attendance and NRT use were associated with better outcomes. In their study of smoking cessation in homeless populations, Okuyemi et al.<sup>28</sup> suggested that increasing NRT adherence has the potential to enhance quitting outcomes. This may be worthy of further investigation among smokers with psychotic disorders.

A third possibility is that the content of the telephone-based intervention may have been especially suitable for people with psychotic disorders. Consisting largely of monitoring and discussing aspects of smoking cessation, the targeted and concrete nature of the intervention may have enhanced its efficacy. Interestingly, the telephone-based intervention was similar in content to the nine-session "medication management" condition employed by Williams et al.,<sup>27</sup> which was found to be as effective as a 24 session intervention similar to the one described above.

Given the efficacy of the telephone-based intervention, a trial of a telephone intervention without any face-to-face component seems warranted among smokers with severe mental illnesses. Few such studies have yet been conducted, although quitlines are being increasingly recognized as potentially effective for smokers with severe mental illnesses.<sup>24,29</sup> There is also evidence that quitline–doctor comanagement of smoking cessation and depression is feasible, valued by smokers, and increases the probability of quit attempts,<sup>30</sup> without exacerbation of depression. The current findings are also consistent with our previous studies,<sup>25–27,31</sup> in that smoking reduction or cessation is not associated with any worsening of psychiatric symptomatology.<sup>32</sup>

Contrary to our prediction, there were no significant differences between conditions with respect to changes in physical activity, body mass index, or self-reported diet. There was wide variability in activity measures, making detection of change difficult. In our pilot trial,<sup>25</sup> eligibility criteria included smoking and being overweight, and we demonstrated improvements in both variables. Our goal in the present study was to improve overall diet and not weight *per se*, as people with severe mental illnesses have poor diets, regardless of weight.<sup>1</sup> In future studies, it may be advantageous to establish stricter eligibility criteria for the health behaviors under investigation. Moreover, it is possible that the first face-to-face session received by all participants, involving feedback of assessment results and motivational interviewing, combined with weekly monitoring in the telephone condition also contributed to our failure to detect differences.

Banham and Gilbody<sup>16</sup> found no cost-effectiveness studies of smoking cessation/reduction measures in people with psychotic disorders. They suggested that future research must consider both cost and how new interventions will fit into existing service structures. Telephone-based interventions are likely to be more cost-effective than face-to-face interventions, and potentially deliverable by a broader cross-section of health and/or research staff. Evaluation of a quitline delivered intervention employing the manual used in the telephone-based intervention in the present study, including costeffectiveness and feasibility of fit, are warranted. More broadly, the modest gains achieved in the current study, together with the health disparities typically experienced by those with psychotic disorders, should strengthen our resolve to develop better, more integrated multicomponent interventions, which can be delivered in an acceptable, effective and sustainable manner.

There are several limitations of the present study. The CVD risk measure used here partly reflects age, so that younger participants do not score highly on such measures at baseline. Apart from number of cigarettes per day, the sample was not selected on the basis of other problematic health behaviors, making comparisons across conditions difficult. Inclusion of participants at all stages of change for quitting smoking, while justifiable, also complicates comparisons with other studies using different recruitment criteria. The follow-up rate of 59% is lower than we have achieved in similar studies<sup>33</sup> and may have been partly due to the burden of assessment in measuring multiple health domains.

In conclusion, face-to-face Healthy Lifestyle and telephone-based interventions for smoking among people with psychotic disorders appear to be feasible and somewhat effective. Given the accessibility of telephone delivered interventions, combined with lower cost, further studies are needed to evaluate telephonic interventions for people with severe mental disorders. We have conducted a small pilot study showing a telephone intervention to be effective for increasing fruit and vegetable consumption and decreasing leisure screen time among people with schizophrenia.<sup>34</sup> If telephonic smoking interventions of sequential or combined behavior change interventions would be of great interest.

#### **Supplementary Material**

Supplementary Tables S1–S5 and Supplementary Analysis can be found online at http://www.ntr.oxfordjournals.org

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#### **Declaration of Interests**

None declared.

