ADDRESSING SMOKING AMONG PERSONS ACCESSING ACUTE PSYCHIATRIC SERVICES: A NEED FOR PROACTIVE AND UNIVERSAL INTERVENTION

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Submitted for the Degree of Doctor of Philosophy

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October, 2016

Statement of Originality

The thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository**, subject to the provisions of the Copyright Act 1968.
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Statement of Authorship

I hereby certify that this thesis is in the form of a series of *papers. I have included as part of the thesis a written statement from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training), attesting to my contribution to any jointly authored papers. (*Refer to clause 39.2 of the Rules Governing Research Higher Degrees for acceptable papers; Appendix 1).

SIGNED:……..……

Alexandra Metse

October, 2016

Acknowledgments

This thesis would not have been possible without the support and assistance of a number of organisations and individuals.

Firstly, I would formally like to thank the University of Newcastle, particularly the School of Psychology, for supporting me to undertake a research higher degree. I also acknowledge the National Health and Medical Research Council and Hunter New England Health District – without their support this research would not have been possible. Importantly, I express sincere gratitude to the participants that contributed their time to this research, and for their willingness to share their experience with the research team.

To my supervisors Jenny Bowman, John Wiggers and Paula Wye, I wholeheartedly thank you for your guidance, support, patience, nurturance, and optimism along this journey. I could have never foreseen the extent of learning that would take place throughout a PhD and will be forever grateful for the time and energy you have all invested to enable me to develop the research skills I have today. As a team we have produced a number of quality publications that will contribute to improving the health of one of the most vulnerable populations in high income countries – an accomplishment of which I am very proud!

A very special thank you in particular to Jenny for fostering a supportive, flexible and reassuring working environment. Many challenges, both academic and personal, have arisen in recent years - without your kindness (and humour!) I am unsure if I would have made it this far. Your dedication to redressing the health inequities experienced by persons with a mental illness is inspiring and has engendered my

passion to continue researching in the field. I am beyond grateful to have had you as my primary PhD supervisor.

A number of individuals and groups were integral to the No Butts Support for Health Project and my PhD experience. To Kim Lilly and the CATI team – thank you for your persistent, professional and flexible approach to the management and undertaking of the follow-up assessments. To all the recruiters, thank you for your dedication to the project, willingness for continued learning, and for giving up your Saturdays for 18 months! A special thank you to Ashikin Hizam, Jane Goodwin, Eliza Skelton, David Wilkinson, Amber Ryan, and Sally Plunkett – your friendly office visits always put a smile on my face, even after the longest of days. To the support callers, thank you for delivering the intervention to our participants with compassion and conscientiousness. Maryanne Robinson, Naomi Cooper, Stephanie Lithgow and Sam McCrabb – I often reflect on how fortunate the project was to have had you at its forefront, thank you for your unwavering commitment. To the grant co-investigators, thank you for your input during the conceptual and design phases of the project, and for your advice and gentle assistance in improving my skills as an early career researcher over the past 4 years.

To all my fellow clinical and research students – including Ashleigh Pasculli, Ally Logatchova, Rebecca Meldrum-Hanna, Lisa Riley, Caitlin Fehily, Jacqueline Bailey, Julia Dray and Danika Tremain - you have all assisted me in some important way, whether helping me to catch-up with clinical content when research took over, debriefing about the challenges of post-graduate studies over coffee (or champagne!), pointing out there is life beyond the PhD, discussing our love of animals, or quoting our favourite movies or TV shows together. To my clinical psychology supervisors – Glen Wand, Gillian Maddock, Chris Wilcox, Kasey Ackers and Kim Evans - thank you for

understanding the demands of a joint masters and PhD program and for flexibly nurturing me through the clinical training.

To the participants in the ‘Tuesday/Thursday Afternoon Think Tank’ - Lyndell Moore, Emma Bence, David Wilkinson, Caitlyn Fehily, Ashikin Hizam and Lauren Gibson – these ‘sessions’ are perhaps some of my fondest memories across the PhD journey, thank you. The amazingly bizarre ideas developed and consequential laughter refuelled my motivation and capacity to stay on task. I can honestly say I do not think I could have reached the point of submission without such sessions. Lyndell, I have learnt so much from you during this process, regarding research and life generally, and I’m so grateful for our ‘unexpected’ bond. Your friendship is one I will always cherish.

To my wonderful (non-work) friends, thank you for keeping me grounded, understanding when I could not attend weekend getaways or mid-week dinners, and for giving me opportunity to debrief when feeling a little overwhelmed. To my beautiful family – the fundamental support you have provided me with over the years has enabled me to reach my goals - I am grateful, thank you. To Lou in particular – thanks for providing pockets of wisdom when I felt defeated by a task, forwarding endless love and encouragement, and for filling our freezer with healthy meals when work was busy!

Lastly, Joseph – my pillar of strength. Your support throughout this journey has been remarkable. Despite working fulltime whilst completing your own PhD, you somehow found the time to provide me with constant reassurance and encouragement. I am so thankful for your belief in me and all that you have done to enable me to achieve this goal. Life has certainly thrown us some curveballs recently, however they somehow felt manageable with you by my side. I am excited to see what we can achieve in the future.

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Paper 2: Metse AP, Wiggers J, Wye P, Moore L, Clancy R, Wolfenden L, Freund M, Van Zeist T, Stockings E, Bowman JA: **Smoking and environmental characteristics of smokers with a mental illness, and associations with quitting behaviour and motivation; a cross sectional study**. *BMC Public Health* 2016, **16**:332. doi: 10.1186/s12889-016-2969-1

Paper 3: Metse AP, Wiggers J, Wye P, Clancy R, Moore L, Adams M, Robinson M, Bowman JA: **Uptake of smoking cessation aids by smokers with a mental illness**. *J Behav Med* 2016, **39**(5):876-886. doi: 10.1007/s10865-016-9757-3

Paper 4: Metse AP, Bowman JA, Wye P, Stockings EA, Adams M, Clancy R, Terry M, Wolfenden L, Freund M, Allan J *et al*: **Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: study protocol for a randomised controlled trial**. *Trials* 2014, **15**(1):266. doi: 10.1186/1745-6215-15-266

Paper 5: Metse AP, Wiggers J, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman JA: **Efficacy of a sustained**

smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge: a randomised controlled trial. *Aust N Z J Psychiatry*. Under review*.

*Evidence to support manuscript submission/acceptance is included in Appendix 2.

Co-author Statement

I attest that Research Higher Degree candidate Alexandra Metse has contributed to publications for which I am a co-author. For all publications, where applicable, Alexandra has:

• Contributed to the development of research questions

• Contributed to research design and methodology

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Additional Publications and Presentations

Publications

Bailey J, Wye P, Stockings E, Bartlem K, Metse AP, Wiggers J, Bowman J: **Smoking cessation care for people with mental illness: carer expectations of health and community services.** *J Smok Cessat* 2016. Under Review.

Bartlem K, Bailey J, Metse AP, Asara A, Wye P, Wiggers J, Clancy R, Bowman J: **Health risk behaviours and interest in change: a survey of psychiatric inpatients.** *Health Psychol* 2016. Under review.

Stockings E, Bowman J, Wilkinson D,, Wiggers J, Bartlem K, Metse AP: **Changes in patient smoking behaviour following a smoke-free psychiatric hospitalisation**. *Nicotine Tob Res* 2016. Under Review.

Presentations

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Accepted presentations to be delivered

Metse AP, Wiggers J*, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman J: **An integrated smoking cessation intervention for mental health patients: a randomised controlled trial.** Oral Presentation: *World Cancer Congress, Paris, 31st October – 3th November, 2016.*

Metse AP, Wiggers J*, Wye P, Wolfenden L, Prochaska JJ, Stockings E, Williams JM, Ansell K, Fehily C, Bowman J: **Smoking and mental illness:**

a bibliometric analysis of research output over time. Oral presentation: *World Cancer Congress, Paris, 31st October – 3th November, 2016.*

Bartlem K, Bailey J*, Metse AP, Wye P, Wiggers J, Clancy R, Bowman J: **Chronic disease risk behaviours among people with a mental illness: prevalence, interest in change and acceptability of risk reduction care.** Oral presentation: *World Cancer Congress, Paris, 31st October – 3th November, 2016.*

Bailey J*, Wye P, Bartlem K, Wiggers J, Stockings E, Metse AP, Bowman J: **Cancer risk behaviour care for people with a mental illness: Family carer expectations of health and community services**. Oral presentation: *World Cancer Congress, Paris, 31st October – 3th November, 2016.*

Metse AP, Wiggers J*, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman J: **An integrated smoking cessation intervention for mental health patients: a randomised controlled trial.** Oral Presentation: *European Public Health Conference, Vienna, 9th -12th November, 2016.*

Metse AP, Wiggers J*, Wye P, Wolfenden L, Prochaska JJ, Stockings E, Williams JM, Ansell K, Fehily C, Bowman J: **Smoking and mental illness: a bibliometric analysis of research output over time.** Oral presentation: *European Public Health Conference, Vienna, 9th - 12th November, 2016.*

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Bartlem K, Bailey J*, Metse AP, Wye P, Wiggers J, Clancy R, Bowman J: **Chronic disease risk behaviours among people with a mental illness:**

prevalence, interest in change and acceptability of risk reduction care. Oral presentation: *European Public Health Conference, Vienna, 9th - 12th November, 2016.*

Metse AP*, Wiggers J, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman, J: **An integrated smoking cessation intervention for mental health patients: a randomised controlled trial.** Oral Presentation: *International Congress of Behavioural Medicine, Melbourne, 7th – 10thDecember, 2016.*

Metse AP*, Wiggers J, Wye P, Wolfenden L, Prochaska JJ, Stockings E, Williams JM, Ansell K, Fehily C, Bowman J: **Smoking and mental illness: a bibliometric analysis of research output over time**. Poster presentation: *International Congress of Behavioural Medicine, Melbourne, 7th – 10th December, 2016.*

Bailey J, Wye P, Bartlem K, Wiggers J, Stockings E, Metse AP*, Bowman J: **Chronic disease risk behaviour care for people with a mental illness: family carer expectations of health and community services.** Oral Presentation: *International Congress of Behavioural Medicine, Melbourne, 7th – 10thDecember, 2016.*

Bartlem K*, Bailey J, Metse AP, Wye P, Wiggers J, Clancy R, Bowman J: **Chronic disease risk behaviours among people with a mental illness: prevalence, interest in change and acceptability of risk reduction care.** Oral presentation: *International Congress of Behavioural Medicine, Melbourne, 7th – 10thDecember, 2016.*

Bailey J, Wye P, Bartlem K*, Wiggers J, Stockings E, Metse AP, Bowman J: **A role for family carers in supporting chronic disease risk behaviour change**

among people with a mental illness? Oral Presentation: *International Congress of Behavioural Medicine, Melbourne, 7th – 10th December, 2016.*

Delivered

Fehily C*, Metse AP, Wiggers J, Wye P, Colyvas K, Bowman J: **Efficacy of an integrated smoking cessation intervention for persons with a mental illness: a randomised controlled trial.** Poster Presentation: *Australian Psychological Society Congress, Melbourne, 13th – 16th September, 2016.*

Metse AP, Wiggers J, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman, J*: **An integrated smoking cessation intervention for mental health patients: a randomised controlled trial.** Oral Presentation: *Society for Research on Nicotine and Tobacco (Europe), Prague, 8th – 10th September, 2016.*

Metse AP, Wiggers J, Wye P, Wolfenden L, Prochaska JJ, Stockings E, Williams JM, Ansell K, Fehily C, Bowman J*: **Smoking and mental illness: a bibliometric analysis of research output over time**. Oral presentation: *Society for Research on Nicotine and Tobacco (Europe), Prague, 8th – 10th September, 2016.*

Bailey J*, Bowman J, Wye P, Bartlem K, Stockings E, Metse AP, Wiggers J: **The provision of smoking cessation care for people with a mental illness: carers' expectations of health and community services.** Oral presentation: *Hunter Cancer Research Alliance Symposium, Newcastle, 13th November, 2015.*

Fehily C*, Metse AP, Wiggers J, Wye P, Colyvas K, Bowman J: **Efficacy of an integrated smoking cessation intervention for persons with a mental illness: a randomised controlled trial.** Oral Presentation: *University of Newcastle, School*

of Psychology Fourth Year Conference, Newcastle, 6th November, 2015.

Metse AP*, Wiggers J, Wye P, Clancy R, Moore L, Adams M, Robinson M, Bowman JA: **Uptake of smoking cessation strategies by smokers with a mental illness.** Oral presentation: *Oceania Tobacco Control Conference, Perth, 20th- 22nd October, 2015.*

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Metse AP*, Wiggers J, Wye P, Clancy R, Moore L, Adams M., Robinson M, Bowman JA: **Uptake of smoking cessation strategies by smokers with a mental illness.** Oral presentation: *Population Health Congress, Hobart, 6th - 9th September, 2015.*

Metse AP*, Wiggers J, Wye P, Moore L, Clancy R, Wolfenden L, Freund M, Van Zeist T, Stockings E, Bowman JA: **Social and environmental determinants of smoking cessation: their prevalence and role among smokers with mental illness.** Oral presentation: *Population Health Congress, 6th - 9th September, 2015.*

Bailey J*, Wye P, Stockings E, Bartlem K, Metse AP, Wiggers J, Stockings E: **The provision of smoking cessation care for people with mental illness: expectations and experiences of 'carers'.** Oral presentation: *Australasian Society for Behavioural Health and Medicine Conference, Perth, 11th – 13th February, 2015.*

Metse AP*, Wiggers J, Wye P, Clancy R, Moore L, Adams M, Robinson M, Bowman JA: **Mental health patients' receptivity to and uptake of a**

smoking cessation intervention. Oral presentation: *World Cancer Congress, Melbourne, 3rd – 6th December, 2014.*

Metse AP*, Bowman JA, Wye P, Stockings EA, Adams M, Clancy R, Terry M, Wolfenden L, Freund M, Allan J, Prochaska JJ, Wiggers J: **Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: study protocol for a randomized controlled trial.** Oral presentation: *World Cancer Congress, Melbourne, 3rd – 6th December, 2014.*

Bailey J*, Bowman J, Wye P, Stocking, E, Bartlem K, Metse AP, Wiggers J: **The provision of smoking cessation care for people with mental illness: expectations and experiences of 'carers'.** Oral presentation: *World Cancer Congress, Melbourne, 3rd – 6th December, 2014.*

Metse AP, Bowman JA, Wye P, Stockings EA, Adams M, Clancy R, Terry M, Wolfenden L, Freund M., Allan J, Prochaska JJ, Wiggers J*: **Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: a study protocol.** Poster presentation: *International Congress of Behavioural Medicine, Netherlands, 20th – 23rd August, 2014.*

Synopsis

In a number of high income countries including Australia, persons with a mental illness smoke at rates two to three times greater than the general population. Consequently, this group experience disproportionate levels of preventable tobacco-related morbidity and mortality, and reduced life expectancy of 10 to 25 years. Despite higher levels of nicotine dependence, smokers with a mental illness are motivated to cease smoking and attempt to quit at similar rates to those without a mental illness, however, find it more difficult to do so successfully. The persistently elevated smoking prevalence, in comparison to the steady decline observed among smokers generally over the past two decades, suggests this group has not equally benefited from population-wide smoking cessation interventions, and that the development of tailored interventions is required.

Hospitals have been identified as opportune settings to initiate the provision of smoking cessation interventions, particularly following the introduction of smoke-free policies and the associated need to treat patient nicotine dependence. Admission to a general hospital setting has been shown to have a positive impact on smoking and quitting behaviours, with smoking cessation care provided during hospitalisation and post-discharge increasing the likelihood of prolonged cessation. Integrating hospital smoking care with support post-discharge may therefore represent an intervention approach for psychiatric services to contribute to reducing the prevalence of smoking among people with a mental illness. The efficacy of integrating psychiatric inpatient and community-based smoking support has been assessed in a limited number of trials, of which yielded equivocal findings. In addition, due to a paucity of research surrounding smoking and mental illness, little is also known regarding the determinants of quitting

behaviour among smokers accessing acute psychiatric services, or their receptivity and uptake of smoking cessation aids following discharge. To address these gaps in the literature, the broad aims of this thesis were to:

1. Assess the quantity and quality of research outputs relating to smoking and mental illness.
2. Explore potential determinants of quitting behaviour among persons with a mental illness.
3. Evaluate receptivity to, and utilisation of smoking cessation aids offered to smokers upon discharge from an acute psychiatric inpatient facility.
4. Examine the efficacy of initiating smoking cessation support during an inpatient psychiatric admission and continuing post-discharge in reducing smoking rates among persons with a mental illness.
5. Based on the findings of the studies undertaken to address the above aims, propose recommendations for future research to facilitate smoking cessation for persons accessing psychiatric services.

A series of studies were undertaken to address the first four aims. The first was a repeat cross-sectional bibliometric review of peer-reviewed publications focussed on smoking among persons with a mental illness. Three other studies were carried out across four acute psychiatric facilities in one local health district in New South Wales, Australia: a cross sectional descriptive study of 754 inpatient smokers examining environmental and smoking determinants of quitting behaviour, a descriptive study of 378 recently discharged smokers receiving proactive and universal smoking cessation support addressing receptivity and uptake of such support, and a randomised controlled trial of a smoking cessation intervention offered to patients (N = 754) during a psychiatric inpatient admission and continued post-discharge.

The findings presented in this thesis have contributed to advancing the field of smoking and mental illness research in a number of areas. First, assessment of the volume and characteristics of peer reviewed publications in the field revealed that research regarding smoking among those with a mental illness has increased over time; however it also revealed more research is needed to inform the development and implementation of effective cessation interventions for this group. Second, among a large and diverse population of psychiatric inpatients who were smokers, a high level of exposure to smoking in the immediate residential environment was identified. Further, quitting behaviours were associated with nicotine dependence, receipt of support to quit from a psychiatrist and residing with another smoker. Third, smokers with a mental illness were found to be receptive to and to utilise offers of evidence-based smoking cessation aids, with those who were older, more nicotine dependent, able to identify as a non-smoker and using smoking cessation aids whilst an inpatient, being more likely to do so. Fourth, integrating psychiatric inpatient smoking care with post-discharge cessation support was found to be efficacious in increasing seven day point prevalence smoking cessation rates and related quitting behaviours at six months post-discharge, with sustained effects on quitting behaviours at 12 months.

Overall, this thesis has highlighted the need to develop tailored interventions to reduce the prevalence of smoking among persons with a mental illness. In the development of such interventions, consideration of the identified determinants of quitting behaviour and of cessation aid uptake may increase effectiveness. The final chapter of this thesis proposes recommendations for future research to increase the effectiveness smoking cessation interventions initiated in inpatient psychiatry and continued post-discharge.

Chapter 1: Background and Rationale

1. Chapter Purpose and Structure

This chapter outlines research pertaining to smoking among persons with a mental illness; with comparison, where applicable, to general smoking literature. The burden and prevalence of both mental illness and tobacco smoking are briefly outlined. Evidence in support of the need to develop tailored cessation interventions for smokers with a mental illness is then presented, including the effectiveness of existing tobacco control measures; factors influencing the quitting process; smoking cessation aids and their efficacy; and the role of health care settings, particularly psychiatric hospitals, in smoking interventions. The chapter highlights the need for further research in the area, particularly that exploring the benefit of utilising psychiatric inpatient facilities as a setting to initiate the provision smoking cessation support to persons with a mental illness, and the benefit of continuing such support into the community setting post-discharge. To conclude this chapter, the thesis aims are presented.

2. Mental Illness: Burden and Prevalence

2.1. Mental Illness: Health and Economic Burden

The Diagnostic and Statistical Manual for Mental Disorders (DSM-V) defines 'mental illness' as clinically diagnosable disorders that significantly interfere with cognitive, emotional and/or social functioning [1, 2]. Mental illness comprises schizophrenia spectrum disorders, mood disorders - both depressive and bipolar, substance use disorders, anxiety, personality and other disorders [2]. A significant disease burden is attributable to mental illness worldwide [3]. The Global Burden of Disease Study found that in 2010, mental illness accounted for 23% of all Years Lived with a Disability (YLD) and 7% of Total Disability Adjusted Life Years (DALYs; years lost to illness, disability or early death) [3]; making it the leading contributor to the non-

fatal disease burden (YLDs) and the fifth largest contributor to the total disease burden (DALYs) [3]. Furthermore, of the 183.9 million DALYs attributable to mental illness, 95% arose from years of healthy life lost due to living with a disability and only 5% from premature mortality [3]. Depression (41%), anxiety (15%) and substance use disorders (11%) accounted for the highest proportion of total DALYs attributable to mental illness [3]. The global burden of mental illness increased by 38% between 1990 and 2010 and, due to population growth and aging, is expected to continue to steadily increase in the future [3].

In Australia, the total burden of disease attributable to mental illness has been estimated to be somewhat higher than international figures, accounting for 13% of total DALYs in 1996 [4] and 2003 [5], and 12% in 2011 [6]. Similar to global trends, mental illness is one of the leading contributors to the non-fatal disease burden in Australia, accounting for 24% and 23% of YLDs in 2003 [5] and 2010 [6] respectively; with depression, anxiety and substance use disorders the largest contributors [6, 7].

Mental illness is one of the leading contributors to the global economic burden of non-communicable diseases [8]. Accounting for both direct (e.g. medical care) and indirect (e.g. lost productivity) costs, in 2010 the global cost of mental illness was estimated at USD$2.5 trillion dollars, with this figure projected to increase to USD$6 trillion by 2030 [8]. In Australia in 2007, annual costs associated with mental illness were estimated at AUD$8.1 billion, comprising $3.8 billion in direct mental health costs and $4.3 billion in other government support costs [9].

2.2. Prevalence of Mental Illness

Persons with a mental illness represent a significant proportion of the adult population worldwide [10]. Results from the World Mental Health Survey, which

examined the prevalence of common mental disorders in 28 countries between 2001 and 2003, indicated between 12% and 47% of persons experience at least one mental health disorder in their lifetime, and between 6% and 27% do so in a 12 month period [10]. The survey revealed that globally, the proportion of mental illness classified as severe ranges between 13% and 37%, while 13% to 48% is considered to be of moderate severity [10]. Prevalence estimates for high income countries including the United States (US) [10, 11], the United Kingdom (UK) [12] and New Zealand (NZ) [13] are at the upper end of the global range, with 32% to 47% of the population in such countries experiencing at least one mental disorder in their lifetime, and 21% to 27% in a 12 month period [10, 14, 15]. In the US and NZ, approximately 25% of mental illness is considered severe, 39% to 41% moderate, and 34% to 36% mild severity [10]. Globally, anxiety (lifetime prevalence 14%, 12-month prevalence 8%) and mood disorders (lifetime prevalence 11%; 12-month prevalence 8%) are the most prevalent [10], with similar figures reported for low and high income countries [10]. The prevalence of substance-use disorders (alcohol, cocaine and opioid) significantly increased worldwide between 1990 and 2010 [16].

The prevalence of mental illness in Australia is similar to that of other high income countries. In 2007, the national household survey indicated 45% of the population aged 18 to 85 years had experienced at least one mental illness in their lifetime, and 20% in the preceding 12 months [17]. Reflecting the international pattern of disorders specific prevalence, anxiety (14%), mood (6%) and substance use (5%) disorders were the most common [18]. In Australia, 10% to15% of mental illness is considered severe, 20% to 30% moderate and 45% to 60% of mild severity [19]. The National Mental Health Report 2013 indicated that the prevalence of mental illness in Australia has remained similar across recent decades [20].

3. The Burden of Smoking Related Chronic Disease and the Prevalence of Tobacco Smoking

3.1. Health Burden

Tobacco smoking remains one of the leading risk factors for preventable morbidity and mortality worldwide [21]. The global disease burden associated with smoking has remained relatively stable in recent decades - accounting for 5% (11.4 million) of total DALYs and 4.6 million deaths (11% of deaths attributable to risk factors) in 1999, and 6% (13.7 million) of DALYs and 5.7 million (11%) deaths in 2010 [21]. Globally, the most common causes of morbidity and mortality associated with smoking are cardiovascular and circulatory diseases (accounting for 48% of tobacco-related DALYs), chronic respiratory diseases (25% DALYs) and cancer (20% of DALYs) [21].

In Australia, the health burden (per cent of total DALYs) associated with tobacco use remained similar between 2003 (8%) [5] and 2011 (9%) [6]. The proportion of cancer (20% and 22%) and cardiovascular disease (10% and 12%) burden attributable to smoking also remained similar between 2003 and 2011 [5, 6].

3.2. Economic Burden

The World Health Organisation (WHO) estimated that the total cost of tobacco use globally, including health care expenditures, productivity losses and other costs was USD$500 billion in 2012 [22]. Direct smoking-related health care costs were USD$170 billion annually in the US in 2010 [23], £5.2 billion in the UK in 2005-2006 [24] and NZD$1.7 billion in NZ in 2005 [25]. The annual economic burden of tobacco in Australia was estimated to be approximately AUD$31.5 billion in 2004-2005 [26], which included USD$1 billion in direct health care costs [27].

3.3. Prevalence of Smoking

As a result of a range of population-level tobacco control measures, the prevalence of smoking in the general population of high income countries has steadily declined over the past three decades, from approximately 30% to 17% in the US [28] and NZ [29], and from 33% to 19% in the UK [30]. In Australia, smoking prevalence more than halved between 1986 (31%) [31] and 2013 (13%) [32]. However, both in Australia and other high income countries a decreasing trend in smoking prevalence has not been observed among subpopulations such as Indigenous groups [33, 34], prisoners [35, 36], homeless persons [37, 38], and those with a mental illness [39-41].

3.4. Tobacco Smoking and Persons with a Mental Illness

3.4.1. Health Burden

In many high income countries the disease burden associated with tobacco use is higher among persons with a mental illness [42, 43]. In the US [43] and UK [44], this population group has an average life expectancy 12 to 25 years shorter than those without a mental illness [43, 44], with the leading causes of excess morbidity and mortality being cardiovascular disease (30%) and cancer (14%) [42] - conditions commonly related to tobacco use [45]. The higher rates of tobacco related mortality among persons with a mental illness is further supported by the findings of a US study of persons with comorbid mental health and substance use disorders who died from natural causes between 1996 and 2005. The study found that 47% of deaths, the majority of which occurred prior to age 59, were tobacco related - 16% more than deceased persons without an identified mental health disorder [46].

In Australia, the disease burden associated with smoking among persons with a mental illness is similar to other high income countries [42]. A retrospective analysis of

population based registers, including mental health information systems and death registrations, between 1985 and 2005 indicated that Australian smokers with a mental illness had an average life expectancy 10 to 16 years shorter than those without such a disorder [42]. It was estimated that 78% of deaths in that period were attributable to chronic diseases such as cardiovascular disease and cancer, for which smoking is a known major cause [45].

3.4.2. Economic and Social Burden

In the UK in 2009/2010 the cost of smoking among persons with a mental illness was estimated at £2.34 billion; 31% (£719 million) of which involved direct medical costs, and 35% (£823 million) and 34% (£797 million) were due to losses associated with reduced productivity and premature mortality, respectively [47]. In Australia in 2005, it was estimated that health systems costs associated with excess smoking by persons with a mental illness was AUD$500 million [48], with a further AUD$2.2 billion dollars in productivity losses [48].

In terms of direct costs to the individual, a significant proportion of the annual income of persons with a mental illness who smoke is expended on purchasing tobacco [17]. Smokers with a mental illness have been estimated to spend 35% of their income on tobacco products [49, 50], with the continuing rise in tobacco prices in high income countries likely to further increase this figure [51]. The considerable proportion of income spent on cigarettes has been reported to sometimes result in smokers with a mental illness prioritising cigarettes over household essentials such as food [52].

In addition, as smoking becomes less acceptable in the general community, tobacco use adds further to the social marginalisation experienced by persons with a mental illness [48]. Persons with a mental illness who smoke are suggested to

experience a further reduced quality of life [44], greater psychiatric symptom severity [53] and utilise health care services more frequently due to their tobacco smoking [17].

3.4.3. Prevalence of Smoking among Persons with a Mental Illness

In high income countries, the prevalence of smoking among persons with a mental illness has remained stable over the past 20 years [39, 54, 55] and is currently at least 2 to 3 times that of the general population [30, 41, 56]. Population surveys suggest that 40%, 44% and 33% of community residing persons with a mental illness in the US [41], UK [57] and NZ [58] smoke, respectively. However, prevalence has been suggested to vary according to diagnosis and setting, with rates of smoking generally higher among persons with psychotic (61% to 88%) [40] and substance abuse disorders (77% to 90%) [59-61], relative to those with anxiety (38 % to 39%) [41, 60], personality (36%) [60] and mood (43% to 46%) [41, 56, 60] disorders. Further, persons with a mental illness in the US and UK, utilising either inpatient (42 to 73%) [62, 63] or community-based (61%) [62] services have been reported to have higher smoking rates than those not accessing mental health services.

Similar to other high income countries, the prevalence of smoking among persons with a mental illness in Australia has remained stable in recent decades [41, 48, 64]. A population survey in 2007 indicated 36% of community-living persons with a mental illness smoke tobacco [41]. In Australia, variation in prevalence estimates have also been observed contingent on diagnosis and setting, with persons diagnosed with anxiety disorders (33%) [41] less likely to smoke tobacco than those with mood (43%) [41], substance use (54%) [41] or psychotic disorders (67%) [64]. Further, the prevalence of smoking has been reported to be higher among those accessing Australian community mental health (51%) [65] and acute psychiatric inpatient (54%) [66]

services, relative to general community samples of persons with a mental illness (36%) [41].

Data from the US, UK and Australia suggests 31% [41], 30% [67] and 32% [41] of continuing smokers respectively have a mental illness. This group have been estimated to consume 42% to 45% of all cigarettes sold in such countries [68-70] and are reported to smoke more heavily than smokers without a mental illness [40, 68, 71]. The absence of a decline in smoking prevalence among persons with a mental illness [39, 54], in contrast to the strong downward trend in the general population [28, 30, 32], has been suggested to indicate that population-level tobacco control measures have been less effective for smokers with a mental illness [67, 72], and that to reduce the disproportionate smoking-related disease burden experienced by this group, smoking cessation strategies tailored to the needs and circumstances of persons with a mental illness are required [67, 72].

4. Reducing Tobacco Related Harm; the Role of Smoking Cessation

4.1. An Overview

Since 2005, population-level tobacco control measures stipulated by the Word Health Organisation (WHO) Framework Convention on Tobacco Control, have been incrementally introduced in 168 countries in an attempt to address the health, social, environmental and economic consequences of tobacco smoking [73]. Such measures aim to reduce smoking prevalence via dissuasion of smoking uptake and/or facilitating cessation, through: price and tax policies, packaging and label requirements, bans on tobacco advertising, education and public awareness schemes, legislation to facilitate public protection from second-hand smoke exposure and reduce acceptability of smoking, and smoking cessation support for smokers to quit in the form of free (or

subsidised) quitting aids - such as Quitline, nicotine replacement therapy (NRT) and health care services [73, 74].

4.2. Impact of Tobacco Control Measures on Persons with a Mental Illness

Research exploring the impact of tobacco control measures among smokers with a mental illness is limited [75-78]. One systematic review examining the effectiveness of increasing tobacco excises in reducing smoking prevalence among youth, persons of low socio-economic status (SES), those with a mental illness and Aboriginal people found that compared to smokers generally, such a measure was more effective for youth and those with low SES, and equally effective for persons with a mental illness [75]. The authors noted however, that only three of 108 studies sourced for the review focussed on persons with a mental illness, and therefore the level of evidence was insufficient to draw strong conclusions for that group.

Two studies have assessed the impact of mass media campaigns on persons with a mental illness; the first of Australian smokers with a diagnosis of schizophrenia [76] and the second of US smokers experiencing recent high levels of non-specific psychologic distress [77]. Both studies concluded that such a strategy had no impact on smoking behaviours or intentions to quit in this population group. In terms of the impact of smoke-free policies in psychiatric inpatient facilities, systematic review evidence suggests such environments promote positive short terms changes in quitting-related behaviour and motivation (during admission and in the weeks following discharge) but do not impact on long term cessation [78]. Given the limited available evidence and the suggestion of limited effect of various tobacco control measures, it is suggested that a need exists to develop and disseminate tobacco control measures specifically targeted at persons with a mental illness [67].

4.3. Smoking Cessation and Persons with a Mental Illness

The Australian National Preventative Health Taskforce [79] suggested that the greatest gains in redressing the inequity in smoking prevalence and tobacco-related harm experienced by persons with a mental illness may come from strategies which focus on smoking cessation, rather than uptake. In high income countries, the majority of psychiatric disorders initially manifest between the ages of 18 and 25 [80], while smoking initiation typically occurs prior to the age of 17 [81, 82]. Hence primary prevention strategies focussing on smoking uptake primarily target age groups where mental illness is yet to develop. Research has consistently indicated that smokers with a mental illness are less likely to be successful in their attempts to quit smoking than those without a mental illness [40, 56, 68], suggesting that potential health benefits may be gained through increasing the likelihood of their successfully quitting. Little research however has examined the process of quitting for smokers with a mental illness; the factors that influence that process; or the effects of cessation strategies for this group.

5. The Process of Quitting Smoking, and Factors Which Influence It

5.1. Process of Quitting for Smokers Generally

Smoking is a complex behaviour that can be difficult to discontinue [83-85]. Despite 40% to 45% of smokers generally making at least one quit attempt annually [86, 87], only a small proportion achieve successful cessation [87, 88]. Systematic review evidence suggests that only 3% to 5% of self-quitters achieve six to12 month prolonged abstinence on a given quit attempt, with the majority relapsing within eight days [88]. Accordingly, achieving sustained cessation is commonly preceded by multiple quitting attempts - with smokers who have attempted to quit multiple times [89] and those

achieving longer periods of abstinence on recent attempts [83] being more likely to achieve sustained cessation.

Theories of health behaviour change acknowledge quitting smoking as a process involving a number of attempts and/or movement through specified stages [90-92]. The Transtheoretical Model [90] for instance proposes smoking cessation to require progression through five stages: pre-contemplation (no intention to quit in the next 6 months), contemplation (intend to quit in next six months, however ambivalent), preparation (intend to quit in the next 30 days, recent unsuccessful quit attempts and consideration of quitting aids), action (quit for a period of less than six months), and maintenance (quit for greater than six months). In the general population of high income nations such as the US, it has been reported that approximately 60% of smokers are in the contemplation or preparation stage at any given time [93], and in some instances, being in these stages has been found to be predictive of cessation [89]. However, other research has suggested many smokers quit spontaneously, including without an overt plan or process [94]; and that unplanned quit attempts are equally likely to result in sustained cessation [94]. Interventions that address factors that contribute to initiating, encouraging or sustaining quitting behaviour or motivations regardless of intention have therefore been suggested to be needed to facilitate the process of cessation for all smokers [95].

5.2. Factors Influencing Quitting among Smokers Generally

Socio-ecological theories [96-98] and a large volume of supporting research highlight the broad spectrum of modifiable factors that are suggested to influence the process of quitting smoking - including both individual factors and others within the physical and social environment. Individual smoking characteristics have consistently

been shown to be associated with quitting behaviour, with smokers who are less nicotine dependent [99, 100], consume fewer cigarettes per day [101, 102], initiated smoking at an older age [83, 103, 104], and have smoked for fewer years being more likely to have made quit attempts and/or be motivated to quit.

Factors within the physical and social environment that are positively associated with quitting behaviour and motivation have been reported to include: residing in a smoke-free home [83, 105-108], lack of exposure to smoke in the immediate environment [83, 89, 105, 108-114], having a spouse who is a non-smoker [109, 111], and perceiving significant others [109, 115-120] and health care providers [100, 121] as supportive of a quit attempt. Such findings have led to smoking cessation interventions with components including: smoke-free workplace policies [122], enhancement of partner support for spouse's smoking cessation [123], and smoking cessation care being delivered by health care providers [124, 125].

5.3. Process of Quitting for Smokers with a Mental Illness

Empirical evidence suggests smokers with a mental illness are at least as motivated as those without a mental illness to quit smoking [66, 126]. Likewise, population survey data suggests that this group of smokers are similarly [56] or more likely [86] to have made recent quit attempts compared to smokers generally. For example, among community residing smokers in the US (N = 14,118), persons with a mental illness were more likely than those without such an illness to have attempted to quit smoking over a 12 month period (59% vs. 44%, respectively) [86]. A survey of Australian psychiatric inpatients similarly suggested that smokers with a mental illness frequently attempt to quit, with 55% attempting at least once in a twelve month period [127]. Further, persons with co-occurring mental illness and substance use disorders accessing US community

mental health services have been reported to make between three and seven quit attempts annually [128]; at least double the number reported for smokers generally [87].

Despite being motivated and making attempts to quit, smokers with a mental illness are less likely than those without such an illness to do so successfully [40, 56, 68]. Population data from the US revealed quit rates, defined as the number of ex-smokers divided by ever-smokers, of between 17% and 41% for smokers with mental illness (contingent on diagnosis) compared to 43% for the general population [68]. Those with bipolar disorder (17%) and non-affective psychosis (27%) had among the lowest quit rates. Further, a meta-analysis of smoking and quitting behaviours among persons with schizophrenia residing in high income countries found significantly lower successful quit rates for this group (9% to 17%), relative to smokers generally (39% to 49%) [40].

