Exploring Retention in a Randomised Controlled Smoking Intervention Trial for Psychiatric Inpatients

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Submitted in partial fulfilment for the degree of Master of Clinical Psychology at the School of Psychology at the University of Newcastle, Australia

January, 2017

Declarations

Statement of Originality

This 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 this copy of my thesis, when deposited in the University Library, being made available for loan and photocopying subject to the provision of the Copyright Act 1968.

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Acknowledgements

First and foremost, special thanks to my primary supervisor, Associate Professor Jenny Bowman for giving me this opportunity to continue on the 'No Butts' project that I was so fortunate to be involved with since 2012. Her knowledge of smoking at a population level and research is outstanding, and I consider myself lucky to have had the opportunity to learn from her expertise. I am truly grateful for your guidance and willingness to be involved in this project even with your busy schedule.

To my secondary supervisor, Alexandra Metse, I am tremendously grateful for your words of encouragement, guidance and continued offers of support through some very trying times during the clinical program. Our mutual passion for the 'No Butts' project has truly made this an enjoyable experience (an emotion rarely expressed by students in my position).

I would also like to thank all of the teaching, administrative, and support staff in the School of Psychology at the University of Newcastle. I have thoroughly enjoyed completing my degree, which would not have been possible without your assistance, expertise and knowledge. My appreciation also goes to Megan Valentine for her help on some complex statistical analysis.

A special mention goes to my family, Ramdulari Abdullah, Noor Hizam Yahaya and Nur Azleen Liyana who has always been there for me. I am forever thankful for their understanding when I am too tired to Skype, for their words of advice, voice of reason and continuous support for me to achieve my dream to be a Clinical Psychologist. Thank you for relentlessly believing in me and never once, questioning my ability to make it this far.

I offer my appreciation to all of those dear to me; my friends and loved ones. To my friends, thanks for listening to my persistent babble, your patience and cooked meals during those challenging times. Last, but certainly not least, I would like to thank every one of my course mate associated with the clinical program. I am glad to have met, shared this journey and formed lifelong friendship with each one of you.

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Structured Abstract

Scope

Low participant retention rates represent a common challenge in smoking cessation trials and detract from the ultimate validity of study findings, yet there has been little previous research examining the factors associated with retention in such trials, and particularly so for smokers with a mental illness. The first section of this thesis presents a critical review of the importance of reporting retention rate, as well as the rates and associated factors in participant retention for smokers both from the general population and those with a mental illness. The critical review also includes an overview of a randomised controlled trial (RCT) titled the 'No Butts' Project. The second section of this thesis presents a manuscript detailing an original research study undertaken within the 'No Butts' Project, a brief description of which is outlined below.

Purpose

The present research aimed to report the retention rates achieved in the 'No Butts' trial that assessed the efficacy of integrating psychiatric inpatient and community based smoking cessation supports on abstinence rates at 1-, 6- and 12-month follow-ups for both the control and intervention group. The current study also aimed to examine the relationship between follow-up time and participant retention, using the 'No Butts' trial. The final aim of the study undertaken and reported on for this thesis was to explore the potential determinants (e.g., participants clinical, demographic and baseline characteristics of smoking) of completing the 12-month follow-up assessment in the "No Butts' project.

Methodology

The 740 participants, recruited across four mental health facilities in Australia, were randomly allocated to either a Control or Intervention group (Normal or Supported Care, respectively). Outcome data was sought from all participants, via computer assisted telephone interview, at 1-month, 6-months and 12-months post discharge. Descriptive statistics were used to report on retention rates for the Supported and Normal Care groups. Data was analysed using McNemar tests, logistic regressions, chi-square tests, and generalised estimating equations.

Results

Overall, retention rates at 1-month, 6-months and 12-months were 63%, 56% and 60% respectively, and did not differ significantly by treatment group. However specifically to males, more participants were retained at 1- month, than at 6-months and 12-months. In general, the odds of being retained at 12-months were higher for participants who had participated in preceding follow-ups. Retention was also greater for smokers who were older, did not identify as Aboriginal/Torres Strait Islander, identified as weekly or irregular smokers at baseline and had a higher level of education.

Conclusions

The results of the present study contribute to the literature on participant retention in smoking cessation trials involving persons with a mental illness. It also provides clinically relevant information that could be applied to improve retention by identifying potential barriers to participant retention at long-term follow-up in a sample of smokers with mental illness.

Keywords: retention, smoking cessation, randomised controlled trial, mental illness

Critical Literature Review

A large proportion of the morbidity and mortality experienced in high income countries including Australia is potentially preventable (Australian Institute of Health and Welfare [AIHW], 2016), with smoking the leading health risk behaviour associated with such burden (Australian Bureau of Statistics [ABS], 2009; AIHW, 2016; Hosseinpoor, Oarker, d'Espaignet & Chatterji, 2011; Lim et al., 2012). In Australia in 2011 it was estimated that 80% and 75% of lung cancer and chronic obstructive pulmonary disease burden respectively, was attributable to tobacco smoking (AIHW, 2016). Currently in Australia, 14.7% of the general population are smokers (Greenhalgh, Bayly & Winstandley, 2015), with approximately one in seven people above the age of 17 smoking daily (ABS, 2015). Significant progress has been made in reducing the prevalence of tobacco use as this figure has halved over the past three decades (AIHW, 2011). Such a decreasing trend in smoking prevalence over time suggests that tobacco control initiatives (AIHW, 2005; Thomas et al., 2008) have been effective in reducing smoking uptake and/or promoting cessation in the general population (Anderson, Jorenby, Scott & Fiore, 2002; West, McNeill, & Raw, 2000).

Smoking and Mental Illness

Individuals with a mental illness are two to three times more likely to smoke than those in the general population (Access Economics, 2007; Lasser et al., 2000). The prevalence of smoking for this group has been estimated to be between 33% and 90% (Lawrence, Mitrou & Zubrick, 2009), with certain subgroups including those with schizophrenia reported to have among the highest smoking rates (De Leon & Diaz, 2005). In contrast to the decreasing trend in smoking prevalence across recent decades evident for smokers generally, the prevalence of smoking has remained

unchanged for this group (Morgan et al., 2010; Szatkowski & McNeill, 2015). Additionally, compared to smokers generally, smokers with a mental illness smoke a greater number of cigarettes per day (Ashton, Miller, Bowden & Bertossa, 2010; Baker et al., 2007), are more nicotine dependent (Filia et al., 2014), and despite being equally motivated to quit (Siru, Hulse, & Tait, 2010; Solty, Crockford, White & Currie, 2009), find it more challenging to do so successfully (Bowden, Miller & Hiller, 2011; De Leon & Diaz, 2005; Lasser et al, 2000; Le Cook et al.,2014). Consequently, this group experience disproportionate tobacco-related morbidity and mortality (Colton & Manderscheid, 2006; Lancet, 2013), including a reduced life expectancy of up to 25 years (Kessler, Chiu, Demler, Merikangas & Walters, 2005). The unchanging prevalence of smoking among smokers with a mental illness may suggest that tobacco control initiatives have been less effective for this group (Le Cook et al., 2014) and that targeted and tailored interventions are required.

While the amount of research focussing on smoking among persons with a mental illness has increased over the past two decades (Metse et al., 2017), the proportion aiming to assess the efficacy or effectiveness of interventions to reduce smoking prevalence has not changed (Metse et al., 2017). The limited available evidence regarding the efficacy of smoking cessation treatments for persons with a mental illness, however, suggests such interventions can be efficacious for this group (Banham & Gilbody, 2010; Ragg & Ahmed, 2008; Prochaska, 2011). For instance, in a systematic review of the effectiveness of smoking cessation interventions on reducing or quitting smoking involving adults with severe mental illness in both inpatient and outpatient settings; it was found that integrated smoking cessation interventions, those that comprise both psychosocial and pharmacotherapeutic cessation strategies, significantly increase the odds of cessation among smokers with

psychotic diagnoses, including bipolar disorder, delusional disorder, schizophrenia and schizoaffective disorder (Banham & Gilbody, 2010).

Additionally, a randomised control trial (RCT) involving smokers in treatment for depression found that integrated medication, motivational feedback and psychological intervention were effective for those smokers to be abstinent (Hall et al., 2006). Similarly, multimodal smoking cessation interventions incorporating nicotine replacement therapy (NRT) and weekly group cognitive behaviour therapy (CBT) have also been found to be effective for smoking reduction and cessation in depression (Gierisch, Bastian, Calhoun, McDuffie & Williams, 2012) and schizophrenia (Evins et al., 2007). Multimodal approaches comprising a combination of pharmacological and cognitive-behavioural interventions work for both individuals with and without mental illness (Banham & Gillbody, 2010; Stead, Kilpillai, Fanshawe & Lancaster, 2016). Further, such multimodal approaches are consistent with best practice guidelines (Stead et al., 2016). Individuals with mental illness require more intensive support to quit compared to individuals without mental illness (Banham & Gillbody, 2010).

