

## ORIGINAL INVESTIGATION

# Impact of a Postdischarge Smoking Cessation Intervention for Smokers Admitted to an Inpatient Psychiatric Facility: A Randomized Controlled Trial

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## ABSTRACT

**Introduction:** Persons with a mental disorder smoke at higher rates and suffer disproportionate tobacco-related burden compared with the general population. The aim of this study was to determine if a smoking cessation intervention initiated during a psychiatric hospitalization and continued postdischarge was effective in reducing smoking behaviors among persons with a mental disorder.

**Methods:** A randomized controlled trial was conducted at an Australian inpatient psychiatric facility. Participants were 205 patient smokers allocated to a treatment as usual control ( $n = 101$ ) or a smoking cessation intervention ( $n = 104$ ) incorporating psychosocial and pharmacological support for 4 months postdischarge. Follow-up assessments were conducted at 1 week, 2, 4, and 6 months postdischarge and included abstinence from cigarettes, quit attempts, daily cigarette consumption, and nicotine dependence.

**Results:** Rates of continuous and 7-day point prevalence abstinence did not differ between treatment conditions at the 6-month follow-up; however, point prevalence abstinence was significantly higher for intervention (11.5%) compared with control (2%) participants at 4 months ( $OR = 6.46, p = .01$ ). Participants in the intervention condition reported significantly more quit attempts ( $F[1, 202.5] = 15.23, p = .0001$ ), lower daily cigarette consumption ( $F[4, 586] = 6.5, p < .001$ ), and lower levels of nicotine dependence ( $F[3, 406] = 8.5, p < .0001$ ) compared with controls at all follow-up assessments.

**Conclusions:** Postdischarge cessation support was effective in encouraging quit attempts and reducing cigarette consumption up to 6 months postdischarge. Additional support strategies are required to facilitate longer-term cessation benefits for smokers with a mental disorder.

## INTRODUCTION

Tobacco use remains a leading global cause of preventable illness and premature death (Lim et al., 2012). General population smoking rates in developed nations have steadily declined over the past 50 years and range from 15% to 20% (Australian Institute of Health and Welfare, 2007; Centers for Disease Control, 2012; World Health Organization, 2009). However, for persons with a mental disorder, rates of smoking have remained unchanged for the past 20 years (Lancet, 2013) and are at least two to three times higher than general population estimates (Lawrence, Hafekost, Hull, Mitrou, & Zubrick, 2013; Lawrence, Mitrou, & Zubrick,

2009; McClave, McKnight-Eily, Davis, & Dube, 2010). The association between smoking and mental illness appears to increase with illness severity, with some of the highest rates of smoking identified among persons with schizophrenia (Diaz, Rendon, Velasquez, Susce, & de Leon, 2006; McClave et al., 2010), and those hospitalized for psychiatric treatment (Benowitz et al., 2009; Lineberry, Allen, Nash, & Galardy, 2009), with smoking rates ranging between 45.9% and 81.8% for these groups (Benowitz et al., 2009; Lineberry et al., 2009; McManus, Meltzer, & Campion, 2010). Consequently, persons with a mental disorder are more likely to die from smoking-related disease (Jones et al., 2004; Osborn et al., 2007) and experience a reduced life expectancy of

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12–15 years (Lawrence, Hancock, & Kisely, 2013). Interventions that reduce smoking rates among persons with a mental disorder are both a clinical and a public health priority (Royal College of Physicians & Royal College of Psychiatrists, 2013).

The recent smoking and mental health report released by the Royal College of Physicians and the Royal College of Psychiatrists highlights the importance of health care services in delivering systematic smoking cessation treatment to smokers with a mental disorder (Royal College of Physicians & Royal College of Psychiatrists, 2013). The introduction of smoking bans (House of Commons Health Committee, 2005; New South Wales Department of Health, 2005) and concurrent provision of behavioral and pharmacological smoking cessation treatment in inpatient psychiatric settings (American Psychiatric Association, 2006; Fiore, Jaen, & Baker, 2008; New South Wales Department of Health, 2002) provides an opportunity to initiate such care (Prochaska, 2010b). Several studies have suggested that a smoke-free psychiatric hospitalization may increase patients' motivation to quit (Shmueli, Fletcher, Hall, Hall, & Prochaska, 2008) and result in reductions in cigarette consumption up to 2 weeks postdischarge (Siru, Hulse, Khan, & Tait, 2010). However, without continued cessation support post-hospitalization, most smokers return to smoking (Prochaska, Fletcher, Hall, & Hall, 2006). Extensive literature demonstrates the efficacy of initiating smoking cessation treatment within general hospital settings (Rigotti, Clair, Munafò, & Stead, 2012), with the chance of cessation success significantly enhanced by including at least a 1-month supportive period post-hospitalization (Bowman & Stockings, 2012). Such support may also represent an effective model for smokers discharged from an inpatient psychiatric facility (Bowman & Stockings, 2012).