5.4. Factors Influencing Quitting among Smokers with a Mental Illness

Similar to the general population, individual characteristics of smoking may influence the process of quitting for smokers with a mental illness. As research suggests smokers with a mental illness, compared to those without such an illness, are more nicotine dependent [40, 56, 60, 69] and consume a greater number of cigarettes per day [40, 56], the association between such smoking characteristics and quitting are likely to be strong for this group [67]. The limited research that has explicitly explored the influence of smoking characteristics on the quitting behaviours of smokers with a mental illness suggests similar findings to those observed among smokers from the general population. For example, among US smokers in a residential substance treatment program [129] and recently discharged from a psychiatric inpatient facility [130], those with lower nicotine dependence were more likely to make a quit attempt lasting at least eight days. Further, in a US epidemiological study, young adults

diagnosed with major depression were more likely to engage in quitting behaviours if they consumed fewer cigarettes per day [131].

Few studies have explored the prevalence of broader physical and social environmental factors among persons with a mental illness; with those that have suggesting a lower prevalence of factors likely to positively influence quitting related behaviours. For instance, a US study of smokers diagnosed with psychotic or mood disorders (N = 124) found only 24% resided in a house where smoking was not permitted inside [132] – compared to 46% in a national representative sample of smokers from the general population [133]. A similar pattern has been observed among Australian smokers with a mental illness (n = 222), where 42% were reported to be living in a smoke-free home, compared to 61% among those with no diagnosed mental health disorder (n = 1434) [71].

Very little research has explored the possible relationships between such factors and quitting behaviour and motivation among persons with a mental illness. Qualitative studies from several countries, including Australia [134], US [135-138], UK [139], Scotland [140], and Canada [141], have however suggested that a lack of support to quit from family and friends [138, 139] and health care professionals [134, 137, 139, 140], and socialising with other smokers [135, 136, 140, 141] are potential barriers to cessation for this group. Only one quantitative study has examined the association between such environmental factors and quitting behaviour and motivation among smokers with a mental illness. Ferron et al. [128] found, among US smokers with co-occurring severe mental illness and substance use disorders (N = 174), that more social contact with non-substance using (including tobacco) friends was positively associated with a higher number of quit attempts. To inform the development of effective smoking cessation interventions for persons with a mental illness, rigorous research assessing the

prevalence of smoking and environmental characteristics among persons with a mental illness, and their associations with quitting behaviour is needed.

6. Effective Smoking Cessation Aids

6.1. Smokers from the General Population

Systematic review evidence demonstrates that a number of pharmacotherapies and behavioural smoking cessation aids are efficacious in facilitating the quitting process for smokers generally. In terms of pharmacotherapies, the three first line effective medications for smoking cessation are NRT, bupropion (a nicotine antagonist), and varenicline (a nicotine receptor partial agonist) [142, 143].

The mechanism of action for NRT involves the temporary replacement of nicotine that would have been obtained via smoking tobacco, thereby reducing the physiological urge to smoke. NRT is reported to increase the relative risk (*RR*) of quitting by approximately 60% (95% confidence interval (CI) 1.53 to 1.68), with some variation contingent on the form used (inhaler: *RR* 1.90, 95% CI 1.36 to 2.67; lozenges: *RR* 1.95, 95% CI 1.61 to 2.36; transdermal patch: *RR* 1.64, 95% CI 1.52 to 1.78; gum: *RR* 1.49, 95% CI 1.40 to 1.60; oral spray: *RR* 2.48, 95% CI 1.24 to 4.94) [144]. NRT is most effective however, when the transdermal patch is used in conjunction with a fast-acting form of NRT, such as gum or lozenges [144, 145]. Systematic review evidence indicates there is no significant difference in the effectiveness of bupropion (*RR* 1.62, 95% CI 1.49 to 1.76; [146]), varenicline (*RR* 2.27, 95% CI 2.02 to 2.55; [147]) and combination NRT (patch plus a fast-acting form; *RR* 1.34, 95% CI 1.18 to 1.51; [144, 145]) in increasing the likelihood of smoking cessation. Of the available pharmacotherapies for smoking cessation, NRT is suggested to best lend itself to large scale-public health utility due to limited side effects and contraindications [144].

Behavioural aids for smoking cessation are commonly based on principles of cognitive behaviour therapy (CBT) [148] or motivational interviewing [149], and can be delivered face-to-face, online, within groups or via telephone [150-152]. Typically, such behavioural aids aim to provide education and advice, and often assist current or prospective quitters to: identify and manage high risk situations, manage nicotine withdrawal symptoms, unpack unhelpful thoughts that could negatively impact on the quitting process, explore ambivalence regarding cessation, and where applicable, support relapse prevention [151, 153, 154]. Evidence from systematic review and meta-analyses suggests individual, face-to-face (*odds ratio* (*OR)* 1.56, 95% confidence interval 1.32 to 1.84) [151] and group-based (*OR* 2.17, 95% CI 1.37 to 3.45) [155] behavioural interventions significantly increase the odds of successful smoking cessation, relative to no intervention. Similarly, motivational interviewing techniques (*RR* 1.26, 95% CI 1.16 to 1.36) [156], multiple sessions of proactive telephone counselling (*RR* 1.37, 95% CI 1.26 to 1.50) [150] and physician advice to quit (brief versus no advice: *RR* 1.66, 95% CI 1.42 to 1.94; intensive versus brief advice: *RR* 1.37, 95% CI 1.20 to 1.56) [157] have been shown to significantly increase the likelihood of cessation. Finally, there is evidence that self-help materials such as printed pamphlets and worksheets improve cessation rates - particularly so when tailored to the individual (*RR* 1.42, 95% CI 1.18 to 1.37) [158].

The use of pharmacotherapies and behavioural aids in combination has been reported to yield the highest effect sizes, and as such is recommended to all smokers attempting to quit [159, 160]. A systematic review and meta-analysis of 41 studies with a total of more than 20 000 participants revealed, relative to usual care or minimal intervention, a significant beneficial effect of using smoking cessation aids concurrently (*RR* 1.83, 95% CI 1.68 to 1.98) [161]. While sub group analyses revealed no evidence

of differential effects according to motivation to quit or treatment provider, there was some evidence of differential effectiveness according to study setting – with trials delivered within health care rather than community settings achieving greater effect sizes [161]. Ensuring smokers have knowledge of and access to pharmacotherapies and behavioural smoking cessation aids is acknowledged to be of considerable importance in increasing smoking cessation attempts [79]. Given this finding, health care settings, including hospitals, have been recognised for over a decade as opportune environments for the provision of smoking cessation advice and quitting aids [124] - a suggestion that is supported by meta-analysis findings indicating that their delivery within such settings increases the likelihood of cessation [161].

6.2. Smokers with a Mental Illness

A number of systematic reviews have assessed the efficacy of pharmacotherapies and/or behavioural smoking cessation aids specifically for persons with a mental illness. While these reviews suggest such aids may be efficacious for this group, the relative paucity of research limits the ability to draw firm conclusions of efficacy. In terms of first line pharmacotherapies, systematic review evidence suggests NRT is efficacious for adults with substance use disorders [162]. Narrative synthesis of five studies in one systematic review revealed that among smokers accessing inpatient or outpatient substance use treatment services, those that used nicotine patches or nicotine gum were significantly more likely to achieve abstinence than those receiving placebos or no NRT [162]. Two further reviews have explored the efficacy of NRT for smoking cessation among persons with depression: in the first, narrative synthesis of 3 trials indicated small, positive effects in all studies [163]; with the second finding positive, although non-significant effects of NRT in one trial (*RR* 2.64, 95% CI 0.93 to 7.45) [164]. In two

additional reviews, insufficient trials for inclusion precluded meta-analyses to assess the efficacy of NRT for persons with severe mental illness from being conducted [165, 166].

Systematic review evidence suggests bupropion increases the likelihood of cessation for persons with a mental illness [165-167]. Relative to placebo, bupropion has been reported in a number of systematic reviews to significantly increase the likelihood of successful cessation for smokers with severe mental illness who were ready to quit (six trials, *OR* 4.51, 95% CI 1.45 to 14.04) [166], and for those with severe mental illness (five trials, RR 2.77, 95% CI 1.48 to 5.16) [167] and schizophrenia specifically (seven trials, *RR* 3.03, 95% CI 1.69 to 5.42) [165], irrespective of quitting intentions. The latter finding is supportive of a previous systematic review examining the efficacy of bupropion for persons with schizophrenia (six trials, *RR* 2.57, 95% CI 1.35 to 4.88), that also reported concurrent use of bupropion and NRT further increased the likelihood of abstinence (*RR* 2.92, 95% CI 0.75 to 11.33) [168]. Two additional meta-analyses focussing on cessation aids for persons with depression have found small positive, non-significant effects of antidepressants, including bupropion, for smoking cessation (three trials, *RR* 1.31, 95% CI 0.73 to 2.34 [163]; five trials, *RR* 1.37, 95% CI 0.83 to 2.27) [164]).

Varenicline has similarly been shown in two systematic reviews to increase the odds of successful cessation in motivated-to-quit smokers with a severe mental illness (five trials; *OR* 5.17, 95% CI 1.78 to 15.06) [166] and smokers with schizophrenia who may or may not have been ready to quit (two trials; *RR* 4.74, 95% CI 1.34 to16.71) [165], relative to placebo. In addition, findings from a recent randomised, double-blind, placebo-controlled and active-controlled trial involving more than 4000 motivated-to-quit smokers with non-acute mental illness recruited across 16 countries also revealed

varenicline, relative to placebo, significantly increased the odds of cessation (*OR* 3·61, 95% CI 3·07 to 4·24) [169]. This review also found varenicline to be more efficacious than bupropion (*OR* 1·75, 95% CI 1·52 to 2·01) and NRT (*OR* 1·68, 95% CI 1·46 to 1·93) for smokers with a mental illness [169].

Due to a number of potential physical (seizures) and psychiatric (suicidal ideation, mania) contraindications associated with the use of bupropion and varenicline specifically for smokers with a mental illness, particularly severe and acute presentations, it has been recommended that use of such therapies occurs under close supervision of a medical practitioner, particularly in the initial few weeks of treatment [67]. Contraindications regarding NRT use, over and above those indicated for persons without a mental illness, have not been raised for people with a mental illness [170].

Behavioural smoking cessation aids involving motivational interviewing, skills training, and group and/or individual counselling may be efficacious for persons with a mental illness [171-173]. A meta-analysis of seven trials involving smokers diagnosed with psychotic disorders and depression revealed no short term (three months) beneficial effect of such aids (*RR* 1.33, 95% CI 0.96 to 1.84), however a significant positive effect at longer term follow-ups (6 or more months) was reported (*RR* 1.35, 95% CI 1.01 to 1.81) [173]. The findings of two other systematic reviews indicated positive, albeit non-significant effects of such behavioural aids on cessation for persons with substance use disorders (six trials; *RR* 1.45, 95% CI 0.59 to 3.57) [171] and for those with chronic illness (including mental illness) (nine trials; *OR* 1.34, 95% CI 0.89 to 2.01) [172].

The incorporation of CBT mood management techniques into behavioural aids may increase their efficacy for persons with depressive disorders [163, 164]. A meta-analysis of 11 trials revealed that the addition of such techniques to individual cessation

counselling significantly increased the likelihood of abstinence for those with current (*RR* 1.42, 95% CI 1.07 to 1.88) or past (13 trials; *RR* 1.38, 95% CI 1.09 to 1.74) depression; although counselling alone was ineffective for this group (two trials; *RR* 1.36, 95% CI 0.77 to 2.42) [164]. An additional meta-analysis of 16 trials, three and 13 of which included participants with current and past depression respectively, similarly found a significant effect on cessation of interventions comprising counselling with a behavioural mood management component (*RR* 1.41, 95% CI 1.01 to 1.96) [163].

The efficacy of using pharmacotherapies and behavioural aids in combination for persons with a mental illness has also been assessed via systematic review and meta-analysis [167]. Among smokers with non-acute psychotic disorders, behavioural support combined with NRT, compared to brief advice, was found to significantly increase the likelihood of cessation (*RR* 2.74, 95% CI 1.10 to 6.81) [167]. An additional review of cessation interventions for smokers with substance use disorders similarly found that, relative to no or brief intervention, combining NRT with behavioural supports significantly increased the likelihood of cessation (five trials; *RR* 2.63, 95% CI 1.21 to 5.70) [171]. The findings of a subsequent systematic review focussed on outpatients with substance use disorders also support the benefit of combining behavioural and pharmacotherapeutic smoking cessation aids [162]. Based on the narrative synthesis of this review it was concluded that combinations of CBT and NRT, and of bupropion, NRT, counselling and contingency management, improved the likelihood of abstinence [162]. As smokers with a mental illness are more nicotine dependent [68, 71] and have greater difficulty in quitting [41, 68, 174], it has been suggested that provision of multiple aids at high intensity (for example, combination NRT and multiple sessions of behavioural support) for extended durations may increase further the likelihood of cessation [175, 176].

6.2.1. Increasing the Utilisation of Smoking Cessation Aids Among Persons with a Mental Illness

Despite evidence of the efficacy of pharmacotherapies and behavioural cessation aids for both smokers generally and for those with a mental illness, evidence suggests that they may not be utilised by a large proportion of both groups of smokers [128, 177-181]. For instance, a population survey in the US involving 2747 smokers who had made a serious quit attempt in the last 12 months indicated the use of behavioural aids (4% to 5%) and pharmacotherapies (18% to 33%) was infrequent [181]. For persons with a mental illness, an online survey of 685 ever-smokers (current and ex-smokers) with bipolar disorder from the US revealed that among ex-smokers (n = 89), 46% used cessation medications, 4% used psychosocial support and 7% used both types of aids to quit; while among current smokers preparing to quit (n = 256), 38% intended to use cessation medications, 12% psychosocial support and 18% both types of aids [177]. Two other studies, while less comprehensive in their reporting, similarly suggested a small proportion of smokers with a mental illness use cessation aids when attempting to quit [130, 132].

For smokers generally, evidence suggests *proactive* (unsolicited) and *universal* (irrespective of clinical and/or smoking characteristics) promotion of smoking cessation aids increases the proportion of smokers utilising such aids [182-184] and in turn, quitting smoking successfully [185]. Proactive engagement can take a number of forms and can occur in a number of settings. For example, telephone based proactive and universal referral of smokers from Australian households to Quitline cessation services, regardless of intention to stop smoking, has been reported to result in 52% of smokers using such a service [182]; in contrast to the 4% of smokers who contact such a service on a self-referral basis [186]. Additionally, the smoking cessation outcomes achieved by

smokers recruited in this way [185] appear to be similar those for smokers who use Quitlines on a self-referral basis [187]. Furthermore, of smokers accessing two general health care services in the US (*N* = 1273), 68% were engaged in web-based smoking cessation support via proactive invitation letters from service clinicians (including weekly letters prompting use of website), with reactive strategies including advertisements in health service newsletters (22%) and physician referral/web postings attracting the remaining smokers [184].

Few studies have assessed the impact of proactive and universal offers of cessation support on uptake outcomes for persons with a mental illness [127, 188, 189]. One such study measured the proportion of participants that accepted offers of NRT from research staff following discharge from a psychiatric inpatient facility [188]. Eighty-eight per cent of participants accepted a one month supply of NRT upon discharge, and approximately half of those requested supply for a second month at a later date. Notably the rate of uptake of NRT in this study was approximately one and a half times that reported in a similar trial where NRT was selectively offered only to smokers who were 'ready to quit', following discharge from an inpatient facility [130]. Schuck and colleagues [188] also explored factors associated with uptake of smoking cessation aids and found later stage of change, more severe mental health symptoms and nicotine dependence, female gender and older age were associated with uptake of the initial offer of NRT, whilst older participants and those with more severe mental health symptoms were more likely to request a subsequent supply. Further, among Australian smokers (*N* = 104) participating in a trial of smoking cessation support provision post-discharge from inpatient psychiatry, proactive and universal offers of aids yielded substantial rates of uptake [127]. Ninety per cent and 68% of participants accepted

offers of telephone counselling and NRT respectively; and 50% of such participants utilised aids consistently (greater than seven instances) across a 16 week period [127].

Health care settings, including hospitals offer unique advantages for the proactive provision of smoking cessation aids [124, 161]. Greater understanding of the impact of proactive and universal offers in this context, including exploration of any factors that may further promote uptake, may therefore be of particular benefit to increase the proportion of smokers with a mental illness using evidence-based cessation aids.

7. Hospitals as a Setting for Proactive Provision of Smoking Cessation Care

7.1. General Hospital Settings

Health care settings are recognised as opportune environments for initiation of smoking cessation intervention [124, 190], with national [191] and international [124, 192] guidelines recommending staff assess the smoking status of all persons accessing health services and if applicable, provide nicotine dependence treatment including NRT and brief advice to quit. Hospitals in particular have been identified as a key setting for initiation of smoking cessation; facilitating both patient access and receptivity to smoking cessation advice [193, 194]. The advent of total smoking bans in hospitals and the associated requirement to treat nicotine dependence [124, 195] have prompted the provision of supported dependence treatment to all admitted patients – further enhancing the opportunistic benefits of promoting cessation in this the setting [124]. Studies investigating the benefits of admission to a smoke-free hospital suggest both motivation to quit and the likelihood of cessation post-discharge are increased [196-198], with the receipt of pharmacological and behavioural aids during admission increasing quit rates further [199].

Integrating smoking cessation care offered by a hospital with community-based cessation support post-discharge is suggested to maximise benefits in terms of cessation [199]. In a meta-analysis of interventions integrating hospital-based cessation care with post-discharge support, provision of behavioural aids for a minimum of four weeks immediately following discharge was found to increase the likelihood of quitting by 37% at six to 12 month follow-up (25 trials, 95% CI 1.27 to 1.48) [199], and the addition of NRT further increased the likelihood of cessation by 54% (six trials, 95% CI 1.34 to 1.79) [199]. While clinical guidelines recommend the provision of a limited supply of NRT and a Quitline referral [200] to all admitted smokers upon discharge, evidence suggests multimodal support of longer duration is of further benefit [199].

7.2. Psychiatric Hospital Settings

Smoke-free psychiatric inpatient facilities have similarly been identified as a key setting to proactively provide smoking cessation intervention for persons with a mental illness [67, 201]. Inpatient psychiatric settings offer smoking cessation opportunities that correspond to those of general hospitals in terms of patient access and receptivity to smoking cessation support [193, 194]. The presence of skilled mental health clinicians may also be of particular benefit for assisting with addressing psychiatric and medical considerations when smoking is ceased or reduced, including monitoring the required dosage of psychiatric medication [202]. Further, admission to a smoke-free psychiatric hospital provides the potential for a supportive environment for smoking cessation not only due to the availability of pharmacological and behavioural smoking cessation support [193, 194], but also due to the absence of smoking cues such as the smell of tobacco smoke and observing others smoking [203]. The opportunity to experience such a smoke-free environment may be of particular significance for smokers with a mental

illness, given their greater likelihood of exposure to smoking within their normal residential environment as compared to other smokers [71, 132].

7.2.1. Provision of Smoking Cessation Care in Psychiatric Inpatient Settings

Despite the patient benefits likely to result from the proactive provision of smoking care within psychiatric hospitals [196-198], the introduction of such care has been met with resistance from staff [204, 205] and patients [206], and its provision is suboptimal [207-209]. For example, data derived from medical record audits in Australia [210] and the US. [63] suggest that documentation of patient nicotine dependence or withdrawal occurs infrequently, and the provision of nicotine dependence treatment, or recording of such provision, is rare (≤0.05%). A survey of Australian psychiatric inpatients similarly revealed only a small proportion of admitted smokers received adequate NRT (20%) [211].

Unique barriers to the proactive provision of nicotine dependence treatment in psychiatric hospitals have been identified [208]. Firstly, smoking tobacco has historically been a normalised behaviour in some psychiatric facilities and encouraged in others [212, 213], with such practices suggested to have led to the formation of an accepted ‘pro-smoking culture’ among patients and staff [208, 214]. Additionally, perceptions held by staff that smoke-free policies and provision of smoking cessation aids will lead to ruptures in therapeutic relationships and adverse psychiatric symptoms, namely aggression have been identified as barriers to treatment provision [215]. However, evidence derived from US studies indicate no changes in rates of disruptive behaviour, discharge against medical advice or prescription of PRN medication following the introduction of smoking care provision and smoke-free policies [216,

217]. Some research has suggested that smoking bans may reduce patient hostility [218] and levels of verbal and physical aggression [219].

A further potential barrier to the proactive provision of smoking cessation aids in psychiatric settings is the belief held by some staff that patients are not interested in quitting [208, 215, 220]. A study of Australian psychiatric inpatients found however, that nearly half (47%) had made a quit attempt in the preceding 12 months [66]. Increasing staff and patient provision and receipt of smoking cessation aids in acute psychiatric facilities is suggested to be needed to maximise the potential of this setting as a platform for reducing the greater tobacco-related disease burden among people with a mental illness [78].

7.2.2. Effectiveness of Integrating Smoking Cessation Care Offered in Inpatient Psychiatry with Post-Discharge Support

Systematic review evidence suggests admission to a smoke-free psychiatric hospital, with provision of smoking cessation aids, may be effective in positively changing the smoking-related behaviours of patients [78]. Stockings and colleagues [78] found that admission was reported to reduce daily cigarette consumption and level of nicotine dependence, and increase quitting motivation and number of quit attempts. In the absence of ongoing support post-discharge however, all such changes were found to dissipate within three months of discharge [78].

In line with general hospital settings, providing continued cessation support to psychiatric inpatients following discharge has the potential to augment the short term positive effects of a smoke-free inpatient admission on smoking-related behaviours [175]. However, only four randomised controlled trials (RCT) to date have assessed the efficacy of this model of care [127, 130, 221, 222]. Among adolescent smokers in the

US (13-17 years; *N* = 191), the efficacy of providing motivational interviewing (two 45 minute sessions) versus brief advice (five to10 minutes of psychoeducation and advice) for smoking cessation whilst admitted to a psychiatric inpatient facility was assessed via RCT. Both groups also received an eight week supply of nicotine patches immediately post-discharge [222]. At one, six and 12 months post-discharge, seven day point prevalence abstinence was 11%, 13% and 14%, respectively for those randomised to receive motivational interviewing and 11%, 9% and 10% for those who received brief advice, with no statistically significant difference at any time point [222]. The authors' concluded motivational-based interventions need to be enhanced and intensified for adolescent smokers admitted to psychiatric inpatient facilities to obtain a benefit.

Prochaska and colleagues [130] demonstrated the efficacy of integrating inpatient smoking care with post-discharge support in a RCT involving predominantly Caucasian and medically insured adult smokers (*N* = 224) admitted to an acute psychiatric facility in the US. Whilst inpatients, intervention group participants were provided with NRT, cessation counselling, and a computer-assisted, stage-tailored intervention program, comprising motivational feedback and self-help material. Post-discharge intervention involved requesting participant's community-based health care clinician to provide cessation support, repetition of the stage-tailored computer program three and six months after hospitalisation and, if assessed as ready to quit within six months of discharge, provision of a 10 week supply of NRT. Approximately half (49%) of participants met the criterion and received a post-discharge supply of NRT. Patients randomised to the intervention condition were significantly more likely than usual care controls to have been abstinent for at least seven days at six (14% versus 7%), 12 (19% versus 11%), and 18 (20% versus 8%) months post hospital discharge. A recent replication trial involving ethnically diverse, uninsured adult smokers with a mental

illness (N = 100) admitted to both acute and non-acute units of an urban public hospital achieved similar effect sizes at six (18% versus 9%) and 12 (26% versus 17%) months post-discharge [221].

An Australian study, undertaken at a time concurrent with the trial of Prochaska and colleagues [130] involved the proactive provision of multimodal smoking cessation support to all smokers admitted to an adult inpatient psychiatric facility upon discharge, irrespective of readiness to quit [127]. Compared to the two US trials involving adults, both of which provided intervention components selectively based on readiness to quit [130, 221], the universal approach adopted by this study reflected clinical guideline recommendations regarding the provision of smoking cessation care to all patients regardless of readiness to quit [192]. In a randomised controlled feasibility trial, inpatient smokers (N = 205) were allocated to receive either a four month multimodal (pharmacotherapy and behavioural aids) smoking cessation intervention, or care as usual upon discharge [127]. The intervention consisted of eight structured smoking cessation support calls delivered fortnightly and 12 weeks of fully subsidised NRT. Support calls were delivered using principles of motivational interviewing [149] and NRT was prescribed in accordance with label recommendations. At four months follow-up, intervention group participants had significantly higher rates of seven day point prevalence abstinence compared to usual care controls (11.5% versus 2%), although this difference was not sustained at six months follow-up, with inadequate power likely to have contributed to such a finding [127]. The study concluded that increased intervention intensity (greater number of cessation support calls and higher dose NRT) and assessment of efficacy with a larger sample and longer follow-up period, was required [127].

8. Summary of Limitation of Existing Research

This literature review has highlighted the disproportionate tobacco-related morbidity and mortality experienced by persons with a mental illness, and the need to reduce the persistently elevated smoking prevalence among this group. The lack of change in smoking rates in recent decades among persons with a mental illness [39, 41, 54], in contrast to the steady decline observed for smokers generally [28, 30, 32], is suggested to be associated with a lesser effectiveness of tobacco control measures for smokers with a mental illness [76-78]. The review found that this group of smokers is at least as motivated to quit as those without a mental illness [66, 126], although they experience greater difficulty doing so successfully [40, 56, 68]. A need for smoking research to identify effective cessation interventions tailored to persons with a mental illness and with a potential population impact was therefore suggested [67].

Despite substantial literature examining modifiable smoking and environmental determinants of quitting behaviour for smokers generally [83, 89, 105, 108-114, 118-120], this review highlighted far less research exploring such relationships for persons with a mental illness [128-130, 134-141]. Of the available research, most adopted qualitative designs [134-141] and none focussed on diverse samples of smokers with acute mental illness, among whom the smoking prevalence is notably high [62, 63, 66]. The identification of determinants of quitting behaviour among smokers accessing acute psychiatric services could inform the development of effective interventions targeted at such smokers [95].

While smoke-free acute psychiatric facilities were highlighted as an opportune setting to initiate the provision of cessation intervention to large and diverse populations of smokers with a mental illness [67, 201], such an approach has only been minimally assessed [127, 130, 221, 222], with all such studies yielding equivocal findings. In

addition, there is a paucity of evidence regarding the receptivity of smokers recently discharged from psychiatric inpatient facilities to the proactive offer of efficacious cessation aids, including combination of NRT and behavioural support [167, 188]. Determining the efficacy of integrating smoking cessation support offered within acute psychiatric services with continued support post-discharge, and patient receptivity to such intervention would assist in the development and implementation of a tailored smoking cessation intervention for smokers with a mental illness, and potentially inform future health service delivery for the treatment of smoking among this group.

9. Aims of the Thesis

To address the evident gaps in the literature, this thesis aimed to:

1. Assess the quantity and quality of research outputs relating to smoking and mental illness.
2. Explore potential determinants of quitting behaviour among persons with a mental illness.
3. Evaluate receptivity to, and utilisation of smoking cessation aids proactively offered to all smokers upon discharge from an acute psychiatric inpatient facility.
4. Examine the efficacy of initiating smoking cessation support during an inpatient psychiatric admission and continuing post-discharge in reducing smoking rates among persons with a mental illness.
5. Based on the findings of the studies undertaken to address the above aims, propose recommendations for future research to facilitate smoking cessation for persons accessing psychiatric services.

This thesis comprises six chapters that address the above aims. Five of these chapters have been written in the style of a journal article in accordance with the University of Newcastle rules regarding ‘submission by publication’ (Appendix 1). Four of the included articles have been published in peer-reviewed journals and the remaining one is currently under review.

Chapter 2: Smoking and Mental Illness: a Bibliometric Analysis of Research Output Over Time

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Manuscript accepted for publication in *Nicotine and Tobacco Research* on 14th September, 2016.

Bibliographic reference: Metse AP, Wiggers J, Wye P, Wolfenden L, Prochaska JJ, Stockings E, Williams JM, Ansell K, Fehily C, Bowman JA: **Smoking and mental illness: a bibliometric analysis of research output over time**. *Nicotine Tob Res* 2016, in press. doi:10.1093/ntr/ntw249

Abstract

Background: The prevalence of smoking among persons with a mental illness has remained unchanged, being two to three times higher than the general population in high income countries. Assessment of the volume and characteristics of research output over time can assist in identifying research priorities to promote progress within a field. The aim of this study was to undertake such an assessment in the field of smoking and mental illness. **Methods:** A descriptive repeat cross-sectional study was conducted of peer-reviewed publications in Medline and PsycINFO for the periods 1993-1995, 2003-2005 and 2013-2015. Publications were classified as data or non-data based; data based publications were further categorised by study type, population, setting, and for intervention-focussed publications by level of evidence and research translation phase. **Results:** Included were 547 articles published in 1993-1995 (n = 65), 2003-2005 (n = 153), and 2013-2015 (n = 329). The number and proportion of data based publications significantly increased over time, although their focus remained predominantly descriptive (≥83%); less than 14% of publications in any period had an intervention focus. The proportion of publications reporting on study populations with multiple diagnostic categories and recruiting from non-mental health settings, significantly increased from 1993-1995 to 2003-2005, however then plateaued by 2013-2015. The level of evidence provided by intervention-focussed publications was suggested to increase over time, however there was no evident variation in translation phase. **Conclusions:** Research has increased over time to characterise smoking among those with a mental illness; however more is needed to inform the development and implementation of effective cessation interventions for this group.

Keywords: Smoking; tobacco use; mental health disorders; bibliometric analysis; research output; treatment and intervention.

Implications

This is the first study to examine the volume and characteristics of research publications in the field of smoking and mental illness over time. The number of publications increased five-fold between 1993-1995 and 2013-2015. Between 1993-1995 and 2003-2005, progression was also indicated by increased: data based publications, diagnostic diversity of samples, and variation in study settings; however further increases in such measures were not evident in 2013-2015. Notably, it continues to be the case that few intervention studies are undertaken. To achieve meaningful changes in the smoking prevalence of this group, a greater focus on research that assesses the effectiveness and implementation of tailored cessation interventions is required.

Background

Smoking remains the leading cause of preventable illness and death in Australia and internationally [21, 24, 223]. While the prevalence of smoking in the general population has steadily declined to between 15% and 20% in high income countries such as Australia, the US and the UK [224-227]; it has remained largely unchanged for persons with a mental illness, and is currently 2-3 times higher than the general population in such countries [40, 56, 68, 228]. Compared to smokers from the general population, people with a mental illness smoke a greater number of cigarettes, have higher levels of nicotine dependence [68, 71], and have more difficulty quitting [68]. Consequently, this population group experience a disproportionate burden of disease associated with tobacco use, including a reduced life expectancy of between 14 and 25 years [42, 43].

Despite a growing recognition of the need to address the high prevalence of smoking among those with a mental illness [67, 229, 230], its intransigence to change in high income nations [39, 41, 67, 231] suggests a failure of tobacco control initiatives to yield improvements for this group of smokers [72, 232]. As a consequence, there is a need for research to determine effective intervention strategies to reduce smoking and its burden for this disadvantaged group [67].

Broadly, across public health research there has been recognition of the need for the focus of research to progress over time such that its findings are increasingly likely to be translated into policy and practice, and hence, to effect improvement in health outcomes at a population level [233-235]. A number of frameworks have been suggested for how such progress might be conceptualised or measured, including the Sequential Model proposed by Nutbeam and colleagues [234, 235] and Flay's Eight Phases of Research [236]. It has been proposed that over time there needs to be an

increasing focus on data based (collecting new information) as opposed to non-data based studies [237-240]; and on intervention research as opposed to descriptive research [233, 237-240]. Further, it has been suggested that intervention-focussed research should increasingly utilise research designs that provide high level evidence (including RCTs and systematic reviews) [233, 238], and move beyond examining efficacy under optimal or controlled conditions to examining effectiveness and implementation in new populations and settings under real world conditions [233-235, 241, 242]. One recently proposed framework has conceptualised this progression of research as occurring over five phases of research translation: T0 to T4 [243-245]. Stages T0 and T1 involve descriptive research that may inform the development of interventions; T2 involves research that evaluates intervention efficacy; while T3 and T4 reflect the further progression of intervention research to addressing questions of implementation in real world practice and to the assessment of population health impact [243-245].

Bibliometric analysis represents one method by which the progression of a research field can be measured [233, 246]. Such analyses have been used to critically examine the progression of research in many fields including Indigenous [238] and rural [247] health, alcohol misuse [237], physical activity and falls prevention [233], and cancer [240, 248-250]. The outcomes of a number of such studies have demonstrated a lack of progression over time, concluding that this may contribute to a lack of impact on public health outcomes [233, 237, 250]. For example, no change in the proportion of data based and non-data based research surrounding the delivery of multidisciplinary cancer care was reported between 1997-2001 and 2002-2006 [250]. With respect to research in the field of physical activity between 1988-1989 and 2008-2009, little variation in the proportion of intervention research being undertaken was noted [233],

and a persistent predominance of efficacy, relative to replication and dissemination trials was evident [233].

Few bibliometric studies have been conducted in the field of smoking research. Sanson-Fisher et al. [239] reported a bibliometric analysis of 'public health' smoking research (that which is non-laboratory and non-clinical) being undertaken across three decades (1987-1988, 1997-1998, 2005-2006) and found that whilst the proportion of data based research increased in 2005-2006, 78% of publications remained descriptive. Another bibliometric analysis of smoking research focussed on smoking and pregnancy; with a particular focus on the volume and country of origin of research, and the gender of the researchers. This review found that between 1900 and 2012, the volume of annual publications increased from 35 to approximately 700; the majority of research was undertaken in the US (35%) followed by the UK (10%); and that researchers were predominantly female (55%) [251]. Neither of these previous bibliometric reviews [239, 251] considered the diversity of study populations or settings utilised in included publications, or any other similar indicators of research progression [242].

Only one bibliometric analysis has investigated the volume and characteristics of research in the field of smoking and mental illness, and this was limited to Australian research published since January 2000 regarding tobacco use in the context of co-occurring physical illnesses (such as cardiovascular disease) [252]. Included publications were identified from a Google Scholar search (n =182) and classified into one or more of 11 domains, and analyses were limited to identifying how many studies were conducted where 'tobacco smoking was the major topic'. The authors concluded that smoking was the major topic for 19% of the publications, but reported no further assessment of the characteristics of such publications or of change over time. This study focused exclusively on persons with a 'severe mental illness', thus excluding a large

proportion of the population of smokers with a mental illness. Further, by limiting the study to specific diagnostic groups, and not considering the study settings, an indication of outcome generalisability and translational utility could not be ascertained [242, 253]. Thus, there is a key gap in the literature examining research outputs among smokers with a mental illness. Examining change in research outputs in this field is particularly important given recent high profile publications identifying smoking and mental illness as a priority area for increased research attention [72, 231, 254, 255].

The current study was conducted to describe the volume and characteristics (data based, study type, study population and study setting) of research publications in the field of smoking and mental illness across three time periods. For intervention-focused research, the level of evidence and phase of research translation were also considered; as indications of progress in the quality of evidence and the potential for population level impact respectively.

Methods

Design

A descriptive repeat cross sectional study was conducted of peer-reviewed publications.

Data sources

Medline and PsycINFO databases were used to locate peer-reviewed publications relating to smoking and mental illness for the years 1993-1995, 2003-2005 and 2013-2015: the objective being to systematically assess trends in study characteristics over time for a sample of publications reporting on smoking and mental illness, rather than the absolute output of publications for the specified periods. Medline

and PsycINFO were utilised as they index the majority of peer-reviewed journals publishing public health and related research, and both databases adopt similar search strategies and platforms – enabling almost identical search strategies to be undertaken. In both databases, the advanced search option was used. 'Keyword' and 'map term to subject heading' options were selected. The search terms and procedures are outlined in Figure 2.1. Final searches for both 'smoking' and 'mental illness' were combined using the 'AND' function and limited to those published in English and by year (1993-1995, 2003-2005 and 2013-2015) to obtain the final search results.

Inclusion and exclusion criteria

Data and non-data based publications were included. Data based publications were those reporting original data or results, or systematically synthesising existing results. Such publications were included if 1) the sample consisted of persons with an identified mental health issue (current or past) and 2) quantitative and/or qualitative data surrounding smoking or related behaviours of such samples were presented. Publications using non-human samples were excluded.

Non-data based publications (those not reporting data or systematically synthesising results) were included if the topic of the paper directly related to smoking and mental illness. Examples of such publications included study protocols, letters to the editor, commentaries and non-systematic literature reviews.

Screening and data extraction

One author (CF) and a research assistant screened publications for inclusion using the title, abstract and where necessary, full text. Data were extracted from included publications according to the data classifications outlined below. To provide a

SMOKING		MENTAL ILLNESS*	
PsycINFO	**Medline**	**PsycINFO**	**Medline**
The keyword ‘smoking’ was searched. Within the MeSH ‘smoking cessation’ the terms ‘nicotine withdrawal’ and ‘smoking cessation’ were selected and searched. Within the MeSH ‘tobacco smoking’ the terms ‘nicotine’ and ‘tobacco smoking’ were selected and searched. The two searches were then combined using the ‘OR’ function.	The keyword ‘smoking’ was searched. Within the MeSH ‘smoking’ the terms ‘tobacco use’ and ‘smoking’ were selected and searched. Within the MeSH ‘smoking cessation’ the terms ‘tobacco use cessation’ and ‘smoking cessation’ were selected and searched. The MeSH term ‘nicotine’ was selected and searched. The three searches were then combined using the ‘OR’ function.	The keyword ‘mental illness’ was searched. Within the ‘mental disorders’ MeSH all narrower terms were selected with the exception of ‘dementia’ and ‘gender identity disorder’. The key word ‘mental health’ was also searched and the following terms selected within the MeSH heading: ‘community mental health’, ‘community mental health services’, ‘mental health services’, ‘community psychiatry’ and ‘mental health programs’. The two searches were then combined using the ‘OR’ function.	The keyword ‘mental illness’ was searched. Within the MeSH ‘mental disorders’ all terms listed below the heading were selected with the exception of ‘delirium, dementia, amnestic, cognitive disorders’ and ‘sexual and gender disorders’. The keyword ‘mental health’ was also searched and all subheadings selected. The two searches were then combined using the ‘OR’ function.