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### SUPPLEMENTARY TABLES

_		Healthy Lifestyles condition $(n = 122)$						
Contact frequency	Session	Planned contact (duration)	Average attendance % ( <i>n</i> )	Average using NRT % ( <i>n</i> )	Planned contact (duration)	Average attendance % ( <i>n</i> )	Average using NRT % ( <i>n</i> )	Assessment phase
								Baseline
Weekly	1	Face-to-face (90 minutes)	89.3 (109)	6.6 (8)	Face-to-face (90 minutes)	90.3 (102)	8.0 (9)	
	2-3	Face-to-face (60 minutes)	76.2 (93)	49.2 (60)	Telephone (10 minutes)	84.1 (95)	67.3 (76)	
	4	Face-to-face (60 minutes)	63.9 (78)	47.5 (58)	Face-to-face (30 minutes)	81.4 (92)	62.8 (71)	
	5-7	Face-to-face (60 minutes)	55.7 (68)	39.3 (48)	Telephone (10 minutes)	71.7 (81)	57.5 (65)	
	8	Face-to-face (60 minutes)	49.2 (60)	33.6 (41)	Face-to-face (30 minutes)	69.9 (79)	50.4 (57)	
Fortnightly	9-11	Face-to-face (60 minutes)	41.8 (51)	25.4 (31)	Telephone (10 minutes)	66.4 (75)	42.5 (48)	15 weeks
Monthly	12-17	Face-to-face (60 minutes)	28.7 (35)	12.3 (15)	Telephone (10 minutes)	49.6 (56)	20.4 (23)	
								12 months

### Table S1. Session Attendance Pattern and NRT Distribution by Treatment Condition

Note. There was a significant overall difference in session attendance between the Healthy Lifestyles (mean = 9.2, SD = 6.0) and telephone (mean = 12.4, SD = 5.2) conditions (P < .001) among those who attended at least one session (n = 211). NRT = Nicotine Replacement Therapy; maximum eligible NRT dose = 7mg, 14mg or 21mg patches + 12 x 2mg lozenges per day; heavy smokers (at least 30 cigarettes per day) were eligible to receive double patching (2 x 21mg patch), in addition to up to 12 x 2mg lozenges per day (with a maximum total dose of 66mg of NRT per day); NRT supply typically ceased around session 14. By sessions 2-3, the two treatment conditions differed in their reported NRT rates (49% vs. 67%,  $\chi^2$  = 7.86, P = .005); however, at 12 months, comparable NRT rates were reported across the intervention period (85% vs. 88%).

Domain	Measures	References	Selected scoring or other details
Cardiovascular Disease (CVD) risk	ASSIGN score: calculated from age, gender, total cholesterol, high-density lipoprotein, systolic blood pressure, diabetes, family history of heart disease, cigarettes per day ( <b>Primary</b> <b>Outcome</b> )	(Woodward, Brindle, & Tunstall-Pedoe, 2007)	Estimated CVD risk scores were derived using the ASSIGN algorithm, based on numerous biomedical parameters (see Column 2), and taking into account the social gradients of CVD. The ASSIGN score has been validated against the Framingham score (Woodward et al., 2007) and provides a measure of the likelihood of having a CVD related event within the next 10 years.
	Blood pressure		Omron Automatic Blood Pressure Monitor - taking the average of three blood pressure measurements.
	Cholesterol and blood glucose		Blood cholesterol and blood glucose levels were measured using finger-prick blood tests and a Cardiochek PA analyser - using the Total Cholesterol (TC), High-density lipoprotein (HDL) and glucose (GLU) test panels and the Low-density lipoprotein (LDL) test panel.
Smoking measures	Cigarettes per day – using the Opiate Treatment Index (OTI) 7-day point prevalence abstinence ( <b>Primary Outcome</b> ) Continuous abstinence Expired carbon monoxide (CO): Self-reported smoking	(OTI; Darke, Hall, Wodak, Heather, & Ward, 1992) (Carmody et al., 2012)	Cigarettes per day was also one of the parameters included in the ASSIGN score. Seven-day point prevalence abstinence rate refers to the proportion who had been abstinent for the seven days preceding the follow-up assessment. This was verified using levels of expired CO, as measured by the Micro 11 Smokerlyser. Continuous abstinence rate refers to the proportion of participants who reported not smoking at all from the nominated quit date to the follow-up assessment. The Micro 11 Smokerlyser assesses breath levels of (CO). CO was measured one hour after participant arrival, to control partially for
	using a Micro 11 Smokerlyser Smoking reduction status ( <b>Primary Outcome</b> )	(Carmody et al., 2012)	participant was unlikely to have smoked in the last 8 hours. Smoking reduction status was based on an assessment of whether or not the participant had reduced their daily cigarette consumption by 50% or greater (including abstinence) relative to baseline.
	Fagerstrom test for nicotine dependence (FTND) Readiness and Motivation to quit smoking (RQM)	(FTND; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) (RQM; Crittenden et al., 1998)	Motivation to quit smoking was measured using the 11-item RQM, which provides an elaborated stages of readiness scale, ranging from 0 (pre-contemplation level 1: not contemplating quitting or cutting down) to 4 (preparation stage)
	Additional questions on smoking history were also included		