This review of the literature will seek to examine the importance of comprehensively reporting retention rate in clinical trials, by exploring The Consolidated Standards of Reporting Trials (CONSORT) statement. It will discuss the retention rates and factors associated with retention reported in past research involving smokers from the general population and smokers with a mental illness, and critique related research. A brief discussion of a RCT that has been undertaken within the context of a smoking cessation trial will follow, concluding with the aims of the present study.

Importance of Comprehensively Reporting Outcomes of Clinical Trials, Including Retention Rate

Comprehensive reporting of clinical trials ensures outcomes are interpreted in the context of methodological considerations. The CONSORT statement, which has been endorsed by an increasing number of journals (Altman, 1996, Huston & Hoey, 1996) and organisations (Devereaux, Manns, Ghali, Wuan & Guyatt, 2002), was first developed in 1996 by the CONSORT Group and was updated in 2001 and 2010 to improve the quality of reporting RCTs (Moher et al., 2010). The document, outlining a minimum set of recommendations for reporting outcomes of RCTs suggests, to improve the quality of research used in decision making in health care settings, it is essential that reports are clear, complete and transparent (Moher et al., 2010). To ensure this is achieved, the statement comprises a 25-item checklist of key details that must be reported, including baseline demographics or characteristics of participants as well as the rate of participant retention. The inclusion of such items aims to avoid biased estimates of treatment effects, as when participants retained differ from those who are not, the study outcomes are unlikely to be representative of all participants in the study (Robinson Dennison, Wayman, Pronovost, & Needham, 2007). In regards to retention specifically, it is important that studies comment on the retention rates in all conditions, as having equal numbers across groups is a key evaluative strength of RCTs (Dumville, Torgerson & Hewitt, 2006).

A systematic review of 87 longitudinal studies undertaken prior to publication of the CONSORT statement in 1996 found that insufficient attention had been provided by researchers to the issue of retention, with 38 of the studies failing to mention retention at all (Goodman & Blum, 1996). The review also found that the majority of the studies that did consider retention did so superficially: only 14 of 49

studies for instance compared the sociodemographic characteristics of those who were retained and not retained. Further, despite the need for researchers to be more transparent about incomplete retention (i.e., presenting reasons for low retention and recommending strategies to maximise retention) (Dumville et al., 2006; Marcellus, 2004), a review of 270 RCTs published in five leading general and internal medicine journals (Annals of Internal Medicine, The British Medical Journal, The Journal of the American Medical Association, The Lancet and The New England Journal of Medicine) post- CONSORT in 1998 found that reporting the figures for participants not retained was generally incomplete (Egger, Juni & Bartlett, 2001). Approximately a quarter of the studies did not report on the number of participants who were not retained for analyses, as suggested by the CONSORT statement.

A longitudinal study undertaken by Wolke et al. (2009) in the United Kingdom followed a sample of 13, 988 children with behavioural disorders. Statistical analyses (pearson correlation and linear regression) were used to explore the impact of low participant retention and found that low participant retention may result in selection biases and inaccurate conclusions being drawn from the study. The result indicated that if those with high disruptive behaviour disorder were not retained in the final sample, the internal and external validity were weakened and the relationship between the independent and dependent variable was systematically underestimated (Wolke et al., 2009). Likewise, Dumville et al. (2006) agreed in an analysis and comment piece that studies with low participant retention rates could introduce systematic bias by not encapsulating the general intended population, instead capturing a specific subsample; hence reducing the generalisability (David, Alati, Ware & Kinner, 2013; Vist et al., 2005).

Complete participant retention is generally unattainable in clinical trials, and optimising retention is often challenging (Leeman et al., 2006; Moher et al., 2010). A review of health care interventions published in six major medicine and surgery journals (Annals of Internal Medicine, Annals of Surgery, The British Medical Journal, The Journal of the American Medical Association, The Lancet, New England Journal of Medicine) involving 133 RCTs published in 2004 (Toerien et al., 2009), found that almost half of the trials (64 RCTs) that reported a sample size calculation failed to retain adequate numbers at outcome assessment (Severi et al., 2011; Toerien et al., 2009). Low retention can prolong recruitment and increase financial burden (Butler et al., 2013; Leon, Demirtas & Hedeker, 2007) due to researchers attempting to recruit more participants to replace those who were not retained. Further, incomplete retention results in issues when analysing and interpreting data, including decreased statistical power (Dumville et al., 2006; Shadish, Cook, Campbell, 2002), decreased validity (Robinson et al., 2007; Rothman, Greenland & Lash, 2008) and reduced generalisability of study outcomes (Lamers et al., 2012; Marcellus, 2004; Vist et al., 2005). More specifically, this occurs when a large sample of participants with a particular profile assigned to one group are not retained, making the two groups no longer comparable on baseline characteristics and consequently these group differences have the potential to confound the effects of the intervention (Sidani, 2015; Valentine & McHugh, 2007).

Therefore, given the significant impact of incomplete retention on study findings, it may be of benefit for the CONSORT statement to include recommendation for researchers to report retention rates between groups, and when retention falls below a certain proportion, examine associated characteristics (Dettori, 2011; Goldberg, Chastang, Zins, Niedhammer, & Leclerc, 2006).

Sacket et al. (1997, as cited in Dettori, 2011) suggested that retention rates below 80% pose serious threats to study validity. Such a finding may be considered if requirements to report on factors associated with retention were recognised and endorsed by CONSORT.

Participant Retention: Rates and Associated Factors

Smokers from the general population. In a systematic review exploring trials reporting attrition rates and identifying factors that influence low retention of adult smokers participating in smoking cessation intervention studies, only eight out of the 189 studies explored characteristics of participants not retained (Belita & Sidani, 2015). The inclusion criteria were studies published between 1980 and 2015; experimental or quasi-experimental design; pharmacological, educational, or behavioural intervention; adult smokers irrespective of their mental health issues; examination of attrition rate; and exploration of factors associated with incomplete retention and/or reasons given by participants for withdrawing. The overall rates of participant retention between studies ranged from 23% to 89%, with five out of the eight studies achieving a retention rate below 65% including those that targeted African-American smokers, smokers with depressive symptoms, and female smokers (Belita & Sidani, 2015). Thus, similar to general health care research that has retention rates ranging between 59% and 99% (Robinson et al., 2007); study retention rates in smoking cessation trials vary significantly according to the group being studied and are often not reported (Curtin, Brown & Sales, 2000).

Smoking related sociodemographic, behavioural and health-related factors have been associated with the rate of lower retention in trials involving smokers generally (Belita & Sidani, 2015). The demographic characteristics typically investigated are age, education, gender, income, employment status, marital status

and race (Belita & Sidani, 2015). However, there is inconsistency on two levels with the influence of these characteristics on retention rates. Specifically, some studies have found that demographic characteristics such as gender, age, education, employment and income to have influenced participant retention, while some have not and when such characteristics have been found to be associated, the direction of association is not always consistent (Belita & Sidani, 2015).

For example, in a review by Belita and Sidani (2015), out of five studies that investigated gender: two studies found that males had lower retention rates compared to females (Ahluwalia et al., 2002; Woods et al., 2002) and a single study found that females had lower retention rates than males (Curtin et al., 2000). Meanwhile, younger age, lower education (Ahluwalia et al., 2002; Leeman et al., 2006), full-time employment (Woods et al., 2002) and lower income (Nevid, Javier, & Moulton, 1996) have been associated with lower rates of participant retention. Conversely, other studies found no relationship between participant retention and age (Brouwer & Pomerleau, 2000; Copeland, Martin, Gieselman, Rash, & Kendzor, 2006; Curtin et al., 2000; Nevid et al., 1996), gender (Nevid et al., 1996), education levels (Brouwer & Pomerleau, 2000; Nevid et al., 1996), income (Woods et al., 2002) and employment status (Ahluwalia et al., 2002; MacPherson, Stipelman, Duplinsky, Brown, & Lejeuz, 2008). In accordance with such findings, another United States Midwestern study that explored strategies to retain college smokers in a smoking cessation trial that reported a 79% retention rate at the 6-month follow-up assessment; found no evidence that participant characteristics were significantly associated with retention (Davidson et al., 2010).