MeSH: Medical Subject Heading
*Substance use disorders were not specifically searched and were categorised separately within the ‘study population’ classification in this review.

Figure 2.1. Database Search Terms and Procedure

measure of quality control, another author (AM) extracted data for a randomly selected subsample (15%) of publications; with complete agreement achieved between reviewers across all classifications.

Publication classification

All included publications were categorised as either data based or non-data based. Data based publications were further classified according to: study type, study population and study setting. No additional classification was undertaken for non-data based publications.

Data based papers

Study type. To determine the focus of each data based publication, such publications were categorised, based on a classification commonly adopted in other bibliometric reviews [233, 237-240], as either:

- Measures: publications that examined the quality (validity or reliability) or acceptability of a measurement instrument used to assess smoking or a related factor/characteristic.
- Descriptive: publications that reported data related to smoking and mental illness, but did not examine the efficacy or effectiveness of a proposed intervention to address smoking.
- Intervention: publications that reported the outcomes of any intervention, or a group of interventions, aimed at addressing smoking. All commonly utilised outcome variables in trials relating to smoking were considered relevant: uptake of smoking, smoking cessation/abstinence, reduction in the number of cigarettes smoked, reduced nicotine dependence, increased quit attempts, increased readiness/motivation to quit and/or interest in quitting.

Publications classified as having an intervention focus were further categorised in terms of the 'level of evidence' (assessed based on study design: systematic reviews/meta-analyses, RCTs, other controlled trials, or other) [256, 257], and 'translation phase' (phases: T2, T3, T4) [243-245, 258].

Study population. The population of people included in each study was categorised according to the following diagnostic groups: (1) 'severe' disorders (a diagnosis of schizophrenia and related psychosis, bipolar disorder and/or major depressive disorder) [259-262]; (2) substance use disorders; or (3) an 'other' disorder (persons with a mental health disorder/s that is not category 1 or 2). Studies consisting of participants with more than one type of mental illness were assigned to all relevant categories. Substance use disorders were classified separately due to the literature reflecting some lack of consensus regarding their status as mental illness [67].

Study setting. The study setting was recorded as either: mental health inpatient, mental health outpatient or community based, generalist health care (including general practitioners), or 'other' (including web or media based, universities, or sub group analyses from population surveys).

Data analysis

Data were analysed using SPSS Statistics version 22 [263]. Descriptive analysis was used to report on the total number of publications, and the number and proportion of publications within each of the classifications (study type, study population and study setting), and sub classifications for intervention publications (level of evidence and research translation phase) across the three time periods.

Chi square or Fisher's exact tests, where applicable, were used to assess for change in the volume and characteristics of publications across the three periods. Where

significant changes were evident, standardised residuals for each period were examined, with scores of greater than or equal to ± 1.96 indicating cells with significant variation from expected [264]. For such analyses, study type was reduced to measures/descriptive and intervention research. Two variables were created for study population: 'severe' only versus all other categories; and greater than one category versus one category only. For study setting, mental health inpatient and mental health outpatient/ community settings were combined to form one category, with generalist health settings, other settings and those using a combination of mental and non-mental health settings combined to form a second. With respect to intervention-focussed research, level of evidence was reduced to three levels (other controlled trials/other, RCTs, and systematic reviews/meta-analyses) and research translation phase to two (T2, T3/T4).

Results

Included publications. Figure 2.2 illustrates the flow diagram for publications identified in the review. Two thousand and forty one publications were identified across the two databases. Two hundred and twenty three duplicates were removed, leaving 1818 to be screened for inclusion. Five hundred and forty seven publications were included in the review.

Volume of data based publications. The total number of publications relating to smoking and mental illness over the three time periods was 547; 65 (12%) in 1993-1995, 153 (28%) in 2003-2005, and 329 (60%) in 2013-2015. The proportion of data based publications, relative to non-data based publications significantly increased from 62% (n = 40) in 1993-1995 to 76% (n = 116) in 2003-2005, however no further increase was evident in 2013-2015 (77%, n = 252) ($\chi^2(2, N = 547) = 6.66$, $p = 0.04$).

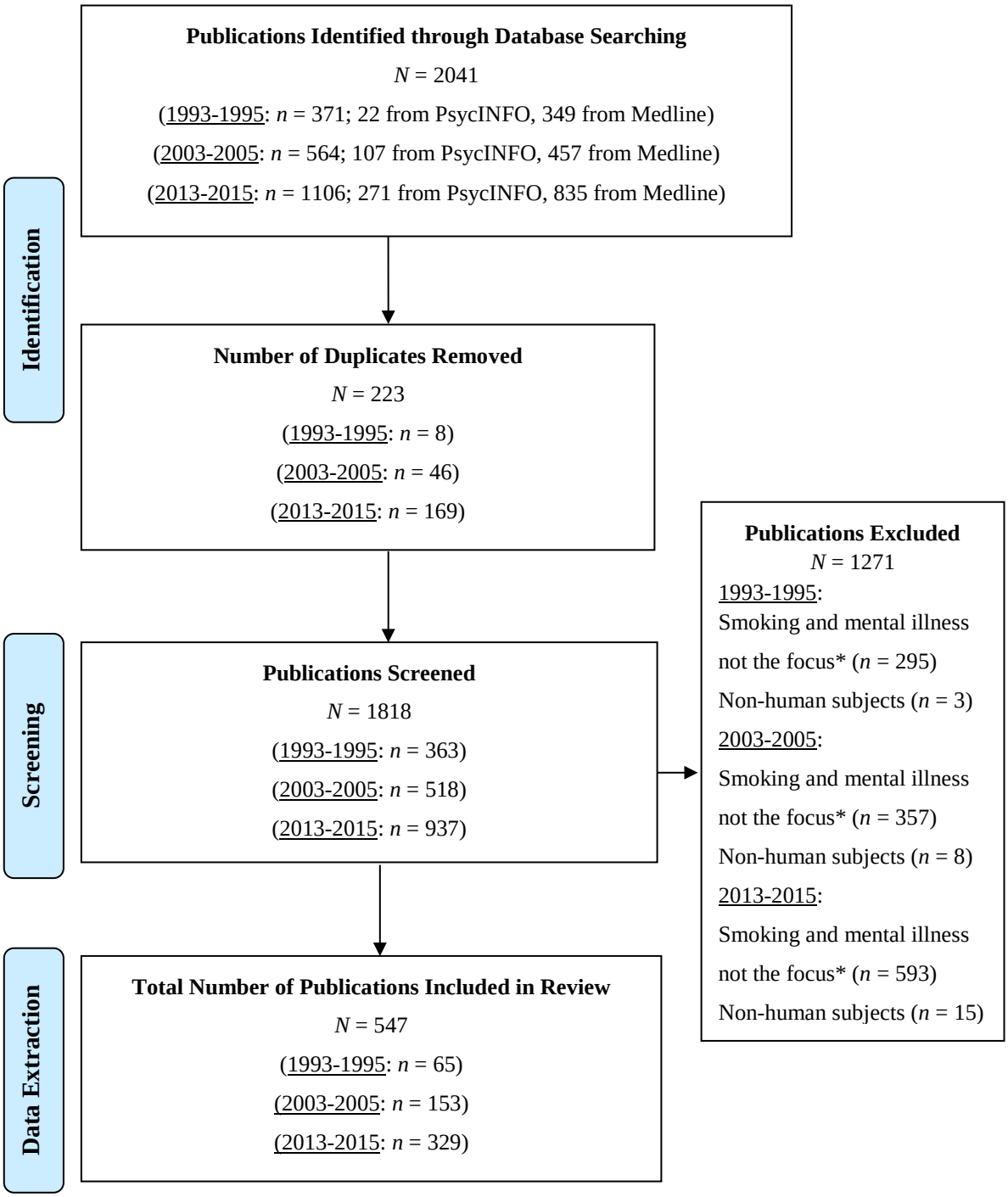

Figure 2.2. Flow Diagram for Inclusion of Articles in the Review.

*Publications that made no mention in the aims nor included any significant analysis or discussion surrounding smoking and mental illness were not included.
Note. References for publications included in the review can be sourced from Appendix 3.

Study type. In 1993-1995, 88% (n = 33) of data based publications were categorised as descriptive, 5% (n = 2) as measures, and 13% (n = 5) as intervention. In 2003-2005 and 2013-2015, 89% (n = 103) and 86% (n = 217) of publications were classified as descriptive respectively, 2% (n = 2) and 1% (n = 2) as measures, and 9% (n = 11) and 13% (n = 33) as intervention research, with no significant difference by study type across the three time periods (p = 0.64; Table 2.1).

Level of evidence. Among the intervention-based publications, the proportion of systematic reviews/meta-analysis-based publications was 0% (n = 0) in 1993-1995, 9% (n = 1) in 2003-2005 and 15% (n = 5) in 2013-2015 (Table 2.2). RCT designs were adopted for 20% (n = 1) of intervention research in 1993-1995, 18% (n = 2) in 2003-2005 and 55% (n = 18) in 2013-2015, with a borderline significant increasing trend across the three time periods (p = 0.06).

Research translation phase. There was little variation in the research translation phase of intervention-focussed publications across the three time periods (p = 1.00): all were classified as T2 in 1993-1995, with identical proportions classified as T2 (91%) and T3 (9%) in both 2003-2005 and 2013-2015 (Table 2.2).

Study population. Table 3 reports the number and proportion of publications reporting on the identified diagnostic categories across the three time periods. The proportion of publications focused on only severe mental disorders was 8% (n = 3) in 1993-1995, 18% (n = 21) in 2003-2005 and 20% (n = 50) in 2013-2015, with no statistically significant change across the three periods (χ^2 (2, N = 408) = 0.17, p = 0.17).

The proportion of publications reporting on more than one of the specified diagnostic categories significantly increased from 28% (n = 11) in 1993-1995 to 56% (n = 65) in 2003-2005, however remained similar in 2013-2015 (57%, n = 144) (χ^2 (2, N =

Table 2.1. Total Number of Publications Related to Smoking and Mental Illness Between1993-1995, 2003-2005 and 2013-2015, According to Study Type

	1993-1995 *n* (%)	**2003-2005** *n* (%)	**2013-2015** *n* (%)
Non-data based research	25 (38)	37 (24)	77 (23)
Data based research	40 (62)	116 (76)	252 (77)
Descriptive	33 (83)	103 (89)	217 (86)*
Measures	2 (5)	2 (2)	2 (1)
Intervention	5 (13)[#]	11 (9)	33 (13)

*Five publications in this category were systematic reviews not relating to intervention efficacy/ effectivenss.

[#]Three publications in this category originated from a single intervention study, whereas in subsequent years all intervention-focussed publications were based on discrete studies.

Table 2.2. Level of Evidence and Research Translation Phase for Intervention Publications Between 1993-1995, 2003-2005 and 2013-2015

	1993-1995 *n* (%)	**2003-2005** *n* (%)	**2013-2015** *n* (%)
Level of evidence			
Meta-analyses/ systematic reviews	0 (0)	1 (9)	5 (15)
RCT	1 (20)	2 (18)	18 (55)
Other controlled trial	2 (40)	3 (27)	3 (9)
Other	2 (40)	5 (45)	7 (21)
Research translation phase			
T2	5 (100)	10 (91)	30 (91)
T3	0 (0)	1 (9)	3 (9)
T4	0 (0)	0 (0)	0 (0)

RCT: Randomised Controlled Trial.

Note: T2 research evaluates intervention efficacy, while T3 research assesses intervention effectiveness and addresses questions of implementation in real world practice. Research in T4 assesses the population health impact of an intervention.

Table 2.3. Study Population and Setting for Data Based Publications Between 1993-1995, 2003-2005 and 2013-2015

	1993-1995 *n* (%)	**2003-2005** *n* (%)	**2013-2015** *n* (%)
Study Population			
Severe* disorders	3 (8)	21 (18)	50 (20)
Substance use disorders	22 (55)	17 (15)	24 (10)
Other disorders	4 (10)	13 (11)	34 (13)
Severe + other	2 (5)	14 (12)	43 (17)
Severe and/or other + substance use disorders	8 (20)	49 (42)	96 (38)
Unclear/ not specified	1 (3)	2 (2)	5 (2)
Study Setting			
Mental health inpatient	17 (43)	19 (16)	37 (15)
Mental health outpatient or community based	8 (20)	27 (23)	65 (26)
Generalist health care	1 (3)	5 (4)	9 (4)
Other	9 (23)	57 (49)	121 (48)
Mental health inpatient + outpatient/ community	5 (13)	7 (6)	10 (4)
Mental health outpatient/ community + other	0 (0)	1 (1)	6 (2)
> 3 settings	0 (0)	0 (0)	4 (2)

408) = 12.50, $p = 0.002$). Of the publications focussing on only one of the diagnostic classifications, 75% concentrated on substance use disorders in 1993-1995, while severe mental disorders was the focus for nearly half (41% and 46%) in 2003-2005 and 2013-2015.

Study setting. The number and proportion of publications undertaken across the specified settings are reported for the three time periods in Table 2.3. The proportion of publications undertaken in mental health inpatient facilities was 43% ($n = 17$) in 1993-1995, 16% ($n = 19$) in 2003-2005 and 15% ($n = 37$) in 2013-2015; while the proportion utilising outpatient or community mental health settings was 20% ($n = 8$) in 1993-1995, 23% ($n = 27$) in 2003-2005 and 26% ($n = 65$) in 2013-2015. 'Other' settings were used for 23% ($n = 9$) of publications in 1993-1995, 49% ($n = 57$) in 2003-2005 and 48% ($n = 121$) in 2013-2015. Relative to mental health specific settings exclusively, the use of generalist health care and/or other settings significantly increased from 23% in 1993-1995 to 54% in 2003-2005, however no further increase was evident in 2013-2015 (57%) (χ^2 (2, $N = 408$) = 15.47, $p < 0.001$).

Discussion

The current study is novel in determining the volume and characteristics of research publications across three time periods, via bibliometric analysis, in the field of smoking and mental illness, and fills a key gap in the literature. Overall, the total number of studies reporting on smoking and mental illness increased five-fold from 65 in 1993-95 to 329 in 2013-15; an increase that was also observed in the number and proportion of data based publications. There was no variation in the proportion of study types across the time periods, with research remaining largely descriptive, with limited focus on intervention and measures. For intervention-focussed research, there was suggestion of

an increase in the adoption of RCT study designs in the most recent period, however the research translation phase remained unchanged over time. Between 1993-1995 and 2003-2005, study populations became more diagnostically heterogeneous, and there was an increased focus on settings other than mental health care specific facilities; however no further increase in such measures were evident in 2013-2015.

As proposed by models of research translation [233-235], the progression of research within a field from describing health issues to the development and assessment of interventions, and, where applicable, their dissemination is required to achieve a population health impact. The sequential model proposed by Nutbeam and others [234, 235] suggests that such progression requires at least some increase in the relative amount of intervention-focussed publications over time. Such an increase was reported by Sanson-Fisher and colleagues [239] in the field of smoking and public health generally between 1987 and 2006. In contrast, the unchanging predominance of descriptive research in the field of smoking and mental illness between the decades compared suggests that such progression has not occurred. While some descriptive research will continue to be important in this field, including causal inference studies which help progress understanding of the relationship between smoking and mental illness, the balance of research effort nevertheless needs to shift towards intervention research given the need to reduce the prevalence of smoking and its negative consequences for people with a mental illness.

It has been suggested in other fields of research that the predominance of descriptive research may be associated with advantages it offers for researchers in terms of greater convenience, productivity and lower cost [233, 238-240]. Possible strategies to promote a greater focus on intervention research may include for instance such research being weighted more favourably by journal editors and/or in academic promotion criteria

[265]. Further, it might be speculated that a lack of policy-driven or translation-focused research funding, in comparison to investigator driven research funding, may have contributed [265], or that 'smoking and mental illness' may not fit neatly into any one area of funding and so to some extent risk falling into a 'funding gap' [72]. Some experts in the US have argued strongly that tobacco use by people with a mental illness continues to be insufficiently prioritised for policy and program attention, and that this population group should be more strongly identified as a 'tobacco use disparity group', particularly at a national level [266].

While there was no difference in the amount of intervention research over time, there was some indication of progression in terms of the level of evidence provided by the intervention research undertaken, with a modest rise in the number and proportion of systematic reviews/meta-analyses and RCTs between 1993-1995 and 2013-2015. The increasing tendency toward synthesising research findings through systematic review/ meta-analyses perhaps also suggests an increased acknowledgement of the importance of this public health issue. However, the stagnation in translation phase - with 9% categorised as T3 in both 2003-2005 and 2013-2015 periods - highlights the need for progression from efficacy trials to those assessing the effectiveness and dissemination of interventions.

The greater diversity of study settings and diagnostic heterogeneity of samples observed across the compared decades may suggest an increase in the generalisability and possibly translational utility of findings [242, 253]. Health care settings remained the predominant focus of research across the time periods, particularly so for intervention research. As such settings have been recognised to provide an opportunity to reach and systematically offer cessation support to all patients [124], including those with a mental illness [67, 212], such a focus could be appropriate [232]. In terms of

mental health specific settings, the increased attention on community/ outpatient mental health settings, relative to inpatient settings, could be speculated to be a positive reflection of a less exclusive focus on severe diagnoses or patients experiencing acute illness episodes, but may also reflect a change in the delivery of mental health care towards a greater focus on community based services in some countries [267, 268]. In Australia, it has been estimated that 64% of smokers with a 12-month mental disorder had not accessed any health services over a period of one year [41]. The increasing focus on settings other than health care settings observed in this study may therefore indicate an increased recognition of the need to address smoking among these community living people with mental illness who do not regularly access the health system [41].

A notable proportion of publications in the current study were restricted to a sample with only one diagnostic classification, i.e. only 'severe' or only substances use disorders. Where only one diagnostic classification was included, the large majority of publications in 1993-1995 focussed on substance use disorders (76%), whereas almost half focused on severe mental disorders in both 2003-2005 and 2013-2015. It might be speculated that the predominant attention to substance-use disorders in 1993-1995 may reflect factors such as an early recognition of the high smoking prevalence among persons with such disorders, or initial concerns over the possibility of adverse events arising from concurrent treatment of tobacco and other substance disorders. The observed shift in focus to severe mental disorders in later periods could be understandable given that the prevalence of smoking among those meeting such criteria has been recognised as particularly high [40, 269]. The increase in the diagnostic heterogeneity of samples however, is likely to promote increased generalisability and translational utility of findings [242, 253].

The findings from the current study should be interpreted in the context of a number of methodological characteristics. Publications were sourced from only two research databases and the findings therefore do not represent the total sum of research undertaken, although this is unlikely to have influenced relative trends in publication characteristics across the time periods. Also, the adopted methodology would not have sourced relevant grey literature and government documents, and allows reflection only on the amount and quality of peer-reviewed publications. Future studies assessing publication characteristics across multiple time periods should utilise a greater number of peer-reviewed databases and, although difficult to systemically undertake, attempt to source non peer-reviewed resources to address these potential limitations. Relevant publications may not have been sourced using our search terms if they related to 'lifestyle interventions' where smoking was addressed, leading to a possible underestimation of the amount of intervention-focussed research. In addition, comparing three-year intervals across two decades may have introduced a selection bias. Employing broader search terms that include all physical health risk behaviours and comparing decades would be of benefit in future studies. Also, while this study considered phase of research translation for intervention-focussed publications, future research might consider the degree to which research across all study types, used large representative samples and therefore had relevance at a population level.

Overall, the total number of studies reporting on smoking and mental illness increased five-fold between 1993-1995 and 2013-2015. The findings from this study suggest a number of other positive indicators of progression between 1993-1995 and 2003-2005, including increased: proportion of data based publications, diagnostic diversity of samples, and variation in study settings; however, no further increase in such measures were evident in 2013-2015. Notably, it continues to be the case that few

intervention studies appear to be undertaken. To achieve meaningful changes in the smoking prevalence of this group, a greater increase in research volume is required, particularly that which assesses the effectiveness and implementation of tailored cessation interventions.

Funding

This work was supported by the National Health and Medical Research Council (NHMRC) (grant number: G1100130) (Appendix 4). Dr Stockings' is supported by the NHMRC Centre of Research Excellence in Mental Health Systems Improvement (CREMSI) (grant number: 1041131). The National Drug and Alcohol Research Centre at the University of New South Wales, Australia is supported by funding from the Australian Government under the Substance Misuse Prevention and Service Improvements Grant Fund. Dr Prochaska is supported by the National Institutes of Health (grant number: HL117736-01) and the State of California Tobacco-Related Disease Research Program (grant number: 24RT-0035).

Declaration of Interests

Dr Prochaska has consulted to Pfizer, which makes smoking cessation medications, and has been an expert witness for plaintiffs' counsel in lawsuits against the tobacco companies. Dr Williams has received unrestricted continuing medical education grants from Pfizer. The other authors declare they have no competing interests.

Acknowledgements

The authors' would like to acknowledge Kristy Rudd for her assistance identifying search terms and database searching. We would also like acknowledge Lauren Gibson for her contribution to the publication screening and data extraction process.

Chapter 3: Smoking and Environmental Characteristics of Smokers with a Mental Illness, and Associations with Quitting Behaviour and Motivation; a Cross Sectional Study

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Manuscript accepted for publication in *BMC Public Health* on 18th March, 2016.

Bibliographic reference: Metse AP, Wiggers J, Wye P, Moore L, Clancy R, Wolfenden L, Freund M, Van Zeist T, Stockings E, Bowman JA: **Smoking and environmental characteristics of smokers with a mental illness, and associations with quitting behaviour and motivation; a cross sectional study**. *BMC Public Health* 2016, **16**:332. doi:10.1186/s12889-016-2969-1.

Abstract

Background: Persons with a mental illness are less likely to be successful in attempts to quit smoking. A number of smoking and environmental characteristics have been shown to be related to quitting behaviour and motivation of smokers generally, however have been less studied among smokers with a mental illness. This study aimed to report the prevalence of smoking characteristics and a variety of physical and social environmental characteristics of smokers with a mental illness, and explore their association with quitting behaviour and motivation. **Methods:** A cross-sectional descriptive study was undertaken of 754 smokers admitted to four psychiatric inpatient facilities in Australia. Multivariable logistic regression analyses were undertaken to explore the association between smoking and environmental characteristics and recent quitting behaviour and motivation. **Results:** Participants were primarily daily smokers (93%), consumed greater than 10 cigarettes per day (74%), and highly nicotine dependent (51%). A third (32%) lived in a house in which smoking was permitted, and 44% lived with other smokers. The majority of participants believed that significant others (68% to 82%) and health care providers (80% to 91%) would be supportive of their quitting smoking. Reflecting previous research, the smoking characteristics examined were variously associated with quitting behaviour and motivation. Additionally, participants not living with other smokers were more likely to have quit for a longer duration (*OR* 2.02), and those perceiving their psychiatrist to be supportive of a quit attempt were more likely to have had more quit attempts in the past six months (*OR* 2.83). **Conclusions:** Modifiable characteristics of the physical and social environment, and of smoking, should be considered in smoking cessation interventions for persons with a mental illness.

Keywords: Smoking, mental illness, characteristics, social, environment, quitting, quitting motivation.

Background

A decreased likelihood of successfully quitting [56, 68] contributes to the persistently higher prevalence of smoking among persons with a mental illness [39-41, 67]. This in turn is reflected in greater morbidity and mortality from tobacco-related diseases and a reduced life expectancy [42, 43].

Successful smoking cessation is often preceded by multiple quit attempts [83, 89], a motivation to quit [89, 130], and a greater capacity to identify as a potential non-smoker [66, 270, 271]. The likelihood of being motivated and attempting to quit has been suggested to be a function of an individual's smoking characteristics such as level of nicotine dependence [99, 100], number of cigarettes smoked per day [101, 102], age of smoking initiation [83, 103], and number of years smoking [272]. While research among smokers with a mental illness specifically has consistently demonstrated high levels of nicotine dependence and heavy smoking (in terms of cigarettes per day) [39-41], far less research has explored the associations of such characteristics with quitting behaviour and motivation. That which has been undertaken however suggests the same patterns of association as found among smokers generally [129, 130, 273]. For instance, lower levels of nicotine dependence have been associated with quit attempts of longer duration (greater than seven days) among smokers from the US attending a residential substance treatment program [129], and following discharge from a psychiatric inpatient facility [130].

Socio-ecological theories also highlight the potential influence of a range of broader physical and social environmental characteristics of smokers on quitting behaviour [98]. Among smokers generally, characteristics associated with both attempts to quit and successful cessation include: residing in a smoke-free home [83, 106, 108]; absence of persons who smoke in the immediate environment [83, 108]; a partner being

a non-smoker [109, 111]; and perception of support to quit from significant others [118, 120] and health care providers [100, 121]. Consequently, intervention strategies to aid smoking cessation have included: the introduction of smoke-free workplace policies [122]; enhancement of partner support for spouse's smoking cessation [123]; smoking cessation care being delivered by health care providers [125]; and increasing the availability of smoking cessation peer support programs [274].

Very little research has explored the prevalence of such physical and social environmental characteristics among persons with a mental illness. In the US, a study reported that only 24% of smokers diagnosed with psychotic or mood disorders occupied a residence where smoking was not permitted inside [132], nearly half that reported in a national representative sample of smokers without a mental illness (46%) [133]. Among clients of US community mental health services, the proportion of smokers with acquaintances that smoked was more than twice that of non-smokers (78 vs 35%) and smokers were reported to have higher rates of household second-hand smoke exposure (47 vs 28%) [275]. In one Australian study, the proportion of smokers with a mental illness living in a smoke-free home was found to be 42%, almost 20% less than those without a mental illness [71].

In addition, few studies have explored the association between the physical and social environmental characteristics of smokers with a mental illness and their quitting behaviour and motivation. In one such study, among US smokers with co-occurring severe mental illness and substance use disorders, Ferron et al. [128] found that more social contact with non-substance using (including tobacco) friends was positively associated with a higher number of quit attempts. Survey data from the UK [276] and US [277] similarly suggest that aspects of the physical and social environment have an impact on smoking and quitting behaviour of smokers with a mental illness. Among

recent quitters with a current mental illness, 46% to 58 % identified social support to quit from friends, family and doctors as key enabling factors in their successful quitting [277]; and among forensic psychiatric inpatients, exposure to others smoking and lack of encouragement from psychiatric staff to quit were identified as barriers to successful smoking cessation [276]. Further, qualitative research undertaken in several countries, including g the US [135, 137], UK [139], Scotland [140], Australia [134], and Canada [141], has suggested that a lack of support to quit from family and friends [139] and health care professionals [134, 137, 139, 140], and socialising with other smokers [135, 140, 141] contribute to continued smoking by this group.

Given the limited evidence available, it is suggested that a greater understanding of the characteristics of smokers with a mental illness that are associated with their quitting behaviour and motivation [95] is required to facilitate the development of effective smoking cessation interventions. We conducted a study that aimed to 1) report the prevalence of smoking characteristics and a variety of physical and social environmental characteristics of smokers with a mental illness and 2) explore the association between such characteristics and recent quitting behaviour and motivation.

Methods

Design and setting

A cross-sectional descriptive study was undertaken in the context of a smoking cessation intervention trial [278] conducted in four adult psychiatric inpatient facilities in New South Wales, Australia.

Sample and recruitment procedure

Research staff approached all patients admitted to the four psychiatric inpatient facilities over a 19 month period (October 2012 and April 2014) to assess for study eligibility [278]. Research staff were independent of the hospitals, received standardised training in mental illness and its impacts, and had completed or were in the process of completing an undergraduate degree in a health related area. Patients eligible for the trial were: current smokers (smoked tobacco in the month prior to admission); at least 18 years of age; willing to provide contact details; and able to give informed consent to participate in the trial. No other exclusion criteria were applied.

Ethics, consent and permissions

Ethics approval was obtained from the Hunter New England Human Research Ethics Committee (reference no: 11/12/14/4.02; Appendix 5.1) and the University of Newcastle Human Research Ethics Committee (reference no: H-2012-0061; Appendix 5.2). Written consent was obtained from all participants.

Data collection procedures

Consenting participants completed a face-to-face structured interview, administered by research staff during their hospital stay. Interviews were administered in a quiet area of the inpatient unit and took approximately 40 minutes to complete. Participants could opt to have short breaks during the data collection process as required. Interviews were carried out prior to participant allocation to the intervention or usual care control condition of the overarching smoking trial [278]. Characteristics of smoking and of the participants' physical and social environment relevant to smoking, and recent quitting behaviour and motivation were collected by the interview.

Participant clinical and demographic information was obtained via the facility electronic medical record system and the participant interview.

Measures

Clinical and demographic information. The following participant data were collected from the patient medical record system: age, gender, relationship status (single, married/de facto, separated/divorced, widowed, did not state/inadequately described), Aboriginal and/or Torres Strait Islander status (Aboriginal and/or Torres Strait Islander, neither, did not state), primary mental health diagnosis at discharge (schizophrenia and related psychoses, anxiety and stress related disorders, mood disorders, substance- related disorders, personality and other disorders), legal status at admission (voluntary, involuntary), and length of stay (total days between admission and discharge).

The following clinical and demographic information was obtained from the participant interview: level of alcohol use (AUDIT-C) [279], education (primary school, third year of high school, school certificate (fourth year high school), Higher School Certificate [HSC] (sixth year high school), TAFE certificate or diploma (tertiary qualification not obtained from a university), bachelor degree, post graduate degree), employment details (full time, part time, household duties, student, unemployed/ other), receipt of a government payment (yes, no), and living circumstances (on own, with others).

Smoking characteristics. The smoking characteristics of participants prior to admission were: smoking status (daily smoker, weekly smoker, irregular smoker [smoked cigarettes less than weekly), cigarettes per day, level of nicotine dependence

(Fagerstrom Test for Nicotine Dependence [FTND])[280], age initiated smoking, and number of years smoked.

Physical and social environmental characteristics. Participants were asked if they: lived in a smoke-free house prior to admission (a place of residence where smoking is not permitted inside; yes, no), lived with smokers prior to admission (lived with at least one other smoker; yes, no), and had a partner who smoked (partner smokes, partner does not smoke/ no partner).

Participants were also asked to rate on a seven point Likert- type scale (‘very supportive’ to ‘actively discourage’, ‘unsure’ and ‘not applicable’), how supportive they perceived the following persons would be if they were to attempt to quit smoking: partner, family, friends, general practitioner (primary care physician; GP), psychiatrist, and ‘other’ mental health professional (psychologists, social workers, nurses, counsellors and case managers). Participants were asked if they had someone in their life they felt was their key support person (a person of whom they could rely and/or routinely provided assistance and general support; yes, no).

Recent quitting behaviour and motivation. Measures of recent quitting behaviour were: a quit attempt in past six months (yes, no); and, for those who had attempted to quit in the past six months, the number of times (once, two to three times, more than three times) and duration of longest quit attempt in that period (days). Quit attempts were defined as not smoking on purpose for a period of at least 24 hours, with the intention of quitting smoking [127].

Measures of smoking related motivation were: readiness to quit and smoking identity. To assess current readiness to change, the Readiness to Quit Smoking Questionnaire [281] was used, eliciting responses to five items in a Likert scale format. Smoking identity was measured using a single question asking respondents to indicate

how easy it was for them to see themselves as a non-smoker [271]. Participants responded on a five point Likert- type scale ranging from very easy to very difficult, with an 'unsure' option.

Analysis

Data were analysed using SPSS Statistics version 22 [263]. The following numerical variables were transformed to categorical variables for the purpose of association analyses: cigarettes per day (1-10, 11-20, 21-30, >31) [282], age initiated smoking (< 14 years, ≥ 14 years) [105], number of years smoked (≤ 10, 11-20, >20 years) [272], number of quit attempts in the past six months (one, two or more) [89, 283], and duration of longest quit attempt in the last six months (less than one month, greater than or equal to one month) [83, 283].

The following variables were categorised to two levels: smoking status (daily smoker, weekly/ irregular smoker), nicotine dependence (low-moderate [FTND score less than or equal to five], high [FTND score greater than or equal to six]) [284], readiness to quit (pre-contemplative, contemplative or a more progressed stage), and ease of seeing self as a non-smoker (easy, difficult/ unsure). All measures pertaining to the degree of perceived social support to quit smoking from significant persons/clinicians were also categorised to two levels (supportive, unsupportive/unsure/not applicable).

Participant clinical and demographic information, smoking and physical and social environmental characteristics, and recent quitting behaviour and motivation were summarised using descriptive statistics.

Chi-square analysis was used to explore univariate associations between each separate smoking and physical and social environmental characteristic, and recent

quitting behaviour and motivation. Variables with a *p*-value of ≤ 0.25 were subsequently entered into multivariable logistic regression models, using both backward elimination and stepwise variable selection to ensure model stability. Significance level was set at 0.05 for the inclusion of variables in the final models. Separate models were developed for five dependent variables: quit attempt in the past six months (yes, no), number of quit attempts in past six months (one, two or more), duration of quit attempt in the past six months (less than one month, greater than or equal to one month), readiness to quit (pre-contemplative, contemplative or a more progressed stage), and ease of seeing self as a non-smoker (easy, difficult or unsure).

Results

Sample

Of the 3,626 patients admitted to the four inpatient facilities in the study period, 64% (*n* = 2,315) were approached by research staff. For those not approached, the primary reasons for non-contact were a short length of stay (less than or equal to one night; 38%) and psychiatric instability for the duration of time spent as an inpatient (35%). Of the 2,315 patients approached, 2,078 (90%) agreed to be assessed for study eligibility, of which 841 (40%) were ineligible, predominantly due to being non-smokers (*n* = 797, 95%). Sixty one per cent (*n* = 754) of eligible smokers consented and completed the survey (Figure 3.1).

Patient clinical and demographic information

Table 3.1 describes the clinical and demographic characteristics of patients approached and not approached, and participants and non-consenters. Approximately

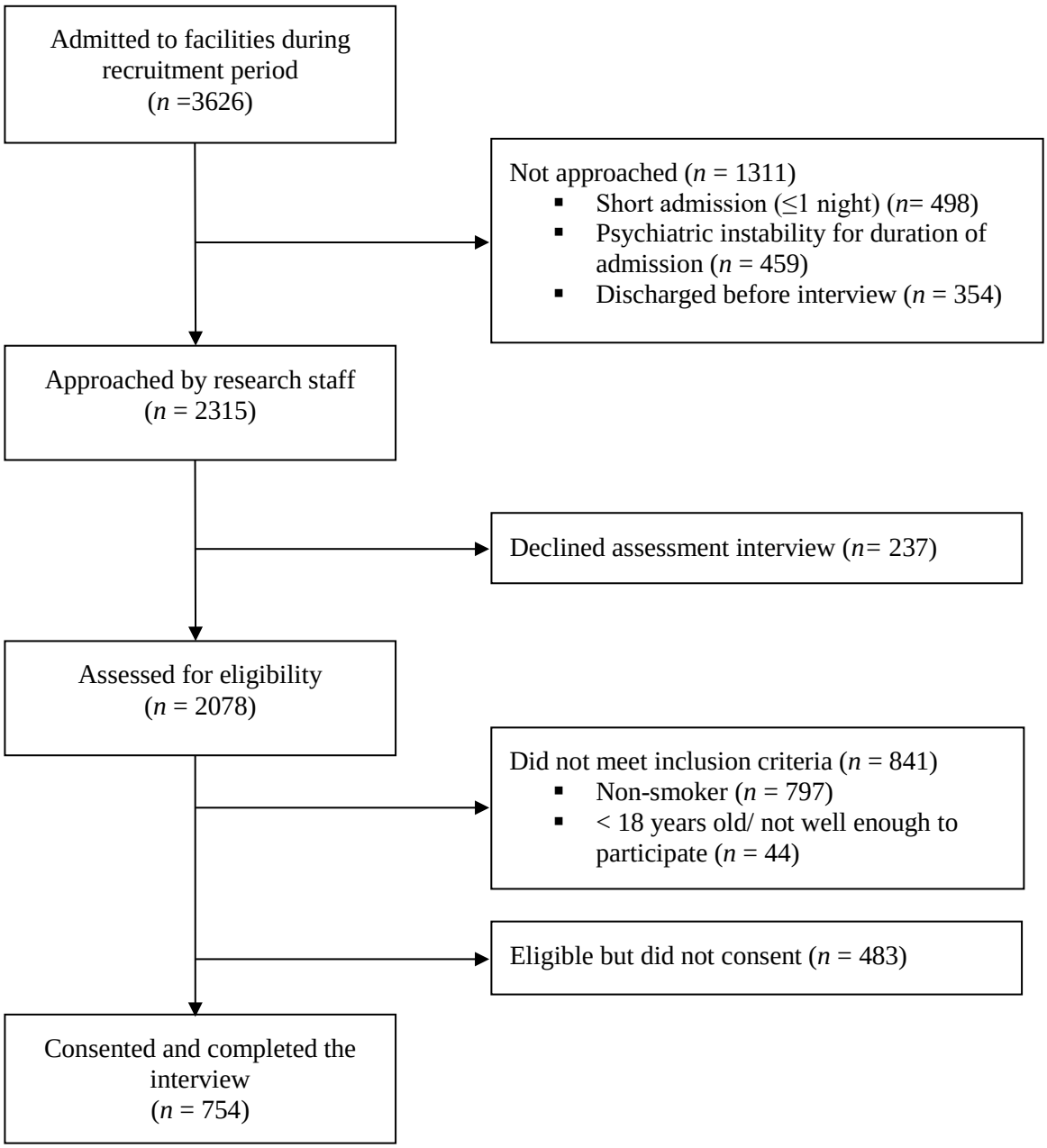

Figure 3.1. Flow diagram Illustrating the Number of Patients Approached, Assessed for Eligibility and Recruited into the Study.