### Table S2. Assessment Measures by Domain Type across the Baseline, 15 weeks and 12 months Assessments

Psychiatric symptomatology and quality of life	Diagnosis was determined using the MINI neuropsychiatric examination Brief Psychiatric Rating Scale (BPRS-24) Beck Depression Inventory (BDI- II) Global Assessment of Functioning (GAF) scale 12 item Short Form survey (SF- 12) Recent hospital admissions	(Sheehan et al., 1998) (BPRS-24; Ventura, Nuechterlein, Subotnik, Gutkind, & Gilbert, 2000) (BDI-II; Beck, Steer, & Garbin, 1988) (GAF; American Psychiatric Association, 1994) (SF-12; Ware Jr, Kosinski, & Keller, 1996)	The SF-12 produces Mental Component Scores (MCS) and Physical Component Scores (PCS), with lower scores indicating greater disability. Number of hospital admissions in the past 12 months.
Health behaviors	International Physical Activity Questionnaire (IPAQ) Number of daily servings (of vegetables, fruit, or combined) Unhealthy eating index (Not used in current analysis)	(IPAQ; Craig et al., 2003)	Assessed overall activity level, including time spent walking and sitting (expressed as minutes per week). Physical activity level was assessed as average minutes walking continuously and briskly per week (based on diary entries). Diet and nutrition were assessed using 24 hour eating habits recall – see below for items covered. An overall unhealthy eating index was also created, with 1 point given for an answer to each question that indicated unhealthy eating habits. The index ranged from 0-12, with higher scores indicating more unhealthy eating habits. Unhealthy eating habits included: non-optimal servings per day of each of the five food groups (e.g., fruit, vegetables, breads, lean meats, and dairy); high fat or high sugar foods; choosing non-wholegrain products; consumption of full sugar soft drinks or cordials; missing breakfast; adding salt to food; using full fat dairy products; and consuming meat with visible fat.
Weight	Weight (Kg), Body Mass Index (BMI), Waist and hip circumference, & waist to hip ratio		Using Seca 770 digital scales.
	Impact of Weight On Quality Of Life (IWOQOL-lite) scale	(IWOQOL-lite; Abraham, 2003)	
Alcohol, cannabis and substance use	Opiate Treatment Index (OTI) Daily caffeine intake	(OTI; Darke, Hall, Wodak, Heather, & Ward, 1992)	Self-reported use of alcohol and cannabis in the previous 28 days were assessed using the Drug Use domain of the OTI. Alcohol consumption is reported as standard drinks per day. Participants were also asked to report their usual daily caffeine intake.