Smoking characteristics have also been associated with lower participant retention in trials involving general population smokers but again not consistent

patterns are observed. Low motivation to quit and higher nicotine dependence have been associated with a lower rate of participant retention in trials involving African-American participants (Belita & Sidani, 2015). By contrast, daily number of cigarettes smoked (Brouwer & Pomerleau, 2000; Leeman et al., 2006) and duration of smoking (Ahluwalia et al., 2002; Copeland et al., 2006; Curtin et al., 2000; MacPherson et al., 2008; Nevid et al., 1996; Woods et al., 2002) did not influence the rate of retention in a number of other studies involving various subgroups of smokers. In two studies involving female smokers with self-reported weight concerns, a lower level of nicotine dependence was found to increase the likelihood of participant retention (Brouwer & Pomerleau, 2000; Copeland et al., 2006). However, no other studies have suggested this relationship exists for other groups of smokers.

A recent study examined the factors associated with retention in an Australian RCT of smoking cessation in low-socioeconomic status (low-SES) smokers (Courtney et al., 2017). The study consisted of 1047 low-SES smokers that were interested in quitting smoking, with data collection occurring via telephone interviews conducted at baseline, at 2-months and 8-months follow-up. The study focused on exploring the association between participants' sociodemographic, mental and physical health, smoking-related behaviour and substance use, and recruitment sources on retention rate at the 8-month follow-up. The study found that increasing age, higher education attainment, higher motivation to quit and more recent quit attempts were related to higher participant retention at 8-months.

Smokers with a mental illness. Systematic review evidence has highlighted that persons with a mental illness are particularly difficult to retain in smoking cessation trials (Bonevski et al., 2014). Despite this, only some smoking cessation

studies with this population group state retention rates, few report characteristics of those retained, and whether they differ between study conditions. For example, a study that focused on 130 smokers with a non-acute psychotic disorder and who were interested in quitting (Baker et al., 2006) defined participants retained as those who completed their follow-up evaluations at 15-weeks, 6-months, and 12-months. The overall retention rates were 93% at 15-weeks, 95% at 6-months and 80% at 12-months with both groups having similar retention rates. However, the study did not explore the factors associated with the high retention rate at the 12-month follow up (Baker et al., 2006; Baker et al., 2007).

Prochaska, Hall, Delucchi and Hall (2014) undertook a RCT that aimed to assess the efficacy of a 'stage of change' based integrated tobacco cessation intervention delivered to smokers in the United States following discharge from inpatient psychiatry. Retention rates of over 80% were reported at each of the follow-up time points (3-, 6-, 12- and 18- months post discharge). However, the sociodemographic and clinical characteristics of the 80% of participants retained at the 12-month follow-up were not reported. The study identified that baseline stage of change was associated with participant retention at 18-months follow-up with participants who were in the contemplation stage instead of the pre-contemplation and preparation stages, being more likely to be retained. Other relevant studies that have reported retention rates without exploring systematic characteristic biases (i.e., merely stating retention rates at the final follow-up point) include Shmueli, Fletcher, Hall, Hall and Prochaska (2008) and Williams et al. (2010). The absence of an examination of participant characteristics that may have been related to retention hinders the opportunity to explore and comment on the nature of potential biases or identify strategies that may improve retention.

A single study was identified that comprehensively assessed factors that influenced participant retention in smoking cessation trials exclusively involving persons with a mental illness. Among 177 participants who had previously been diagnosed with major depressive disorder; gender, age, education attainment, income and socioeconomic status were found to not be associated with retention, whereas fewer cigarettes smoked per day and lower level of depressive symptoms were factors associated with higher retention (Curtin et al., 2000). By contrast, two studies that investigated participants' level of depressive symptoms in their study through depressive screening measures found that participants' depressive symptoms did not influence retention rates (Ahluwalia et al., 2002; Brouwer & Pomerleau, 2000). Similarly, in a study involving 53 African-American smokers with depressive symptoms (MacPherson et al., 2008) no relationship was found between participants' demographic and clinical factors and the rate of participant retention.

The limited research examining factors associated with retention in smoking cessation trials involving persons with a mental illness has yielded equivocal findings. The contrasting results related to the impact of depressive symptoms on retention rates found by Curtin et al. (2000) compared to Ahluwalia et al. (2002) and Brouwer and Pomerleau (2000) may be associated with a variety of factors, such as the: retention time period investigated, characteristics of the population targeted and type of smoking cessation intervention under evaluation. In addition, with the exception of studies exploring participants' depressive symptoms using different measures (Ahluwalia et al., 2002; Brouwer & Pomerleau, 2000), the set of factors that were explored in the current literature on retention rate in smoking cessation trials differed across studies. Therefore, there are only a limited number of studies investigating the same factors associated with retention rate.

Further, all of the research exploring factors associated with retention has been limited to studies undertaken in the United States, indicating that there is a gap in research worldwide (Kim, Hickman, Gali, Orozco & Prochaska, 2014). Unfortunately, there is no research in Australia that explicitly examines the barriers to retention for smokers with a mental health illness (Bonevski et al., 2014). In fact, there is a general lack of Australian research on smokers with mental illness; with a systematic review conducted by Bryant, Bonevski, Paul, McElduff , and Attia (2011) involving 32 studies between 1997 and 2010, finding only one Australian study that focused on smokers with mental health disorders (Baker et al., 2006).

Smokers with mental health illness are understudied, particularly in terms of retention rates and associated factors in cessation trials even though they face some unique challenges that may reduce the likelihood of study retention. For example, persons with a mental illness also have characteristics that make follow-up more challenging; including housing instability and intermittent telephone access (Bonevski et al., 2014). Moreover, smokers with mental health disorders tend to have higher nicotine dependence (Forman-Hoffman, Hedden, Glashen, Davies & Colpe, 2016; Williams, Steinberg, Griffiths & Cooperman, 2013), more smokers in their social network (Access Economics, 2007), and higher levels of daily stress (Morisano, Bacher, Audrain-McGovern & George, 2009); however the association between these factors and retention are yet to be examined. Given the high smoking rates among smokers with mental illness, there is a need to explore participant retention in intervention trials targeting this group. Exploring factors associated with retention is important to better understand the relationship between participant demographics and smoking characteristics, retention related variables, and to

facilitate the development of effective strategies to improve participant retention in smoking cessation trials.

The study undertaken and reported on for this thesis describes follow-up rates and explores factors associated with retention of smokers with a mental illness, and has been undertaken within the context of a smoking cessation trial; 'No Butts'. Specifically, the present study focuses on participants enrolled in a trial of a four-month integrated smoking intervention offered to smokers immediately following discharge from inpatient psychiatry. Follow-up data was collected at 1-, 6-and 12-months post discharge.

Overview of the 'No Butts' Project

To address smoking among persons with a mental illness, research assessing the effectiveness of large scale, population level smoking cessation interventions tailored to persons with mental illness is required. Hospitals have been identified as an opportune setting to initiate smoking cessation support (Stockings et al., 2014), however evidence suggests that support needs to be continued post discharge in order to maximise benefits in terms of cessation (Bowman & Stockings, 2012; Shmueli et al., 2008). A RCT, titled the 'No Butts' project, adopted this approach and assessed the efficacy of integrating inpatient smoking cessation care with post discharge support (Metse et al., 2014). Seven hundred and fifty four patients were recruited across four mental health facilities in New South Wales, Australia. To be eligible, patients must have been a current smoker, at least 18 years of age, able to understand the research and give informed consent, and be willing to provide contact details. All inpatients who met these criteria were eligible, regardless of motivation/readiness to quit or level of nicotine dependence.

Consenting participants were then randomly allocated to one of two groups (Normal Care or Supported Care). 'Normal Care' participants received hospital treatment as usual, whilst 'Supported Care' participants also received a brief motivational interview and a package of self-help material for abstaining from smoking whilst in hospital, and, a referral to Quitline, 12-weeks free combination NRT, and 16-weeks of motivational telephone-based counselling following discharge. To evaluate the efficacy of integrating inpatient and post discharge smoking cessation support on abstinence rates, follow-up assessments took place at 1-, 6- and 12 months post discharge, via computer-assisted telephone interview (CATI). The inclusion of a 12-month follow-up point is beneficial as it is the 'gold-standard' for assessment of effectiveness for smoking cessation intervention trials (West, Hajek, Stead & Stapleton, 2005).

Aims of the Current Study

Comprehensive reporting of retention and associated factors is required to ensure trial outcomes are considered in the context of potential systematic biases and reduced generalisability. A limited number of studies have explored factors associated with retention in smoking cessation trials involving persons with a mental illness, particularly in the Australian context. The present study aimed to: (1) report the retention rates achieved in the 'No Butts' project at 1-, 6- and 12-month follow-ups for both the control and intervention group; (2) examine the relationship between follow-up time and participant retention; (3) and explore potential determinants (e.g., participant demographics, clinical and baseline characteristics of smoking) of completing the 12-month follow-up assessment. Notably, this study involved participants who may or may not have been interested in quitting, and as a result could assess whether motivation had an impact on retention.