Table 3.1. Clinical and Demographic Characteristics of Not Approached and Approached Patients, and Participants and Non-consenters

	Not Approached (*n* = 1311)	Approached (*n* = 2315)	Non-Consenters (*n* = 483)	**Participants** (*n* = 754)
Gender (%)				
Male	60.0	55.4	63.4	61.3
Age (years)				
Mean (SD)	39.8 (17.1)	41.8 (14.2)	38.9 (11.7)	38.7(12.0)
Media (Range: min-max)	37 (10-94)	41 (18-93)	38 (18-82)	38 (18-76)
Relationship status (%)				
Single	59.0	58.6	70.8	63.7
Married/De facto	25.7	24.1	17.4	20.7
Separated/Divorced/ Widowed	14.2	16.5	10.8	15.0
Not stated/inadequately described	1.0	0.7	1.0	0.7
Aboriginal and/or Torres Strait Islander Status (%)				
Aboriginal and/or Torres Strait Islander	12.8	11.6	17.7	13.5
Neither Aboriginal or Torres Strait Islander / Unknown	87.2	88.4	82.3	86.5
Employment status (%)				
Full time	-	-	-	15.1
Part time	-	-	-	11.4
Student	-	-	-	2.8
Unemployed/ household duties/other				70.7

Table 3.1. Continued.

	Not Approached (*N* = 1311)	Approached (*N* = 2315)	Non-Consenters (*N* = 483)	**Participants** (*N* = 754)
Highest education level achieved (%)				
Up to Third Year of High School	-	-	-	28.4
Higher School Certificate (HSC)	-	-	-	13.4
Tertiary	-	-	-	25.6
Receipt of a government payment (%)				
Yes	-	-	-	77.1
Diagnosis type (%)				
Schizophrenia and related psychosis	14.1	27.6	37.1	19.5
Anxiety and stress related disorders	20.3	8.5	6.4	13.0
Mood disorders	23.1	30.8	22.4	26.7
Substance related disorders	21.2	15.6	18.0	23.1
Personality and other disorders	21.3	17.4	16.1	17.8
Alcohol use (AUDIT- C) (%)*				
Harmful/hazardous	-	-	-	64.5
Non-harmful/hazardous	-	-	-	35.5
Length of stay (days)				
Mean (SD)	12.4 (62.1)	16.8 (28.7)	17.6 (24.4)	14.3 (17.9)
Median (Range: min-max)	2 (0-1715)	10 (0-945)	10 (0-236)	9 (0-147)
Legal status on admission (%)				
Voluntary	55.6	53.2	49.3	53.2
Involuntary	44.4	46.8	50.7	46.8

one third (30%) of participants lived on their own, 66% with a partner or with others, and 4% reported being homeless (not in table).

Prevalence of smoking characteristics

Participants smoking characteristics are described in Table 3.2. Almost all (93%) were daily smokers; 51% were assessed as highly nicotine dependent; nearly three quarters (74%) smoked > 10 cigarettes per day; 68% had commenced smoking before 16 years of age; and more than half (55%) had smoked for more than 20 years.

Prevalence of physical and social environmental characteristics

Forty four per cent of participants lived with at least one other smoker, and 32% lived in a house where smoking was permitted inside (Table 3.3). Fifty one per cent of those with a partner reported that their partner smoked.

Almost all participants (92%) could identify a key support person in their life on whom they could rely and/or routinely provided assistance and general support. Seventy one per cent of participants with a partner believed the partner would be supportive of them making a quit attempt. Eighty two per cent and 68% of participants believed their family and friends would be supportive of them quitting, respectively. Eighty one, 91 and 80% of participants believed that their psychiatrist, GP, or another mental health professional, respectively, would be supportive of them attempting to quit.

Quitting behaviour and motivations

Thirty one per cent of participants had attempted to quit in the past six months; with 57% of those who had done so having made a single quit attempt, and 30% and 13% having attempted to quit two to three times or more than three times, respectively.

Table 3.2. Smoking Characteristics

	Total (N = 754)
Smoking status (%)[1, 2, 3, 4, 5]	
Daily	93.0
Weekly/ Irregular	7.0
Cigarettes Per Day (%)[1, 2, 3, 5]	
1-10	26.1
11-20	36.2
21-30	23.2
> 30	14.5
Level of nicotine dependence (%)[1,3, 5]	
Low-moderate	48.8
High	51.2
Age initiated smoking (%)[4, 5]	
< 12	21.8
12 - < 14	21.0
14 - < 16	25.2
16 - < 18	16.2
≥18	15.9
Number of years smoked (%)[1, 2, 3, 4, 5]	
≤ 10	18.3
11-20	26.9
> 20	54.8

Entered into regression analyses:
[1]Quit attempt in the past 6 months
[2]Number of quit attempts in the past 6 months
[3]Length of longest quit attempt in past 6 months
[4]Readiness to quit
[5]Ease of seeing oneself as a non-smoker.

Table 3.3. Physical and Social Environmental Characteristics

	% (*n*)*
Lived with smokers (%)[3,4]	
Yes	43.6 (329)
Lived in a smoke-free house (%)[3]	
Yes	68.0 (513)
Partner smoking status (%)[4]	
Partner smokes	50.6 (79)
Identify a key support person (%)	
Yes	92.4 (697)
Perceived social support to quit smoking from:	
Partner (%)[3, 4]	
Supportive	71.2 (111)
Unsupportive	28.2 (44)
Unsure	0.6 (1)
Family(%)[5]	
Supportive	82.3 (552)
Unsupportive	8.9 (60)
Unsure	8.8 (59)
Friends(%)[4]	
Supportive	68.0 (433)
Unsupportive	13.1 (84)
Unsure	18.8 (120)
Psychiatrist (%)[2]	
Supportive	80.9 (408)
Unsupportive	7.0 (35)
Unsure	12.1 (61)
General Practitioner (%)[2]	
Supportive	91.4 (601)
Unsupportive	2.9 (19)
Unsure	5.8 (38)
Other mental health professional (%)[2]	
Supportive	80.2 (469)
Unsupportive	8.5 (50)
Unsure	11.3 (66)

*Total numbers vary due to applicability
Entered into regression analyses:
[1]Quit attempt in the past 6 months
[2]Number of quit attempts in the past 6 months
[3]Length of longest quit attempt in past 6 months
[4]Readiness to quit
[5]Ease of seeing oneself as a non-smoker

Of those who had made a quit attempt in the past six months, 21% were abstinent for at least one month.

In terms of motivation and readiness to quit, 45% of participants were assessed as being either contemplative or at a more progressed stage. Forty three per cent reported it would be easy to see themselves as a non-smoker, whereas 43% and 14% reported it would be difficult or that they were unsure.

Smoking, physical and social and environmental characteristics associated with quitting behaviour and motivation

Variables with a p-value of ≤ 0.25 in the chi-square analyses and hence entered in the multivariable logistic regression models are noted in Tables 3.2 and 3.3. The findings of the five regression models were as follows:

Quit attempt in the past six months: Weekly/irregular smokers were twice as likely as daily smokers to have attempted to quit in the past six months (*OR* = 2.07, 95 % CI: 1.17 to 3.64, $p < 0.05$) (Table 3.4). Those who had been smoking for less than 10 years were 1.65 (95 % CI: 1.11 to 2.47, $p < 0.05$) times more likely than those who had smoked for more than 20 years to have attempted to quit in the past six months.

Number of quit attempts in the past six months: Smokers who perceived their psychiatrist to be supportive of them quitting smoking were 2.83 (95 % CI: 1.64 to 4.88, $p < 0.001$) times more likely than those who perceived their psychiatrist to be unsupportive or who did not have a psychiatrist to have attempted to quit two or more times in the past six months.

Table 3.4. Multivariable Logistic Regression Results for Smoking and Physical and Social Environmental Characteristics Associated with Quitting Behaviour and Motivation

Predictor		% (*n*)	OR	95 % CI Lower	95 % CI Upper
Model 1: Quit attempt in the past six months[1]					
Smoking status					
	Weekly/ Irregular	7.0 (53)	2.07*	1.17	3.64
	Daily	93.0 (701)	Ref		
Years smoked					
	≤ 10	18.3 (138)	1.65*	1.11	2.47
	11-20	26.9 (203)	0.99	0.68	1.43
	> 20	54.8 (413)	Ref		
Model 2: Number of quit attempts in the past six months[2]					
Perceived support from psychiatrist					
	Supportive	54.7 (128)	2.83**	1.64	4.88
	Unsupportive/ not applicable	45.3 (106)	Ref		
Model 3: Duration of quit attempt in the past six months[3]					
Lived with smokers					
	No	56.4 (132)	2.02*	1.002	4.06
	Yes	43.6 (102)	Ref		
Cigarettes per day					
	1-10	32.9 (77)	16.23*	2.05	128.24
	11-20	34.2 (80)	4.23	0.52	34.61
	21-30	21.8 (51)	5.88	0.70	49.50
	31+	11.1 (26)	Ref		

Table 3.4. Continued.

Model 4: Readiness to quit[4]				
Age initiated smoking				
≥ 14 years old	57.3 (432)	1.40*	1.04	1.87
< 14 years old	42.7 (322)	Ref		
Model 5: Identity as a smoker[5]				
Smoking status				
Weekly/ Irregular	7.0 (53)	2.79*	1.47	5.29
Daily	93.0 (701)	Ref		
Nicotine dependence				
Low- moderate	48.8 (368)	2.34**	1.72	3.18
High	51.2 (386)	Ref		
Number of years smoked				
≤ 10	18.3 (138)	2.34**	1.55	3.52
11-20	26.9 (203)	1.24	0.87	1.77
> 20	54.8 (413)	Ref		

[1](Reference: no)
[2](Reference: one quit attempt; only participants who had attempted to quit were included)
[3](Reference: < 1 month; only participants who has attempted to quit were included)
[4](Reference: precontemplative)
[5](Reference: difficult to see self as non-smoker)
*$p < 0.05$
** $p < 0.001$
Ref: reference category.

Duration of quit attempt in the past six months: Smokers of 1-10 cigarettes per day were 16.23 (95 % CI: 2.05 to 128.24, $p < 0.05$) times more likely to have made a quit attempt of longer duration, compared to heavier smokers (31 cigarettes or more). Participants not residing with other smokers were 2.02 (95% CI 1.002 to 4.06, $p < 0.05$) times more likely to have quit for one month or longer in the past six months.

Readiness to quit: Participants who started smoking at the age of 14 or after were 1.40 (95% CI 1.04 to 1.87, $p < 0.05$) times more likely be in the contemplative or a more progressed stage of change, relative to those who initiated smoking prior to the age of 14.

Identity as a smoker: Weekly/irregular smokers were 2.79 (95% CI 1.47 to 5.29, $p < 0.05$) times more likely than daily smokers to easily see themselves as a non-smoker; low-moderate nicotine dependent smokers were 2.34 (95% CI 1.72 to 3.18, $p < 0.001$) times more likely to easily see themselves as a non-smoker than highly dependent smokers; and participants who had been smoking for less than 10 years were 2.34 (95% CI 1.55 to 3.52, $p < 0.001$) times more likely to easily see themselves this way than participants who had smoked for more than 20 years.

Discussion

This is the first study reporting both the prevalence of a range of smoking and physical and social environmental characteristics of smokers with a mental illness, and the association of such characteristics with quitting behaviour and motivation. In line with previous research, assessment of smoking characteristics indicated a high prevalence of daily smoking, high nicotine dependence and heavy smoking in terms of cigarettes per day; and further, that smoking appeared to be a long-established behaviour. With respect to physical environmental characteristics, smoking was

'present' in the home lives of many participants: nearly one half lived with others who were also smokers and for one third, the home was not smoke-free. Whilst with respect to social environmental characteristics, perceived support for quitting from significant others and health professionals was variable, with a lack of support most evident for friends; one third (32%) not indicating that friends would be supportive.

The results suggest that despite many participants expressing interest in quitting and making recent quit attempts, reflecting the findings of previous research [56, 66], a number of smoking and physical and social environmental characteristics may serve to sustain their tobacco use. In line with the broader smoking literature [99, 100] as well as previous research among smokers with a mental illness [129, 130], 'lighter' smokers (less nicotine dependent, smoking fewer cigarettes or less than daily) were more likely to have attempted or to be at least contemplating quitting. Such findings suggest a potential benefit of interventions aimed at reducing cigarette consumption among persons with a mental illness in not only decreasing the degree of immediate harm caused by heavy smoking [285] but also increasing the likelihood of subsequent quit attempts and cessation [67, 286]. The findings that those who had been smoking for a fewer number of years were more likely to envisage life without smoking and to have recently attempted to quit, and that smokers who initiated smoking at a younger age were likely to be less 'ready' to quit, similarly reflects findings from general population smokers [83, 103] and perhaps highlights the importance of providing cessation intervention to young smokers and to all smokers as soon as possible after initiation.

In terms of the physical environment, previous research has reported the presence of smoking in the home environment to be less prevalent among the general Australian population, than for the participants in this study: 34% [287] (as compared to 44%) living with another smoker, and only seven per cent [288] (as compared to 32%)

residing in a home that was not smoke-free. Further, differences between Australian smokers without a mental illness are also evident in comparison to smokers in the present study: 21% residing in a home that was not smoke-free (as compared to 32%), and 42% of those with a current partner reporting their partner to be a smoker (as compared to 51%) (International Tobacco Control Policy Evaluation Study: Unpublished 2013 and 2014 Survey Data). In line with research undertaken with smokers generally [105, 106, 109], the potential influence of other smokers in the immediate environment was indicated by the finding in this study that participants who did not live with other smokers were more likely to have recently made a quit attempt of at least one month duration.

With respect to the social environment, almost all participants (92%) identified a key support person whom they relied on and/or who routinely provided assistance and support for their well-being and functioning; suggesting the potential to involve support persons, and possibly family carers [289] in smoking cessation interventions. While evidence suggests that involvement of family carers in treatment delivery can be effective in improving mental health outcomes for persons with a mental illness [290], the potential of such carers to support someone with a mental illness to quit smoking appears not to have been explored by research. One US survey of recent quitters with a mental illness does suggest however, that family and friendship networks generally could have a role in encouraging and supporting quitting behaviour [277]. In the present study, while a majority of participants perceived that family, a partner and friends would be supportive of their making a quit attempt, nevertheless quite significant proportions also reported either that such people would be unsupportive of a quit attempt or that they were uncertain of their support (family 18%; partner 29% and

friends 32%), indicating a need for further research to explore their potential to play a role in smoking cessation interventions for this group.

The large majority of participants perceived their GP (91%), psychiatrist (81%) and other mental health professional/s (80%) to be supportive of a quit attempt. Physician advice has been identified to have a particularly positive impact on smoking and quitting behaviour [291] and this was reinforced by the study finding that those participants who perceived psychiatrists as supportive of quitting were more likely to have recently made a greater number of quit attempts. Although the differences in the perceived support across the health professional groups were minimal, 'other' mental health professionals were least likely to be seen as supportive; a finding somewhat reflective of previous research suggesting allied health professionals, including psychologists are less likely to routinely assess for or offer intervention for smoking [292], despite the likely efficacy of their doing so [125]. It is possible that higher rates of nicotine dependence reported among some mental health professions, compared to their general health counterparts contributes to a more benign perception of smoking [293] and hence a lower likelihood of intervening. Given the integral role of mental health professionals in caring for persons with a mental illness, and the professional status in particular of psychiatrists, the importance of their accepting provision of smoking cessation care as part of their professional role has been noted previously [294].

The strengths of this study include its conduct with a large and diverse sample of smokers with a mental illness and a relatively high consent rate. However, it is noted that smokers who stayed in the hospital for one night or less and those with psychotic type disorders may be underrepresented, while patients with anxiety/stress and substance-related disorders may be over-represented as compared to aggregate

descriptive statistics for the facility's patient population during the recruiting period. The sample consisted of smokers who had consented to take part in an overarching smoking trial and it is unknown whether the prevalence and role of physical and social environmental factors may have differed somewhat for this sample as compared to the broader group of smokers with a mental illness. It is noted that findings need to be interpreted in the context of the cross sectional study design. Future research employing a longitudinal design would add strength to the conclusions that could be drawn. The utilisation of solely self-report data may also pose a limitation, in that accounts of recent quitting behaviour may have been under or over-estimated.

Conclusions

This paper provides evidence for the importance of considering characteristics of smoking and also of the physical and social environment in cessation interventions for persons with a mental illness. With respect to the latter, it expands previous knowledge in this field in identifying the importance of encouraging physical environments that promote smoking cessation and the potential benefit of engaging significant others and health care providers, particularly psychiatrists.

Competing Interests

The authors declare they have no competing interests.

Authors' Contributions

APM drafted the manuscript and participated in the conception, design and coordination of the study. JAB, JW and PW conceived the study, participated in its design and coordination, and assisted in drafting the manuscript. ES, LM and RC

participated in the study design, implementation and interpretation of findings, and assisted with manuscript preparation. LW and MF contributed to the design of the study, interpretation of findings and drafting of the manuscript. TVZ contributed to the analyses, interpretation of findings and manuscript preparation. All authors critically revised and approved the final manuscript for publication.

Availability of Supporting Data

The datasets generated and analysed during the current study are not publicly available to preserve the privacy of participants, however are available from the corresponding author on reasonable request.

Acknowledgements

The authors would like to thank the participants, clinicians and the research team, in particular the recruiting staff that enabled this study to be undertaken.
Funding: This research was funded by the National Health and Medical Research Council (grant number: G1100130).

Chapter 4: Uptake of Smoking Cessation Aids by Persons with a Mental Illness

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Manuscript accepted for publication in *Journal of Behavioural of Medicine* on 10th June, 2016.

Bibliographic reference: Metse AP, Wiggers J, Wye P, Clancy R, Moore L, Adams M, Robinson M, Bowman JA: **Uptake of smoking cessation aids by smokers with a mental illness**. *J Behav Med* 2016, **39**(5):876-886. doi: 10.1007/s10865-016-9757-3.

Abstract

Background and aims*:* Psychiatric inpatient settings represent an opportunity to initiate the provision of tobacco cessation care to smokers with a mental illness. This study describes the use of evidence-based smoking cessation aids proactively and universally offered to a population of psychiatric inpatients upon discharge, and explores factors associated with their uptake. **Method:** Data derived from the conduct of a RCT were analysed in terms of the proportion of participants (N = 378) that utilised cessation aids including project delivered telephone smoking cessation counselling and NRT, and Quitline support. Factors associated with uptake of cessation aids were explored using multivariable logistic regression analyses. **Results:** A large proportion of smokers utilised project delivered cessation counselling calls (89%) and NRT (79%), while 11% used the Quitline. The majority accepted more than seven project delivered telephone cessation counselling calls (52%), and reported NRT use during more than half of their accepted calls (70%). Older age, higher nicotine dependence, irregular smoking and seeing oneself as a non-smoker were associated with uptake of behavioural cessation aids. Higher nicotine dependence was similarly associated with use of pharmacological aids, as was NRT use whilst an inpatient. **Conclusions:** Most smokers with a mental illness took up a proactive offer of aids to support their stopping smoking. Consideration by service providers of factors associated with uptake may increase further the proportion of such smokers who use evidence-based cessation aids and consequently quit smoking successfully.

Keywords: Tobacco use, mental disorders, treatment utilisation, pharmacotherapy, behavioural aids, smoking cessation.

Background

Tobacco smoking is one of the leading risk factors for preventable chronic disease and death in Australia and worldwide [21]. Over the past two decades, the proportion of smokers in Australia [295] and other high income countries [54, 227] has approximately halved. However among persons with a mental illness, smoking prevalence remains between 34% and 88% [40, 56, 64], with some of the highest rates of smoking observed among clients with psychotic disorders [40] and those within acute psychiatric settings [40, 66]. People with a mental illness also smoke a greater number of cigarettes and are more nicotine dependent than smokers without a mental illness [68, 71].

A reduced life expectancy of between 14 to 25 years is experienced by people with a mental illness; with tobacco related conditions, including cardiovascular disease and cancer, being the leading causes of premature mortality [42, 43]. Historically smoking has been assumed to offer a means of managing mental health symptoms for this subgroup [296], however recent evidence suggests cessation actually improves such symptoms [53, 297]. The need to reduce the disproportionately high rate of smoking among persons with a mental illness has been recognised internationally as a public health priority [41, 67].

Despite evidence suggesting persons with a mental illness have a desire to quit [39, 66], attempt to quit at rates similar to that of smokers generally [56], and that quitting aids (e.g. telephone counselling, NRT) are efficacious for this population [163, 167], lower rates of quitting success are reported for smokers with a mental illness [56, 66, 68, 298]. Increasing access to and use of smoking cessation aids shown to be most effective in promoting quitting behaviours and cessation – multimodal approaches

incorporating both pharmacotherapeutic and behavioural components [67, 124, 167] – is therefore of particular importance for smokers with a mental illness.

Offering cessation aids in a manner which is *proactive* and *universal* - that is, unsolicited, and irrespective of clinical characteristics (such as physical or mental health status) or smoking characteristics such as 'readiness to change') - has been reported to increase the uptake of such aids among smokers in the general population. For example, telephone based proactive and universal recruitment of smokers to Quitline cessation services has been reported to result in 52% of smokers using such a service [182]; a greater proportion than the four per cent of smokers who contact the service on a self-referral basis [186]. Notably, the smoking cessation outcomes achieved by smokers recruited in this way [185] appear to equate to those for smokers who use Quitlines on a self-referral basis [187].

Review evidence suggests admission to general [199] and psychiatric [67] hospitals provides a key opportunity to initiate smoking cessation care; particularly since the introduction of smoke-free policies in such settings. With respect to such care offered immediately following discharge from a psychiatric inpatient facility, only two studies have reported the uptake of proactively and universally offered smoking cessation aids [127, 188]. Stockings et al. [127] reported 90% and 68% of participants accepted an offer of telephone counselling and NRT respectively on at least one occasion post-discharge. Approximately 50% of such participants utilised seven or more weeks of counselling and/or NRT. No analysis was reported regarding the factors associated with uptake of smoking cessations aids. In the second study, Schuck et al. [188] reported 88% of participants opted to receive a one month supply of NRT following discharge from an inpatient psychiatric facility, with approximately half of those requesting a second months supply. Later stage of change, more severe mental

health symptoms and nicotine dependence, female gender and older age were associated with uptake of the initial offer of NRT, whilst older participants and those with more severe mental health symptoms were more likely to request a subsequent supply. No study has as yet explored the factors associated with uptake of both pharmacotherapeutic and behavioural aids when offered to all smokers following a psychiatric admission. Identifying such factors may inform strategies to encourage the use of efficacious multimodal cessation supports.

This study describes the uptake of NRT and two telephone based behavioural aids (project delivered telephone smoking cessation counselling and Quitline), proactively offered to a population of Australian mental health patients upon discharge from an inpatient facility, and explores factors associated with their uptake. On the basis of limited previous research [188], smokers who are: older, female, contemplating quitting, more nicotine dependent, and experiencing more severe psychiatric illness may be more likely to take up NRT.

Methods

Design and setting

A descriptive study was undertaken of patients following discharge from four acute adult psychiatric inpatient facilities in New South Wales, Australia.

Sample and recruitment procedure

Between October 2012 and April 2014, research staff approached all admitted patients in the four facilities to assess their eligibility for participation in a RCT assessing the efficacy of providing smoking cessation support upon discharge. Eligible patients were: current smokers (smoked tobacco in the month prior to admission), 18

years of age or above, willing to provide contact details to facilitate communication post-discharge, and able to give informed consent. Consenting patients completed a baseline interview and were the allocated to either a usual care or intervention condition [278]. Those in the intervention condition constituted the sample for this study.

Intervention delivery post-discharge

Once discharged from hospital, participants were proactively offered: 12 weeks of fully subsidised NRT, 16 weeks of project delivered telephone smoking cessation counselling, and a proactive referral to the New South Wales Quitline telephone service. Each participant was allocated to a counsellor trained in motivational interviewing [149] who provided all components of the intervention (telephone cessation counselling, NRT provision, and proactive Quitline referral). Between 11 and 15 telephone cessation counselling calls were provided over a 16 week period (the first within three days of discharge, then weekly for five weeks, weekly or fortnightly tailored in accordance with participant preference for the subsequent seven weeks, and fortnightly between weeks 12 and 16). When calls were unanswered counsellors reattempted daily until the due date of the next call.

NRT was offered to participants during every cessation counselling call in the first 12 weeks of the intervention. If the offer of NRT was accepted, it was posted to participants immediately following the completed cessation counselling call. Participants were offered and encouraged to utilise a combination of both patches and adjunctive forms of NRT, the latter of which could include lozenges, mini lozenges, gum, inhalers, and oral spray.

The counselling staff offered participants a proactive Quitline referral at the time of the first telephone call. The New South Wales Quitline offers a free and individually

tailored telephone service to assist consumers in the process of quitting. This service commonly offers advice and support surrounding quitting preparation, relapse prevention, and cessation maintenance.

Data collection procedures

Clinical and demographic information was obtained via the electronic medical record system. Characteristics of patient smoking behaviours, social and environmental factors, and other demographic data were collected for all participants via face-to-face interview during the inpatient stay.

Smoking variables in hospital were collected for a subsample of participants (45%) by research staff delivering the telephone cessation counselling during the first call post-discharge. Data pertaining to uptake of proactively offered smoking cessation aids were collected by participant self-report (use of NRT and Quitline) and logs of intervention delivery (number and duration of calls) completed by telephone counsellors at the time of each call.

Measures

Uptake of smoking cessation aids. Use of project delivered cessation counselling*:* the measures were contact status (accepted at least one counselling call [yes, no]), and number and duration of calls accepted. A call was recorded as ‘accepted’ if the following was achieved: smoking status and NRT requirements assessed, and at least one (of 16) motivational interviewing techniques implemented. Examples of such techniques include exploring importance and confidence to change, and rolling with resistance.

Use of NRT: the measures were self-reported use of project supplied NRT throughout intervention (yes, no), type of NRT used (patch only, adjunctive only, patch and adjunctive), and number of calls reporting NRT use.

Use of Quitline: a single measure assessed participant self-reported use of Quitline at any point during intervention period (yes, no).

Clinical and demographic features. Information collected via the patient medical record system included: age, gender, relationship status (single, married/de facto, separated/divorced, widowed, did not state/inadequately described), Aboriginal and/or Torres Strait Islander status (Aboriginal and/or Torres Strait Islander, neither or unknown), mental health diagnosis at the time of discharge (schizophrenia and related psychosis, anxiety and stress related disorders, mood disorders, substance-related disorders, personality and other disorders), legal status on admission (voluntary, involuntary), and total length of stay (total days between admission and discharge including periods of leave).

Information collected as part of the face-to-face interview included: education (primary school, third year of high school, school certificate, Higher School Certificate [HSC], TAFE certificate or diploma, bachelor degree, post graduate degree), employment details (full time, part time, household duties, student, unemployed/ other), receipt of a government payment (yes, no), and level of alcohol use (AUDIT-C) [279] .

Characteristics of smoking. Measures at baseline were: smoking status (daily smoker, weekly smoker, irregular smoker [smoked cigarettes less than weekly in month prior to admission]), cigarettes per day, level of nicotine dependence (FTND) [280], age when started smoking, number of years smoked, readiness to quit (Readiness to Quit Questionnaire) [281], identity as a smoker (ease of seeing self as a non-smoker [easy,

difficult, unsure]) [271], and quitting history (ever tried to quit [yes, no]; quit attempt in past 12 months [yes, no]).

Social and environmental factors. Measures at baseline were: lived in a smoke-free house prior to admission (smoke-free house was defined as a place of residence where no one is allowed to smoke inside; yes, no), lived with smokers prior to admission (yes, no), and current support from anyone in their life to quit smoking (yes, no).

Smoking variables in hospital. Measures collected at the time of the first supportive telephone call post-discharge were: participant use of NRT (yes, no) and smoking behaviour (smoked, did not smoke) whilst in hospital. These measures were introduced after the commencement of data collection, and are available for the latter 45% of participants recruited.

Analysis

Data were analysed using IBM SPSS Statistics version 22.

The following variables were transformed from numerical to categorical for the purpose of the association analysis: age when started smoking (≤ 14 years, > 14years) [105], number of years smoked (≤ 10, > 10 - ≤ 20, > 20 years) [272], and alcohol use (AUDIT score of greater than or equal to three for women and greater than or equal to four for men was considered to be harmful/ hazardous, scores below these cut offs were coded as non-harmful/ hazardous) [279].

The following categorical variables were reduced to two levels: diagnosis (psychotic, non-psychotic disorders) [40, 298], relationship status (partnered, not partnered), employment (paid employment, no paid employment), smoking status (daily smoker, weekly/irregular smoker), readiness to quit (pre-contemplative, contemplative

or a more progressed stage) [281], ease of seeing self as non-smoker (easy, difficult/ unsure), type of NRT used during the intervention (single, optimal NRT use [patch plus adjunctive]) [144]. Highest level of education attained was reduced to three levels (up to school certificate, HSC, tertiary).

Descriptive statistics were used to summarise patient clinical and demographic characteristics, characteristics of smoking, social and environmental factors, smoking variables in hospital, and the degree of intervention uptake. Categorical data were described using proportions and continuous data using means, standard deviations, medians and ranges.

Chi-square and logistic regression analyses were used for exploratory analysis of possible univariate associations between measures of cessation aid uptake and a range of variables: clinical and demographic features, characteristics of smoking (including motivation to quit), social and environmental factors, and smoking variables in hospital (included in Tables 4.1 and 4.2). Univariate associations with a p-value of ≤ 0.25 were entered into multivariable logistic regression models [299] using both backward elimination and stepwise variable selection to determine model stability. If applicable, generalised linear mixed models were used to account for over dispersion by adding a random effect to account for variability between participants. Six logistic regression models were developed: acceptance of at least one project delivered cessation counselling call (yes, no); proportion of project delivered calls accepted (n / 15); use of NRT (yes, no); proportion of calls reporting NRT use (n / number calls accepted); type of NRT used (single form, patch plus adjunctive); use of Quitline (yes, no). The critical p-value was set at $p \leq 0.01$ to account for multiple comparisons.

Results

Sample

Of the 3626 patients admitted to the four inpatient facilities within the recruitment period, 64% (*n* = 2315) were approached by research staff, with patients not being approached due to either a short length of stay (less than or equal to one night; 38%) or psychiatric instability for the duration of time spent as an inpatient (35%). Of the patients approached, 53% (*n* = 1237) were eligible, of whom 61% (*n* = 754) consented to participate in the trial. Three hundred and seventy nine patients were allocated to receive the intervention. One participant allocated to the intervention condition was not discharged at the time of project completion providing a sample for this study of 378 patients. Data pertaining to smoking care received in hospital were collected for 169 participants.

Patient clinical and demographic features, characteristics of smoking, and smoking variables in hospital

Patients approached to participate in the trial, compared to those not approached, had a longer length of stay; and were more likely to have a mood disorder or be diagnosed with schizophrenia and related psychosis; and less likely to be diagnosed with an anxiety disorder. Study participants were less likely than non-consenters to be diagnosed with schizophrenia and related psychosis and more likely to be diagnosed with an anxiety disorder.

Table 4.1 describes the clinical and demographic features of patients approached/ not approached and study participants/ non-consenters. Table 4.2 describes participant smoking characteristics, social and environmental factors, and smoking variables in hospital.

Table 4.1. Clinical and Demographic Features of Approached and Not Approached Patients, and Participants and Non-consenters

	Not Approached (*N* = 1311)	Approached (*N* = 2315)	Non-consenters (*N* = 483)	**Participants (*N* = 378)**
Gender (%)				
Male	60.0	55.4	63.4	61.4
Age (years)[2, 5]				
M (SD)	39.8 (17.1)	41.8 (14.2)	38.9 (11.7)	39.1 (12.0)
Mdn (Range: Min- Max)	37 (10-94)	41 (18-93)	38 (18-82)	38.5 (19-74)
Relationship status (%)				
Single	59.0	58.6	70.8	66.4
Married/De facto	25.7	24.1	17.4	18.0
Separated/Divorced	11.0	14.2	10.2	12.7
Widowed	3.2	2.3	0.6	2.4
Not stated/inadequately described	1.0	0.7	1.0	0.5
Aboriginal and/or Torres Strait Islander Status (%)[1, 2, 3]				
Aboriginal and/or Torres Strait Islander	12.8	11.6	17.7	14.0
Neither Aboriginal or Torres Strait Islander/ Unknown	87.2	88.4	82.3	86.0
Diagnosis type (%)[2, 3, 4]				
Schizophrenia and related psychosis	14.1	27.6	37.1	19.0
Anxiety and stress related disorders	20.3	8.5	6.4	11.9
Mood disorders	23.1	30.8	22.4	27.0
Substance-related disorders	21.2	15.6	18.0	25.4
Personality and other disorders	21.3	17.4	16.1	16.7
Length of stay (days)				
Mean (SD)	12.4 (62.1)	16.8 (28.7)	17.6 (24.4)	15 (18.7)

Table 4.1. Continued.

	Not Approached (*N* = 1311)	Approached (*N* = 2315)	Non-consenters (*N* = 483)	**Participants (*N* = 378)**
Median (Range: Min-Max)	2 (0-1715)	10 (0-945)	10 (0-236)	8 (0-121)
Legal status on admission (%)[1, 4, 5]				
Voluntary	55.6	53.2	49.3	52.1
Employment status (%)[1]				
Full time	-	-	-	13.0
Part time	-	-	-	12.7
Student	-	-	-	2.6
Unemployed/ household duties/ other	-	-	-	71.7
Highest education level achieved (%)[1, 2, 3, 4, 6]				
Up to Third year of High School	-	-	-	28.8
School Certificate	-	-	-	34.1
Higher School Certificate (HSC)	-	-	-	15.1
Tertiary	-	-	-	22.0
Receipt of a government payment (%)[4, 5, 6]				
Yes	-	-	-	78.0
Alcohol use (AUDIT- C) (%)[$,1, 2, 5]				
Harmful/ hazardous	-	-	-	64.5
Non-harmful/ hazardous	-	-	-	35.5

'-' data not obtained for respective sample
$ n= 377 due to missing data
Entered in to regression analyses:
[1]Acceptance of at least one telephone supportive call
[2]Accepting a higher proportion of calls
[3]NRT use
[4]Higher proportion of calls reporting NRT use
[5]Optimal use of NRT
[6]Use of Quitline

Table 4.2. Characteristics of Smoking, Social and Environmental Factors, and Smoking Variables in Hospital

	Total (*N* = 378)
Smoking status (%)[6]	
Daily	93.4
Weekly/ Irregular	6.6
Cigarettes Per Day[1, 2]	
Mean (SD)	21.8 (14.4)
Median (Range: Min-Max)	20.0 (1-100)
FTND total [1, 2, 4, 5, 6]	
Mean (SD)	5.5 (2.5)
Median (Range: Min-Max)	6.0 (0-10)
Readiness to quit (%)[3, 6]	
Pre-contemplative	55.3
Contemplative or a more progressed stage	44.7
Age when started smoking (%)[4, 5]	
<12	23.3
12 - <14	21.2
14 - <16	20.9
16 - <18	17.5
18+	17.2
Number of years smoked (%)[2, 5, 6]	
≤ 10	16.4
> 10 - ≤20	28.0
>20	55.6

Table 4.2. Continued.

	Total (N = 378)
Ever tried to quit (%)[1, 2, 3, 6]	
Yes	87.0
Quit attempt in past 12 months (%)[2, 4, 5, 6]	
Yes	49.2
Ease of seeing self as non-smoker (%)[1]	
Easy	40.2
Difficult	43.4
Unsure	16.4
Lived in a smoke-free house (%)[1, 4]	
Yes	70.1
Lived with smokers (%)	
Yes	43.7
Support from anyone to quit smoking (%)[2, 6]	
Yes	94.7
Smoked in hospital (%)[#, 2, 4]	
Yes	52.1
Used NRT in hospital (%)[#, 3, 4]	
Yes	85.2

N= 169
FTND: Fagerstrom Test for Nicotine Dependence.
SD: standard deviation.
Entered in to regression analyses:
[1]Acceptance of at least one telephone supportive call
[2]Accepting a higher proportion of calls
[3]NRT use
[4]Higher proportion of calls reporting NRT use
[5]Optimal use of NRT
[6]Use of Quitline.

Uptake of smoking cessation aids

Use of project delivered cessation counselling. The median time taken to initially contact participants post-discharge was three days, with calls having a mean duration of 14.6 (*SD* = 11) minutes each. The large majority of participants (89%) accepted at least one cessation counselling call, and the mean number of calls accepted was 7 (*SD* = 4.3) (Table 4.3). Approximately half of the participants (52%) accepted more than seven cessation counselling calls.

Use of NRT. Seventy nine percent of participants used NRT at least once throughout the intervention, 70% reported using NRT during more than half of their accepted calls. Three quarters of participants (75%) who reported using NRT at all, used the optimal combination (patch plus adjunctive) for at least some part of the time.

Use of Quitline. Eleven per cent of participants used Quitline throughout the intervention period.

Smoking cessation aid uptake and associations with patient characteristics, social and environmental factors, and smoking variables in hospital

Variables with a p-value of ≤ 0.25 in the chi-square analyses and initially included in the multivariable logistic regression models are identified in Tables 4.1 and 4.2. Between six and 12 variables were entered into each model, contingent on the dependent variable of interest. Significant findings and those approaching significance are shown in Table 4.4.