	· · · · ·	Healthy Lifestyles	Telephone
Session	Measure	condition	condition
		Mean (SD)	Mean (SD)
1	Overall duration (minutes)	109.	7 (35.6)
	Discussion of CVD risk behaviors:		
	Diet (minutes)	13.	2 (8.5)
	Exercise discussion (minutes)	7.6	6 (5.1)
	Smoking (minutes)	36.9	9 (14.0)
	Cognitive Therapy Scale:		
	Therapy adherence (%)	91.1 ( <i>i</i>	n = 31/34)
2-17	Overall duration (minutes)	59.6 (14.9)	16.7 (8.7)
			(Excl. Sess. 4 & 8): 13.2
			(4.6)
			(Sess. 4 & 8): 28.9 (8.7)
	Discussion of CVD risk behaviors:		
	Diet (minutes)	5.0 (6.71)	1.5 (0.9)
	Exercise discussion (minutes)	3.7 (4.2)	1.0 (0.6)
	Smoking (minutes)	24.2 (13.0)	4.8 (2.9)
	Cognitive Therapy Scale:		
	Therapy skills rating	3.71 (0.78)	-
	Therapy adherence (%)	89.4 ( <i>n</i> = 152/170)	93.3 ( <i>n</i> = 126/135)

### Table S3. Treatment Session Duration, Treatment Fidelity and Therapist Competence

*Note.* Overall, 1271 sessions (56.3%) were recorded (Healthy Lifestyles condition = 65.1%; Telephone condition = 49.3%); technical problems (i.e., difficulties recording from the telephone) largely accounted for the differential rates across conditions. A randomly selected 25% representative subsample of the recorded sessions was included in the current evaluation (i.e., with proportionate coverage of treatment conditions and sessions). Therapy skills were rated on a six point scale (0-5): inadequate, mediocre, satisfactory, good, very good, and excellent.

Measure	Overall $(n = 235)$	Healthy Lifestyles condition (n = 122)	Telephone condition ( <i>n</i> = 113)	Condition comparison <i>P</i> value
Body Mass Index (BMI)	30.6 (6.3)	30.5 (6.0)	30.6 (6.6)	.853
Waist circumference (cm)	104.61 (16.92)	104.82 (16.71)	104.38 (17.20)	.845
Weight (kg)	90.91 (20.83)	91.68 (21.40)	90.11 (20.28)	.570
Waist to hip ratio	0.95 (0.09)	0.95 (0.09)	0.95 (0.10)	.752
Diastolic blood pressure	80.54 (11.75)	80.97 (11.52)	80.06 (12.04)	.560
Systolic blood pressure	123.06 (16.09)	123.08 (14.32)	123.05 (17.85)	.989
HDL cholesterol	1.08 (0.77)	1.09 (0.97)	1.08 (0.49)	.957
LDL cholesterol	3.56 (1.26)	3.58 (1.23)	3.53 (1.29)	.770
Total cholesterol	5.00 (1.60)	4.85 (1.46)	5.15 (1.74)	.171
Blood glucose	5.55 (2.13)	5.18 (1.42)	5.94 (2.63)	.007

### Table S4. Mean (SD) for Baseline Biomedical Measures: Overall and by Treatment Condition

*Note*. HDL = High-density lipoprotein; LDL = Low-density lipoprotein.