Only one recently published study, conducted in the United States, has examined smoke-free inpatient adult psychiatry as a setting for initiating smoking cessation treatment (Prochaska, Hall, Delucchi, & Hall, 2013). Abstinence rates at 18 months postdischarge were higher among patients receiving motivational smoking cessation treatment combined with nicotine replacement therapy (NRT) (20%) relative to usual care controls (7.7%). These findings support the initiation of smoking cessation treatment within inpatient psychiatry, however no such research has been conducted in the Australian context (Stockings et al., 2011). To address this evidence gap, a study was undertaken to examine the efficacy of a smoking cessation intervention initiated during a psychiatric hospitalization and continued postdischarge in increasing smoking cessation and quit attempts and in reducing cigarette consumption and nicotine dependence among Australian psychiatric inpatients.

## METHODS

### Design

A single site, stratified (psychotic/nonpsychotic diagnosis), blinded, individually randomized controlled (intervention vs. treatment as usual control) parallel-group trial was conducted. As details of the trial have been reported previously (Stockings et al., 2011), study design and methods are presented in summarized form here.

### Participants and Setting

Study participants were patients of a discrete psychiatric facility located within a large, regional public hospital in NSW,

Australia over a 12-month period (May 2010–11). The psychiatric facility had up to 2,000 discharges per year, and comprised six units, of which three were included in this study (comprising a total of 66 beds): one comorbid acute mental health and substance use unit and two acute adult mental health units. The three excluded units (comprising 34 beds) were two psychiatric emergency care short stay units and one older persons unit. In accordance with state-wide policy directives, a total smoking ban was implemented in the facility in 2006, prohibiting smoking in all hospital buildings and grounds (New South Wales Department of Health, 2005) and treating staff were required to provide nicotine dependence treatment to all smokers (New South Wales Department of Health, 2002). Patient inclusion criteria were, being: at least 18 years of age, a self-reported current or occasional smoker, able to provide a contact telephone number and/or address, capable of completing a face-to-face baseline survey, and being fluent in English.

Ethics approval for the study was obtained from the Hunter New England Human Research Ethics Committee, HREC reference no: 08/04/16/5.10, and the University of Newcastle Human Research Ethics Committee reference no: H-2008-0191. The trial was registered on the Australian New Zealand Clinical Trials Registry ACTRN1260900046525.

### Recruitment Procedure

Ward lists were used to determine new patient admissions on a daily basis, and trained project officers (independent of the hospital) liaised with clinical staff to determine patient capability to complete the baseline interview, and mental health diagnosis. Each patient was approached as soon as possible following admission and stabilization, and patients identified to be smokers were invited to participate in the trial.

### Randomization

A randomization sequence was computer generated by a statistician independent of the research team using SPSS for windows version 19.0 (IBM Corp., released 2010) and was stratified by mental health diagnosis (psychotic and nonpsychotic) with a 1:1 allocation, prior to recruitment. Randomization was achieved by each consenting participant drawing a sequentially numbered envelope from a series of envelopes containing an equal distribution of control and intervention. All project and clinical staff working in the hospital setting and follow-up interviewers were blinded to the randomization sequence.

### Treatment Conditions

#### Control

Participants allocated to the 'treatment as usual' control condition received nicotine dependence treatment provided by the facility as standard care during admission and on discharge. In accordance with state-wide guidelines (New South Wales Department of Health, 2002), such care could have involved: assessment of smoking status and nicotine dependence on admission, provision of brief advice to quit, provision of NRT during admission and for 3 days upon discharge, and a postdischarge smoking care plan included on the discharge summary. Previous research in this setting has suggested that the provision of such care is limited and variable (Wye et al., 2010).

### Intervention

In addition to treatment as usual, all participants allocated to the intervention condition received self-help smoking cessation literature and a 10- to 15-min motivational interview with the project officer, immediately following completion of the baseline interview. The focus of this motivational interview was to explore ambivalence and barriers toward smoking cessation and to encourage behavior change via the uptake and use of the intervention support components. Information regarding a participants' engagement in the study was entered into the online discharge summary system for the information of treating clinicians postdischarge. At the time of discharge, patients collected a 2-week supply of project NRT (tailored to personal preferences and severity of nicotine dependence). Upon discharge, all participants received 4 months of fortnightly telephone smoking cessation support with a designated counselor who offered: 12-week additional supply of tailored NRT, a referral to a free state government-operated telephone quit service 'Quitline', and a referral to community-run smoking cessation groups (delivered by allied health staff in local community mental health services; tailored for persons with a mental disorder). Each telephone support call followed a standardized script and covered topics including: usage of the intervention supports, review of NRT dosage, assistance with correct NRT use, monitoring and managing nicotine withdrawal symptoms, techniques to improve smoking outcomes, and general psychological support and encouragement. While quitting smoking was the focus of the intervention, a harm minimization approach was also employed, through encouraging uptake of cessation supports and a reduction in daily cigarette consumption.