Acceptance of at least one project delivered cessation counselling call. A trend approaching significance was found for seeing self as a smoker: Participants who found it difficult to see themselves as a non-smoker were half as likely as those who

Table 4.3. Uptake of Smoking Cessation Aids

	Total (*N* = 378)
Acceptance of at least one project delivered cessation counselling call (%)	
Yes	88.6
Time till contact post-discharge (days)	
Mean (SD)	12.4 (29.1)
Median (IQR)	3 (7)
Number of project delivered calls accepted (%)	
0-3	27.0
4-7	21.4
8-11	39.4
12-15	12.2
Duration of project delivered calls accepted (minutes)	
Mean (SD)	14.6 (10.7)
Median (IQR)	13 (13)
Used NRT at all during the course of the intervention (%)	
Yes	79.1
Of those who used NRT (*n* = 299), type of NRT used (%)	
Patch only	7.4
Adjunctive only	17.4
Optimal (patch and adjunctive)	75.3
Proportion of completed calls reported using NRT (%)	
0-25	24.1
26- 49	6.1
50-74	20.4
75+	49.5
Use of Quitline (%)	
Yes	10.8

SD: Standard deviation.

Table 4.4. Predicting Smoking Cessation Aid Uptake from Patient Characteristics, Social and Environmental Factors, and Smoking Variables in Hospital

Predictor	B	SE	OR	95 % CI		*p*
				Lower	Upper	
Model 1: Acceptance of at least one project delivered cessation counselling call[1]						
See self as non-smoker						
Difficult	-0.77	0.39	0.46	0.22	0.99	0.05
Easy	1					
Model 2: Proportion of cessation counselling calls accepted[2]						
Age						
1 year	0.022	0.01	1.02	1.01	1.04	< 0.001
10 years			1.25	1.11	1.42	
Model 3: Use of NRT [3,4]						
Used NRT in hospital						
Yes	1.21	0.60	3.35	1.04	10.81	0.04
No	1					
Model 4: Proportion of calls where NRT use was reported[5]						
Nicotine dependence*						
1 point	0.045	0.02	1.05	1.01	1.08	0.01
3 points			1.14	1.03	1.28	
Model 5: Optimal NRT use (patch plus adjunctive)[6,7]						
Nicotine dependence*						
1 point	0.184	0.05	1.20	1.08	1.34	0.001
3 points			1.74	1.26	2.39	

Table 4.4. Continued.

Model 6: Use of Quitline[8]						
Smoking status						
Daily	-2.27	0.55	0.10	0.04	0.31	< 0.001
Weekly/ Irregular	1					
Nicotine dependence*						
1 point	0.232	0.08	1.26	1.09	1.47	0.003
3 points			2.01	1.27	3.15	

[1](Reference category: No)
[2](Reference category: No)
[3](Reference category: No)
[4] This model includes data pertaining to smoking related care received in hospital (*n* = 169)
[5](Reference category: No)
[6](Reference category: single type of NRT)
[7]This model only includes participants who used NRT (*n* = 299)
[8](Reference category: No). *FTND

could easily see themselves as non-smokers, to accept at least one cessation counselling call post-discharge (*OR*: 0.46, $p = 0.05$; Table 4.4).

Proportion of cessation counselling calls accepted. The proportion of calls accepted increased as age increased (*OR for 1 year increase in age:* 1.02, $p < 0.001$); thus older participants were more likely to accept a greater proportion of calls.

NRT use. A trend approaching significance was found for use of NRT in hospital: Participants who used NRT whilst they were an inpatient were more than three times as likely to use NRT following discharge (*OR*: 3.35, $p = 0.04$).

Proportion of calls where NRT use was reported. The proportion of calls using NRT increased with increasing nicotine dependence (*OR for 1 point increase in nicotine dependence:* 1.05, $p = 0.01$), therefore those with higher nicotine dependence reported using NRT during a greater proportion of accepted calls.

Optimal NRT use. Nicotine dependence was associated with optimal NRT use: the likelihood of using both patches and adjunctive NRT increased with increasing nicotine dependence (*OR for 1 point increase in nicotine dependence:* 1.20, $p = 0.001$).

Use of Quitline. Baseline smoking status and nicotine dependence were associated with the use of Quitline. Compared to weekly/irregular smokers, daily smokers were 0.10 times less likely to have used Quitline throughout the intervention period. The likelihood of using Quitline increased as nicotine dependence increased (*OR for 1 point increase in nicotine dependence:* 1.26, $p = 0.003$).

Discussion

This is the first study to describe the uptake of smoking cessation aids offered proactively and universally to a population of smokers upon discharge from an acute psychiatric inpatient facility, and to explore factors associated with the uptake of both

pharmacological and behavioural aids. The study illustrated a high likelihood of use of cessation aids: almost all participants (89%) utilised at least one cessation strategy and more than three quarters (79%) used both pharmacological and behavioural aids. A higher level of nicotine dependence was found to be positively associated with the proportion of calls where NRT use was reported, optimal NRT use and use of Quitline. Greater use of behavioural aids (project-delivered telephone support calls and Quitline) was also associated with older age and other smoking-related characteristics; demonstrating some concordance with findings of previous research among both smokers with a mental illness [188] and in the general population [300], and suggesting that interventions might be tailored to such characteristics in order to promote uptake. A trend approaching significance was found for a positive association of NRT use during the inpatient stay with a greater likelihood of uptake of NRT offered post-discharge; although this finding was not a strong association, it may have particular clinical and policy significance and is worthy of further exploration. The study suggests that proactive and universal offers of cessation aids by clinicians, and consideration of factors associated with uptake, could increase the proportion of smokers with mental illness who use evidence-based cessation aids.

The rate of uptake of pharmacological and behavioural smoking cessation aids was comparable to other studies that proactively and universally offered cessation supports to persons with mental illness [127, 188] and general population smokers [301-303]. Notably the rate of uptake of NRT in this study was approximately one and a half times that reported in a similar trial where NRT was selectively offered only to smokers who were ‘ready to quit’, upon discharge from a psychiatric inpatient facility [130]. These findings support research among general population smokers regarding the

benefits of universally offering cessation aids to all smokers, including those who may not indicate being ready to quit at that time [182, 199, 304].

In terms of the use of behavioural smoking cessation aids, the great majority of participants (89%) accepted at least one project delivered telephone cessation counselling call, with the likelihood of doing so perhaps increased by being able to see oneself as a non-smoker, although this association was a trend only. Strength of smoking identity has also been suggested to be associated with quitting-related motivations or behaviours [66, 270]. Among general population smokers, van den Putte et al. [270] found weak identification as a smoker to be associated with increased quit attempts and Stockings et al. [66] found, among mental health inpatients, that lack of enjoyment from smoking was associated with readiness to quit. Such findings together with those of the present study suggest smoking identity may be a psychological barrier to both smoking cessation and utilising cessation aids, and potentially of value to consider in the design of interventions which offer aids to smokers with mental illness. Further, the finding that a greater proportion of calls were accepted by older rather than younger participants is congruent with young adult smokers in general being more difficult to engage in smoking cessation intervention [305], and with research among smokers with a mental illness suggesting that older persons are more likely to use smoking cessation medications consistently throughout an intervention [188].

Approximately 10% of participants used Quitline; at least double the proportion of smokers in Australia who might be expected to contact the service annually on a self-referral basis [186]. This rate of uptake is especially notable given that a proactive Quitline referral was systematically offered by project counsellors on only a single occasion, at the point of first contact post-discharge, and further that it occurred in the context of the intensive telephone based behavioural support already being offered by

project counsellors. The likelihood of using Quitline increased with increasing nicotine dependence, a finding congruent with previous research that found higher nicotine dependence to increase the likelihood of taking up smoking cessation intervention among persons with a mental illness [188]. By contrast, participants who smoked daily prior to hospital admission, as opposed to less often, were less likely to utilise the Quitline, perhaps being more likely to see the intensive phone support offered by the project as more suitable to their needs. Such a suggestion remains speculative however and other explanations may also be posited.

With respect to the uptake of pharmacological smoking cessation aids, a substantial majority (79%) of participants used NRT on at least one occasion. An association approaching significance suggested that the likelihood of doing so may have been increased by the use of NRT during the inpatient stay. Previous research has suggested that suboptimal and selective provision of nicotine dependence treatment within smoke-free psychiatric inpatient settings increases the likelihood of patients experiencing nicotine withdrawal symptoms [63], and the findings of this study suggest that research should further explore whether it may also decrease the proportion of patients who utilise NRT for cessation support following discharge. Seventy per cent of participants used NRT during ≥ 50% of their accepted calls, and 75% of those who used NRT post-discharge used it ‘optimally’ for at least some part of the time, that is, using a combination of both patch and adjunctive forms of NRT [144]. Participants with higher nicotine dependence were more likely to report NRT use during a higher proportion of calls and use NRT optimally; associations with evident clinical congruency.

Neither psychiatric diagnosis nor a measure of motivation (readiness to quit) were associated with any measure of strategy uptake. The former finding suggests positively that such aids may have equal appeal regardless of the nature or severity of

psychiatric illness, and the latter that patients can be engaged in using cessation supports even if not assessed initially as having a high motivation to quit. Both findings suggest support for the benefit of proactively and universally offering smoking cessation aids to smokers with a mental illness.

The findings of the current study should be considered in the context of a number of its design characteristics. Patients who stayed in the hospital for one night or less and those with psychotic type disorders were underrepresented, while those with anxiety/stress disorders were over represented as compared to the facility's entire patient population during the recruiting period. The study sample consisted of smokers who had consented to participate in a smoking related trial; and although 'readiness to quit' was not an eligibility criterion, the outcomes of this study may have been influenced by a self-selection bias. In addition, the possible impact on strategy uptake of a number of different counsellors occasionally delivering the intervention to particular participants, and infrequent disruption of intervention delivery as a result of circumstances such as participant readmission to hospital, could not be determined. Finally, while exploring the possible associations between the uptake of aids and smoking cessation was not within the scope of this paper, this will be addressed in a further publication.

The results from this study suggest that following an inpatient admission, a high proportion of smokers with a mental illness will take up proactively and universally offered cessation aids. Consideration of factors associated with uptake may further increase the proportion of smokers with mental illness who use evidence-based cessation supports, and consequently quit smoking successfully [124, 167]. The provision of proactive Quitline referrals to all smokers upon discharge, may result in at least a two fold increase in the proportion of smokers utilising this service. Clinicians

can therefore assist in redressing the significant smoking related health inequities experienced by persons with mental illness by following clinical guidelines [124, 200] and proactively and universally offering patients smoking related care.

Acknowledgements

The authors would like to acknowledge Naomi Cooper, Stephanie Lithgow, Melissa Jackson, Samantha McCrabb, Katrina Tillock and Joanne Burr for their contributions to the delivery of the intervention. We would also like to acknowledge the clinicians and participants who made this study possible.

Funding: This research was funded by the National Health and Medical Research council (Grant Number: G1100130).

Compliance with Ethical Standards

Conflict of interest: Alexandra P. Metse, John Wiggers, Paula Wye, Richard Clancy, Lyndell Moore, Maree Adams, Maryanne Robinson and Jenny A. Bowman declare they have no conflict of interest.

Human rights and informed consent: All procedures were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Ethics approval: Ethics approval for this research was obtained from the Hunter New England Human Research Ethics Committee (reference no: 11/12/14/4.02) and the University of Newcastle Human Research Ethics Committee (reference no: H-2012-0061).

Chapter 5: Evaluating the Efficacy of an Integrated Smoking Cessation Intervention for Mental Health Patients: Study Protocol for a Randomised Controlled Trial

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Manuscript accepted for publication in *Trials* on 17th June, 2014.

Bibliographic reference: Metse AP, Bowman JA, Wye P, Stockings EA, Adams M, Clancy R, Terry M, Wolfenden L, Freund M, Allan J *et al*: **Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: study protocol for a randomised controlled trial**. *Trials* 2014, **15**(1):266. doi: 10.1186/1745-6215-15-266.

Abstract

Background: Smoking rates, and associated negative health outcomes, are disproportionately high among people with mental illness, compared to the general population. Smoke-free policies within mental health hospitals can positively impact on patients' motivation and self-efficacy to address their smoking. However, without post-discharge support, preadmission smoking behaviours typically resume. This protocol describes a RCT that aims to assess the efficacy of linking mental health inpatients to community based smoking cessation supports upon discharge as a means of reducing smoking prevalence. **Methods/design:** Eight hundred participants with acute mental illness will be recruited into the randomized controlled trial whilst inpatients at one of four psychiatric inpatient facilities in the state of New South Wales, Australia. After completing a baseline interview, participants will be randomly allocated to receive either: 'Supported Care', a multimodal smoking cessation intervention; or 'Normal Care', consisting of existing hospital care only. The 'Supported Care' intervention will consist of: a brief motivational interview and a package of self-help material for abstaining from smoking whilst in hospital; and following discharge, 16 weeks of motivational telephone-based counselling, 12 weeks of free NRT, and a referral to the Quitline. Data will be collected at one, six and 12 months post-discharge via computer-assisted telephone interview. The primary outcomes are abstinence from smoking (seven day point prevalence and prolonged cessation), and secondary outcomes comprise daily cigarette consumption, nicotine dependence, quit attempts, and readiness to change smoking behaviour. **Discussion:** If shown to be effective, the study will provide evidence in support of systemic changes in the provision of smoking cessation care to patients following discharge from psychiatric inpatient facilities. **Trial**

registration: Australian New Zealand Clinical Trials Registry: ACTRN12612001042831. Date registered: 28th September 2012.

Key words: Smoking cessation, mental illness, inpatient, community, multimodal intervention.

Background

Tobacco use is the second leading cause of modifiable morbidity and mortality worldwide [21]. In Australia, the prevalence of smoking in the general population has halved over the past three decades to approximately 15% [295]. However, depending on diagnosis and setting, between 33% and 90% of people with mental illness continue to smoke [41, 61]. Patients with psychotic disorders have among the highest smoking prevalence (74% - 88%) [40]. Smokers with a mental illness also smoke more heavily, are more nicotine dependent and find it more difficult to quit compared to the general population [40, 68, 71]. As a consequence, smokers with a mental illness are more likely to have a chronic disease and to have a shorter life expectancy [43, 67, 254, 306].

For smokers in the general population [124, 307] and for those with a mental illness [167, 308] multimodal smoking cessation interventions, utilising both pharmacological interventions (such as NRT) and psychosocial supports (such as behavioural counselling and self-help materials), have demonstrated efficacy in increasing the likelihood of quitting successfully. Interventions of a longer duration and greater intensity are more efficacious for both groups of smokers [67, 199, 309, 310]. Further, neither making a quit attempt nor successfully ceasing smoking has been found to negatively impact on [167], and may even improve, psychiatric health [53, 130, 201, 311].

Hospitals have been recognised as a key setting for initiating the delivery of smoking cessation care [130, 199, 312, 313]. The implementation of total smoking bans in mental health hospitals [67, 314], and the ensuing need to manage inpatient nicotine withdrawal [124, 200] reinforces the need to provide smoking cessation treatment in this setting [315]. Evidence suggests that the initiation of smoking cessation treatment in the inpatient psychiatric setting also increases patient motivation and self-efficacy to

change their smoking behaviour, both as an inpatient and following discharge [316]. However, as is the case in general medical settings [317], evidence from psychiatric settings suggests that without post- discharge support, smoking is likely to return to preadmission levels within two weeks [318]. Such findings suggest a need for adequate and consistent support to encourage a sustained quit attempt and prevent relapse [175, 318, 319]. Systematic review evidence from general medical settings suggests that multimodal post-discharge cessation support of at least four weeks in length or greater can result in higher rates of successful smoking cessation [199].

A recent RCT has demonstrated the effectiveness of linking mental health inpatients to community based smoking support following discharge. Prochaska and colleagues [130] reported a significant difference in point prevalence abstinence at 18 months post-discharge; 20% and 8% for intervention and control conditions respectively. Over a period of up to six months post-discharge, intervention group participants were able to take up both pharmacological (NRT for a total duration of up to 10 weeks) and psychosocial (face-to-face, computer-based, and self-directed reading) smoking cessation support, tailored to their readiness to stop smoking. An opportunity may exist to enhance and extend such positive findings by providing multi-modal smoking cessation support to all smokers, proactively and intensively immediately following discharge, regardless of assessed readiness to change.

To assess the feasibility of such an approach we conducted a pilot RCT of an intervention consisting of the provision of psychological and pharmacological support to smokers admitted to one inpatient psychiatric facility. Inpatient smokers were randomly allocated to a multimodal smoking cessation intervention or treatment-as-usual control. Smoking cessation treatment was initiated for all smokers during admission and continued for a four month period post-discharge with assessments made

at one week and at two, four and six months [320]. At the end of treatment (four months), participants in the intervention group had significantly higher rates of seven-day point prevalence abstinence than controls (12% versus 2%), but this difference was not sustained at six months follow-up [127]. Based on the findings of these previous studies, the objective of this study is to conduct a RCT to test the effectiveness of a multi-modal smoking cessation intervention, initiated within mental health inpatient facilities for all smokers and continued post-discharge, on 12 month post-discharge smoking cessation rates.

Methods

Study design and setting

A RCT with blinded follow-up will be conducted (Figure 5.1). Participants will be recruited as inpatients at one of four acute mental health facilities within one Local Health District in New South Wales, Australia. At the time of recruitment, participants will be randomly allocated to either an intervention (Supported Care) or control (Normal Care) group. Participants allocated to the Supported Care condition will receive a brief motivational interview and a package of self-help material for abstaining from smoking whilst in hospital, and intensive psychosocial and pharmacological support for 16 weeks upon hospital discharge. Participants in the Normal Care condition will receive standard hospital and discharge smoking cessation care.

Follow-up assessments will be conducted at one, six and 12 months post-discharge for both conditions. The primary outcome measures comprise seven-day point prevalence of smoking abstinence and prolonged smoking abstinence. Secondary outcome measures will include: number of cigarettes smoked per day, nicotine dependence, quit attempts, and readiness to change smoking behaviour. The effect of

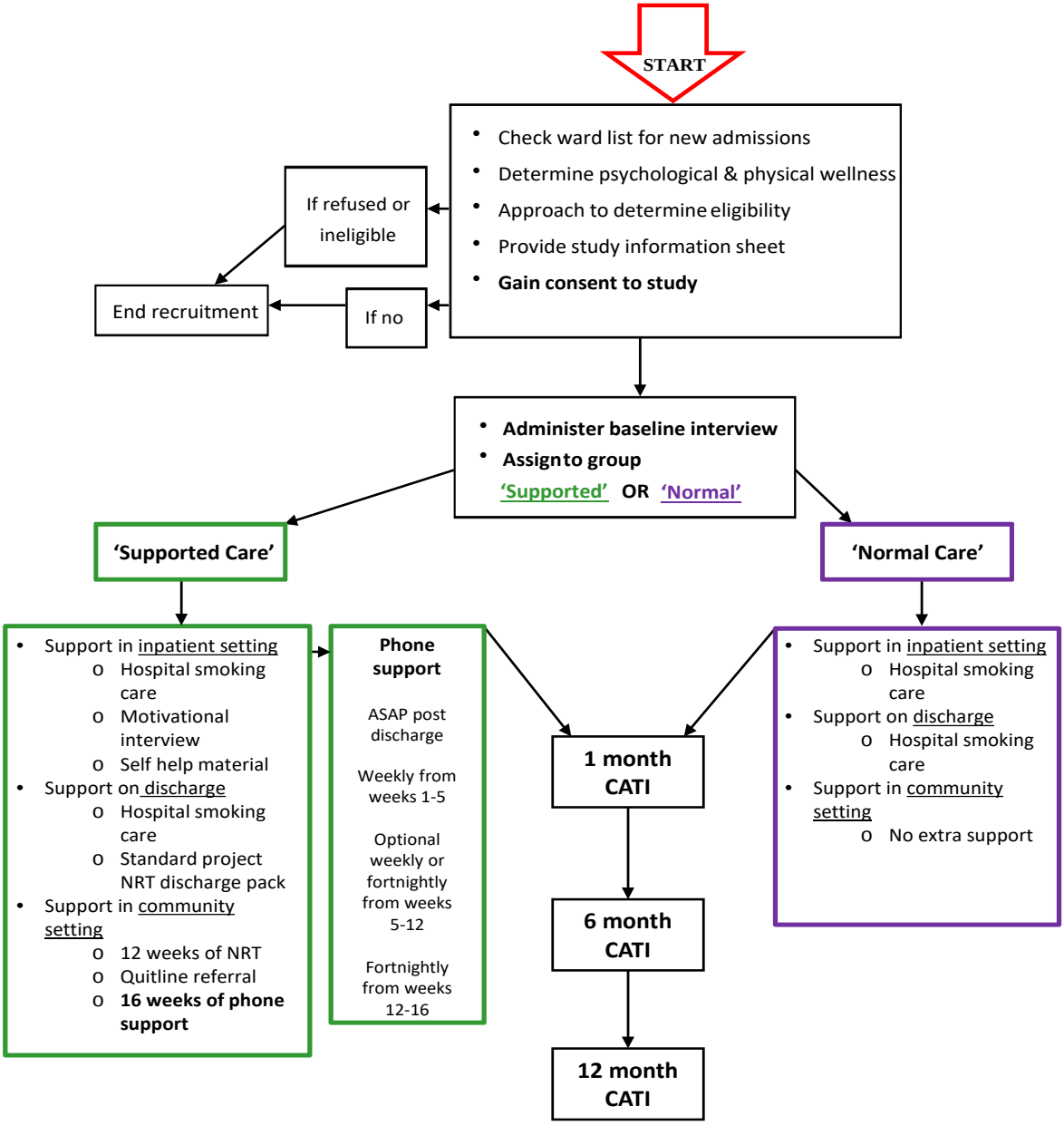

Figure 5.1. Study Design.

ASAP, as soon as possible; CATI, computer-assisted telephone interview; NRT, nicotine replacement therapy.

the intervention will be assessed by comparing primary and secondary outcome measures between intervention and control groups at each follow-up point.

Ethics approval for the study has been obtained from the Hunter New England Human Research Ethics Committee, HNEHREC reference no: 11/12/14/4.02 and the University of Newcastle Human Research Ethics Committee reference no: H-2012-0061. The trial is registered on the Australian New Zealand Clinical Trials Registry ACTRN12612001042831. Date registered: 28th September 2012.

Recruitment process and inclusion criteria

Research staff (independent of the hospitals), all of whom will receive standardised training in mental illness and its impacts, will approach nurse unit managers in the four units on a daily basis to identify newly admitted patients. The nurse unit managers will advise whether individual patients are sufficiently psychiatrically stabilised and capable of completing the baseline interview. If so, patients will be approached to determine if they meet the eligibility criteria to participate in the study. Patients will be eligible if they: are a current smoker (smoked cigarettes daily, weekly or less than weekly in the month prior to admission); 18 years of age or above; understand the research, have capacity to ask and answer questions in relation to the benefits and potential harms (that is have capacity to give informed consent); and are willing to provide contact details (including phone number and mailing address) to facilitate communication once discharged. No exclusion criteria will be applied. Patients who meet the eligibility criteria will be given a detailed explanation of the project requirements and invited to participate in the trial. Informed consent will be gained from all participants (Appendix 6). Patients who elect not to take part, and who are subsequently readmitted to the facility during the recruitment phase will be re-

approached and re-offered the opportunity to participate. Patients will only be recruited once, regardless of the number of readmissions within the study recruitment phase. Eight hundred participants will be recruited over a period of 18 months.

Randomisation, allocation concealment and sequence generation

A random allocation sequence using permuted block randomisation (with a block size of ten) will be generated by a statistician independent of the project prior to the commencement of recruitment. Randomisation will be carried out separately by site and stratified by diagnosis type to account for differences in smoking levels and nicotine dependence (psychosis, non-psychosis type diagnosis) [40, 321]. Participant allocation to group (1:1 ratio) will occur immediately post baseline data collection. Research staff will provide participants with a sequentially numbered, opaque, sealed envelope. The envelope will contain a coloured piece of paper that indicates allocation to either the Supported Care or Normal Care condition. Research staff involved in recruitment and outcome data collection will be blind to the order of patient condition assignment.

Data collection procedures

For eligible and consenting patients, baseline data will be collected during admission via a face-to-face baseline interview, administered by research staff in a quiet area of the unit. The baseline data collection interview will be developed based on previous pilot research undertaken by the research team [320]. After the completion of the baseline interview, clinical and demographic information will be collected by research staff from patient medical records.

Follow-up data will be collected via computer assisted telephone interviews (CATI) from all participants at one, six and 12 months post-discharge. In addition, process data will be collected during support calls to assess intervention uptake.

Intervention

a) Normal care

Participants allocated to the Normal Care condition will receive standard hospital smoking care only, as routinely delivered by hospital staff. This may include brief advice to quit, provision of NRT whilst admitted to the inpatient facility, up to three day supply of NRT upon discharge, and/or a referral to Quitline as per mandatory local area health guidelines [195, 200]. Previous research suggests that standard hospital care is likely to be limited [210, 322].

b) Supported care

In addition to standard smoking care provided by the hospital, participants allocated to the Supported Care condition will be provided with a range of evidence-based smoking cessation supports [124, 310]. Following the baseline interview supported care participants will be provided with smoking cessation written self-help material [323], including information tailored to people with mental illness [324-326] and NRT usage advice, and a brief motivational interview (10-15 minutes) designed to evoke ambivalence regarding smoking behaviour and reinforce positive intentions to address smoking [154]. Content of the motivational interview will encourage consideration of: lifestyle behaviours; pros and cons of both continuing to smoke and quitting; impact of smoking on life in five years from the time of interview; and importance of and confidence to quit [154].

Upon discharge from hospital, all Supported Care participants will receive a standard project pack of NRT, which contains: Seven 21 milligram nicotine patches; one nicotine inhaler with six 10 milligram cartridges; 30 pieces of four milligram nicotine gum; and 20 four milligram nicotine lozenges. NRT discharge packs will also contain a brief tip sheet for NRT use and the management of NRT side effects, as well as a project reminder card outlining each aspect of the intervention. Within participating units, the process for providing discharge NRT packs will be negotiated in consultation with nurse unit managers and treating staff, in accordance with usual protocols for discharge, and storage of medications. The participant's GP and if applicable, community mental health team, will be notified of their clients' involvement in the project, via the standard and automated delivery of discharge records to relevant health professionals, and asked to support their participation in the project [199].

Once discharged from hospital, participants in the Supported Care arm will receive up to 16 weeks of psychosocial [150] and 12 weeks of pharmacological support [124, 307, 327]. Psychosocial support will initially be delivered through five weekly telephone support calls, followed by seven weeks of weekly or fortnightly telephone support calls (tailored based on participants preference), tapering to four weeks of fortnightly support calls between weeks 12 and 16 (Figure 5.1). The content of the calls will be delivered utilising a framework of motivational interviewing techniques [328], and incorporate behavioural strategies to assist with addressing smoking. Support call staff will prompt participants to utilise the Quitline, and offer to send a Quitline referral on their behalf. Support calls will be delivered by research staff that either have a relevant allied health qualification and/ or experience working with people with mental illness. All support callers will receive both standardised mental health training and

ongoing motivational interviewing based training and supervision from an experienced clinical consultant.

Ongoing NRT provision will be offered by research staff to all supported care participants, with delivery by mail. The amount and frequency of NRT provided will vary by participant in accordance with personal preference, degree of nicotine dependence (measured using time to first cigarette) [280], and nicotine withdrawal symptoms [329]. Within the initial 12 weeks of support post-discharge, participants are able to optionally elect any combination of the following NRT products: Patches (21, 15, 14 or seven milligram); lozenges and/or mini lozenges (two and four milligram); gum (a variety of flavours; two and four milligram); inhalers (10 and 15 milligram refill cartridges); oral spray (one dispenser contains 150 one milligram sprays); and oral strips (two and a half milligram). Pharmacological support will be provided in accordance with an evidence-based, combination NRT algorithm aimed at smokers with a high level of nicotine dependence and who have more difficulty quitting [330].

Measures

The primary and secondary outcome measures will be collected via CATI at one, six and 12 months post-discharge.

Primary outcome measures: The primary outcome measure will be abstinence from smoking, both seven day point prevalence and prolonged abstinence. Participants who report being abstinent from smoking for seven days or greater will be required to submit a breath sample to validate their quit attempt. CATI interviewers will organise a time to carry out this procedure and project staff, blind to allocation group, will meet participants in a public place or their home as soon can be arranged, to verify abstinence. Breath samples will be taken using a Micro^{+} Smokerlyser (Bedfont

Scientific Ltd, www.bedfont.com/smokalyzer), where the exhaled carbon monoxide (CO) level must not exceed 6.99ppm for the self- reported abstinence to be considered valid [331, 332].

Secondary outcome measures: Secondary outcome measures will include number of cigarettes smoked per day, quit attempts made (number and duration), nicotine dependence (assessed using the FTND) [280], and readiness and motivation to quit (Readiness and Motivation to Quit Smoking Questionnaire) [281].

Process measures

a) All participants

Details regarding the delivery of any smoking-related care and/or support, received during the initial and any subsequent hospital admissions, will be collected by CATI staff at each of the three follow-up points.

b) Supported care participants only

As part of the motivational interview administered following assignment to supported care, participants will be asked to rank on a scale from one to 10 both importance of, and confidence to, quit smoking. To assess the degree of Supported Care intervention delivery, descriptive data will be collected during support calls by the designated support caller, including: the receipt and usage of discharge NRT pack; contact with, and perceived effectiveness of Quitline support (if applicable); intensity and duration of support calls; dose, type, amount, usage and perceived effectiveness of NRT; side effects of NRT use; and nicotine withdrawal symptoms. Data assessing the degree of participant satisfaction with the intervention will also be collected by CATI interviewers after the completion of the twelve month follow-up.

Patient characteristics: Demographic and clinical information including age, gender, marital status, mental health diagnosis (primary and secondary), and Aboriginal and/or Torres Strait Islander status will be collected by recruitment staff from patient medical records, after the completion of the baseline interview. Education levels, employment status, identity as a smoker (items based on the PRIME theory of addiction [271]), and levels of perceived support to quit smoking from partner, family, friends, and relevant health professionals will be collected as part of the baseline interview. Other patient characteristics including alcohol consumption (Alcohol Use Disorders Identification Test) [333], psychological distress (the six item version of the Kessler Psychological Distress Scale) [334], and perceived levels of stress (Perceived Stress Scale [four item version]) [335] will also be assessed at baseline and each of the follow-up points.

Intervention cost: Descriptive data on direct costs of the intervention will be collected as a part of routine project delivery and administration throughout the project, and include all costs associated with inpatient and post-discharge intervention.

Sample size

Considering 80% power with a five per cent significance level, 332 participants per group will be required to detect a four per cent difference (one versus five percent for Normal and Supported Care participants, respectively) in prolonged abstinence at 12 months post-discharge. This sample size will also be adequate to detect a 10% difference in point prevalence abstinence at 12 months post-discharge [130].

Statistical analysis

Data will be analysed using IBM SPSS Statistics 22 (International Business Machines Corporation, http://www-01.ibm.com/software/au/analytics/spss/).

Prior to any statistical analysis baseline predictors of attrition will be examined. If it appears missing data is related to a measured aspect of the participants, those measures will be included as covariates in the hypothesis-testing models. The modelling strategy will allow the use of all collected data in our estimation. Sensitivity analyses will check that methods of dealing with missing data do not have a major impact on study conclusions. Outcome analyses, based on coding missing subjects as "smoking", will allow direct comparison of findings with the research literature.

Analysis of primary outcome measures: A linear model with estimation via Generalized Estimating Equations, using the logit link function given the dichotomous outcome variable, will be used to examine abstinence versus smoking status at 12 months by condition. The data collected at one and six months will also be examined; however the 12 month follow-up will be the primary focus. Generalized Estimating Equations, a multivariate extension of generalised linear models, accounts for dependence of responses within individuals due to repeated measures. Any covariates identified in preliminary data analyses may be added to the model. Subgroup analyses will be considered, likely by dependence and diagnosis (psychosis versus non-psychosis) [40, 336]. All analyses will be conducted using intent-to-treat principles, with participants retained in their originally assigned groups [337].

Analysis of secondary outcome measures: Chi square and *t*- test (or Mann-Whitney) analysis will be used to compare the number of quit attempts, nicotine dependence, cigarettes smoked per day, and motivation to change smoking behaviour

between the intervention and control conditions. Descriptive statistics will be used to report process data.

Discussion

Further research is needed to assess the effectiveness of a proactive and integrated approach to the provision of smoking cessation treatment to psychiatric inpatients immediately upon discharge, regardless of a patient's assessed readiness to quit, in increasing abstinence and secondary smoking-related outcomes. This RCT builds upon pilot work [320], and incorporates enhanced elements including: a larger sample size and greater statistical power, longer assessment of outcomes to 12 months post-discharge, use of a more structured motivational interviewing framework in the delivery of psychosocial support, and a more comprehensive and flexible NRT protocol in the delivery of pharmacological support.

The conduct of this trial and its findings will substantively strengthen the base of evidence available to inform the development and delivery of smoking cessation treatment to persons with a mental illness. It will hence contribute to redressing the significant health and social inequities experienced by this population sub-group as a consequence of tobacco smoking.

Trial Status

Recruitment for this project commenced in October 2012, with a plan to proceed until April 2014. Follow-up data collection has commenced; it is anticipated that it will conclude in June, 2015.

List of Abbreviations

NRT: Nicotine Replacement Therapy

CATI: Computer Assisted Telephone Interview

Competing Interests

None

Author's Contributions

APM drafted the manuscript and participated in the conception, design and coordination of the study. JAB, PW, RC, ES, MA and JW helped draft the manuscript and participated in the conception, design and coordination of the study. MT, JJP, LW, MF and JA helped draft the manuscript and participated in the conception and design of the study. All authors critically revised and approved the final manuscript for publication.

Acknowledgements

The trial is funded by the National Health and Medical Research Council (grant number: G1100130) and is supported by both the University of Newcastle, Australia and Hunter New England Population Health.

The authors would like to acknowledge the input of Kim Colyvas, University of Newcastle, for generating the randomisation sequence and for advice regarding analyses of outcome data.

Chapter 6: Efficacy of a Universal Smoking Cessation Intervention Initiated in Inpatient Psychiatry and Continued Post-Discharge: A Randomised Controlled Trial

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Manuscript submitted to the *Australian and New Zealand Journal of Psychiatry* on 15th July, 2016.

Bibliographic reference: Metse AP, Wiggers J, Wye P, Wolfenden L, Freund M, Clancy R, Stockings E, Terry M, Allan J, Colyvas K, Prochaska JJ, Bowman JA:

Efficacy of a sustained smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge: a randomised controlled trial. *Aust N Z J Psychiatry*. Under review.

Abstract

Background: Interventions are required to redress the disproportionate tobacco-related health burden experienced by persons with a mental illness. This study aimed to assess the efficacy of a universal smoking cessation intervention initiated within an acute psychiatric inpatient setting and continued post-discharge in reducing smoking prevalence and increasing quitting behaviours. **Method:** A RCT was undertaken across four psychiatric inpatient facilities in Australia. Participants (N = 754) were randomised to receive either usual care (n = 375) or an intervention comprising a brief motivational interview and self-help material whilst in hospital, followed by a four-month pharmacological and psychosocial intervention (n = 379) upon discharge. Primary outcomes assessed at six and 12 months post-discharge were seven day point prevalence and one month prolonged smoking abstinence. A number of secondary smoking-related outcomes were also assessed. Subgroup analyses were conducted based on psychiatric diagnosis, baseline readiness to quit and nicotine dependence. **Results:** Seven day point prevalence abstinence was higher for intervention participants (16.9%) than controls (9.5%) at six months post-discharge (*OR* 1.07, p = 0.03), but not at 12 months (14.2% and 12.3%, respectively; *OR* 1.02, p = 0.46). Significant intervention effects were not found on measures of prolonged abstinence at either six or 12 month post-discharge. Differential intervention effects for the primary outcomes were not detected for any subgroups. At both six and 12 months post-discharge, intervention group participants were significantly more likely to: smoke fewer cigarettes per day, have reduced cigarette consumption by ≥ 50% and to have made a least one quit attempt, relative to controls. **Conclusions:** Universal smoking cessation treatment initiated in inpatient psychiatry and continued post-discharge was efficacious in increasing seven day point

prevalence smoking. **Trial registration:** Australian New Zealand Clinical Trials Registry: ACTRN12612001042831. Date registered: 28 September 2012.

Keywords: Smoking cessation, intervention, mental illness, inpatient, community mental health services.

Background

The prevalence of tobacco smoking among persons with a mental illness has remained unchanged for the past 20 years [39, 231, 254] and is currently at least two to three times higher than that of the general population in a number of high income countries, including Australia [56, 227, 338]. As a consequence this group continues to experience disproportionate levels of preventable tobacco-related morbidity and mortality, and a reduced life expectancy of 10 to 25 years [42, 43, 339]. In addition, smoking prevalence is associated with mental illness severity and acuity, with up to 88% of those with psychotic disorders [40, 56, 64] and psychiatric inpatients [40, 60, 66] reported to be smokers. Despite higher levels of nicotine dependence [68, 71], smokers with a mental illness wish to quit smoking [66, 126], and attempt to do so at similar rates to smokers without a mental illness [56], using both pharmacological and psychosocial support strategies [127, 188]. Despite this, a greater difficulty in successful quitting [41, 68, 174, 269] and a persistently elevated smoking prevalence [39, 231], suggest that this group has not benefited as much from population-wide smoking cessation interventions relative to those without a mental illness [54, 72]. To address this inequity, the development of tailored smoking cessation intervention approaches have been recommended for this population group [67, 176], and are a recognised clinical and public health priority [67, 232].