		Healthy Lifestyles condition		Telephone condition		Difference between groups	
Measure	Follow-up time	Mean change	Ρ	Mean change	Ρ	Least square mean difference	Group effect
		(99% CI)		(99% CI)		(99% CI)	P value
Body Mass Index (BMI)	15 weeks	0.4 (-0.3, 1.0)	.133	0.0 (-0.5, 0.6)	.948	-0.4 (-1.6, 0.8)	.379
	12 months	0.2 (-0.9, 1.2)	.688	-0.5 (-1.4, 0.3)	.102	-0.8 (-1.9, 0.4)	.077
Waist circumference (cm)	15 weeks	-0.4 (-2.6, 1.8)	.651	-0.6 (-2.4, 1.2)	.373	-0.6 (-4.2, 2.9)	.640
	12 months	-0.7 (-3.6, 2.3)	.556	-1.7 (-4.8, 1.5)	.161	-1.1 (-4.6, 2.4)	.411
Weight (kg)	15 weeks	0.6 (-0.8, 2.0)	.258	-0.1 (-1.8, 1.6)	.904	-1.9 (-4.9, 1.2)	.111
	12 months	-0.7 (-3.6, 2.3)	.556	-1.7 (-4.8, 1.5)	.161	-1.1 (-4.6, 2.4)	.411
Waist to hip ratio	15 weeks	0.00 (-0.02, 0.02)	.747	-0.01 (-0.04, 0.02)	.214	-0.0 (-0.1, 0.0)	.340
	12 months	0.00 (-0.02, 0.03)	.685	-0.01 (-0.04, 0.02)	.312	-0.0 (-0.1, 0.0)	.307
Diastolic blood pressure	15 weeks	-1.1 (-6.1, 3.8)	.555	1.9 (-1.5, 5.3)	.143	2.0 (-4.2, 8.1)	.401
	12 months	-0.3 (-4.9, 4.4)	.875	-0.7 (-5.8, 4.4)	.715	-0.6 (-6.7, 5.6)	.811
Systolic blood pressure	15 weeks	-5.0 (-11.0, 1.0)	.030	-0.9 (-6.0, 4.2)	.644	4.3 (-3.4, 12.1)	.145
	12 months	-1.4 (-6.8, 3.9)	.484	-1.7 (-8.2, 4.9)	.495	-0.2 (-7.9, 7.5)	.946
HDL cholesterol	15 weeks	0.3 (-0.6, 1.2)	.435	0.1 (-0.1, 0.4)	.145	0.3 (-0.1, 0.7)	.071
	12 months	0.1 (-0.2, 0.4)	.477	0.3 (-0.2, 0.7)	.110	0.3 (-0.1, 0.8)	.068
LDL cholesterol	15 weeks	-0.1 (-0.5, 0.3)	.428	0.0 (-0.3, 0.3)	.800	0.1 (-0.4, 0.6)	.530
	12 months	-0.1 (-0.6, 0.3)	.428	-0.4 (-0.8, 0.1)	.035	-0.2 (-0.7, 0.3)	.383
Total cholesterol	15 weeks	0.4 (0.1, 0.8)	.004	-0.1 (-0.6, 0.4)	.642	-0.1 (-0.8, 0.7)	.849
	12 months	0.1 (-0.5, 0.7)	.674	-0.4 (-1.4, 0.6)	.273	-0.3 (-1.1, 0.4)	.254
Blood glucose	15 weeks	0.6 (-0.1, 1.2)	.024	0.7 (-1.5, 2.9)	.399	1.3 (-1.4, 4.0)	.215
	12 months	0.9 (-0.1, 1.8)	.015	-0.9 (-1.9, 0.1)	.024	-0.6 (-3.4, 2.2)	.560

 Table S5. Mean Change from Baseline (99% CI) for Biomedical Measures by Intervention Condition

Note. HDL = High-density lipoprotein; LDL = Low-density lipoprotein; generalized linear mixed models were used to examine change over time and group effects, controlling for study site and baseline scores.

# SUPPLEMENTARY ANALYSIS: Impact of baseline smoking stage of change on cigarette consumption changes

At baseline, approximately 15% (33/121) of participants fell into the "precontemplation" stage of change for quitting smoking, 56% (124/221) were at the "contemplation" stage, and 29% (64/221) were at the "preparation" stage (Crittenden et al., 1998). Because the interventions addressed multiple health behaviors and included motivational elements, participants at all stages of change for quitting smoking were included. To assess the impact of this decision, we conducted some supplementary analyses of changes in cigarette consumption, using the same predictors and covariates as in the main generalized linear mixed model analyses (see Table 2 and Supplementary Table S5), but with the addition of baseline stage of change (0-2: pre-contemplation; 3: contemplation; 4: preparation) and its interaction with treatment condition.

There were no significant stage of change by treatment condition interactions in the analysis of smoking reductions at 15 weeks and 12 months. However, baseline stage of change did predict changes in cigarettes per day at 12 months ( $F_{(2, 124)} = 5.02$ , P = .008). Consequently, it is likely that the magnitude of the observed mean overall reduction at 12 months (of 8.6 cigarettes per day) would have been greater had those at earlier stages of change been excluded; for example, if the precontemplators were dropped from this analysis (n = 18), the mean reduction from baseline would have been larger by 1.1 cigarettes per day (n = 115). Conversely, from an intervention delivery perspective, these findings suggest that possibly we should have included a more formal and comprehensive motivational interviewing (MI) component in the current trial to more fully engage with participants at earlier stages of change.