### Measures

#### Sample Characteristics at Baseline

Sociodemographic and clinical characteristics of the sample were collected on the day of recruitment via face-to-face survey and medical record audit and comprised: unit of admission, length of stay (calculated from date of admission and date of discharge), age, gender, marital status, completed education, current employment, receipt of government pension, primary mental health diagnosis, psychological distress (Kessler Psychological Distress scale [K10]; Kessler et al., 2003), and alcohol consumption (AUDIT-C; Babor, Higgins-Biddle, Saunders, & Monteiro, 1990). Patient reported receipt of nicotine dependence treatment during admission, including receipt of NRT and brief advice to quit, and adherence to the smoke-free policy was obtained at the 1-week follow-up assessment to account for the entire admission. Smoking-related characteristics comprised: age of smoking onset, daily cigarette consumption, nicotine dependence (Fagerstrom Test for Nicotine Dependence [FTND]; Heatherton, Kozlowski, Frecker, & Fagerström, 1991), previous quit attempts (in lifetime and in the past 12 months), stage of change for quitting (Readiness and Motivation to Quit Questionnaire [RMQ]; Crittenden, Manfredi, Lacey, Warnecke, & Parsons, 1994), lifetime NRT use, cannabis use (in lifetime and in the past 12 months), and if cannabis is usually mixed with tobacco.

#### Primary and Secondary Outcomes

Follow-up data were collected via computer-assisted telephone interview at 1 week and at 2, 4 (aligned with completion of the

intervention period), and 6 months postdischarge. The 4-month assessment was designed to occur at the completion of the intervention period, however differences in the timing of intervention onset and difficulties in contacting participants meant that this assessment may have occurred slightly before or after treatment had ceased. The primary smoking-related outcomes were the differences in validated continuous (from date of discharge) and 7-day point prevalence abstinence between treatment conditions. For participants who self-reported abstinence in a follow-up assessment, an appointment was made to meet with a project officer at a convenient time and location within 3 days of the interview to complete an expired breath carbon monoxide (CO) assessment using a MICRO+ Smokerlyzer to verify smoke-free status. Self-reported abstinence was reassessed immediately prior the CO assessment, and the cut-off for abstinence set at <10 parts per million (Hughes et al., 2003; West, Hajek, Stead, & Stapleton, 2005).

Secondary smoking-related outcomes were the differences in prevalence of quit attempts, daily cigarette consumption, and level of nicotine dependence (FTND; Heatherton et al., 1991) between treatment conditions. Quit attempts were defined as not smoking for a period of at least 24 hr with the intent to quit (not including hospitalization). We also assessed changes in psychological distress between treatment conditions using the K10 at each follow-up assessment.

#### Use of Intervention Supports

For participants in the intervention condition, use of each of the smoking cessation supports (NRT, Quitline, and smoking cessation groups), and details regarding number of, and duration of support calls were recorded during each fortnightly telephone support call with the designated counselor.

#### Variable Transformation

Responses to the following variables were reduced to two levels: K10 (low or moderate psychological distress [10–29] and high psychological distress [30–50]; Australian Bureau of Statistics, 2001), education level (<higher school certificate, higher school certificate, or greater), employment (paid employment, no paid employment), and nicotine dependence (not dependent [FTND ≤ 5] and dependent [FTND ≥ 6]; Fagerstrom et al., 1996). Participants were classified as having hazardous levels of alcohol consumption if AUDIT-C scores were ≥3 for women and ≥4 for men (Bradley et al., 2007). Responses to the following variables were reduced to three levels: age (< 30, 31–45, and 46+) and mental health diagnoses (mood disorders, schizophrenia and related psychosis, other).

#### Analyses

SPSS for windows version 20.0 (IBM Corp., released 2011) and SAS 9.3 for windows (SAS Institute Inc., 2011) were used to analyze the data. Descriptive statistics were used to summarize the sample's sociodemographic, clinical, and smoking-related characteristics and receipt of nicotine dependence treatment at baseline. Chi-square analyses and independent samples *t*-tests were used to examine differences between consenters and non-consenters, between participants in the intervention and control conditions, and between those who did and did not complete each follow-up assessment.