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Manuscript formatted to be submitted to American Psychological Association Journal

Exploring Retention in a Randomised Controlled Smoking Intervention Trial for Psychiatric Inpatients

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Word Count: 6422 words

Abstract

Low participant retention rates represent a common challenge in smoking cessation trials and detract from the ultimate validity of study findings, yet there has been little previous research examining the factors associated with retention, particularly so for smokers with a mental illness. This study examined the retention of smokers with a mental illness in a randomised controlled trial that assessed the efficacy of integrating psychiatric inpatient and community based smoking cessation supports on abstinence rates. Seven hundred and forty participants were included in this study: 367 and 373 were allocated to the control and intervention group, respectively. Outcome data were sought from all participants at 1-month, 6-months and 12-months post-discharge. Generalised estimating equations analysis was used to explore the clinical and socio-demographic factors associated with retention at 12-months. Overall, retention rates at 1-, 6- and 12-months were 63%, 56% and 60%, respectively, and did not differ significantly by treatment group. However, specifically to males; more participants were retained at 1-month, than at 6- and 12-months. In general, the odds of being retained at 12-months were higher for participants who had participated in preceding follow-ups. Retention was also greater for smokers who were older, did not identify as Aboriginal/Torres Strait Islander, identified as weekly or irregular smokers at baseline and had a higher level of education. The present study contributes to the literature on participant retention in smoking cessation trials and may assist to address potential barriers to participant retention at long-term follow-up in a sample of persons with mental illness.

Keywords: retention, smoking cessation, randomised controlled trial, mental illness

Exploring Retention in a Randomised Controlled Smoking Intervention Trial for Psychiatric Inpatients

Tobacco smoking is the leading health risk behaviour associated with preventable chronic disease and death in high income countries, including Australia (Australian Bureau of Statistics, 2009; Australian Institute of Health and Welfare [AIHW], 2016; Hosseinpoor, Oarker, d'Espaignet & Chatterji, 2011; Lim et al., 2010). Presently in Australia, 14.7% of the general population are daily smokers (ABS, 2015). Over the past 30 years, significant progress has been made in reducing the prevalence of tobacco use (Villanti, McKay, Abrams, Holtgrave & Bowie, 2010), with the proportion reduced by half in Australia (AIHW, 2016) and other high income countries (Cook et al., 2014). This decreasing trend in smoking prevalence over time suggests that tobacco control measures have been effective in reducing smoking uptake and/or promoting cessation in the general population (Anderson, Jorenby, Scott & Fiore, 2002; West, McNeill, & Raw, 2000).

Smoking and Mental Illness

However, the prevalence of smoking for individuals with a mental illness has not changed over the past two decades (Morgan et al., 2010) and has been estimated to be between 33% and 90% (Lawrence, Mitrou & Zubrick, 2009), with some of the highest rates of smoking observed in those within acute psychiatric settings (Stockings et al., 2011). Compared to general population smokers, smokers with mental illness are at least two times more likely to smoke (Lasser et al., 2000), smoke a greater number of cigarettes per day (Ashton, Miller, Bowden & Bertossa, 2010; Baker et al., 2007), are more nicotine dependent (Filia et al., 2014) and find it more challenging to quit (De Leon & Diaz, 2005; Le Cook et al., 2014). Consequently, the life expectancy among individuals with severe mental illness is

between 14 and 25 years less when compared with the general population (Kessler, Chiu, Demler, Merikangas & Walters, 2005). This implies that smoking among individuals with a mental illness is a significant public health issue. The unchanging prevalence of smoking and associated health burden among smokers with a mental illness suggests that tobacco control measures have been less effective for this group (Le Cook et al., 2014) and that research aimed at developing tailored intervention approaches is required.

Although the amount of research on smoking among individuals with mental illness has increased over the past 20 years (Metse et al., 2017), the proportion aiming to assess the effectiveness or efficacy of interventions to reduce smoking prevalence has not changed (Metse et al., 2017). The limited available evidence regarding the efficacy of smoking cessation treatments for persons with a mental illness (Bonevski et al., 2015), however, suggests such interventions can be efficacious for this group (Banham & Gilbody, 2010; Ragg & Ahmed, 2008; Prochaska, 2011; Schuck et al., 2016). Additional rigorous intervention research targeted at people with mental illness is required to develop evidence-based approaches to smoking cessation for this population group.

Importance of Comprehensively Reporting Retention Rate

Randomised control trials (RCTs) are generally acknowledged as the ‘gold standard’ for evaluating the efficacy and effectiveness of health care interventions (Sidani, 2015; Toerien et al., 2009). The Consolidated Standards of Reporting Trials (CONSORT) statement was first developed in 1996 and was updated in 2001 and 2010 has been endorsed by increasing number of organisations (Devereaux, Manns, Ghall, Wuan & Guyatt, 2002) and journals (Altman, 1996, Huston & Hoey, 1996) was developed by the CONSORT Group to improve the quality of reporting on

RCTs (Moher et al., 2010). The statement comprises a 25-item checklist of key details that must be reported, including both demographics and baseline characteristics of participants as well as the rate of participant retention. The inclusion of such items aims to assist readers to assess the generalisability (Wright et al., 2006), comparability and relevance of the research results (Toerien et al., 2009). In regards to retention specifically, it is essential that studies comment on the retention rates in all groups, as having equal numbers across groups is a key evaluative strength of RCTs (Dumville, Torgerson & Hewitt, 2006).

However, despite the need for researchers to be more transparent about incomplete retention and attrition (Dumville et al., 2006; Marcellus, 2004), a systematic review of 87 longitudinal studies undertaken in 1996 prior to publication of the CONSORT statement found that retention had not been provided sufficient attention by researchers, with 38 of the studies failing to mention retention at all (Goodman & Blum, 1996). The review also found that the majority of the studies that did consider retention did so superficially: only 14 of 49 studies for instance compared the sociodemographic characteristics of those who were retained and not retained.

A review of RCTs of health care interventions published in 2004 involving 133 RCT reports (Toerien et al., 2009), found that 48% of the trials that reported a sample size calculation failed to retain adequate numbers at outcome assessment (Severi et al., 2011; Toerien et al., 2009). Inadequate retention rate can prolong recruitment and increase financial burden (Butler et al., 2013; Leon, Demirtas & Hedeker, 2007) as researchers attempt to recruit more participants to replace those who are not retained and place additional effort to retain participants. Further, low retention results in issues when analysing and interpreting data, including decreased

statistical power (Dumville et al., 2006; Shadish, Cook, Campbell, 2002), decreased validity (Robinson, Dennison, Wayman, Pronovost & Needham, 2007; Rothman, Greenland & Lash, 2008) and reduced generalisability of study outcomes (Lamers et al., 2012). Therefore, exploration of the characteristics and factors associated with retention is essential to address these issues (Goldberg, Chastang, Zins, Niedhammer & Leclerc, 2006).

Participant Retention: Rates and Associated Factors

Smokers from the general population. In a systematic review exploring trials reporting attrition rates and identifying factors that influence low retention of adult smokers participating in smoking cessation intervention studies, only eight RCTs in the United States out of the 189 articles explored characteristics of participants not retained (Belita & Sidani, 2015). The inclusion criteria were studies published between 1980 and 2015; experimental or quasi-experimental design; pharmological, educational, or behavioural intervention; adult smokers irrespective of their mental health issues; examination of attrition rate; and exploration of factors associated with incomplete retention and/or reasons given by participants for withdrawing. The overall rates of participant retention between studies ranged from 23% to 89%, with five out of the eight studies achieving a retention rate below 65% including those that targeted African-American smokers, smokers with depressive symptoms, and female smokers (Belita & Sidani, 2015).

In the review by Belita and Sidani (2015), the demographic characteristics typically investigated were age (Curtin, Brown & Sales, 2000; Copeland, Martin, Gieselman, Rash & Kendzor, 2006), education level (Brouwer & Pomerleau, 2000; Leeman et al., 2006), gender (Curtin et al., 2000; Geraghty, Torres, Leykin, Perez-Stable & Munoz, 2012; Wagner et al., 1990), income (Nevid, Javier & Moulton,

1996), employment status (MacPherson, Stipelman, Duplinsky, Brown & Lejeuz, 2008), marital status (Ahluwalia et al., 2002; Geraghty et al., 2012; Wagner et al., 1990; Woods et al., 2002) and race (Brouwer & Pomerleau, 2000; Copeland et al., 2006). However, the influences of these factors on retention rates were inconsistent with some studies finding demographic characteristics such as gender, age, education, employment and income influenced retention rates, while others did not (e.g., between retention rate and age, gender, education levels, income and employment status) and when associations were found that the direction of association is not always consistent (Belita & Sidani, 2015). In a United States study, subsequent to Belita and Sidani (2015) review, exploring strategies to retain college smokers at a Midwestern university in a cessation trial reported a 79% retention rate at the 6-month follow-up assessment, and found no evidence that participant characteristics were significantly associated with retention (Davidson et al., 2010).