Hospitals have been identified as an opportune setting to initiate smoking cessation interventions [193, 194], particularly following the introduction of smoke-free policies and the associated requirement to treat patient nicotine dependence [124, 195]. In general hospital settings, an inpatient stay has been associated with increased motivation to quit and likelihood of cessation [196-198]. The provision of smoking cessation support post-discharge has been shown to further increase the likelihood of

successful quitting in general hospital patients by up to 65% [199, 340]. For persons with a mental illness, systematic review evidence suggests that a smoke-free psychiatric hospitalisation can have a positive impact on smoking behaviours including daily cigarette consumption, motivation to quit and number of cessation attempts [78]. However, without ongoing smoking cessation support these effects are suggested to dissipate within three months of discharge [78].

Only three RCTs have assessed the efficacy of integrating inpatient smoking care with post-discharge cessation support for adult smokers with a mental illness [127, 130, 221]. Prochaska and colleagues [130] demonstrated the efficacy of such an approach in a RCT involving predominantly Caucasian and medically insured smokers (N = 224) admitted to one acute psychiatric facility in the US. All admitted patients were offered NRT during their hospitalisation. Whilst inpatients, intervention group participants additionally received a computer-assisted, stage-tailored smoking cessation program and cessation counselling. Post-discharge intervention was offered over six months and involved repetition of the stage-tailored computer program at months three and six. If, during this time participants were assessed by the program as ready to quit, a 10-week supply of nicotine patches was also offered. Patients randomized to the intervention condition were significantly more likely than usual care controls (brief cessation advice and quit-line referral) to be abstinent for at least seven days at six (14% versus 7%), 12 (19% versus 11%), and 18 (20% versus 8%) months post hospital discharge. A feasibility and replication controlled trial of the same intervention involving ethnically diverse, uninsured smokers with a mental illness (n = 100) admitted to both acute and non-acute units of an urban public hospital achieved similar effect sizes at six (18% versus 9%) and 12 (26% versus 17%) months post-discharge [221].

A third study involving patients from one inpatient psychiatric facility in Australia assessed the efficacy, via RCT, of a universal smoking cessation intervention initiated during admission and continued immediately following discharge [127]. Intervention components were proactively offered to all smokers, irrespective of clinical (e.g. psychiatric diagnosis) or smoking (e.g. readiness to quit) characteristics. Inpatient smokers (N = 205) were randomised to receive either a four month post-discharge smoking cessation intervention (comprising telephone counselling and combination NRT), or usual care [127]. At four months post-discharge, those receiving the intervention had significantly higher rates of seven day point prevalence abstinence compared to usual care controls (12% versus 2%), although this difference was not sustained at six months post-discharge. The study concluded that increased intervention intensity was required to achieve longer term effects.

To address the equivocal findings of the limited number of reported trials, a RCT was conducted of a smoking cessation intervention initiated for all smokers admitted to four Australian acute psychiatric inpatient facilities and continued for a period of four months post-discharge. The primary aim was to examine differences in rates of seven day point prevalence and one month prolonged smoking abstinence between intervention and control groups at six and 12 months post-discharge. The secondary aims were to: 1) assess differences in point prevalence and prolonged abstinence according to psychiatric diagnosis, baseline readiness to quit and nicotine dependence; and 2) examine intervention effects in terms of cigarette reduction, quit attempts, nicotine dependence and readiness to quit.

Methods

Design and setting

A two arm, parallel group RCT was undertaken with participants recruited from four public adult inpatient psychiatric facilities in one regional health district in New South Wales, Australia. Six clinical units (20-25 beds each) were included from the four facilities. A smoke-free policy was implemented in the facilities in 2006 [341] with clinical guidelines directing staff to offer and provide nicotine dependence treatment to all hospitalised smokers [195, 200]. The study methods have been previously reported [278].

The Human Research Ethics Committees of Hunter New England Health (reference no: 11/12/14/4.02) and the University of Newcastle (reference no: H-2012-0061) approved the research, which was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12612001042831).

Recruitment procedure, inclusion criteria and permissions

Trained research staff independent of the hospitals, liaised with nurse unit managers daily to identify new patients sufficiently clinically stable to be approached for the study. Study eligibility criteria were: having smoked any number of cigarettes in the month prior to hospital admission [127]; 18 years of age or above; capable of providing informed consent; and having a current contact details. Eligible patients were invited to provide written consent to participate.

Randomisation

A statistician generated a patient random allocation sequence, concealed from recruitment staff, prior to commencement of the study. Randomisation was carried out

separately by site, stratified by diagnosis (psychotic/non-psychotic) using a 1:1 allocation ratio and implemented via provision of a sequentially numbered, opaque, sealed envelope to all consenting participants immediately following baseline data collection. Participants were informed by recruiting staff whether they would receive the multimodal intervention or treatment as usual.

Treatment conditions

Intervention: Whilst an inpatient, in addition to standard hospital smoking cessation care [200], all smokers allocated to the intervention group received two additional evidence-based smoking cessation treatments [144, 150] from research staff: self-help material [323] tailored to smokers with a mental illness [324-326] and a brief 10-15 minute motivational interview [154] designed to promote ambivalence about smoking, guide patients toward behaviour change, and/or positively reinforce intentions to address smoking. At discharge, all such participants received a study-supplied sample pack of NRT (unless medically contraindicated) that included nicotine patches (7 x 21 mg), inhalator with cartridges (6 x 10 mg), gum (30 x 4 mg) and lozenges (20 x 4 mg), and instructions for NRT use. GPs and/or community mental health clinicians (where applicable) were notified of their client's involvement in the study via inclusion of information in the standard hospital discharge summary, and asked to encourage use of the cessation supports provided.

Immediately following discharge, all participants were provided up to four months of tailored telephone behavioural smoking counselling support (minimum of 11 contacts) [150] and an additional 12 weeks of free NRT (weekly/ fortnightly supplies provided following telephone support calls) [144]. Participants were assigned to a telephone counsellor with the intention of receiving continuity of care from that

counsellor. Telephone counselling support was provided (~ 15 minutes) every week during the initial five weeks post-discharge, weekly or fortnightly (contingent on participant preference) during the subsequent seven weeks, and fortnightly during the last month of the intervention period. The counselling sessions were manualised, but tailored to the individual. A motivational interviewing framework was employed [328, 342] to increase motivation for smoking behaviour change and encourage use of the cessation strategies (NRT and Quitline). Systematic monitoring of counselling calls was undertaken by a mental health clinician with experience in training in motivational interviewing (RC).

NRT (patch and oral forms) was prescribed in accordance with an evidence-based, combination-NRT algorithm for highly dependent smokers [330], offered by the telephone counsellors and delivered by mail. The counselling staff prompted participants to utilise the New South Wales Quitline, a free government-provided service providing telephone support and quit advice. If participant consent was provided, a referral was sent to the service on their behalf.

Control: Participants allocated to the control group received routine hospital smoking cessation care only, as per the state clinical guideline [200]. Such care may have included assessment of smoking status and nicotine dependence on admission, brief advice to quit, provision of NRT whilst an inpatient, up to three days NRT supply upon discharge, referral to the New South Wales Quitline, and/or a post-discharge smoking cessation care plan included on the discharge summary [200]. Limited and variable provision of such care has been reported previously in the facilities [210, 322].

Data collection procedures

Baseline data pertaining to primary and secondary outcomes and smoking characteristics were collected between October 2012 and April 2014 by research staff via face-to-face interview during the period of admission. Patient clinical and demographic data were obtained from the facilities' electronic medical record system and the baseline interview. For intervention participants only, measures of intervention uptake were collected by the telephone counsellor during each post-discharge telephone counselling call.

Follow-up outcome data were collected via computer assisted telephone interview (CATI) at six and 12 months post hospital discharge (May 2013 to June 2015) - i.e., four and eight months post the completion of the intervention, respectively. For those participants who self-reported seven day point prevalence abstinence at six or 12 months post-discharge, CO assessments were collected (using a Micro^{+} Smokerlyser) as soon as possible post CATI completion, by research staff either in participants' homes or an enclosed public place. Research staff involved in outcome data collection, including CO assessment, were blind to participant allocation.

Measures

Primary outcomes. The two primary outcomes were self-reported seven day point prevalence and one month prolonged smoking abstinence [343, 344]. Patients were asked: 'when did you last smoke tobacco?' For biochemical verification of self-reported seven day point prevalence abstinence, expired breath CO assessments with readings less than seven parts per million (ppm) were used to confirm abstinence [332, 343, 345]. Participants with a reading greater than or equal to seven ppm and those who refused/did not complete a CO assessment were classified as non-abstinent. If CO

assessments were obtained greater than three days after completion of the CATI interview, self-reported abstinence was used [261] (given the lower validity of CO readings for longer periods of abstinence [346]).

Secondary outcomes. Secondary outcome measures were number of cigarettes smoked per day [127, 261], reduction in cigarettes smoked relative to baseline (proportion), quit attempts (a period of abstinence lasting at least 24 hours with the intention to quit [127]; number and duration since hospital discharge), nicotine dependence (assessed using the FTND [280]), and readiness to quit [281].

Clinical and demographic information. Data collected for all admitted patients within the recruitment period from the electronic medical record system were: age, gender, relationship status, Aboriginal and/or Torres Strait Islander status, primary mental health diagnosis at discharge, legal status on admission, and total length of stay (days between admission and discharge) (Table 6.1).

Clinical and demographic information collected for participants only during the baseline interview were: highest level of education attained, employment details, receipt of a government payment, and alcohol use (AUDIT-C) [279] (Table 6.1).

Smoking characteristics. The following characteristics of smoking were collected for participants at baseline: smoking status, age of smoking initiation, and number of years smoked (Table 6.2).

Uptake of offered intervention. For participants allocated to the intervention group, data pertaining to the uptake of the offered post-discharge intervention components (telephone behavioural smoking counselling provided by the study, NRT, and Quitline referral) were collected and have been the focus of a previous paper [347].

Variable transformation

The following secondary outcome variables were transformed from continuous to categorical format for the purpose of conducting analyses: number of quit attempts (two measures: none versus greater than or equal to one; less than or equal to one versus greater than or equal to two), duration of longest quit attempt (less than one month, greater than or equal to one month) [87, 348], and nicotine dependence (low-moderate [FTND score less than or equal to five], high [FTND score greater than or equal to six]) [284]. Categorical variables reduced to two levels were: diagnosis (psychotic, non-psychotic), employment status (paid, unpaid), Aboriginal and/or Torres Strait Islander status (Aboriginal and/or Torres Strait Islander, neither Aboriginal nor Torres Strait Islander / not stated or inadequately described), smoking status (daily smoker, weekly/ irregular smoker), and readiness to quit (pre contemplative, contemplative or a more progressed stage). Highest level of education attained was reduced to three levels (up to school certificate, beyond school certificate and up to HSC, tertiary). To improve normality of the distribution, a log transformation was applied to the secondary outcome variable, cigarettes per day [349].

Analyses

Data were analysed using SPSS Statistics version 22 [263]. Descriptive statistics were used to summarise clinical, demographic and smoking (where applicable) characteristics of admitted, approached and non-consenting patients, and study participants.

Primary and secondary outcomes analyses. Outcome analyses were conducted using intention to treat principles, with all participants retained in originally assigned groups [337]. Generalised Linear Mixed Models (GLMMs) were used to

assess for differences in primary and secondary outcomes by allocation group over time. Intervention effects were determined via allocation group (intervention and control) by time (baseline, six and 12 months post-discharge) interactions. A compound symmetry residual covariance structure was used to model correlation associated with repeated time measurements. For outcomes where no baseline measure was applicable (i.e. seven day point prevalence and prolonged abstinence, and proportion of cigarettes cut down), an additional set of models with main effects only were fitted. Marginal means, odd ratios (*OR*) and 95% CI were determined from the fitted models. Allocation group differences at six and 12 months post-discharge were assessed using simple effects [350].

Clinical and demographic factors significantly associated with attrition (age, Aboriginal and/or Torres Strait Islander status; education level; Table 6.3), determined via chi square analyses with a p-value ≤ 0.05 were entered into all models to control for the Missing At Random assumption (MAR) inherent in GLMMs. Recruitment site was also entered and, where the main effect was significant, differential effects were tested using interaction terms (all two and three way interactions with allocation group and time). Sensitivity analyses were conducted for primary outcomes, using a conservative approach where all missing data were coded as 'not abstinent' [351]. The threshold for statistical significance for all models was set at $\alpha = 0.05$.

Subgroup analyses. To determine if intervention effects differed according to psychiatric diagnosis and baseline nicotine dependence and readiness to quit, subgroup analyses were undertaken for both primary outcomes at six and 12 month post-discharge. Where main effects of diagnosis, nicotine dependence, or readiness to quit were significant, differential effects were subsequently assessed via entry of interaction terms (subgroup x allocation group; subgroup x allocation group x time) into the model.

Per protocol analyses. Adopting the same statistical method described for the primary analytical approach, per protocol analyses were undertaken for the two primary outcome measures: seven day point prevalence and one month prolonged abstinence, at both six and 12 months post-discharge [352, 353]. Such analyses assessed for differences in the primary outcomes between the control group and intervention sub-groups, which were defined in terms of the amount of the intervention received and calculated as a percentage using the formula: (number of calls completed + number of instances using NRT + use of Quitline) / (number of calls offered [*n* =15] + resupplies of NRT offered [*n* = 13] + offer of proactive Quitline referral [*n* = 1])* 100. Seven such per protocol models were created, with per cent intervention received increasing by 5% intervals from 55% to 85%.

Results

Participants

Of 3626 patients admitted within the recruitment period, 64% (*n* = 2315) were approached by research staff, with patients not being approached primarily due to either a short length of stay (less than or equal to one night; 38%), psychiatric instability for the duration of time spent as an inpatient (35%), or discharge prior to staff availability to undertake the assessment interview (27%). Of the 2315 patients approached, 2078 (90%) agreed to be assessed for study eligibility, of which 841 (40%) were ineligible, predominantly due to non-smoking status (*n* = 797, 95%; overall smoking prevalence: 62%). Sixty one per cent (*n* = 754) of eligible smokers consented and were randomised to the intervention (*n* = 379) or control group (*n* = 375). Follow-up rates did not differ by allocation and were, for the intervention group: six month post-discharge: 56%, 12 months post-discharge: 61%; and control group: six months post-discharge: 58%, 12

months post-discharge: 60%. Figure 6.1 describes the flow of participants through the trial.

Clinical and demographic characteristics of approached and not approached patients, as well as non-consenters and study participants (by allocation group) are provided in Table 6.1. Given the large sample sizes statistical tests were not conducted [354, 355], however differences in the median length of stay and diagnosis of patients were suggested for those approached and not approached to participate in the trial, and in the diagnosis between study participants and non-consenters. Participants allocated to the intervention and control groups did not differ in terms of clinical, demographic (Table 6.1) or smoking (Table 6.2) characteristics at baseline or among those lost to follow-up (Table 6.3).

Primary Outcomes

Seven-day point prevalence abstinence. Biochemical verification tests were conducted for 40% of participants self-reporting seven day point prevalence abstinence at six and 12 month post-discharge discharge (six months 40% (24/60); 12 months 40% (19/47)). For the remaining 60%, tests were not completed due to issues contacting and reaching participants, compounded by a large geographical study area (130 000 square kilometres). Of the completed tests, 40% were undertaken within three days (six months 38% (9/24); 12 months 42% (8/19)). Of the tests conducted in three days, 84% confirmed the participant as being abstinent. Agreement between self-reported abstinence and biochemical verification did not differ between allocation groups ($\chi^2(1, N = 43) = 1.43, p = 0.23$).

The proportions of participants abstinent for seven days or greater were 16.9% and 9.5% for intervention and control groups at six month post-discharge, and 14.2%

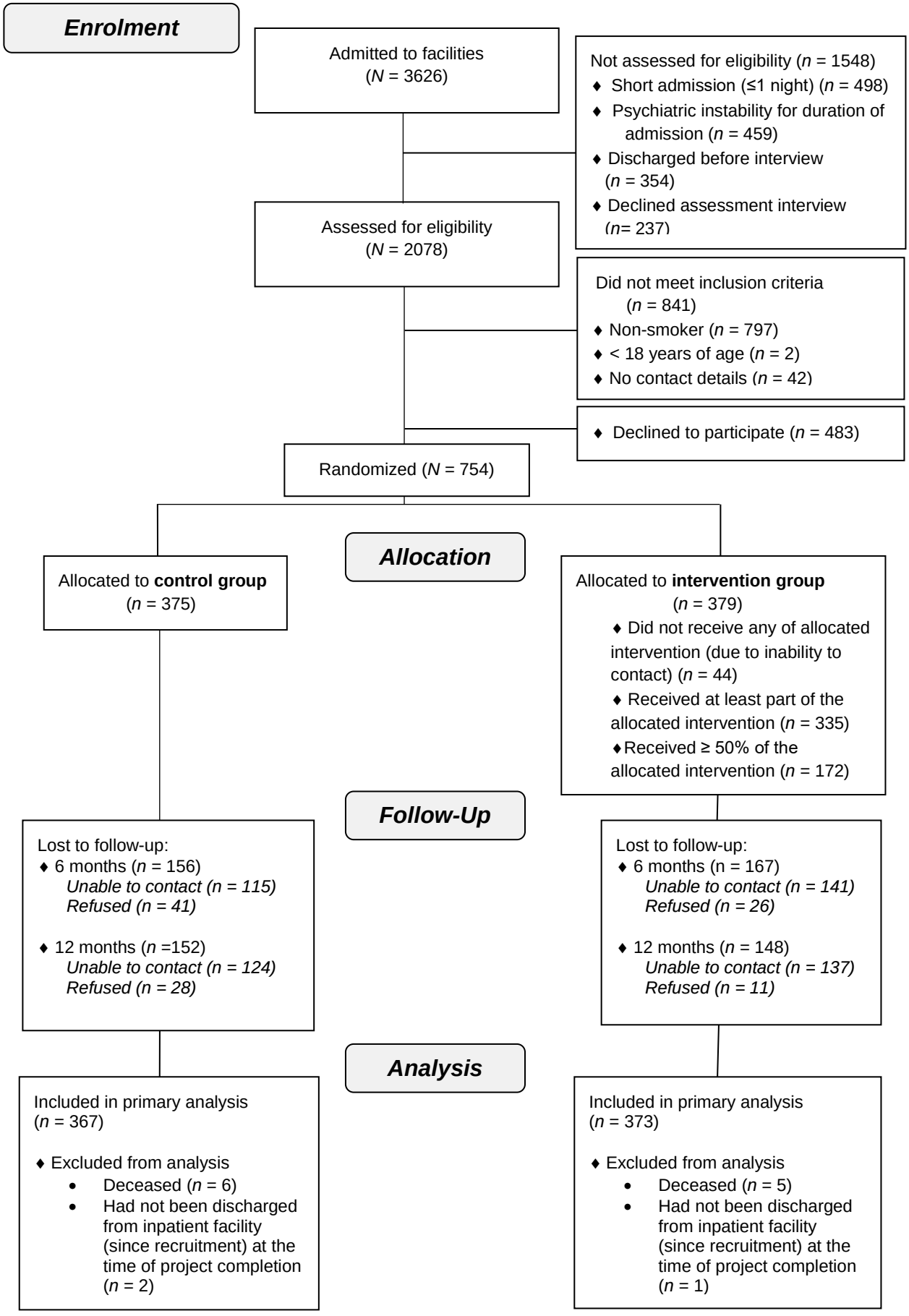

Figure 6.1. Participant Flow Diagram

Table 6.1. Clinical and Demographic Characteristics of Approached and Not Approached Patients, and Study Participants and Non-Consenters

	Not Approached (*n* = 1311)	Approached (*n* = 2315)	Non-Consenters (*n* = 483)	**Participants**	
				Control Group (*n* = 375)	Intervention Group (*n* = 379)
Gender (%)					
Male	60.0	55.4	63.4	61.3	61.2
Age (years)					
Mean (SD)	39.8 (17.1)	41.8 (14.2)	38.9 (11.7)	38.3 (12.0)	39.1 (11.9)
Median (Range: Min- Max)	37.0 (10-94)	41.0 (18-93)	38.0 (18-82)	38.0 (18-76)	38.0 (19-74)
Relationship status (%)					
Single	59.0	58.6	70.8	60.8	66.5
Married/De facto	25.7	24.1	17.4	23.5	17.9
Separated/Divorced	11.0	14.2	10.2	13.9	12.7
Widowed	3.2	2.3	0.6	1.1	2.4
Not stated/inadequately described	1.0	0.7	1.0	0.8	0.5
Aboriginal and/or Torres Strait Islander Status (%)					
Aboriginal and/or Torres Strait Islander	12.8	11.6	17.7	13.1	14.0
Neither Aboriginal or Torres Strait Islander / Not stated or inadequately described	87.2	88.4	82.3	86.9	86.0
Employment status (%)					
Full time	-	-	-	17.3	12.9
Part time	-	-	-	10.1	12.7
Household duties	-	-	-	3.5	3.2
Student	-	-	-	2.9	2.6
Unemployed/ other	-	-	-	66.1	68.6
Highest education level achieved (%)					
Primary School	-	-	-	5.6	7.1
Third year of High School	-	-	-	22.1	21.9
School Certificate	-	-	-	31.2	34.0

Table 6.1. Continued.

	Not Approached (*n* = 1311)	Approached (*n* = 2315)	Non-Consenters (*n* = 483)	**Participants**	
				Control Group (*n* = 375)	Intervention Group (*n* = 379)
Higher School Certificate	-	-	-	11.7	15.0
TAFE or Diploma	-	-	-	22.4	15.6
Bachelor / Post Graduate Degree	-	-	-	7.0	6.3
Receipt of a government payment (%)					
Yes	-	-	-	76.0	78.1
Primary mental health diagnosis (%)[a]					
Schizophrenia and related psychosis	14.1	27.6	37.1	20.0	19.0
Anxiety and stress related disorders	20.3	8.5	6.4	13.9	12.1
Mood disorders	23.1	30.8	22.4	26.4	26.9
Substance related disorders	21.2	15.6	18.0	20.8	25.3
Personality and other disorders	21.3	17.4	16.1	18.9	16.7
Recruitment Site (%)[b,c]					
Site1	34.4	49.1	49.5	46.7	46.7
Site 2	16.5	13.3	11.0	18.9	19.0
Site 3	23.1	18.2	25.5	14.1	15.3
Site 4	26.0	19.4	14.1	20.3	19.0
Length of stay (days)					
Mean (SD)	12.4 (62.1)	16.8 (28.7)	17.6 (24.4)	13.6 (16.0)	15 (18.9)
Median (Range: Min- Max)	2 (0-1715)	10 (0-945)	10 (0-236)	9 (0- 147)	8 (0-121)
Legal status on admission (%)					
Involuntary	44.4	46.8	50.7	45.6	48.0

SD: Standard deviation. '-' data not obtained for respective sample

[a] Based on ICD-10 classification. [b] Site 1: 66 beds; Site 2: 20 beds; Site 3: 25 beds; Site 4: 24 beds. Proportion of approached and recruited patients is relative to unit size. [c] One unit from Site 1 provided specialised drug and alcohol services to patients with a comorbid psychiatric disorder.

Table 6.2. Participant Baseline Characteristics of Smoking and Alcohol Use

	Group	
	Control (*n* = 375)	Intervention (*n* = 379)
Smoking status (%)		
Daily	92.8	93.1
Weekly	3.7	3.4
Irregular	3.5	3.4
Cigarettes Per Day (%)		
1-10	27.5	24.8
11-20	35.2	37.2
21-30	22.9	23.5
>30	14.4	14.5
Level of nicotine dependence (%)		
High	50.7	51.7
Low-moderate	49.3	48.3
Readiness to quit (%)		
Pre-contemplative	54.7	55.1
Contemplative or a more progressed stage	45.3	44.9
Age initiated smoking (%)		
<12	20.0	23.5
12- <14	20.8	21.1
14- <16	29.6	20.8
16- <18	14.9	17.4
≥18	14.7	17.2
Number of years smoked (%)		
≤ 10	20.0	16.6
> 10 - ≤20	25.9	28.0
>20	54.1	55.4
Quit attempt in past 12 months (%)		
Yes	42.7	49.3

Table 6.2. Continued.

	Group	
	Control (n = 375)	Intervention (n = 379)
Number quit attempts in past 12 months (%)[a]		
One	45.0	44.4
Two- three	38.1	36.9
Four or more	16.9	18.7
Length longest quit attempt in past 12 months (%)[a]		
< 1 month	71.8	73.8
≥ 1 month	28.2	26.2
Alcohol use (AUDIT-C) (%)[b]		
Harmful/ hazardous	62.1	64.5
Non-harmful/ non-hazardous	37.9	35.5

[a]Control: n = 160
Intervention: n = 187
[b]Control: n = 367
Intervention: n = 372
SD: Standard deviation
IQR: Interquartile range

Table 6.3. Baseline Characteristics of Participants Lost to Follow-Up at 12 Months

	Group	
	Control (*n* = 152)	Intervention (*n* = 148)
Gender (%)		
Male	65.1	61.5
Age (years)[a]		
M (SD)	36.6 (11.6)	37.3 (11.4)
Mdn(Range: Min- Max)	35.0 (19-76)	36.5 (19-67)
Relationship status (%)		
Single	65.1	65.5
Married/De facto	18.4	17.6
Separated/Divorced	13.1	12.9
Widowed	2.0	3.4
Not stated/inadequately described	1.3	0.7
Aboriginal and/or Torres Strait Islander (%)[a]		
Aboriginal and/or Torres Strait Islander	19.1	17.6
Neither Aboriginal or Torres Strait Islander / Not stated or inadequately described	80.9	82.4
Employment (%)		
Full time	20.4	15.5
Part time	9.9	12.8
Household duties	3.9	1.4
Student	2.0	2.0
Unemployed/ other	63.8	68.3
Highest education level achieved (%)[a]		
Primary School	5.9	7.4
Third year of High School	26.3	22.3
School Certificate	32.2	36.5
Higher School Certificate (HSC)	7.2	17.6
TAFE of Diploma	20.4	12.8
Bachelor/ Post Graduate Degree	7.9	3.4

Table 6.3. Continued.

	Group	
	Control (n = 152)	Intervention (n = 148)
Receipt of a government payment (%)		
Yes	72.4	80.4
Primary mental health diagnosis (%)		
Schizophrenia and related psychosis	21.1	18.2
Anxiety and stress related disorders	11.2	12.2
Mood disorders	21.1	25.7
Substance related disorders	24.3	24.3
Personality and other disorders	22.4	19.6
Smoking status (%)		
Daily	95.4	95.9
Weekly/ Irregular	4.6	4.0
Cigarettes Per Day (%)		
1-10	23.7	24.3
11-20	36.8	41.2
21-30	19.7	22.3
>30	19.7	12.2
Level of nicotine dependence (%)		
High	56.6	48.6
Readiness to quit (%)		
Pre-contemplative	48.7	52.0
Contemplative or a more progressed stage	51.3	48.0

and 12.3% at 12 months, with no significant group-by-time interaction (F[2, 841] = 3.1, p = 0.10; Table 6.4) and a borderline significant main effect of group (F[1, 841] = 3.14, p = 0.08; *OR* 0.82, 95% CI 0.49 to 1.38). Simple effects models showed that at six months post-discharge, those in the intervention group were significantly more likely than control participants to be abstinent (*OR* 1.07, 95% CI 1.01 to 1.14), although this effect was not sustained at 12 months (p = 0.46). Sensitivity analyses showed no intervention effect via the group-by-time interaction (F[2, 1467] = 0.45, p = 0.50), main effect of group (F[1, 1467] = 1.001, p = 0.32) or simple effects models (6 month: *OR* 1.02, 95% CI 0.99 to 1.05; 12 month: *OR* 1.01, 95% CI 0.97 to 1.04).

Subgroup analyses. Subgroup analyses revealed that for participants allocated to the intervention group the odds of seven day point prevalence abstinence did not differ on the basis of psychiatric diagnosis (six month: *OR* 1.04, 95% CI 0.93 to 1.17; 12 month: *OR* 1.01, 95% CI 0.90 to 1.12), readiness to quit (six month: *OR* 1.01, 95% CI 0.94 to 1.09; 12 month: *OR* 1.08, 95% CI 0.98 to 1.18) or nicotine dependence (6 month: *OR* 0.93, 95% CI 0.84 to 1.02; 12 month: *OR* 1.02, 95% CI 0.90 to 1.07).

Per protocol analyses. The data used to calculate per cent intervention receipt groups are reported in Table 6.5. For seven day point prevalence abstinence, group-by-time interactions were significant for two intervention receipt groups: 80% intervention receipt (F[2, 475] = 4.91, p = 0.03) and 85% intervention receipt (F[2, 462] = 8.57, p = 0.004). Simple effects models revealed at 6 months post-discharge, those receiving 80% (*OR* 1.25, 95% CI 1.02 to 1.52) and 85% (*OR* 1.30, 95% CI 1.04 to 1.62) of the offered intervention were significantly more likely than control participants to be abstinent for at least seven days, although these effects were not sustained at 12 months post-discharge (both ps > 0.58; Table 6.6). While group-by-time interactions were significant for three other intervention receipt groups: 65% (F[2, 568] = 4.48, p = 0.04), 70%

Table 6.4. Results from Generalised Linear Mixed Models for Categorical Outcome Variables Prolonged and Point Prevalence Abstinence, Quit Attempts (Number and Duration), 50% Reduction in Cigarette Consumption, Nicotine Dependence, and Readiness to Quit for the Intervention and Control Groups at the 6- and 12-Month Post-Discharge Follow-Up Assessments

	6-Month Follow-Up					12-Month Follow-Up				
Measure/ Group	%[a] (*n*)	*OR*	95% CI Lower	95% CI Upper	*p*-value	%[a] (*n*)	*OR*	95% CI Lower	95% CI Upper	*p*-value
Prolonged abstinence										
Intervention (*n* = 373)	12.1 (45)	1.02	0.96	1.08	0.45	11.8 (44)	1.01	0.96	1.07	0.61
Control (*n* = 367)	9.5 (35)	1				10.1 (37)	1			
Point prevalence abstinence										
Intervention (*n* = 373)	16.9 (63)	1.07	1.01	1.14	0.03	14.2 (53)	1.02	0.96	1.09	0.46
Control (*n* = 367)	9.5 (35)	1				12.3 (45)	1			
Quit attempt										
Intervention (*n* = 373)	65.4 (244)	1.22	1.11	1.34	<0.001	77.5 (289)	1.21	1.11	1.32	<0.001
Control (*n* = 367)	45.8 (168)	1				58.3 (214)	1			
Number of quit attempts										
Intervention (*n* = 373)	37.3 (139)	1.17	1.07	1.28	.001	50.7 (189)	1.23	1.12	1.35	<0.001
Control (*n* = 367)	21.6 (83)	1				30.0 (110)	1			
Duration of quit attempts										
Intervention (*n* = 373)	20.9 (78)	1.09	1.02	1.18	.017	24.1 (90)	1.07	0.98	1.17	0.12
Control (*n* = 367)	12.0 (44)	1				16.9 (62)	1			
50% reduction in cigarette consumption										
Intervention (*n* = 373)	58.2 (217)	1.24	1.13	1.36	<0.001	53.9 (201)	1.10	1.00	1.21	0.04
Control (*n* = 367)	36.8 (135)	1				44.1 (162)	1			
Nicotine dependence										
Intervention (*n* = 373)	71.3 (266)	1.09	1.00	1.18	0.06	65.4 (244)	1.04	0.96	1.14	0.32
Control (*n* = 367)	63.2 (232)	1				61.0 (224)	1			
Readiness to quit										
Intervention (*n* = 373)	53.6 (200)	1.07	0.97	1.17	0.18	52.8 (197)	1.01	0.92	1.11	0.88
Control (*n* = 367)	47.1 (173)	1				52.0 (191)	1			

Note. OR: odds ratio; CI: confidence interval; [a]Marginal means

Table 6.5 Intervention Receipt

	Total (*N*= 378*)
Received at least one project delivered cessation counselling call (%)	
Yes	88.6
Number of project delivered calls received (%)	
0-3	27.0
4-7	21.4
8-11	39.4
12-15	12.2
Duration of project delivered calls received (minutes)	
Mean (SD)	14.6 (10.7)
Median (IQR)	13 (13)
Received NRT at all during the course of the intervention (%)	
Yes	79.1
Number of instances received NRT	
0-2	33.6
3-5	20.4
6-9	27.4
10-13	18.6
Of those who received NRT (n= 299), type of NRT received (%)	
Patch only	7.4
Adjunctive only	17.4
Optimal (patch and adjunctive)	75.3
Use of Quitline (%)	
Yes	10.8

*N= 378 as one participant had not been discharged from inpatient facility (since recruitment) at the time of project completion

Table 6.6. Results from Generalised Linear Mixed Models for Dichotomous Categorical Variable Point Prevalence Abstinence, According to Per Cent Intervention Received

Group	6 Months Post-Discharge					12 Months Post-Discharge				
	%[a] (n)	*OR*	95% CI		*p*-value	%[a] (n)	*OR*	95% CI		*p*-value
			Lower	Upper				Lower	Upper	
55% received (*n* = 139)	17.4 (24)	1.08	0.995	1.17	0.07	14.6 (20)	1.02	0.95	1.11	0.54
Control (*n*= 367)	9.7 (36)	1				12.2 (45)	1			
60% received (*n* = 126)	17.9 (23)	1.08	0.99	1.18	0.09	14.0 (18)	1.01	0.93	1.10	0.77
Control (*n*= 367)	10.3 (38)	1				12.9 (47)	1			
65% received (*n* = 98)	20.1 (20)	1.10	0.997	1.22	0.06	13.2 (13)	1.00	0.92	1.10	0.93
Control (*n* = 367)	10.2 (37)	1				12.8 (47)	1			
70% received (*n* = 85)	20.2 (17)	1.11	0.996	1.24	0.06	13.4 (11)	1.01	0.92	1.11	0.82
Control (*n* = 367)	9.8 (36)	1				12.3 (45)	1			
75% received (*n* = 68)	23.0 (16)	1.14	0.996	1.29	0.06	13.8 (9)	1.01	0.91	1.12	0.88
Control (*n* = 367)	10.3 (38)	1				13.0 (48)	1			
80% received (*n* = 41)	32.6 (13)	1.25	1.02	1.52	0.03	17.6 (7)	1.05	0.89	1.23	0.58
Control (*n* = 367)	10.3 (38)	1				13.0 (48)	1			
85% received (*n* = 32)	37.2 (12)	1.30	1.04	1.62	0.02	11.9 (4)	0.98	0.84	1.14	0.79
Control (*n* = 367)	11.1 (41)	1				14.0 (51)	1			

Note. OR: odds ratio; CI: confidence interval; [a]Marginal means

(F[2, 549] = 4.17, p = 0.04) and 75% (F[2, 525] = 5.12, p = 0.02), simple effects models revealed only borderline differences between such groups and control participants at six months post-discharge (all ps = 0.06), and no significant difference at 12 months (all ps ≥ 0.82). Group-by-time interactions and main effects were non-significant for the 55% and 60% intervention receipt models (all ps ≥ 0.09).

One month prolonged abstinence. The proportions of participants abstinent for one month or longer were 12.1% and 9.5% for intervention and control groups respectively at six month post-discharge, and 11.8% and 10.1% respectively at 12 months post-discharge, with no significant group-by-time interaction (F[2, 841] = 0.02, p = 0.98; Table 6.4) or main effect of group (F[1, 841] = 0.80, p = 0.37; *OR* 0.86, 95% CI 0.48 to 1.54). Sensitivity analyses similarly showed no intervention effect for the group-by-time interaction (F[2, 1467] = 0.05, p = 0.95) or main effect of group (F[1, 1467] = 0.47, p = 0.49).

Subgroup analyses. Subgroup analyses revealed the odds of one month prolonged abstinence did not differ among intervention group participants contingent on psychiatric diagnosis (six month: *OR* 1.04, 95% CI 0.93 to 1.15; 12 month: *OR* 1.04, 95% CI 0.95 to 1.14), readiness to quit (six month: *OR* 1.08, 95% CI 0.98 to 1.19; 12 month: *OR* 1.09, 95% CI 0.996 to 1.19) and level of nicotine dependence (six month: *OR* 0.94, 95% CI 0.86 to 1.02; 12 month: *OR* 0.99, 95% CI 0.91 to 1.07).

Per protocol analyses. The likelihood of one month prolonged abstinence at six and 12 month post-discharge did not vary between the control group and any of the intervention receipt groups, with all group-by-time interactions and main effects of group being non-significant (all ps > 0.13; Table 6.7).