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### **APPENDIX 7**

Manic exacerbation induced by nicotine patch

# Manic exacerbation induced by nicotine patch

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#### To the Editor

Nicotine replacement therapy has been widely marketed as a safe form of treatment to aid smoking cessation (Mulligan et al., 1990). One such therapy is nicotine patches, which are readily available in chemists worldwide. Patches are prescribed to patients that cease smoking in hospital to prevent nicotine withdrawal. We would like to present an interesting case of mania induced by the use of nicotine patches.

A 35-year-old man with a past history of bipolar disorder was on an involuntary treatment order for I year, and prescribed risperidone 6 mg and sodium valproate 2000 mg daily. He improved with treatment and was discharged to a community mental health team, but disengaged with treatment and follow-up after his treatment order lapsed and remained stable in the community for 2 years before his recent manic episode.

He presented in June 2011 with a 2-week history of deterioration in his mental state with accompanying manic symptoms but no psychosis. There was no alcohol or illicit substance use history. His recent life course was unremarkable except for his health concerns related to his mitochondrial myopathy which was diagnosed when he was young. Clarification of possible triggers to his manic episode revealed a recent abrupt cessation of cigarette smoking after a 20-year history of nicotine dependence (40 cigarettes/day). He started transdermal nicotine patches of the maximum 21 mg strength the next day and used them 24 hours a day, changing them every morning.

Within 3 weeks of starting the nicotine patch, his energy levels increased and his sleep decreased to 3 hours overnight. He was noted by family to be irritable with uncontrollable anger and physical aggression towards property. At the time of admission, he had increased psychomotor activity, pressured speech, and an elevated mood.

All investigations conducted were normal but his MRI showed early onset generalized cerebral atrophy that was more than expected for his age.

He was started on low dose quetiapine (100 mg/day) as he was apprehensive about the potential side effects of an antipsychotic on his myopathy. Nicotine patches were ceased at the time of his admission to hospital. He improved within a week on quetiapine initiation and the cessation of nicotine patches. He was therefore discharged after a brief admission on 100 mg of quetiapine.

The temporal correlation between the onset of his manic symptoms and the use of nicotine patches continuously suggested a possible correlation between excessive nicotine levels and the precipitation of a manic episode. The quick resolution of his manic symptoms on a relatively low dose of quetiapine and with the cessation of nicotine patches supported this possible association. However, there is paucity of literature exploring this relationship (Benazzi, 1989; Labbate, 1992; Foulds and Toone, 1995; Foulds, 1996; Scurlock and Lucas, 1996).

There are two possible mechanisms by which the use of nicotine patches could have precipitated a manic episode. One possible explanation is a disruption of sleep/wake cycle induced by nicotine patches which acted as a stimulant (Foulds and Toone, 1995).

The other putative mechanism may involve the stimulation of mesolimbic dopaminergic cells mediated through cholinergic input via nicotinic receptors. Stimulation of nicotinic receptors by nicotine leads to a release of dopamine from mesolimbic neurons. Cigarette smoking is a pulsatile nicotine delivery system unlike transdermal skin patches that deliver nicotine

continuously. In smokers, there is an upregulation of nicotinic cholinergic receptors over time to compensate for the fact that nicotine keeps turning the receptors off (Stahl, 1996). The use of nicotine transdermal patches in a reformed smoker can therefore lead to increased occupancy of nicotinic cholinergic receptors on mesolimbic dopaminergic neurons causing increased dopaminergic activity. In our patient having a vulnerable brain together with the fact he was not on maintenance mood stabilization treatment would have increased his vulnerability to a manic relapse under this potential hyperdopaminergic milieu.

The understanding of this potential risk is of clinical relevance given increased use of nicotine patches after the implementation of the non-smoking policy within health settings. This case report highlights the importance for clinicians to educate vulnerable patients about the proper use of nicotine patches and its potential stimulant and/or overdose effects especially with concurrent cigarette smoking. Based on this report and the limited literature covering this topic, we propose that this relationship be studied further in the future.

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