Smoking characteristics have also been associated with participant retention in trials involving smokers generally. Low motivation to quit among African-American smokers has been associated with lower retention rate (Ahluwalia et al., 2002; Woods et al., 2002). Meanwhile, daily number of cigarettes smoked (Brouwer & Pomerleau, 2000; Leeman et al., 2006) and duration of smoking was not related to retention rate (Ahluwalia et al., 2002; Copeland et al., 2006; Curtin et al., 2000; MacPherson et al., 2008; Nevid et al., 1996; Woods et al., 2002) in a number of other studies involving various subgroups of smokers.

A recent Australian RCT in the Australian Financial Interventions for Smoking Cessation that recruited 1047 low-socioeconomic status smokers that were interested in quitting smoking examined factors associated with retention. The study

reported a final retention rate of 84% and found that increasing age, higher education attainment, higher motivation to quit and more recent quit attempts were linked with participant retention at 8-month follow-up (Courtney et al., 2017).

Smokers with a mental illness. Systematic review evidence has highlighted that persons with a mental illness are particularly difficult to retain in smoking cessation trials (Bonevski et al., 2014). Further, few studies report characteristics of those retained, and whether they differ between study groups. For example, a study that focused on 130 smokers with a non-acute psychotic disorder and who were interested in quitting (Baker et al., 2006) reported retention rates of 93% at 15-weeks, 95% at 6-months and 80% at 12-months with both treatment groups having similar retention rates. However, the study did not explore the factors associated with the high retention rate at the 12-month follow-up (Baker et al., 2007). Similarly, there are studies among smokers with mental illness that report retention rates between 75% (Williams et al., 2010) at 12-month follow-up and 90% (Shmueli et al., 2008) at 3-month follow-up without exploring systematic characteristic biases. The absence of an examination of participant characteristics that may have been related to retention hinders the opportunity to explore and comment on the nature of potential biases or identify strategies that may improve retention.

Only a single study from Belita and Sidani (2015) review was identified to have comprehensively assessed factors associated with the 66% retention rate at 1.5 months in a smoking cessation trial involving females with a mental illness, and the sample consisted of only those with a history of depression (Curtin et al., 2000). Among 177 participants who had previously been diagnosed with major depressive disorder, age, education attainment, income and socioeconomic status were found to not be associated with retention, whereas less cigarettes per day and lower level of

depressive symptoms were positively associated with retention (Curtin et al., 2000). By contrast, two studies that included participants with different levels of depressive symptoms found that the severity of depressive symptoms did not influence retention rate (Ahluwalia et al., 2002; Brouwer & Pomerleau, 2000).

The limited research examining factors associated with retention in smoking cessation trials involving persons with a mental illness has yielded equivocal findings. The contrasting results may be associated with a variety of factors, such as the: retention time period investigated, characteristics of the population targeted, type of smoking cessation interventions under evaluation and study demand characteristics (e.g., number and length of follow-ups). In addition, with the exception of depressive symptoms, the set of factors that were explored in the current literature on retention rates in smoking cessation trials were inconsistent across studies (Belita & Sidani, 2015). Further, all of the research exploring factors associated with retention is limited to studies from the United States and there is limited literature presently regarding the barriers to retention for smokers with mental health issues undertaken within Australian samples (Bonevski et al., 2014).

Smokers with mental health disorders are understudied and face some unique challenges that may reduce the likelihood of study retention. For example, individuals with a mental illness also have characteristics that make follow-up more challenging, including housing instability, intermittent telephone access, low-socioeconomic status, substance abuse issues and less understanding of and exposure to research (Bonevski et al., 2014). Moreover, smokers with mental health illness are inclined to have higher nicotine dependence (Forman-Hoffman, Hedden, Glashen, Davies & Colpe, 2016; Williams, Steinberg, Griffiths & Cooperman, 2013), more smokers in their social network (Access Economics, 2007) and higher levels of daily

stress (Morisano, Bacher, Audrain-McGovern & George, 2009), however the association between these factors and retention are yet to be examined.
Given the high smoking rates among smokers with mental illness, there is a need to explore participant retention in intervention trials targeting this group.

The present study describes follow-up rates and explores factors associated with retention for smokers with a mental illness in a RCT of a smoking cessation intervention initiated in inpatient psychiatry and continued multimodal smoking intervention offered to smokers directly following discharge (Metse et al., 2014). Unlike previous studies that had a shorter final follow-up point of 8-months (Courtney et al., 2017), follow-up data were collected at 1-, 6-and 12-months post discharge in this current study. The inclusion of a 12-month follow-up point is beneficial as it is the 'gold-standard' for assessment of effectiveness for smoking cessation intervention trials (West, Hajek, Stead & Stapleton, 2005). Notably, this study involved participants regardless of motivation/ readiness to quit or level of nicotine dependence, and as a result can assess whether these factors has an impact on retention.

Aims of the Current Study

The literature on retention of adults with a mental illness in tobacco cessation trials is sparse, resulting in potential systematic biases in research outcomes, reduced generalisability and minimal identified strategies that may improve retention. As there are a limited number of studies exploring factors associated with retention, particularly in the Australian context, the present study aims to: (1) report the retention rates achieved for smokers with a mental illness within the context of a smoking cessation trial in the 'No Butts' RCT project at 1-month, 6-months and 12-months follow-up for both the control and intervention group, (2) examine the

relationship between follow-up time and participant retention and (3) explore potential determinants (e.g., participant demographics, clinical and baseline characteristics of smoking) associated with completing follow-up assessments at 12-months.

Method

Design

This research is a secondary analysis of data from a RCT that assessed the efficacy of integrating inpatient smoking cessation care with post discharge support through blinded follow-up (Metse et al., 2014). The project was funded by the National Health and Medical Research Council (#G1100130) and was supported by both the University of Newcastle, Australia and Hunter New England Population Health (Metse et al., 2014). The trial reporting was in accordance with the CONSORT statement and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12612001042831).

Setting and Participants

Participants were recruited by trained research staff (independent of the hospitals) across four acute inpatient mental health facilities within a Local Health District in New South Wales, Australia. Participants were required to be above the age of 17, assessed as safe to approach, a current cigarette smoker (smoked in the month before admission), able to understand the research, provide informed consent and be willing to provide contact details (phone number and mailing address) to facilitate communication once discharged. Smokers did not have to be motivated to quit or be highly nicotine dependent to participate. No other exclusion criteria were applied.

Procedure

Participants were presented with an information statement about the study (See Appendix C) prior and were required to complete a consent form (See Appendix D) to participate in the study. Baseline data were collected from eligible and consenting participants by research staff via face-to-face administration of a structured interview, in a confidential manner. Participants were then given a sequentially numbered, opaque, sealed envelope immediately after baseline data collection which randomly allocated them to one of two groups (Normal Care or Supported Care).

'Normal Care' participants received standard hospital treatment as usual, which may have included brief advice to quit smoking, provision of nicotine replacement therapy (NRT) whilst in hospital, up to three days supply of NRT upon discharge and/or a referral to Quitline. In addition to the standard smoking care provided by the hospitals, 'Supported Care' participants received a brief motivational interview and a package of self-help material for abstaining from smoking whilst in hospital, and, a referral to Quitline, 12-weeks free combination NRT, and 16-weeks of motivational telephone-based counselling following discharge. Follow-up assessments in which interviewers were blinded to participants condition were conducted at 1-, 6- and 12-months post discharge, via computer-assisted telephone interview (CATI) for participants in both groups.

This study also implemented strategies to maintain and optimise contact with participants through systematic and thorough collection of contact details (i.e., obtaining land/mobile telephone numbers/email address and secondary contact details), multiple call attempts (a minimum of 10 calls), sending reminders via text-messages (a text-message were sent to participants 10 days before the scheduled

interview date to remind participants of the interview), as well as the provision of reimbursement ($20 per follow-up call) for completion of each follow-up assessment.

Recruitment commenced in October 2012 and concluded in May 2014, while collection of follow-up data concluded in July 2015. Comprehensive details regarding support offered to the Normal Care and Supported Care group, randomisation method used for participant allocation, and measures can be found in the published study protocol paper (Metse et al., 2014).

Study Measures

The primary outcome for this study was retention, defined as successful completion of the CATI at 1-month, 6-months, and 12-months post discharge. Retention is not a single cumulative measure of completion of the CATI at all three follow-up points but rather completion of the CATI at each of the three follow-up points.