Table 6.7. Results from Generalised Linear Mixed Models for Dichotomous Categorical Variable One Month Prolonged Abstinence, According to Per Cent Intervention Received

Group	6 Months Post-Discharge					12 Months Post-Discharge				
	%[a] (n)	*OR*	95% CI		*p*-value	%[a] (n)	*OR*	95% CI		*p*-value
			Lower	Upper				Lower	Upper	
55% received (*n* = 139)	10.8 (15)	1.02	0.95	1.09	0.66	10.1 (14)	1.01	0.95	1.08	0.70
Control (*n*= 367)	9.0 (33)	1				9.3 (34)	1			
60% received (*n* = 126)	11.9 (15)	1.02	0.94	1.09	0.67	9.5 (12)	0.997	0.93	1.07	0.94
Control (*n*= 367)	9.8 (36)	1				10.1 (37)	1			
65% received (*n* = 98)	12.2 (12)	1.03	0.95	1.12	0.47	8.2 (8)	0.98	0.92	1.06	0.65
Control (*n* = 367)	9.8 (36)	1				10.1 (37)	1			
70% received (*n* = 85)	15.3 (13)	1.05	0.96	1.16	0.30	8.2 (7)	0.98	0.91	1.06	0.59
Control (*n* = 367)	9.8 (36)	1				10.1 (37)	1			
75% received (*n* = 68)	17.6 (12)	2.18	0.96	1.22	0.20	8.8 (6)	0.98	0.90	1.07	0.64
Control (*n* = 367)	10.1 (37)	1				10.6 (39)	1			
80% received (*n* = 41)	26.8 (11)	1.17	0.97	1.42	0.10	12.2 (5)	1.02	0.89	1.17	0.81
Control (*n* = 367)	9.8 (36)	1				10.1 (37)	1			
85% received (*n* = 32)	25.0 (8)	1.17	0.96	1.44	0.12	9.4 (3)	0.996	0.86	1.16	0.96
Control (*n* = 367)	10.9 (40)	1				10.9 (40)	1			

Note. OR: odds ratio; CI: confidence interval; [a]Marginal means

Secondary Outcomes

Group-by-time interactions revealed a significant intervention effect for four of seven secondary outcomes including cigarettes per day (F[2, 1440] = 5.41, p = 0.005; Table 6.8), proportion of cigarettes cut down (F[1, 5.16) = 5.410, p = 0.02), quit attempt (F[2, 1578] = 7.11, p = 0.001), and number of quit attempts (F[2, 1525]) = 6.2, p = 0.002; Table 6.4), with intervention group participants smoking significantly fewer cigarettes per day and being more likely to reduce cigarette consumption and attempt to quit one or more times at both the six and 12 month post-discharge follow-ups, relative to controls.

There was no significant group-by-time interaction for nicotine dependence (F[2, 1579]) = 1.25, p = 0.29), readiness to quit (F[2, 1580]) = 0.99, p = 0.37) or duration of longest quit attempt (F[2, 1415]) = 1.03, p = 0.36).

Discussion

The universal smoking cessation intervention initiated during admission to a psychiatric inpatient facility and continued for a period of four months immediately post-discharge was efficacious in reducing the seven day point prevalence of smoking at six months post-discharge but not at 12 months. The intervention did not impact rates of one month prolonged abstinence at either six or 12 month post-discharge. Among those receiving the intervention, per protocol analysis showed that the degree of intervention received was positively associated with a greater likelihood of quitting for seven days, whilst diagnosis, readiness to quit and nicotine dependence were not. The intervention resulted in reduced daily cigarette consumption and increased quit attempts, behaviours

Table 6.8. Results from Generalised Linear Mixed Models for Continuous Outcome Variable Cigarettes Per Day for the Intervention and Control Groups at the 6- and 12-Month Post-Discharge Follow-Up Assessments

	Mean (SE)			**95% CI**		
Measure/ follow-up	Control Group	Intervention Group	Mean difference	Lower	Upper	*p*-value
Cigarettes per day						
Baseline	16.81 (1.05)	17.00 (1.05)	0.19	-0.19	0.57	0.84
6-month	12.03 (1.07)	9.59 (1.07)	-2.44	-2.93	-1.95	0.004
12-month	12.65 (1.07)	10.55 (1.07)	-2.10	-2.59	-1.61	0.02

that may precede future successful cessation [83, 89]. The findings suggest a short term benefit of linking all smokers in inpatient mental health facilities with community based post-discharge smoking cessation support. Further research is required to identify strategies for achieving sustained smoking cessation; the importance of doing so supported by the high smoking prevalence typical of psychiatric inpatients (62% in the present study).

The finding of a significant seven per cent absolute difference in seven day point prevalence of abstinence at six months in this trial is similar to that of two US trials (eight per cent and nine per cent) [130, 221] and greater than that reported in an earlier Australian trial (12%) [127]. The absence of a significant intervention effect in seven day point prevalence abstinence at 12 months however contrasts with the outcomes in the US trials [130, 221], and may be related to participant, methodological or jurisdictional differences between the studies. In the present study, the universal intervention approach reflected clinical guidelines recommending that clinicians systematically assess smoking status and offer cessation care to all smokers, regardless of assessed readiness to quit [124, 192]. This approach is in keeping with research that suggests quitting can occur spontaneously and that the availability of cessation assistance can promote a quit attempt [83, 94, 356]. In contrast, the cessation support in the US studies entailed an offer of one intervention component, NRT contingent on patient ‘readiness’ to quit, with such offer being made at any point over a period of up to six months post-discharge. The US researchers suggest that their sustained outcome, with an apparent increasing intervention effect over time for point prevalence abstinence is consistent with such a stage-based approach [130].

Results from subgroup analyses suggest the intervention component was acceptable and efficacious for all smokers – with neither measure of abstinence being associated

with psychiatric diagnosis, readiness to quit or level of dependence. Neither US trial [130, 221] assessed for differences in intervention effects according to the specified subgroups. However across both intervention and control conditions, Hickman et al. [221] found those with psychotic disorders to be more likely to be abstinent relative to those with unipolar depression; and Prochaska et al. [130] found that participants who were ready to quit and those with lower nicotine dependence were more likely to be abstinent. The lack of parallel approach to analyses precludes direct comparisons, nevertheless the absence of differential intervention effects in the current study may have been related to: equal provision of intervention components, including NRT, to all participants regardless of readiness to quit and NRT prescription occurring in accordance with degree of nicotine dependence [357].

In line with the findings of previous research among both smokers generally [124, 153] and those with a mental illness [308, 348, 358], results from the per protocol analyses suggest a dose-response relationship between the degree of intervention receipt and likelihood of abstinence: smokers in receipt of greater amounts of the intervention (80+%) were 25-35% more likely to achieve seven day point prevalence abstinence at six months post-discharge, compared to controls. Such a finding suggests the importance of strategies for optimising access to and utilisation of cessation supports [359, 360]. For smokers without a mental illness, systematic review evidence suggests further participant education regarding the benefits of tobacco cessation aids and provision of additional problem-solving based support to overcome potential barriers to aid utilisation, enhance adherence to cessation interventions (*RR* 1.14, 95% CI 1.02 to 1.28, *n* = 1630), which in turn leads to a higher likelihood of cessation (*RR* = 1.16, 95% CI 1.01 to 1.34, *n* = 3049) [359]. As no such research exists for persons with a mental

illness, identification of strategies to improve access and/or utilisation of cessation supports for this group of smokers is needed.

The positive effects of the intervention on secondary outcomes including reduced cigarette consumption and greater number of quit attempts, are congruent with those of the previous Australian trial [127]. Given such changes in smoking behaviour have been shown to increase the subsequent likelihood of successful cessation among smokers generally [83, 89, 101, 102], these findings suggest the intervention is likely to have been efficacious in progressing smokers with a mental illness toward cessation. Only one paper was identified that has previously investigated the possible relationship of such changes in smoking behaviours on cessation for smokers with a mental illness. Okoli et al. [348] reported a positive relationship between the length of a previous quit attempt and seven day point prevalence abstinence.

Strengths of this study included a large and heterogeneous study population; promoting external validity and allowing for investigation of intervention effect that may have been contingent on psychiatric diagnosis, readiness to quit, degree of nicotine dependence and dose of intervention received. Limitations included high participant attrition and incomplete biochemical verification of point prevalence abstinence; both of which may have resulted in biases likely to overestimate the intervention effect. Other smoking trials with persons with a mental illness have encountered such issues, some similarly adopting a biochemically verified-self report hybrid measure of abstinence [261]. A further limitation may have been sub-optimal intervention exposure; which in contrast was likely to have resulted in an underestimate of intervention effect.

Declaration of Interest

Dr Prochaska has consulted to Pfizer, which makes smoking cessation medications, and has been an expert witness for plaintiffs' counsel in lawsuits against the tobacco companies. All other authors declare no competing interests.

Funding Source

This research was funded by the National Health and Medical Research Council (grant number: G1100130). Dr Stockings is supported by an Australian National Health and Medical Research Council (NHMRC) early career fellowship (#1104600). Dr Prochaska is supported by the National Institutes of Health (HL117736-01) and the State of California Tobacco-Related Disease Research Program (24RT-0035).

Acknowledgements

The authors would like to thank the participants, clinicians and research team that enabled this study to be undertaken.

Manuscript Publication Status at PhD Award

This manuscript was accepted for publication in the Australian and New Zealand Journal of Psychiatry. In accordance with comments received during the review process, some of the analyses were revised; however, overall study findings remained unchanged. Refer to the journal for the finalised published version of the manuscript.

Chapter 7: Summary of Key Findings and Implications for Future Research

Introduction

Effective interventions are needed to redress the disproportionate tobacco-related morbidity and mortality experienced by persons with a mental illness. Admission to a smoke-free acute psychiatric facility provides an opportunity to initiate the provision of smoking support to patients, with potential benefits in terms of cessation if such support is extended post-discharge. In this context, based on the findings of the literature review in Chapter 1, the research presented in this thesis was undertaken to address several evidence gaps in the field relating to knowledge of: 1) the volume and characteristics of peer reviewed published research regarding smoking among persons with a mental illness, 2) the determinants of quitting behaviour for smokers accessing acute psychiatric services, 3) the receptivity of such smokers to proactive offers of smoking cessation aids following discharge, and 4) the impact on smoking cessation of initiating cessation support for all smokers in inpatient psychiatry and continuing post-discharge.

Chapter 2 assessed the volume and characteristics of research in the field of smoking and mental illness over a period of two decades. Chapter 3 examined the prevalence of smoking and physical and social environmental characteristics of smokers accessing acute psychiatric services, and explored the association between such characteristics and recent quitting behaviour and motivation. Chapter 4 described the uptake of NRT and two telephone based behavioural smoking cessation aids, proactively offered to a population of psychiatric inpatients upon discharge, and explored factors associated with such uptake. Finally, Chapter 5 reported the methodology and Chapter 6 the outcomes of a RCT of the efficacy of an intensive multimodal smoking cessation intervention, initiated within psychiatric inpatient facilities for all smokers and continued post-discharge.

CHAPTER 7: SUMMARY OF FINDINGS AND IMPLICATIONS

This concluding chapter provides a brief summary of Chapters 2 to 6, focusing on the key findings and their significance, and outlines a number of recommendations for future research.

Summary of Key Findings

Chapter 2: Assessment of the Volume and Characteristics of Research in the Field of Smoking and Mental Illness

Chapter 2 reported the findings of a descriptive repeat cross-sectional study of peer-reviewed publications in Medline and PsycINFO for the field of smoking and mental illness. The study described the volume and characteristics of publications across three time periods (1993-1995, 2003-2005 and 2013-2015), and for intervention-focused research, examined the level of evidence and phase of research translation.

The study identified a five-fold increase in the total number of publications in the field of smoking and mental illness between 1993-1995 and 2013-2015, an increase (15%) in the proportion of data-based publications, greater diagnostic heterogeneity of study samples, and a greater focus on settings other than mental health specific facilities. Much of this progression however, occurred between 1993-1995 and 2003-2005, with no further change between 2003-2005 and 2013-2015. Across the time periods there was no increase in the proportion of research focussing on intervention studies; with the predominant type of research studies being descriptive (71% - 88%). Of the intervention research that was undertaken, there was a suggested increase in the adoption of RCT study designs (20% in 1993-1995 to 55% in 2013-2015) and systematic reviews/ meta-analyses (0% in 1993-1995 to 15% in 2013-2015). No variation in the proportion of studies that addressed research translation was evident, remaining less than 10% across the study period.

The unchanging predominance of descriptive research across the study period indicated that a shift in focus toward the development and testing of interventions has not occurred for the field of smoking and mental illness – such a shift, in contrast, has been reported for the field of smoking and public health generally [239]. The rise in the

number and proportion of RCTs and systematic reviews/meta-analyses between 1993-1995 and 2013-2015 may, however, suggest some progression in terms of the level of evidence provided by the intervention research undertaken [233, 238]. The increase in heterogeneity with respect to the study settings and psychiatric diagnosis of samples across the study period may suggest an increase in the generalisability of findings in the field of smoking and mental illness [242, 253]. Nevertheless, the stagnation in translation phase of intervention-focussed research indicated a continuing focus on the assessment of intervention efficacy under optimal conditions, with little movement toward assessment of effectiveness and implementation in real world conditions [242]. Overall, the study highlighted the need for more research in this field, particularly rigorous research assessing the effectiveness and implementation of tailored smoking cessation interventions to facilitate population-level changes in the smoking rates of persons with a mental illness.

Chapter 3: Smoking and Environmental Determinants of Cessation among Smokers with a Mental Illness

Chapter 3 reported findings from a cross-sectional descriptive study of patients admitted to four acute psychiatric facilities in New South Wales, Australia. The study sought to address the smoking and physical and social environmental characteristics of admitted smokers, and to explore possible associations of such characteristics with quitting behaviour and motivation.

Consistent with previous research [66, 318, 361], the study found a high prevalence of tobacco use and heavy smoking among those admitted to acute psychiatric facilities. Sixty-two per cent of inpatients smoked tobacco and, of the participating smokers, 51% were highly nicotine dependent, 93% smoked daily and

74% consumed greater than 10 cigarettes per day. Additionally, smoking appeared to be a long-established behaviour, with 68% initiating tobacco use prior to the age of 16.

The findings of the study suggested a high level of exposure to smoking in the home environment of persons with a mental illness (32% to 44%), and variable support for smoking cessation across social support networks (68% to 91%). Approximately half of participants lived with others who were also smokers, and a third resided in a home that was not smoke-free – a proportion 11% greater than that estimated for Australian smokers generally [71]. While a majority of participants believed that significant others (68% to 82%) and health care providers (80% to 91%) would be supportive of their quitting smoking, between 9% and 32% of participants perceived that significant others and health care professionals would be unsupportive of a quit attempt, with a perceived lack of support being reported most commonly for friends (32%).

The study further suggested that a number of smoking and physical and social environmental characteristics may serve to sustain the tobacco use of persons with a mental illness. Daily smoking, higher nicotine dependence, heavier smoking (consumption of a greater number of cigarettes per day), and longer periods as a smoker was associated with a reduced likelihood of recent quitting behaviour and motivation. Participants living with other smokers and those perceiving their psychiatrist to be unsupportive of a quit attempt were significantly less likely to have recently engaged in quitting behaviour. These results are consistent with the findings of research conducted among smokers generally, where it has been found that an absence of exposure to smoking in the immediate environment [83, 106, 108] and endorsement of smoking cessation by health care providers [100, 121] enhance the likelihood of a quit attempt and successful smoking cessation.

Chapter 4: Uptake of Smoking Cessation Aids by Smokers with a Mental Illness

Chapter 4 reported the findings of a descriptive study of patients following their discharge from four acute psychiatric facilities in New South Wales, Australia. The study aimed to describe the uptake of proactively and universally offered cessation aids including NRT and telephone based smoking cessation aids, and explore factors associated with the uptake of such aids.

The study found that following discharge from a psychiatric inpatient facility, a large proportion of smokers were likely to accept proactively offered evidence-based smoking cessation aids. Almost all participants (89%) utilised at least one cessation aid, more than three quarters (79%) used both pharmacological and behavioural aids, and approximately half used such aids on an ongoing basis (greater than seven instances; 52%). As a result of the single offer of a proactive Quitline referral, 11% of smokers used the Quitline service in the 4 months following discharge - at least double the proportion of smokers in the general Australian population who might be expected to contact the Quitline annually on a self-referral basis [186].

The study also illustrated that in order to further promote cessation aid uptake, a number of individual and contextual characteristics could be considered during intervention development, such as strategies to engage smokers who are less nicotine dependent, younger and not able to easily identify as a non-smoker. Additionally, NRT use during admission was found to be weakly associated with a greater likelihood of cessation aid uptake post-discharge and although requiring further investigation, may be a finding with particular clinical and policy significance. The lack of association between psychiatric diagnosis and motivation to quit with any measure of uptake may suggest that aids were equally appealing regardless of the nature or severity of

psychiatric illness, and that patients could be engaged in using cessation supports even if not assessed initially as having a high motivation to quit.

Chapters 5 and 6: A Sustained Smoking Cessation Intervention for Psychiatric Patients

Chapters 5 and 6 described the methodology and outcomes, respectively, of a RCT of a smoking cessation intervention initiated in four acute psychiatric units in New South Wales Australia, and continued post-discharge. Whilst in hospital, the intervention involved provision of a brief motivational interview and tailored self-help material. In the four months following discharge, additional smoking cessation support involved 16 weeks of project delivered supportive smoking cessation counselling, 12 weeks of free NRT, and a proactive referral to the New South Wales Quitline. The intervention was provided proactively and universally to all smokers in order to maximise the reach and uptake of smoking cessation aids [182].

The trial outcomes demonstrated that the intervention was efficacious in reducing the point prevalence of smoking at six months post-discharge, but not at 12 months. Per protocol analyses showed that the degree of cessation support received was positively associated with a greater likelihood of point prevalence abstinence, with those in receipt of at least 80% of the intervention significantly more likely than controls to be abstinent at six (*OR* 1.25, 95% CI 1.02 to 1.52) but not 12 (*OR* 1.05, 95% CI 0.89 to 1.23) months post-discharge. Subgroup analyses revealed diagnosis, readiness to quit and nicotine dependence were not associated with either primary outcome. In addition, participants receiving the intervention were more likely reduce their daily cigarette consumption and increase the number of quit attempts - behaviours that may precede future successful cessation [83, 89]. The findings suggest that the

intervention was effective in increasing cessation at six months post-discharge, and in encouraging cigarette reduction and quit attempts up to 12 months post-discharge. The lack of effect on prolonged abstinence, or either abstinence outcome at 12 month post-discharge also suggests more research is required to identify strategies that promote quitting behaviours and sustained smoking cessation among smokers with a mental illness.

The following final sections of this thesis provide suggestions for future research in this area, including strategies to increase the size and sustainability of the effect of smoking cessation interventions for persons with a mental illness, particularly those initiated in inpatient psychiatry and continued post-discharge.

Smoking Interventions Initiated in Inpatient Psychiatry and Continued Post-discharge: Increasing Effect Size and Sustainability

Chapter 2 identified that more intervention research is needed to redress the tobacco-related health inequities experienced by persons with a mental illness. The smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge, described in Chapters 5 and 6 of this thesis, yielded significant and sustained effects on quitting behaviour and cigarette reduction, and a temporary (six months) effect on point prevalence abstinence. The magnitude and sustainability of the intervention effect on abstinence may have been attenuated by a number of factors identified in the literature and by the findings of Chapters 3, 4 and 6 including: environments of the participants that were unconducive to quitting [96-98], including psychiatric inpatient, residential and social environments; suboptimal use of cessation aids [124, 358]; and premature discontinuation of cessation support provision [62, 319]. Such factors suggest a need for further research that aims to enhance the effectiveness of interventions intended to reduce the rate of smoking among persons with a mental illness, including the clients of acute psychiatric services.

Promoting Environments Conducive to Quitting

Psychiatric inpatient settings

As identified in Chapter 1, smoke-free psychiatric inpatient facilities are an opportune setting to initiate the provision of smoking cessation support [67, 201] – facilitating patient receptivity to the provision of smoking cessation care and providing periods of supported abstinence to admitted patients [193, 194]. Admission to a smoke-free hospital has been shown to lead to positive changes in smoking behaviours including reduction in number of cigarettes smoked, quitting motivation and cessation

[196-198, 316]. However, evidence of poor adherence by health facilities generally to smoke-free policies and nicotine dependence treatment guidelines [196, 197, 211, 318] suggests that a positive impact of such policies on smoking behaviours is not being optimised. For example, a survey of 650 US adults admitted to a general hospital setting with a smoke-free policy found that those who received inadequate nicotine dependence treatment were almost four times more likely to smoke upon discharge [197]. Similarly, among 354 smokers admitted to US Veterans affairs hospitals, those who did not smoke during admission had an odds of quitting at 6 months post-discharge 2.7 times higher than those who did smoke during admission [196]. Similar results have been found in psychiatric settings: a descriptive study of 90 patients discharged from a US acute psychiatric unit found those who experienced greater cravings and withdrawal symptoms during admission were significantly more likely to resume smoking the day of discharge [318].

Chapter 4 reported that over half of the study participants (52%) continued to smoke throughout their hospital admission, and those that did not use NRT whilst an inpatient were less likely to use cessation aids post-discharge. Such findings, and those of Rigotti [197], Duffy [196] and Prochaska [318] described above, suggest that consistent enforcement of smoke-free policies and the provision of appropriate doses of NRT in psychiatric inpatient settings have the potential to increase the likelihood that smokers with a mental illness will quit smoking, or attempt to do so, post-discharge.

In this context, future intervention research aiming to increase smoking cessation among persons admitted to psychiatric inpatient units should seek to strengthen the cessation benefits of a smoke-free policy in two ways: consistent implementation of smoke-free policies, and ensuring all smokers are systematically provided with appropriate doses of NRT [362]. With respect to the former strategy, a

systematic review of intervention trials from general hospital settings suggests that delegation of specific responsibilities regarding smoke-free policy enforcement and related staff training improved consistency of such enforcement (two trials, *OR* 3.2, 95% CI 2.0 to 5.2) [124]. Research assessing the effectiveness of such strategies on the consistent implementation of smoke-free policies in mental health settings is needed.

In terms of provision of appropriate doses of NRT by staff, systematic review evidence from general hospital settings indicate that clinical audits and provision of feedback in the context of pre-specified performance indicators increases staff adherence to clinical practice guidelines [208, 360, 363], including the provision of pharmacological and behavioural nicotine dependence treatment. For example, in a systematic review involving 140 randomised trials, audit and feedback processes were found to increase staff adherence with clinical care guidelines (adjusted risk difference (RD) 4.3%, interquartile range 0.5% to 16%; 49 trials) [363, 364]. The review also suggested such processes were most effective when provided: both verbally and in writing, by a supervisor or colleague, on a number of instances, and with clear targets and an action plan [363]. Assessment of the effectiveness of such strategies in increasing the provision of appropriate doses of NRT in mental health settings is needed.

A further consideration for future research relating to enhancing staff delivery of smoking cessation care in inpatient psychiatry concerns improving the quality of advice and support to quit provided by psychiatrists. Research suggests that clinician advice to quit [100, 121, 157], particularly when delivered by a physician [125], increases quitting behaviour and likelihood of cessation among smokers generally. A meta-analysis of 43 studies examining the efficacy of health provider advice and support to quit for smoking cessation in the general population indicated that the likelihood of

patient cessation was higher when support was delivered by physicians (*RR* 1.87, 95% CI 1.42 to 2.45) compared to nurses (*RR* 1.76, 95% CI 1.21 to 2.57) and other professionals (*RR* 1.18, 95% CI 0.67 to 2.10) [125]. The finding of Chapter 3 that smokers with a mental illness who perceived their psychiatrist to be supportive of cessation were nearly three times more likely to have made a number of recent quit attempts supports such previous research [121, 125]. However advice and support to quit from treating psychiatrists has been previously reported to occur minimally in routine practice in the US [294, 365] and Australia [366].

Whilst no trials have assessed the impact of psychiatrist-provided smoking support on cessation outcomes of patients, outcomes of a quasi-experimental study undertaken across three sites (one university and two medical centres) in the US suggest that implementation of an evidence-based tobacco treatment curriculum in psychiatry residency programs improved residents' knowledge, attitudes and confidence for treating inpatients smoking [367]. Future intervention trials initiated in inpatient psychiatry should consider the inclusion of strategies to increase the provision of advice and support to quit by treating psychiatrists to potentially increase cessation outcomes.

Residential and social environments

With respect to smokers generally, research has demonstrated the negative impact of environmental factors on the likelihood of smoking cessation including exposure to tobacco smoke [83, 89, 105, 108-114] and lack of social support to quit [109, 115-120]. In terms of exposure to tobacco smoke, a review of cross-sectional and longitudinal studies identified positive associations at a population level between smoke-free homes and adult smoking behaviours including cessation and cigarette reduction [106]. Chapter 3 reported that a third of smokers accessing acute mental

health services lived in dwellings that were not smoke-free and nearly half lived with other smokers. In comparison, surveys of the Australian general population indicate seven per cent [288] and 34% [287] occupy residences that are not smoke-free and live with other smokers, respectively. The findings of Chapter 3 also indicated that living with other smokers reduced the odds of making a quit attempt of greater than one month duration. Such findings highlight the potential benefit of developing strategies to reduce the ubiquity of smoking in the residential environments of smokers with a mental illness.

A number of interventions have been shown to increase the prevalence of smoke-free homes in the general population [368-371]. A systematic review involving seven RCTs published between 2009 and 2014 found in-home counselling interventions (1 to 10 sessions) with follow-up phone calls or mailed self-help materials reduced air pollution levels in homes of the general population for up to 12 months (N = 681, *standardised mean difference*: −0.18, 95% CI −0.34 to −0.03, p = 0.02) [372]. A selective review of reviews and RCTs conducted by the International Agency for Research on Cancer (IARC) suggested clinician-delivered individual and group-based (with others occupying the residence) interventions involving face-to-face counselling, motivational interviewing and education, and self-help materials increased the adoption of smoke-free homes in general population samples [373]. In addition, a recent RCT of an intervention to increase the rate of smoke-free homes among low-income smokers (N = 498) in the US found brief intervention comprising one coaching call and three personalised letters resulted in a significant 15% increase in the proportion of smoke-free homes, relative to the control condition, at three and six month follow-ups [369]. The intervention content was based on Social Cognitive Theory [374] and the Transtheoretical Model of Behaviour Change [90, 375]. Interventions to increase the

adoption of smoke-free homes have not been trialled among persons with a mental illness. The continuing lower prevalence of smoke-free homes for this population group however suggests that large-scale population level interventions may need to be augmented with additional, individualised strategies [67, 176]. Research is required to identify effective intervention approaches.

The provision of social support to quit smoking by family and peers has been associated with a higher likelihood of cessation among smokers generally [110, 118, 120, 376]. In a longitudinal study of 128 US smokers enrolled in a university cessation program for instance, those with higher levels of partner support for cessation and general social support were more likely to be abstinent at three months follow-up ($p < 0.05$) [110]. The finding of Chapter 3 that 32% of participants either perceived their friends to be unsupportive of a quit attempt or they were uncertain of their support, suggests interventions that promote social support for smoking cessation may be of benefit for smokers with a mental illness.

Interventions to increase social support for others to stop smoking have been reported to show promise in increasing cessation rates among smokers generally [274, 376-378]. Among such smokers, a systematic review of RCTs suggested enhancement of partner support for quitting increased the likelihood of cessation (*OR* = 1.83, 95% CI, 0.9 to 3.47; two trials) [123]. A further systematic review has reported that interventions involving the provision of support to quit by non-smokers in the home environment increases the odds of cessation by 1.64 (95% CI 1.09 to 2.46; two trials) for smokers generally [378].

A single review has examined the efficacy of interventions aimed at increasing support for smoking cessation among persons with a mental illness [379]. Narrative synthesis of the four identified studies (all non-randomised designs) indicated a positive

impact of interventions whereby support to quit was provided by an ex-smoker (abstained for ≥ 12 months) with a mental illness who was not previously known to participants and had received training in the provision of cessation support [379]. Such supportive interventions were associated with rates of cessation up to 20% as well as significant reductions in cigarette consumption [379], however a need for more rigorous efficacy trials using RCT designs was highlighted. Given many persons with a mental illness do not have a partner (as reported in Chapter 3) or a consistent/ reliable social network [380], interventions utilising ex-smokers with a mental illness not previously acquainted with the individual may be particularly relevant [377]. In addition, as many persons with a mental illness have a key support person or family carer [381], engaging such persons and providing training in the provision of cessation support may also represent an opportunity for supporting smoking cessation [377]. No rigorous studies have reported the efficacy or effectiveness of such an approach, and strategies to increase the degree of social support for smokers with a mental illness, including those accessing acute psychiatric services, to quit smoking warrant further exploration.

Increasing the Consistency of Smoking Cessation Aid Utilisation

Results of the per-protocol analyses for the RCT described in Chapter 6, indicated a positive association between the likelihood of abstinence and the 'dose' of the intervention received. At six months post-discharge, participants in receipt of 55% of the interventions were 1.08 (95% CI 0.995 to 1.17) times more likely to be abstinent, whereas those in receipt of 85% of the intervention were 1.30 (95% CI 1.04 to 1.62) times more likely be so. Similar findings were reported in an Australian study examining the effectiveness of an intervention consisting of NRT, motivational interviewing, and cognitive behaviour therapy for smokers with psychotic disorders

accessing outpatient mental health services [358]. While there were no overall difference between intervention (*n* = 147) and control groups (*n* = 151) in that trial, those who completed all 8 sessions of the intervention, compared to those who completed less than five, were significantly more likely to be abstinent at three (*OR* 6.8, 95% CI 2.2 to 20.1), six (*OR* 5.5, 95% CI 1.5 to 20.1) and 12 (*OR* 3.2, 95% CI 1.01 to 10.2) month follow-ups [358].

Although the adoption of a proactive and universal intervention approach in the trial described in Chapters 5 and 6 resulted in a high proportion of smokers with a mental illness utilising smoking cessation aids at least once across the intervention period (89%), only nine per cent of participants utilised 85% or more of the aids on offer, highlighting the need for additional strategies to facilitate a greater proportion of participants to utilise all cessation aids offered. For smokers generally, systematic review evidence has suggested the likelihood of adherence to smoking cessation medication is increased (*RR* 1.14, 95% CI, 1.02 to 1.28, *N* = 1630) by a number of strategies including: increased provision of information relating to smoking cessation medication use, psychological counselling to manage any consequences/side-effects, and clinician monitoring and feedback regarding actual and anticipated effect of medication on cessation outcomes [359].

The consistency of smoking cessation aid use may also be increased by monetary incentives [382] and automated telephone prompts [383]. With regard to the use of incentives, a systematic review involving 19 controlled trials suggested the provision of monetary incentives increased adherence by persons in the general population to a number of medicinal treatments by approximately 20% [384]. In terms of smoking cessation aids specifically, Hennrikus and colleagues [382] offered smokers (*N* = 2402) employed at 24 US worksites in the Minneapolis–Saint Paul metropolitan

area an incentive of $10 for registering with a telephone based cessation counselling program, and an additional $20 for completing three quarters of its requirements. Results revealed the provision of monetary incentives more than doubled rates of enrolment and increased consistency of cessation aid use, however did not translate into increased cessation rates [382].

While there is no evidence for the effectiveness of monetary incentives in increasing adherence to pharmacotherapies or behavioural aids for smoking cessation for persons with a mental illness, studies of strategies to increase adherence to other treatments in this population group indicate a positive effect of such an approach [385, 386]. For instance, a systematic review of randomised and nonrandomised trials assessing the impact of monetary incentives on treatment adherence among smokers with a mental illness found such incentives significantly increased rates of adherence to psychiatric treatment (three trials), physical exercise regimes (one trial) and substance misuse treatment programmes (10 trials) [386]. Further, in a cluster RCT involving persons (N = 141) with psychotic disorders accessing community mental health services in the UK, provision of £15 following administration of antipsychotic medication increased subsequent adherence with this medication by 12% (p = 0.003) across the 12 month study period [385]. Secondary outcome analysis revealed the odds of adhering to at least 95% of prescribed medications was 8.2 (95% CI 2.0 to 33.7) times higher for those receiving monetary incentives, relative to controls [385].

With regard to the impact of automated telephone prompts, a narrative systematic review of 13 RCTs and clinical controlled trials suggested that such prompts increased adherence to treatments for a number of chronic conditions among smokers generally (9/13 studies indicated significant effect; none of the included studies focussed tobacco cessation medications) [387]. In a study of the impact of automated

telephone prompts on the use of smoking cessation aids specifically, Rigotti and others [383] assessed the effect of such prompts scheduled for patients discharged from a general hospital at two, 14, 30 and 60 days post-discharge to increase the consistency of cessation counselling use. Those receiving the automated prompts (n = 198) were significantly more likely than those not receiving such prompts (n = 199) to be engaged in counselling at one (37% vs. 22%), three (58% vs. 41%) and six (69% vs. 51%) months post-discharge [383].

Research involving persons with a mental illness suggests a positive impact of telephone prompts on adherence to treatments [388, 389]. However, such research is limited to treatments other than smoking cessation aids. For instance, in a systematic review of seven RCTs, narrative synthesis revealed a positive effect of telephone prompts on adherence to pharmacotherapeutic treatments and appointment attendance among persons with substance use, affective and psychotic disorders [389]. Further, in a multicentre RCT automated telephone prompts significantly increased antipsychotic medication adherence among persons with a schizophrenia (p = 0.03, N = 254) [388].

Such findings provide guidance as to what strategies could be used to enhance the uptake of cessation aids offered to smokers following discharge from inpatient psychiatry, and the findings of Chapter 4 provided additional insight regarding the particular types of patients to whom such strategies could be targeted. Smokers who were less nicotine dependent, of younger age and could not easily see themselves as a non-smoker were found to be less likely to use cessation supports across the study period. Such findings are supported by a US study that found younger and less nicotine dependent smokers to be less likely to use cessation aids following discharge from inpatient psychiatry; as were smokers who were unmotivated to quit, experiencing less severe mental health symptoms, and male [188]. No research to date has assessed

strategies to increase engagement and the utilisation of cessation aids for specific groups of smokers with a mental illness, however research with subgroups of smokers in the general population suggests a potential benefit of targeted approaches [390-394]. For instance, a recent US trial explored the engagement of young adult smokers without a mental illness (18 to 25 years; $N = 79$) in a cessation intervention delivered via Facebook [394], where content was tailored according to individual's readiness to quit and led to higher levels of engagement ($p = 0.009$) [394]. The identification of strategies to better engage young adult smokers with a mental illness, and other subgroups who may be less likely use cessation aids, is needed and may increase the effectiveness of smoking interventions for this group, including those delivered following discharge from inpatient psychiatry.

Provision of Extended Smoking Cessation Support Following Discharge from Inpatient Psychiatric Care

The outcomes of Chapter 6 supported that of a previous Australian trial assessing the impact of initiating smoking cessation support in inpatient psychiatry [127], in demonstrating that the effect of an intervention on abstinence dissipated soon after discontinuation. In order to prolong the effect on abstinence and potentially capitalise on the sustained positive changes in quitting behaviours shown to precede successful cessation (including increased quit attempts and cigarette reduction) [83, 89] yielded by the intervention, future research is required to investigate the benefits and feasibility of providing longer-term cessation support to smokers discharged from inpatient psychiatry.

Benefits of longer-term support

Across of a range of settings, research has consistently demonstrated that smoking cessation interventions of longer duration result in larger effect sizes, including those delivered within hospital settings and following discharge [124, 199, 395]. A systematic review of 50 randomised and quasi-randomised trials assessing the impact of initiating smoking cessation support in general hospital settings suggested a benefit of interventions of longer duration [199]. At six months follow-up, interventions comprising a single contact in hospital lasting less than 15 minutes (*RR* 1.14, 95% CI 0.82 to 1.59), one or more contacts in hospital lasting more than 15 minutes (*RR* 1.10, 95% CI 0.96 to 1.25) or any hospital contact with post-discharge support lasting less than one month (*RR* 1.07, 95% CI 0.93 to 1.24) did not increase the likelihood of abstinence [199]. In contrast, interventions with any hospital contact and extended follow-up support of at least one month duration significantly increased the likelihood of successful cessation (*RR* 1.37, 95% CI 1.27 to 1.48) [199]. Furthermore, a narrative selective review of elements of effective hospital inpatient smoking cessation interventions similarly suggested interventions of longer duration increased the likelihood of abstinence, with optimal effects on cessation achieved if in-hospital intervention components last 20 minutes or more and post-discharge support was extended for at least three months [395]. Lastly, findings of the systematic review and meta-analysis undertaken as part of the most recent US clinical practice guidelines for the treatment of tobacco use and dependence [124] indicated use of combination NRT (patch plus adjunctive) for more than 14 weeks (*OR* 3.6, 95% CI 2.5 to 5.2) was significantly more effective than the use of such pharmacotherapies for a lesser period (six to 14 weeks; *OR* 2.2, 95% CI 1.3 to 3.6).

The findings of the two previous US trials assessing the efficacy of integrating smoking cessation care offered within inpatient psychiatric facilities with post-discharge support [130, 221] have similarly suggested interventions of longer duration are required for persons with a mental illness to achieve sustained cessation. Both trials [130, 221] maintained the availability of cessation support for a period of six months, two months longer than the intervention described in Chapters 5 and 6, and found effects on cessation did not dissipate for up to 18 months post-discharge (effect sizes: six months 8% to 9%, 12 months 9% to 10%, 18 months 12% [130, 221]). The duration of support that would yield even larger and more sustained effects on cessation outcomes for persons with a mental illness however, is unknown.

Provision of longer periods of smoking cessation support via technology modalities

Providing face-to-face smoking cessation support over long periods has the potential to present a number of logistical challenges including cost, availability and access [396, 397]. Technology-based interventions offer the potential for greater flexibility, feasibility, access and cost-effectiveness [124, 150, 396-402] and hence may provide an option for the provision of ongoing cessation support to smokers following discharge from inpatient psychiatry. For smokers generally, systematic review evidence suggests face-to-face smoking cessation interventions increase the likelihood of cessation by 56% to 98% (one-on-one interventions: *OR* 1.56, 95% CI 1.32 to 1.84, 21 trials [151]; group interventions: *RR* 1.98, 95% CI 1.60 to 2.46, 13 trials) [155]. Similar effect sizes have been estimated in reviews of smoking cessation interventions delivered via the internet (*RR* 2.10, 95% CI 1.25 to 3.52, two trials [403]), text messaging (*OR* 2.2, 95% CI 1.77–2.62; 2 trials [404]; *OR* = 1.63, 95% CI 1.19 to 2.24; 22 trials [405])

and other smart phone-based technologies (such as applications) (*RR* 2.03, 95% CI 1.40 to 2.94, two trials [152]).