Clinical information collected included mental health diagnoses (psychosis vs. non-psychosis), length of hospital stay (days) and hospitalisation status (voluntary vs. involuntary). Demographic characteristics included the participant's gender, age, participant's identification as Aboriginal and/or Torres Strait Islander (ATSI), highest education level, employment status, identity as a smoker (daily, weekly or less than weekly in the month before admission), living circumstances and marital status.

Smoking characteristics collected included age started smoking, nicotine dependence assessed using the Fagerstrom Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker & Fagerstrom, 1991), number of cigarettes smoked per day, motivation and readiness to quit assessed using the Readiness and

Motivation to Quit Smoking Questionnaire (Crittenden, Manfredi, Lacey, Warnecke & Parsons, 1994) as well as number of previous quit attempts.

Statistical Analysis

Participant data was not included in the analysis if a next-of-kin advised the participant was deceased or if the participant was not discharged from the mental health facility by the end of the project. The study focused on the 740 inpatients that were successfully recruited with 367 and 373 participants randomised into the control and intervention group, respectively.

Analyses were conducted using IBM SPSS Statistics 24 (International Business Machines Corporation, 2016). Descriptive statistics were used to report on retention rates for the Normal Care and Supported Care group. McNemar tests and logistic regressions were conducted to explore the relationship between the retention rates at 1-month and 6-months for both groups along with all possible interactions, with the retention rates at the 12-month follow-up assessment. Chi-square tests were conducted to investigate any differences in demographic and smoking characteristics between the participants retained and lost at 12-months follow-up.

Generalised estimating equations (GEE) were used to model participant retention (retained or lost) at 1-, 6- and 12-months for both groups along with all possible interactions, and explore potential associations between retention with clinical, demographic and smoking characteristics. All variables for clinical, demographic and smoking characteristics were included into GEE even if it was not significant at chi-square tests. The Quasi Likelihood under Independence Model Criterion (QIC)[b] and Corrected Quasi Likelihood under Independence Model Criterion (QICC)[b] were used to determine the optimal correlation matrix and the effect of any potential confounding characteristics. A priori, all analyses were

conducted with a type I error of ∝=.05.

Results

Participants

Three thousand six hundred and twenty-six patients were admitted to the psychiatric inpatient facilities during the recruitment period; 2078 were assessed for eligibility, and 61% (N = 754) of eligible smokers were recruited into the smoking cessation intervention trial. Fourteen participants were excluded from this study due to being deceased (n = 11) or not discharged from hospital (n = 3) at project completion. The 740 participants were randomised into Normal Care (n = 367) and Supported Care (n = 373) groups. Fewer participants were single in the Normal Care compared to Supported Care group (p = .04) (Table 1). In relation to education, there were fewer participants in the Normal Care group who highest level of education was completion of high school certificate or lower compared to those allocated to the Supported Care (p = .04), with more participants in the Normal Care group having completed tertiary level of education.

Table 1

Comparison of Demographics at Study Baseline by Group Allocation

Variable	Normal Care *n* = 367	Supported Care *n* = 373	Overall *N* = 740
Age [a]	38.30 (12.01)	39.08 (11.96)	38.69 (11.99)
Age started smoking [a]	15.45 (4.40)	15.61 (4.83)	15.53 (4.62)
Length of stay [a] (days)	13.36 (15.92)	15.11 (18.78)	14.24 (17.43)
Cigarettes smoke per day [a]	21.02 (13.19)	21.81 (14.49)	21.42 (13.86)
Sex [a] (Male)	224 (61 %)	228 (61%)	452 (61%)
Cultural Background [b] (ATSI)	48 (13%)	53 (14 %)	101 (14%)
Diagnosis [b] (Psychosis)	82 (22%)	84 (23%)	166 (22%)
Legal status [b] (Involuntary)	167 (46%)	179 (48%)	346 (47%)
Relationship status [b] (Single)	279 (76%)*	306 (82%)*	585 (79%)
Living circumstances [b] (Own)	103 (28%)	116 (31%)	219 (30%)
Highest education level [b] (High school certificate or lower)	258 (70%)*	292 (78%)*	550 (74%)
Employment status [b] (Unpaid workforce)	267 (73%)	277 (74%)	544 (74%)
Type of smoker [b] (Daily smoker)	342 (93%)	348 (93%)	690 (93%)
Stage of quitting [b] (Pre-contemplation)	200 (55%)	207 (56%)	407 (55%)
Quit attempt [b] (No)	260 (71%)	252 (68%)	512 (69%)
Number of quit attempts [b] (At least once)	107 (29%)	121 (32%)	228 (31%)
Nicotine dependence [b] (High)	189 (52%)	192 (52%)	381 (52%)

[a] Mean (SD)

[b] Number (%)

* $p < .05$

Retention

According to McNemar tests, the retention rates did not change significantly over the course of the project. Of those 740 participants, 63% completed the 1-month follow-up, 56% completed the 6-month follow-up, and 60% completed the final

12-month follow-up. Notably, the care participant's received made no difference to these retention rates, as seen in Table 2.

Table 2

Retention Status at All Three Follow-up Points by Group Allocation

Retention rate	Normal Care	Supported Care	P-value
1-month	232 (63%)	233 (62%)	.83
6-months	211 (57%)	206 (55%)	.53
12-months	215 (59%)	225 (60%)	.63

Relationship between Preceding Follow-ups with the Final Follow-up

Outcomes of the logistic regression analysis revealed no significant relationship between allocation group and retention rate, however allocation group was retained in the final model to control for the support provided. No interactions were statistically significant. The odds of being retained at 12-months were the same for those in the Normal Care group compared to those in the Supported Care group. The odds of participants being retained at 12-months were 1.8 (95% CI: 1.25, 2.59, $p = .002$) times higher for those who were retained at 1-month, compared to those who were lost at 1-month. Also, the odds of participants being retained at 12-months were 6.01 (95% CI: 4.20, 8.60, $p < .001$) times higher for those who were retained at 6- months, relative to those who were lost.

Table 3

Odds of Retention at 12-months by Preceding Follow-up Points

Follow-up assessment	OR	95% CI		P-value
		Lower	Upper	
1-month	1.80	1.25	2.59	.002
6-months	6.01	4.20	8.60	< .001

OR: odds ratio; CI: confidence interval.

Factors Associated with Retention

Chi-square and GEE analyses revealed factors associated with retention at 12-months included participant's older age, participants not identifying themselves as Aboriginal and/or Torres Strait Islander, identity as a non-daily smoker at baseline, higher education level and being female. No interaction terms were significant.

Specifically, the GEE analysis using exchangeable correlation matrix, showed that the proportion of participants aged over 50 who were retained was significantly higher than the proportion of participants retained from the other younger age groups ($p < .001$). The proportion of participants that were retained at 12-month follow-up who identified as Aboriginal and/or Torres Strait Islander (46%) was significantly less than the proportion that were retained who did not identify as Aboriginal and/or Torres Strait Islander (62%) ($p = .002$). Participant retention was also related to identity as a smoker at baseline, with analyses revealing that the proportion of participants who were retained at the 12-month follow-up and who were daily smokers (58%) were significantly less than the proportion retained who were weekly or irregular smokers (74%) ($p = .036$). For education level, the GEE showed that the proportion of participants who were retained and who completed a tertiary education (65%) were significantly higher than the proportion who did not complete school certificate (56%) that were retained ($p = .004$).

Table 4

Factors Associated with Retention Rate at 12-months

Predictors	OR	95% CI		P-value
		Lower	Upper	
Age				
18-25	0.21	0.12	0.30	< .001
26-35	0.14	0.05	0.22	.001
36-50	0.13	0.06	0.21	.001
51 and over	1			
Aboriginal and Torres Strait Islander Status				
Identify	0.16	0.07	0.24	< .001
Did not identify	1			
Identity of smoker at baseline				
Daily smoker	0.11	0.01	0.22	.036
Weekly/Irregular smoker	1			
Education level				
Less than school certificate	0.11	0.03	0.18	.004
Up to HSC	0.06	-0.01	0.13	.074
Tertiary	1			

OR: odds ratio; CI: confidence interval.

Finally, in the GEE, the gender and time interaction was significant ($p = .046$). Significantly fewer male participants were retained at 12-months, relative to the 1-month follow-up ($p = .013$). Similarly, significantly fewer male participants were retained at 6-months, relatively to the 1-month follow-up ($p < .001$) (not in table).