For smokers with a mental illness there is a paucity of research assessing the efficacy of smoking cessation interventions delivered via technology modalities. Two US studies have assessed the efficacy of internet-based smoking cessation interventions for persons with a mental illness [406]. In a RCT involving 222 community-dwelling smokers with depressive symptoms, participants in receipt of a tailored web-based cessation intervention, utilising the Acceptance and Commitment Therapy framework, were more likely to be abstinent than those accessing support from a generic smoking cessation website (Smokefree.gov) at three months follow-up (20% versus 12%) [407]. Further, in a pre-post study a self-directed internet-based cessation intervention developed specifically for persons with schizophrenia (n = 6) resulted in 20% of participants quitting smoking, and 60% reducing daily cigarette consumption [406]. The authors of both studies highlighted the importance of tailoring such interventions for persons with a mental illness [406, 407], including the need to simplify the navigation process of the web page and ensuring content is brief, explicit and concrete [406-408].

No other trials of cessation support delivered to smokers with a mental illness via a technology medium have been undertaken, however treatments for other conditions delivered to people with a mental illness via such mediums have suggested their feasibility, acceptability and efficacy [409, 410]. For instance, in a pre-post study of a smartphone intervention to increase capacity of persons with schizophrenia (N = 33) to manage their mental health symptoms, 90% of participants rated the intervention as highly acceptable [409], which was also reflected by the high rate of use (used on 87% of days) [409]. After one month of use, a significant reduction in depression, psychotic symptoms and general psychopathology was observed [409]. Given

technology devices are increasingly ubiquitous [411], their utilisation, either in isolation or conjunction with other mediums, has the potential to be used for the delivery of longer term smoking cessation support for persons with a mental illness - both following discharge from inpatient psychiatry and in other contexts.

Provision of longer-term smoking cessation support via existing services

Quitline. Telephone Quitlines represent a further option for the provision of longer-term smoking cessation support to psychiatric patients following discharge. Systematic review evidence indicates Quitline telephone support increases cessation rates in the general population (*OR* 1.6, 95% CI 1.4 to 1.8, 9 trials) [124]. Two recent population based studies have assessed the effectiveness of Quitline for smokers with a mental illness [412, 413]. The first, a descriptive longitudinal study of 125 261 smokers accessing a US state Quitline, found that a majority of service users identified to have at least one mental health condition, 52% [412]. However, rates of six month prolonged abstinence were significantly lower for those with such a condition (multiple mental illnesses: 21.8%, one mental illness: 28.6%) compared to callers with no mental health illness (33.7%) [412]. The second study, involving 3 132 callers to three US state Quitlines, similarly found that those identifying to have a mental health disorder were a third less likely to be abstinent for at least 30 days at seven months follow-up (*OR* = 0.63, 95% CI 0.51 to 0.78) [413].

In both Quitline studies [412, 413], support was offered only to those who were ready to quit and comprised an initial intake session (~50 minutes duration) and up to four sessions in the month following a set quit date. A four week supply of nicotine patches, commencing at the quit date, was also provided. It might be speculated that the lesser effectiveness of Quitlines for persons with a mental illness in these studies may

be related to such factors as the short duration of intervention (one month), provision of unimodal NRT – despite combination NRT being the most effective for highly dependent smokers, and the non-tailored structured approach where all smokers had to be ready to quit and set a quit date soon after contact with the service [413, 414]. Provision of support over extended periods without the need to have immediate quitting intentions, and perhaps prescription of high dose combination NRT represent possible strategies for tailoring the Quitline service for smokers with a mental illness, and future research might explore whether their implementation increases its effectiveness for this group [413, 414].

Maintaining telephone contact with persons with a mental illness has been reported to be difficult [127, 221, 316, 415]; findings supported by the high rate of attrition noted in Chapter 6 of this thesis. In the context of providing extended smoking cessation telephone support via Quitline, it may therefore be important to consider the previously discussed strategies (incentives and prompts, modifying approach) to increase uptake and consistency of service use [382, 383, 415].

Community-based mental health services. Primary and secondary health care workers such as GPs and community/ outpatient mental health clinicians are also potential sources of ongoing cessation support for smokers discharged from inpatient psychiatry. Firstly, as primary care physicians, GPs have important and acknowledged role to address smoking [170, 416]. Frequency of patient contact [417] and effectiveness of physician advice for smoking cessation [157] enhance the opportunity for GPs to reduce smoking prevalence. For instance, a population survey undertaken by the Australian Health Performance Authority indicated that in 2012-2013 the average Australian sought treatment from a GP 5.6 times, with those with a mental illness likely to seek treatment on a higher number of instances [417]. In addition, for smokers

generally systematic review evidence suggests brief physician advice to quit, relative to no intervention, significantly increases the likelihood of abstinence for up to 12 months (*RR* 1.66, 95% CI 1.42 to 1.94) [157].

Clinical practice guidelines recommend GPs assess the smoking status of all patients, and if relevant, provide advice to quit and referral to cessation services (such as Quitline) [170]. However, research suggests GP provision of such care is suboptimal [418, 419]. For example, in cross sectional survey of 13 017 Australians seeking treatment from a GP, 24% reported that their smoking status was assessed and/or they received advice to quit [418]. Numerous effective strategies have been identified to increase the provision of smoking cessation care in general practice, including GP training [420], implementation of reminder systems [421] and audit and feedback [421]. The intervention described in Chapters 5 and 6 involved notifying GPs of their patients' participation in a smoking cessation program, however no further GP involvement was sought. As a means of providing ongoing support to smokers following discharge from inpatient psychiatry, investigation of the impact of greater GP involvement via implementation of evidence-based strategies to increase provision of cessation care to this group is warranted.

Involvement of GPs in smoking cessation support offered to psychiatric inpatients following discharge may also provide the continued physician oversight and support required to explore potential benefits and harms of pharmacotherapies other than NRT. A recent double-blind, randomised, placebo-controlled clinical trial of the neuropsychiatric safety and efficacy of varenicline for smokers with a diagnosed mental illness (N = 4116) found varenicline to be more effective than the nicotine patch in facilitating cessation (*OR* 1·68, 95% CI 1·46 to 1·93) [169]. Use of varenicline was not associated with more adverse neuropsychiatric events. However, the generalisability of

the study findings to all patients discharged from inpatient psychiatric facilities is unknown as eligible participants in the study were psychiatrically stable for six months prior to enrolment, motivated to quit, and without a co-morbid substance use disorder. The safety of varenicline for diverse populations of smokers with a mental illness, including those recently accessing inpatient and outpatient mental health services or who experience substance related co-morbidity (~30% [422]) is yet to be confirmed [423].

Community/outpatient mental health services could also be considered as a source of ongoing smoking cessation support following discharge from an inpatient psychiatric admission. Despite recommendations that all mental health services routinely assess the smoking status of clients and if applicable, provide advice to quit and referral to an appropriate specialist cessation service [414, 424-426], provision of such care in these settings has been reported to be suboptimal and variable [427-429]. For example, a cross sectional telephone survey of 558 clients accessing community mental health services in Australia found 73% of clients had their smoking status assessed, however only 48% of identified smokers were then advised to quit and provided with an appropriate referral [429]. A survey of 282 community mental health clinicians in Canada similarly reported low provision of care, with 31% routinely assessing clients smoking status, 21% consistently exploring client interest in addressing smoking, and 20% often providing behavioural support such as counselling [430].

There is a large literature that suggests various clinical practice change interventions are effective in supporting the implementation of clinical guideline recommendations in routine care delivery [363, 431-433]. Such interventions include monitoring and feedback, training and education, provision of practice change support,

and leadership and consensus are effective in increasing the provision of routine clinical care including the assessment and treatment of smoking, in general community health settings [363, 431-433]. However, very little research has explored the efficacy of such strategies in enhancing the delivery of smoking cessation care by community mental health settings, and that which exists suggests a need for a tailored approach [434, 435]. For example, the results of a recent multiple baseline trial in Australian community mental health services indicated a multi-strategic clinical practice change intervention incorporating strategies identified to be effective in general health settings was ineffective in increasing rates of assessment, advice to quit or referral to appropriate cessation support such as the Quitline [434]. In order for community mental health services to be a viable option for the provision of ongoing cessation support for smokers with a mental illness, including those recently discharged from inpatient psychiatry, further research is required to identify effective strategies for increasing the provision of smoking cessation care in such services. In light of the evolving nature of mental health care provision in high income countries [436], future research might also broaden its focus to increasing the provision of smoking cessation care in newly established mental health services, such as community managed organisations (CMOs) [436, 437].

Conclusions

Persons with a mental illness, including those accessing psychiatric services, experience disproportionate tobacco-related morbidity and mortality. This thesis highlighted the need for more intervention-focussed research to address this health inequity, particularly at a level which may translate to having an impact across the population of smokers with a mental illness. An intervention was trialled where multimodal smoking cessation support was proactively and universally offered to all psychiatric inpatients upon discharge, with the results indicating such an approach was efficacious in increasing cessation rates at six months and encouraging cigarette reduction and quit attempts up to 12 months post-discharge. Psychiatric inpatients were found to have a high prevalence of tobacco use and heavy smoking, as well as a high level of exposure to smoking in immediate residential environments, and variable support for smoking cessation across support networks. Despite such findings, most smokers were motivated to quit and initially engaged in cessation support. The results of this thesis support previous research in suggesting inpatient psychiatry is a promising setting for the initiation of smoking cessation interventions for persons with a mental illness. However, to enhance the effectiveness and sustainability of such an intervention, future research should consider: 1) strategies to promote environments (psychiatric inpatient, residential and social) conducive to quitting, 2) approaches to increase the consistency of cessation aid use, and 3) options for delivering longer-term smoking cessation support to smokers following discharge from inpatient psychiatry.

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Appendices

Appendix 1: The University of Newcastle Thesis by Publication Guidelines

Office of Graduate Studies Information Sheet Thesis by Publication

A thesis may be submitted in the form of a series of published papers and the additional rules specific to this style of thesis are presented below. **It is important to note that the general rules for a University of Newcastle thesis are also applicable. Please ensure you also refer to** The Rules Governing Research Higher Degrees for the full scope of applicable rules.

Rule 39.1 A thesis by publication will include:

i. a full explanatory overview that links the separate papers and places them in the context of an established body of knowledge;

ii. a literature review;

iii. if detailed data and descriptions of methods are not otherwise given within the separate papers, they must be included in the body of the thesis or as appendices to the thesis;

Rule 39.2 For a thesis by publication:

i. the separate papers provided under sub-clause 39.1(i) must be published, in press or submitted to scholarly media only, i.e. refereed publications classified by current national standards and refereed conference papers, however at least 50% of these papers must have been published. Papers published up to three years prior to enrolment may be included provided they were published in scholarly media and do not represent more than 50% of the total papers;

ii. publications submitted by the candidate for another degree may only be referred to in the thesis literature review;

iii. the number of papers submitted should demonstrate that the body of work meets the requirements of the degree as outlined in the relevant schedule;

iv. the candidate must be the lead author in at least 50% of the papers written in the time of their formal Research Higher Degree candidature. Any published paper of which the candidate is a joint author may only be included in the thesis provided the work done by the candidate is clearly identified. The candidate must include in the thesis a written statement from each co-author attesting to the candidate's contribution to a joint publication included as part of the thesis. These statements

must be endorsed by the Assistant Dean (Research Training).

v. the Assistant Dean (Research Training) may seek the approval of the Dean of Graduate Studies to include a paper that is outside the scope of these rules.

Considerations

• Each discipline area will have different issues to consider in the decision to submit a thesis in the form of a series of published papers.

• It is essential that you discuss your options carefully with your supervisor(s). The thesis by publication must reflect a sustained and cohesive theme, an integrated whole that sits logically in the context of the available literature. Overall the material presented for examination needs to equate to that which would otherwise be presented in the traditional thesis format.

• The review process for some journals is significant resulting in lengthy waiting periods for papers to be accepted and this can delay thesis submission/completion. Time management and selection of journals/publishers is critical. Focusing on publication rather than research may lead to candidates being tempted to publish sections of their work prematurely and missing opportunities to fully capitalize on the significance of the work.

• Consider the thesis from the examiners' view point - if the publications do not have a clear cohesion and the contribution to knowledge is not clearly demonstrated, then the thesis

may attract criticism and be rejected by examiners. The content of the thesis remains a matter of professional judgment for the supervisor(s) and candidate.
• Any published paper of which the candidate is a joint author may only be included in the thesis provided the work done by the candidate is clearly identified. The candidate must include in the thesis a written statement from each co-author attesting to the candidate's contribution to a joint publication included as part of the thesis. The statement/s need to be signed by the Faculty Assistant Dean (Research Training). A sample statement is provided below.

• We strongly advise that you arrange for the signatures from co-authors to be collected as soon as the paper is prepared or submitted for publication rather than trying to collect them at the time of thesis submission.

• There is no minimum or maximum requirement on the number of papers. Of equal, or perhaps more importance than quantity, is the quality of the journals. Please refer to your school or faculty for more specific guidance on the number and length of papers that would normally be expected in your discipline.

Alternative option

As discussed above, you need to consider if your publications will form a sufficient body of cohesive work to meet the requirements of thesis by publication. You may like to consider the other option of including publications within a standard thesis format, either in the body or as an appendix as supported in the rule below.

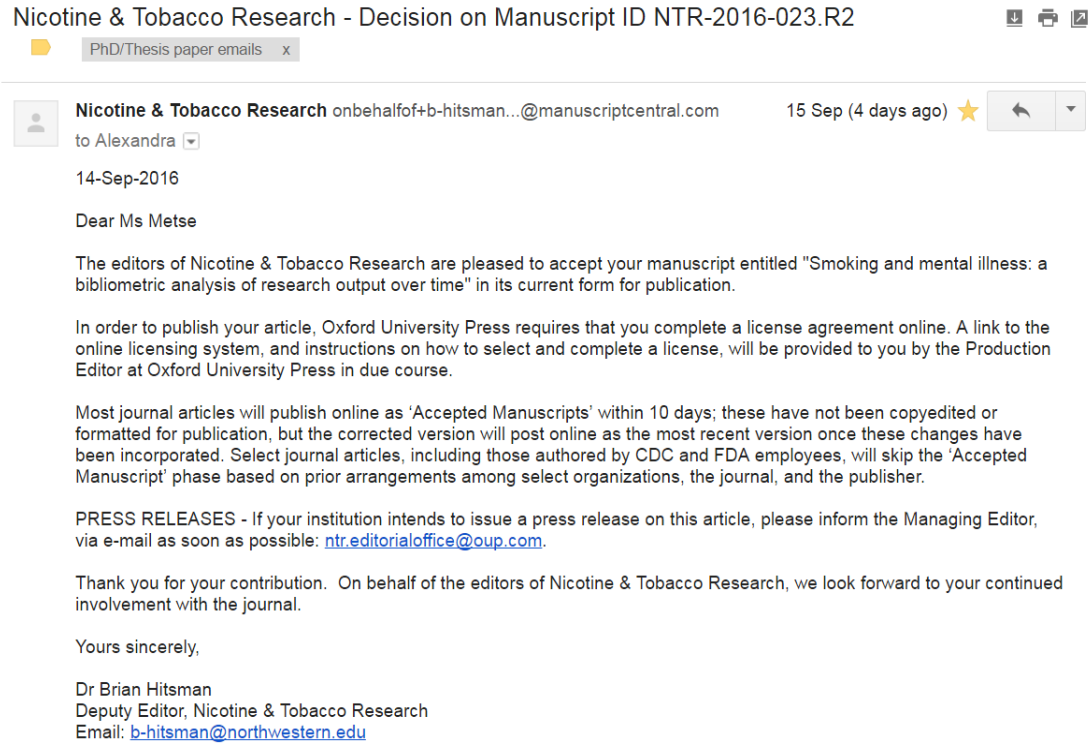
Rule 38.5. A thesis may:

i. Include publications arising as a consequence of the research undertaken for a thesis.

When the candidate includes a co-authored published paper or co-authored scholarly work, or a substantive component of a co-authored published paper or co-authored scholarly work in the body of the thesis, the candidate must include in the thesis a written statement attesting to their contribution to the joint publication. This statement must be signed by the supervisor. A statement is not required when publications are included as an appendix to the thesis.

Appendix 2: Evidence to Support Manuscript Submission and Publication

Appendix 2.1 Acknowledgement of acceptance of Chapter 2 for publication



Nicotine & Tobacco Research - Decision on Manuscript ID NTR-2016-023.R2

PhD/Thesis paper emails x

Nicotine & Tobacco Research onbehalfof+b-hitsman...@manuscriptcentral.com 15 Sep (4 days ago)

to Alexandra

14-Sep-2016

Dear Ms Metse

The editors of Nicotine & Tobacco Research are pleased to accept your manuscript entitled "Smoking and mental illness: a bibliometric analysis of research output over time" in its current form for publication.

In order to publish your article, Oxford University Press requires that you complete a license agreement online. A link to the online licensing system, and instructions on how to select and complete a license, will be provided to you by the Production Editor at Oxford University Press in due course.

Most journal articles will publish online as 'Accepted Manuscripts' within 10 days; these have not been copyedited or formatted for publication, but the corrected version will post online as the most recent version once these changes have been incorporated. Select journal articles, including those authored by CDC and FDA employees, will skip the 'Accepted Manuscript' phase based on prior arrangements among select organizations, the journal, and the publisher.

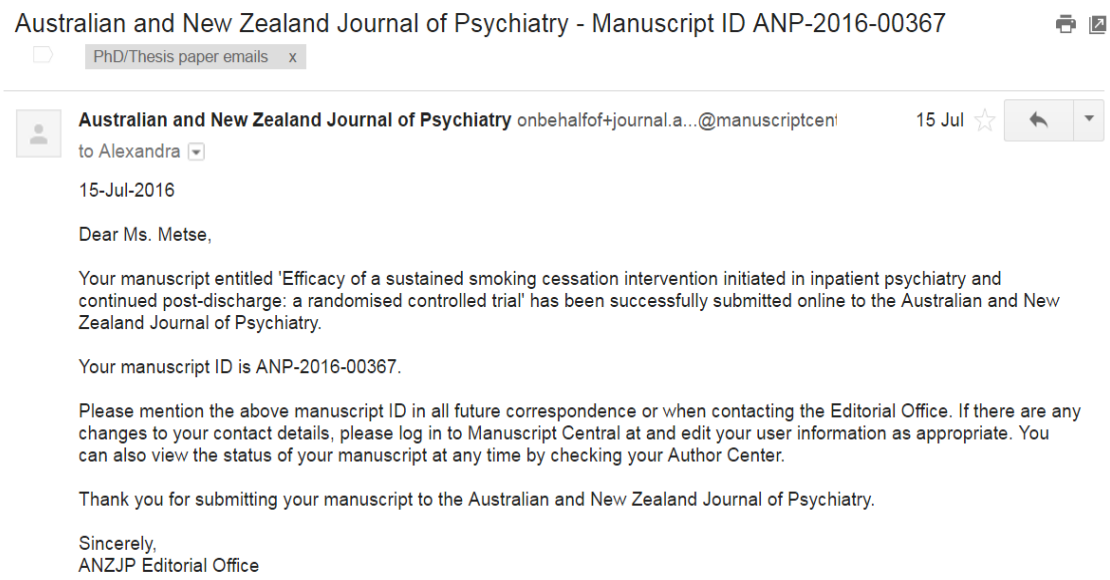
PRESS RELEASES - If your institution intends to issue a press release on this article, please inform the Managing Editor, via e-mail as soon as possible: ntr.editorialoffice@oup.com.

Thank you for your contribution. On behalf of the editors of Nicotine & Tobacco Research, we look forward to your continued involvement with the journal.

Yours sincerely,

Dr Brian Hitsman
Deputy Editor, Nicotine & Tobacco Research
Email: b-hitsman@northwestern.edu

Appendix 2.2 Acknowledgement of Chapter 6 submission



Australian and New Zealand Journal of Psychiatry - Manuscript ID ANP-2016-00367

PhD/Thesis paper emails x

Australian and New Zealand Journal of Psychiatry onbehalfof+journal.a...@manuscriptcent 15 Jul

to Alexandra

15-Jul-2016

Dear Ms. Metse,

Your manuscript entitled 'Efficacy of a sustained smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge: a randomised controlled trial' has been successfully submitted online to the Australian and New Zealand Journal of Psychiatry.

Your manuscript ID is ANP-2016-00367.

Please mention the above manuscript ID in all future correspondence or when contacting the Editorial Office. If there are any changes to your contact details, please log in to Manuscript Central at and edit your user information as appropriate. You can also view the status of your manuscript at any time by checking your Author Center.

Thank you for submitting your manuscript to the Australian and New Zealand Journal of Psychiatry.

Sincerely,
ANZJP Editorial Office

Appendix 3: Supplementary Material for Chapter 2

References for publications included in the review

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Appendix 4: Funding Source for Chapters 2 to 6

In reply please quote: NHMRC Project Grant Application APP1026421

Associate Professor Jennifer Bowman
Faculty of Science and IT
School of Psychology
University Drive
Callaghan NSW Australia 2308

Dear Associate Professor Bowman

NHMRC Project Grant Application: APP1026421
Scientific Title: Evaluating The Efficacy Of An Integrated Smoking Cessation Intervention For Mental Health Patients: A Randomised Controlled Trial

I am pleased to advise that the Minister for Mental Health and Ageing, the Hon Mark Butler MP, has approved funding for your National Health & Medical Research Council (NHMRC) Project Grant to commence in 2012.

This letter provides you with important information about how to accept the offer of funding, the final approved budget within this offer and the Assessment Summary of your application.

Accepting this offer
The formal offer of grant funding for your application will be made under the NHMRC Funding Agreement between the Australian Government and your Administering Institution (the Funding Agreement). Your Administering Institution is responsible for informing you about the requirements of the Funding Agreement, including the amount and duration of funding, conditions or milestones, co-funding and reporting requirements.[1]

Your Institution has until 31 January 2012 to advise NHMRC of your acceptance or the offer may be withdrawn.

Before payments for this grant commence, your Research Administration Office must provide NHMRC with notification that all clearances required for the research to commence, have been obtained. If you wish to accept the offer of funding, or have any queries, please contact your Research Administration Officer (RAO).

[1] A copy of the Funding Agreement is available at http://www.nhmrc.gov.au/grants/administering-grants/nhmrc-funding-agreement

Approved Budget

The approved budget for this Project Grant is $1,442,270.25 over a period of 4 years. This budget was determined by the Grant Review Panel (GRP) during its assessment of the application. You should note that this budget (excluding any equipment component) is provided as a one-line grant and grantees may expend the funds as necessary to support the research project provided that:

1. grant funds are applied only to achieve the approved research objectives of the grant;
2. all expenditure is an accordance with the requirements of the Funding Agreement, noting that use of funding for some purposes is expressly excluded in the Funding Agreement;
3. all expenditure complies with the Guidelines for Direct Research Costs (see funding_policy_2012.pdf
4. funding approved for specific pieces of Equipment is used for this purpose;
5. funding is not used to provide infrastructure that should be provided by the institution; and
6. annual financial reports itemise expenditure against outgoings, including Salaries, Equipment and Direct Research Costs.

We will shortly provide a Schedule to the Funding Agreement, which will include a breakdown of the GRP-agreed budget.

Outcome of the Assessment

The Grant Review Panel (GRP) Assessment Summary provides information about your application's ranking, relative to that of other applications, as assessed by the GRP[2]. Detailed descriptions of the Category Scores are available in the *NHMRC Project Grants Funding Policy for funding commencing in 2012* (the Funding Policy) available at funding_policy_2012.pdf and in the *NHMRC Project Grant Peer Review Guidelines for funding commencing in 2012* available at peer_review_guidelines_nhmrc_2012.pdf .

Participation in NHMRC Peer Review

This year's assessment process for Project Grants involved approaching more than 18,000 members of the research community, in addition to the work of the GRPs. NHMRC is grateful for this enormous contribution and will acknowledge it through our website's peer review honour roll.

NHMRC is now moving towards the opening of the Project Grant round for funding commencing in 2013. To ensure that every application in that round has the best probability of two external assessments, we are reminding everyone that holds an NHMRC grant of their obligation to contribute to the peer review process, as set out in Clause 23.1 of the Funding Agreement, which states:

> "…the Administering Institution must make available to NHMRC, free of charge but subject to NHMRC providing reasonable notice to the Administering Institution, the services of Specified Personnel to provide professional input into reviewing or assessing applications made under a Scheme in the Personnel's area of expertise, as required by NHMRC. Each Specified Person may be required to review at least five (5) of Scheme applications each calendar year."

As a Chief Investigator, we ask that you maintain your CV/Profile information up to date in RGMS to assist our identification of appropriate peer reviewers.

[2] Guidance on interpreting the GRP Assessment Summary is available at http://www.nhmrc.gov.au/grants/outcomes-funding-rounds

Thank you for commitment to Australia's health and medical research system. We wish you success in your future endeavours.

Yours sincerely

[Authorised for Electronic Transmission]

Virginia Hart
Executive Director
Research Programs Branch
17 October 2011

ENC: GRP Assessment Summary

Appendix 5: Ethics Approval for Chapters 3 to 6

Appendix 5.1. Hunter New England Health Human Research Ethics Approval

NSW GOVERNMENT Health
Hunter New England
Local Health District

21 February 2012

A/Professor Jenny Bowman
School of Psychology
University of Newcastle

Dear Professor Bowman,

Re: Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: a randomised controlled trial (11/12/14/4.02)

HNEHREC reference number: 11/12/14/4.02
HREC reference number: HREC/11/HNE/464
SSA reference number: SSA/11/HNE/484

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following sites:

- **Hunter New England Mental Health**

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to the research governance officer.

Yours faithfully

Dr Nicole Gerrand
Research Governance Officer
Hunter New England Local Health District

Hunter New England Research Ethics & Governance Unit
(Locked Bag No 1)
(New Lambton NSW 2305)
Telephone (02) 49214 950 Facsimile (02) 49214 818
Email: hnehrec@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/research_ethics_and_governance_unit

Health
Hunter New England
Local Health District

15 February 2012

A/Professor J Bowman
School of Psychology
University of Newcastle

Dear Professor Bowman,

Re: Smoking cessation for mental health inpatients (11/12/14/4.02)

HNEHREC Reference No: 11/12/14/4.02
NSW HREC Reference No: HREC/11/HNE/464
SSA Reference No: SSA/11/HNE/484

Thank you for submitting the above protocol for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **14 December 2012.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee's Terms of Reference are available from the Hunter New England Local Health District website: http://www.hnehealth.nsw.gov.au/Human_Research_Ethics.

I am pleased to advise that following acceptance under delegated authority of the requested clarifications and revised Information Statement by Dr Nicole Gerrand Manager, Research Ethics & Governance, the Hunter New England Human Research Ethics Committee has granted ethical approval of the above project.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

- For the Information Statement Sheet and Consent Form (Version 3 dated 14 February 2012); and
- For the HNE Mental Health "Smoke Free" Combined QA & Baseline Patient Interview (Version 1 dated 29 November 2011)

For the protocol: **Smoking cessation for mental health inpatients**

Approval has been granted for this study to take place at the following sites:

- **Hunter New England Mental Health Inpatient Facilities:**
  - **Calvary Mater Newcastle**
  - **Maitland**
  - **Taree**
  - **Tamworth**

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Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of **3** years from the date of this letter, after which a renewal application will be required if the protocol has not been completed.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- A report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is **February 2012.** A proforma for the annual report will be sent two weeks prior to the due date.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.
- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.
- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - any serious or unexpected adverse events
        - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee
        - Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Ethics & Governance, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.
        - All other safety reporting should be in accordance with the NHMRC's Safety Monitoring Position Statement – May 2009 available at http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf
        - Serious adverse events are defined as:
            - Causing death, life threatening or serious disability.
            - Cause or prolong hospitalisation.
            - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.
    - Unforeseen events that might affect continued ethical acceptability of the project.

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APPENDICES

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand, as soon as possible.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **11/12/14/4.02** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Associate Professor M Parsons
Chair
Hunter New England Human Research Ethics Committee

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Appendix 5.2. University of Newcastle Human Research Ethics Approval

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Associate Professor Jennifer Bowman**
Cc Co-investigators / Research Students:	**Professor John Wiggers** **Doctor Paula Wye** **Associate Professor Judith Prochaska** **Ms Megan Freund** **Doctor Luke Wolfenden** **Doctor Libby Campbell** **Associate Professor John Allan** **Associate Professor Jill Williams** **Mr Richard Clancy** **Ms Margaret Terry** **Professor Amanda Baker** **Professor David Castle** **Ms Jenny Knight** **Conjoint Associate Professor Dinesh Arya** **Mr Louis Lecathelinais** **Miss Emily Stockings** **Ms Kathryn Martin** **Miss Amber Ryan** **Miss Jane Goodwin** **Ms Joanne Burr** **Ms Maryanne Robinson** **Mrs Ava Read** **Mrs Katrina Quick** **Mrs Kimberley McGovern** **Mrs Carolyn Russ** **Mr David Wilkinson** **Miss Alexandra Metse** **Mrs Sally Plunkett** **Mrs Trish Forsythe** **Mr Alexander Cameron**
Re Protocol:	**NO BUTTS: Support for Health**
Date:	**10-Dec-2012**
Reference No:	**H-2012-0061**

Thank you for your **Variation** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to a variation to the above protocol.

Variation to;
1. Change the title of the project to NO BUTTS: Support for Health;
2. Add the following people to the research team; Ms Kimberley McGovern as co-investigator; Ms Joanne Burr as research assistant; Ms Maryanne Robinson as research assistant; Ms Kathryn Martin as research assistant; Ms Ava Read as research assistant; Ms Carolyn Russ as research assistant; Ms Patricia Forsy as research assistant; Ms Amber Ryan as research assistant; Ms Aishikin Hizam as research assistant; Ms Sally Plunkett-Ward as research assistant; Ms Jane Goodwin as research assistant; Mr Alexander Cameron as research assistant; Mr David Wilkinson as research assistant; Ms Katrina Quick as research assistant; Ms Alexandra Metse as student researcher;
3. Patient Interview (Version 2 dated 6 September 2012;
4. Participant Information Statement (Version 4 dated 6 September 2012);
5. Participant Consent Form (Version 4 dated 6 September 2012); and
6. Unable to Contact Participant letter (Version undated)

Your submission was considered under **Expedited Review of External Approval** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **External HREC Approval Noted** effective **07-Dec-2012**.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Research Services
Research Integrity Unit
HA148, Hunter Building
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 18999
F +61 2 492 17164
Human-Ethics@newcastle.edu.au

RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
NHMRC (National Health & Medical Research Council)/Project Grant(**)	Evaluating the efficacy of an integrated smoking cessation intervention for mental health patients: a randomised controlled trial	Bowman Jennifer,	G1100130

Appendix 6: Information Statement and Consent Form for Chapters 5 and 6

Appendix 6.1: Information Statement

Assoc Prof Jenny Bowman
School of Psychology
Faculty of Science and IT
University of Newcastle
ph 49215958 fax 49216980
Email jenny.bowman@newcastle.edu.au

Information Statement for the Research Project:

'No Butts' Support for Health

Document version no. 4 Date 06/09/12

You are invited to participate in the research project identified above which is being conducted by Associate Professor Jenny Bowman at the University of Newcastle and a number of other researchers: Associate Professor John Wiggers, Dr Paula Wye, Associate Professor Judith Prochaska, Dr Megan Freund, Dr Luke Wolfenden, and Dr Elizabeth Campbell.

Why is the research being done?

The purpose of the research is to identify strategies which are effective in assisting people to reduce or cease their tobacco smoking. We believe that an approach that links mental health services with supports in the community, such as the Quitline, is likely to help. This research will help test whether this is the case.

Who can participate in the research?

We are seeking to recruit people who are mental health inpatients of the Mater Hospital, Maitland Hospital, Taree Hospital and Tamworth Hospital who are aged 18 years and over, who identify themselves as smokers at the time of admission.

What choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. The doctors and treating clinicians here at the hospital will not be informed as to whether you have decided to take part or not.

If you do decide to participate but later decide to withdraw, you can do so at any time without giving a reason. In that event, any information collected from you or about you would be destroyed.

What would you be asked to do?

If you agree to participate, you will be asked to do six things:

1. Take part in a brief interview and questionnaire survey here today, about your smoking and your mental well-being, eg. 'How many cigarettes do you smoke per day?', 'In the last 12 months, have you tried to quit smoking?' and 'In the last four (4) weeks, how often did you feel depressed?'. This will take about 20 minutes.
2. Agree to us accessing your medical records which have already been collected by the hospital: smoking status, psychiatric diagnoses, medication use, and use of Nicotine Replacement Therapy (NRT) and any nicotine withdrawal symptoms experienced as an inpatient.
3. Agree to being assigned, by chance, to either an intervention group (where as part of the research we will offer a number of options to assist you in addressing your smoking after discharge from hospital), or a Control group (where this does not happen). A control group is required to test whether the intervention has any effect on smoking behaviour. The options which will be offered to you if assigned to the Smoking Intervention group include: referral to the Quitline, referral to your GP, extended provision of NRT, and telephone counselling support.
4. Agree to us contacting you again – by telephone - in 1 month, 6 months, and 12 months following your discharge to ask some similar questions about your smoking and strategies you may have tried to help you reduce or cease smoking.
5. In order to help us locate you at the project follow-up points, a) agree to us seeking contact information for you from Hunter New England health services and b) provide home address and telephone details for family members, friends, or other agencies you would be happy for us to phone or post a letter to in order to up-date contact information for you. We would contact these people or services only if we have difficulty locating you for project follow-up, and seek only your current phone number and address details which would be used by the research team to contact you.
6. Agree to providing a breath sample if selected to do so at the time of a follow-up phone call to allow us to measure the amount of tobacco you have smoked in the past 24 hours. To collect this breath sample, members of the research team will arrange to meet you at a healthcare service, or other public facility convenient to you. If this is not possible, it may be arranged to visit you at home. Not all participants will be selected to provide a breath sample, and you will be informed at the time of each follow-up call if you have been selected to do so on that occasion.

What are the risks and benefits of participating?

There are no known risks to you in taking part in this research.

While there may be no direct benefits for you personally in taking part, your participation in this research may ultimately help to improve the assistance available to people with mental health conditions for addressing their tobacco smoking. If you are assigned at random to the Smoking Intervention group for this research project, you will be offered a number of options for support as mentioned above in point 3.

How will your privacy be protected?

The information you provide will be treated with strictest confidence.

The research requires that we collect some personal information, including your name and contact details. This is so that we can obtain some information already collected by the hospital (mentioned above), and also so that we can contact you for follow-up telephone surveys. Your personal information will not be used for any other purpose. Your personal information and all other study information (including questionnaires) will be kept in a locked cabinet in the project research office at the University.

Interview and questionnaire information, and data entered from them onto computer, will be retained for a period of 5 years at the University following the completion of the study. After this time the information will be destroyed.

Will there be any costs associated with participation?

There is no financial cost associated with participation.

How will the information collected be used?

Individual participants will not be identified in any reports arising from this project. The results may be reported in a paper submitted for publication in a scientific journal, and also possibly at an appropriate scientific conference. They may also form part of a student's research thesis.

What do you need to do to participate?

Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact the researcher.

If you would like to participate, please read and sign the consent form attached.

Further information

If you would like further information please contact Associate Professor Jenny Bowman at the University of Newcastle (ph 49215958, email jenny.bowman@newcastle.edu.au) or the No Butts project team (ph 49217781).

Thank you for considering this invitation.

Principal Investigators

Assoc Prof Jenny Bowman
Chief Investigator

Dr Paula Wye

Prof John Wiggers

Dr Megan Freund

Assoc Prof Judith Prochaska

Dr Luke Wolfenden

Dr Elizabeth Campbell

Complaints about this research

This project has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Health, Ref No. 11/12/14/4.02.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics and Governance, Hunter New England Human Research Ethics Committee, Hunter New England Health, Locked bag 1, New Lambton NSW 2305, telephone 02 49214950, email hnehrec@hnehealth.nsw.gov.au

Appendix 6.2: Consent Form

Assoc Prof Jenny Bowman
School of Psychology
Faculty of Science and IT
University of Newcastle
ph 49215958 fax 49216980
Email jenny.bowman@newcastle.edu.au

Consent Form for the Research Project:

'No Butts' Support for Health
Document version no.4 Date 06/09/12

This research project is being conducted by Associate Professor Jenny Bowman at the University of Newcastle and a number of other researchers.

Please read the statements below, and add your name, signature and date at the bottom if you are willing to take part.

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statements, a copy of which I have retained.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to:

1. Take part in an interview / survey here today, about smoking and my psychological well-being
2. Allow the researchers access to information already collected about me by the admitting hospital (being smoking status, psychiatric diagnoses, medication use, and use of NRT and nicotine withdrawal symptoms experienced while I have been an inpatient)
3. Be assigned, by chance, to either a Supported Care intervention group (where in addition to standard hospital smoking care, I would be provided with encouragement and support to address smoking following discharge) or a Usual Care control group (where I would receive standard hospital smoking care, including brief smoking advice and provision of, and advice about nicotine replacement therapy)
4. Be contacted, by telephone – in 1 month, 6 months and 12 months time - for the collection of follow-up information about smoking and any strategies I may have used to reduce or cease smoking.
5. Provide contact details for family members, friends, or other agencies, and give permission for these bodies and local health care services to release my contact information (phone numbers and address only) to members of the research team, for them to use in contacting me for project follow-up phone calls.
6. Provide a breath sample, if I am selected to do so at the time of a follow-up call, to measure the amount of tobacco I have smoked in the last 24 hours,

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

Print Name:……

Signature:…… Date:……..