Discussion

Participant retention is a challenge in intervention trials, particularly in socially disadvantaged groups such as those with mental illness (Bonevski et al.,

2014). The retention rates did not change over the course of the 'No Butts' project with 63%, 56% and 60% of the 740 participants completing the 1-, 6- and 12-month follow-ups, respectively. The follow-up rates at all three time points, irrespective of gender, was similar in both the control and intervention groups. Next, retention at 1- or 6-months was positively associated with retention at 12-month follow-up; as participants were two and six times more likely to be retained at the 12-month follow-up if retained at 1- and 6-months follow-up respectively. Finally, the study found that participants' demographic and clinical characteristics including older age, participants who did not identify to be Aboriginal and/or Torres Strait Islander, identity as a non-daily smoker at baseline, higher education level and being female were key predictors of adult smoking cessation study retention at 12-months. Therefore, the findings suggest that additional measures are required to engage smokers with such characteristics throughout the course of the study in order to increase retention at the trial endpoint.

A recent review by Belita and Sidani (2015) explored factors influencing retention rates for adult participants in smoking cessation intervention studies between 1980 and 2015. The retention rates reported in the review varied between 23% and 89%. Two studies involved persons with a mental illness: the first involved female smokers with a history of major depressive disorder and had a retention rate of 66% at treatment completion (after 6 weeks) (Curtin et al., 2000); while the study included 53 smokers with symptoms of depression and had a retention rate of 60% after a single session (MacPherson et al., 2008). Comparison between results of the current study and this prior research should be viewed in the context of study samples and settings differences. Similar to MacPherson et al. (2008) that included both males and females in their study; the present study obtained an identical

retention rate of 60% at 12-month follow-up. The lower retention rate in the present study compared to Curtin et al. (2000) could be due to the current study involving male participants whom have been observed to be more likely lost to follow-up in smoking cessation intervention studies than females (Ahluwalia et al., 2002; Woods et al., 2002). However, a study among 298 smokers diagnosed with a psychotic disorder that explored gender differences, found that majority of the gender differences across a range of smoking characteristics and outcomes that have been reported in smokers from the general population were not found in the sample of smokers diagnosed with psychosis (Filia et al., 2014). Therefore, it can be noted that factors associate with retention may be different for those with mental illness compared to those without. Hence, further research specific to mental health population is warranted.

In addition, the current study found that the proportion of male participants retained at 6-month and 12-month follow-ups was significantly less compared to male participants retained at 1-month follow-up. The reason for the higher retention at 1-month follow up is not possible to identify in the study, however, it could be speculated that the lower retention rate among males at later follow-up could possibly be due to them not being ready to quit smoking and refusing to be retained in the study as they have the view that the study is encouraging them to quit smoking (Belita & Sidani, 2015). Hence, this suggests that earlier follow-up assessment may result in more successful engagement particularly for males with a mental illness participating in smoking cessation interventions and that strategy to encourage participant retainment at later follow-ups is required. However, it should be noted, studies that had required participants to be interested in quitting smoking, found no differences in the readiness and motivation to quit smoking according to gender

(Filia et al., 2014). Another possible explanation for the higher retention rate for males at 1-month, compared to 6- and 12-months could be that males are more engaged in completing follow-up assessment immediately following engagement with research personnel.

Retention rates were not associated with the care participants received as there were no differences in the retention rates between participants in the Normal Care and Supported Care at all three follow-up points. The retention rates differ slightly from the range reported in previous Australian smoking cessation trials involving persons with a mental illness. The retention rates reported by Baker et al. (2006) in the trial of 298 smokers with a psychotic disorder were 85%, 82% and 83% at 3-, 6- and 12-months respectively. A number of methodological differences between the studies however may be related to the difference in retention rates, including recruitment setting (community health agencies versus inpatient psychiatric unit) and participant's motivation to quit. The smokers targeted in the study by Baker et al. (2006) were required to express an interest in quitting smoking.

In contrast, the present study included all smokers regardless of their intention and motivation to quit. This could be the reason for the lower retention rates in the present study as smokers who were more committed and motivated to quit were more likely to be retained in a RCT of smoking cessation (Courtney et al., 2017; Nevid et al., 1996). A further possibility could be due to participants not receiving their preferences or favourable views for treatment (Normal Care vs. Supported Care) (Sidani, 2015). Previous research has suggested that participants who do not receive their treatment of choice or perceive the treatments as unacceptable are more likely to not be retained (Sidani, 2015).

Retention at 1- or 6-months was positively associated with retention at 12-month follow-up. Participants were approximately two times more likely to be retained at the 12-month follow-up if retained at 1-month follow-up. Meanwhile, participants were six times more likely to be retained at 12-month follow-up if retained at 6-months. This suggests that completion of an earlier follow-up before the final follow-up assessment may increase retention at the trial endpoint. An explanation for this is that regular contact with participants has been reported as an effective method in maximising retention (Bonevski et al., 2014; Sidani, 2015). Further, prior contact with participants can also be seen as a strategy to increase rapport and hence increase retention (Bonevski et al., 2014).

Interestingly, there was no association between retention at both preceding follow-ups (1- and 6-months) and the final follow-up. This finding supports the phenomenon of contact fatigue (Geraghty et al., 2012), whereby for participants who received a higher volume of study associated contact this reduces the novelty of study-related contacts resulting in participants ignoring researchers contact (Geraghty et al., 2012). Therefore, researchers should allocate adequate effort and resources to try and retain participants in at least one preceding follow-up prior to the final follow-up, whilst also taking into consideration that extensive effort to retain them in earlier follow-ups before the final follow-up may have a negative outcome.

The results suggest that retention was not associated with mental health diagnosis, but was associated with several demographic characteristics. The study found that there was no significant difference in retention for those with psychotic or non-psychotic disorders/illnesses. However, the factors that were associated with retention in this adult smoking cessation study were age, identifying as Aboriginal and/or Torres Strait Islander, identifying as a smoker at baseline, education level and

gender. These results suggest a need for additional strategies to engage smokers who are: younger, identify as Aboriginal and/or Torres Strait Islander, heavier smokers and with lower educational levels.

Consistent with the literature for both general and mental health smokers (Courtney et al., 2017; Leeman et al., 2006) the present study found higher rates of retention for older smokers. It is plausible that the lower retention rate in younger smokers is due to them having a greater number of complex life responsibilities including balancing children and work (Warner et al., 2013) that may interfere with their full participation in the study (Woods et al., 2002). Hence, to make it convenient for younger smokers to participate in a smoking cessation trial, additional strategies that could perhaps be included apart from flexibility in time of research activities is for the delivery of the follow-ups to be online instead of via telephone calls (Belita & Sidani, 2015). Further, the higher retention rate among older smokers could due to differing motivation and urgency to quit smoking between younger and older smokers, with the former perhaps believe that they can leave quitting smoking until they are older. Such an explanation may explain the relatively consistent finding across the literature that younger smokers are more difficult to engage in smoking cessation trial (Metse et al., 2016; Schuck et al., 2014; Villanti, et al., 2010).

This study found that participants who identified themselves as Aboriginal and/or Torres Strait Islander had a lower retention rate compared to those who did not identify as such. The finding contradicts with Courtney et al. (2017) that reported no differences in retention rates across these populations. However, Courtney and colleagues had a smaller sample size of Indigenous population compared to the current study (7% vs. 14%). The smaller sample size could explain the null finding

as the study could have insufficient power. While it is not possible to identify the reason for the lower retention rate in smokers that identified as Aboriginal and/or Torres Strait Islander in this study, researchers should ensure that common barriers for Indigenous Australian such as access, sociocultural factors and participants' beliefs (Bonevski et al., 2015) are addressed.

Infrequent smokers that reported weekly and irregular smoking at baseline were more likely to be retained at 12-month follow-up compared to participants who identified as daily smokers. However, consistent with past research among smokers from both the general population and smokers with mental illness, this study found that there was no association between number of cigarettes smoked per day and retention (Brouwer & Pomerleau, 2000; Copeland et al., 2006; Curtin et al., 2000; Leeman et al., 2006; MacPherson et al., 2008; Nevid et al., 1996; Woods et al., 2002). No previous research has examined the impact of smoking regularity on retention in trials. Therefore, further research is warranted to explore this association and how to better engage regular smokers in cessation trials.

The finding that participants with higher educational attainment were more likely to be retained at the 12-month follow-up is consistent with that of previous smoking cessation trials involving women (Borrelli et al., 2002) and low-socioeconomic status (Courtney et al., 2017) smokers. An explanation for this could be that participant's low literacy level may negatively impact on retention rate due to his or her understanding of the research requirements. This is parallel to previous findings that low literacy levels are related with poor treatment adherence and low smoking cessation rates in African-American (Ahluwalia et al., 2002) and female smokers (Borrelli et al. 2002). However, this explanation is merely an assumption as participant's low literacy level was not assessed in the current study. There is also a

possibility that highly educated adults may instil higher expectations for achievement in themselves, making them more likely to follow through with the research (i.e., completing follow-up assessments) (Belita & Sidani, 2015). Therefore, clear and simple communication of expectations related to participants' involvement in research activities and expressing appreciation for participants' involvement both orally and in writing should be provided (Sidani, 2015), considering the prevalence of tobacco consumption is frequently highest among those with low education attainment (Hosseinpoor et al., 2011).

A recent systematic review of the barriers to retention in medical research for socially disadvantage groups including individuals with mental health illness (Bonevski et al., 2014) found that the most common barrier was difficulty in maintaining participant contact due to frequent phone number and address changes. The review suggested that this issue could be addressed through the collection of multiple contact details, including land and mobile telephone numbers, email address and secondary contact details. This strategy has been reported to be important in maintaining contact with participants who are smokers (Sidani, 2015) and was implemented in the current study.

Notably, a number of the smoking characteristics that have commonly been related with retention in other smoking cessation studies such as nicotine dependence (Borrelli et al., 2002) and recent quit attempts (Courtney et al., 2017), were not related to retention in the present study. However, these findings are consistent with one previous study that found nicotine dependence and prior quit attempts were not predictive of study retention in smoking cessation involving homeless smokers (Richards et al., 2015). Thus, further research is required to explore these issues, particularly among individuals with mental illness.

The current study employed a number of strategies in an attempt to increase retention, including reimbursement for completion of follow-up calls and text message reminders regarding impending assessments. Previous research suggests that reimbursement is an effective strategy in improving retention rates (Festinger et al., 2005). Adoption of this strategy in the present study part way through the 12-month follow-up may account for the relatively stable retention rates across time, in contrast to the decreasing rates commonly observed in smoking cessation trials (Bonevski et al., 2014). Text-message reminders prior to participant's scheduled interviews were adopted in an attempt to reduce the impact of participant forgetfulness, a practical barrier to retention identified in the literature (Woods et al., 2002). Given multiple strategies to increase retention were employed, it was not possible to distinguish which strategy, if any, impacted on retention rates in the current study. It is likely that, an approach that combines a rigorous follow-up process, reminder and participant reimbursement may be useful ways to optimise retention in this population. A significant proportion of participants were not retained, suggesting further strategies are required.

General Limitations

There are limitations to the present study. The sample excluded smokers without a home or mobile telephone because the study was predominantly phone-based. In addition, the current study did not explore the background factors in the context of the research that could potentially impact on retention (Marcellus, 2004). For instance, the characteristics of the research assistant, predominantly their interactional and communication style and the characteristics of the study protocol, including recruitment strategies (proactive vs. reactive) may impact on participant retention (Belita & Sidani, 2015). In previous research, proactive recruitment

strategies were found to minimise or maximise the odds of retention (Ahluwalia et al., 2002). Another limitation was that the study only recruited participants from a psychiatric inpatient setting. This could have impacted on the retention rate as recruitment settings have been found to be associated with participant retention in other research (Courtney et al., 2017; Robinson et al., 2007). Therefore, future research is needed to assess retention rates achieved within different recruitment methods, and clinical settings that smokers with mental health issues access. Finally, due to availability of data, the study did not investigate the characteristics of smokers who did not consent to participate in the trial.

Conclusion

The present study adds to the literature surrounding participant retention in smoking cessation trials involving persons with a mental illness. The findings support that of previous research in demonstrating that low retention is a challenge faced by researchers implementing clinical trials. They also highlight a need for strategies to engage subgroups who are more likely not to be retained. Maximising retention in clinical trials is a priority to ensure that systematic biases are not introduced, increasing generalisability and statistical power.

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Appendix A

American Psychological Association Journal: Scope and Submission Guidelines

Retrieved from: http://www.apa.org/pubs/authors/instructions.aspx

Manuscript Preparation

Prepare manuscripts according to the *Publication Manual of the American Psychological Association* (6th edition). Manuscripts may be copyedited for bias-free language (see Chapter 3 of the *Publication Manual*). Additional guidance on APA Style is available on the APA Style website.

Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the *Manual*.

Below are additional instructions regarding the preparation of display equations, computer code, and tables.

Display Equations

We strongly encourage you to use MathType (third-party software) or Equation Editor 3.0 (built into pre-2007 versions of Word) to construct your equations, rather than the equation support that is built into Word 2007 and Word 2010. Equations composed with the built-in Word 2007/Word 2010 equation support are converted to low-resolution graphics when they enter the production process and must be rekeyed by the typesetter, which may introduce errors.

To construct your equations with MathType or Equation Editor 3.0:

- Go to the Text section of the Insert tab and select Object.
- Select MathType or Equation Editor 3.0 in the drop-down menu.

If you have an equation that has already been produced using Microsoft Word 2007 or 2010 and you have access to the full version of MathType 6.5 or later, you can convert this equation to MathType by clicking on MathType Insert Equation. Copy the equation from Microsoft Word and paste it into the MathType box. Verify that your equation is correct, click File, and then click Update. Your equation has now been inserted into your Word file as a MathType Equation.

Use Equation Editor 3.0 or MathType only for equations or for formulas that cannot be produced as Word text using the Times or Symbol font.

Computer Code

Because altering computer code in any way (e.g., indents, line spacing, line breaks, page breaks) during the typesetting process could alter its meaning, we treat computer code differently from the rest of your article in our production process. To that end, we request separate files for computer code.

In Online Supplemental Material
We request that runnable source code be included as supplemental material to the article. For more information, visit Supplementing Your Article With Online Material.

In the Text of the Article
If you would like to include code in the text of your published manuscript, please submit a separate file with your code exactly as you want it to appear, using Courier New font with a type size of 8 points. We will make an image of each segment of code in your article that exceeds 40 characters in length. (Shorter snippets of code that appear in text will be typeset in Courier New and run in with the

rest of the text.) If an appendix contains a mix of code and explanatory text, please submit a file that contains the entire appendix, with the code keyed in 8-point Courier New.

Tables

Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

If your manuscript was mask reviewed, please ensure that the final version for production includes a byline and full author note for typesetting.

Review APA's Checklist for Manuscript Submission before submitting your article.

Submitting Supplemental Materials

APA can place supplemental materials online, available via the published article in the PsycARTICLES® database. Please see Supplementing Your Article With Online Material for more details.

Abstract and Keywords

All manuscripts must include an abstract containing a maximum of 250 words typed on a separate page. After the abstract, please supply up to five keywords or brief phrases.

References

List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Examples of basic reference formats:

- **Journal Article:**
  Hughes, G., Desantis, A., & Waszak, F. (2013). Mechanisms of intentional binding and sensory attenuation: The role of temporal prediction, temporal control, identity prediction, and motor prediction. *Psychological Bulletin, 139,* 133–151. http://dx.doi.org/10.1037/a0028566
- **Authored Book:**
  Rogers, T. T., & McClelland, J. L. (2004). *Semantic cognition: A parallel distributed processing approach.* Cambridge, MA: MIT Press.
- **Chapter in an Edited Book:**
  Gill, M. J., & Sypher, B. D. (2009). Workplace incivility and organizational trust. In P. Lutgen-Sandvik & B. D. Sypher (Eds.), *Destructive organizational communication: Processes, consequences, and constructive ways of organizing* (pp. 53–73). New York, NY: Taylor & Francis.

Figures

Graphics files are welcome if supplied as Tiff or EPS files. Multipanel figures (i.e., figures with parts labeled a, b, c, d, etc.) should be assembled into one file.

The minimum line weight for line art is 0.5 point for optimal printing.

For more information about acceptable resolutions, fonts, sizing, and other figure issues, please see the general guidelines.

When possible, please place symbol legends below the figure instead of to the side.

APA offers authors the option to publish their figures online in color without the costs associated with print publication of color figures.

The same caption will appear on both the online (color) and print (black and white) versions. To ensure that the figure can be understood in both formats, authors should add alternative wording (e.g., "the red (dark gray) bars represent") as needed.

For authors who prefer their figures to be published in color both in print and online, original color figures can be printed in color at the editor's and publisher's discretion provided the author agrees to pay:

- $900 for one figure
- An additional $600 for the second figure
- An additional $450 for each subsequent figure
- Permissions
- Authors of accepted papers must obtain and provide to the editor on final acceptance all necessary permissions to reproduce in print and electronic form any copyrighted work, including test materials (or portions thereof), photographs, and other graphic images (including those used as stimuli in experiments).
- On advice of counsel, APA may decline to publish any image whose copyright status is unknown.

Appendix B

Notice of Ethical Approval

HUMAN RESEARCH ETHICS COMMITTEE

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 Ashikin Hizam** **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 Ashikin 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

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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 C

Information Statement

Assoc Prof Jenny Bowman
School of Psychology
Faculty of Science and IT
University of Newcastle
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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 D

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

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

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:……..