Outcome analyses were conducted on an intention to treat basis with participants retained in their originally assigned groups (Pagoto et al., 2009). The primary endpoint for all outcomes was defined as the 6-month follow-up assessment. For all smoking-related outcomes (with the exception of continuous abstinence) and for psychological distress, generalized linear mixed modeling was used to examine differences between treatment conditions over time (intervention group [ $n = 104$ ] vs. control group [ $n = 101$ ]) (Chakraborty & Gu, 2009). To examine predictors of the primary abstinence outcomes, we entered baseline demographic variables (age, gender, education level, pension status, mental health diagnosis, and readiness to quit smoking), use of the intervention components, psychological distress (K10), alcohol consumption (AUDIT-C), and cannabis use as covariates into the generalized linear mixed models. A significant intervention effect was determined based on a significant group-by-time interaction. For variables where no baseline assessment was applicable (i.e., point prevalence abstinence, quit attempts, and 50% reduction in cigarettes per day), a significant intervention effect was determined based on a main effect of condition at the primary endpoint. Due to the low number of counts due to zero cells for the continuous abstinence variable, chi-square Fischer's exact tests were used in lieu of generalized linear mixed modeling to examine differences between treatment conditions at each follow-up assessment separately. For this analysis, a significant intervention effect was determined based on a significant difference between treatment conditions at the primary endpoint.

For categorical outcomes, missing data were classified as non-abstinent, as not having made a quit attempt, or as failing to achieve the 50% reduction in the number of cigarettes smoked. If participants exhaled above 10 parts per million of CO during biochemical validation of self-reported abstinence, or if they failed to provide a CO sample, they were classified non-abstinent (Hughes et al., 2003; West et al., 2005). Smoking reduction was calculated based on whether participants had reduced their daily cigarette consumption by 50% or greater (including abstinence) since baseline (Baker et al., 2006; Evins et al., 2007; Gelkopf et al., 2012). Odds ratios (ORs), uncertainty estimates (95% CI) and  $p$  values were reported where appropriate, with the control group as the reference point ( $OR = 1.00$ ). The threshold for statistical significance was set at  $p < .01$ .

## RESULTS

### Participants

Participant recruitment and attrition characteristics are presented in Supplementary Figure 1. Of the 1,174 patients admitted to the study units during the 12-month study period, 716 (61.0%) were assessed for eligibility of which 297 (41.4%) were eligible for inclusion, and 205 provided consent (69.0%) and were randomized (101 control and 104 intervention). Follow-up rates were 75.1% of consenting participants at 1 week, 75.6% at 2 months, 72.2% at 4 months, and 64.4% at 6 months and did not differ between treatment conditions at any time point. There were no significant differences in characteristics for those who completed the follow-up assessments compared to those who did not, at any time point.

Sociodemographic and clinical characteristics by treatment condition are provided in Table 1. Mean length of stay

for all patients admitted during the study period was 22.6 days ( $SD = 78.0$ ). Mean number of days from admission to consent to the trial was 11.4 days ( $SD = 19.5$ ). Consenters had significantly longer lengths of stay than nonconsenters ( $M = 31.5$ ,  $SD = 38.5$ , vs.  $M = 13.5$ ,  $SD = 15.2$ ,  $t(279) < .0001$ ) but did not differ from nonconsenters with respect to any other characteristics. The mean age of consenting participants was 37.6 years ( $SD = 10.9$ ), and the majority were male (53.7%), single (68.1%), and received a government pension (82.0%). The primary mental health diagnoses were schizophrenia and related psychosis (33.7%), substance-related disorders (21.5%), unipolar depressive disorders (18.5%), and bipolar disorders (14.1%). There were no significant differences in the sociodemographic or clinical characteristics between treatment groups at baseline, indicating that the randomization was successful.

### Receipt of Nicotine Dependence Treatment in Facility

At 1 week postdischarge, most participants (84.8%) reported using NRT during hospitalization. However, under a third of participants (32.5%) reported receiving advice to quit from a treating staff member, and the majority of participants continued to smoke during admission (82.9%). There were no significant differences in receipt of nicotine dependence treatment or adherence to the smoking ban during hospitalization between treatment groups (Table 1).

### Smoking-Related Characteristics of Participants

Participants smoked an average of 23 cigarettes per day, with the majority (53.7%) classified as nicotine dependent (FTND  $\geq 6$ ; Fagerstrom et al., 1996). Over half of participants (55.1%) had made one or more quit attempt in the previous 12 months. There were no significant differences in smoking-related characteristics between treatment groups at baseline (Table 2).

### Use of Intervention Support Options

Of the 104 participants randomized to the intervention condition, 94 received at least some of the allocated intervention. Of these, 43 (45.7%) received at least seven support calls, with a mean of 5.1 ( $SD = 3.1$ ) calls received, and a mean duration of 14.9 ( $SD = 6.3$ ) min per call, resulting in an average of 76.0 ( $SD = 62.6$ ) min of supportive counseling throughout the intervention phase. A total of 71 intervention participants (68.3%) used NRT, with a mean duration of 7.1 weeks ( $SD = 4.2$ ). The most commonly used therapy was nicotine patch in combination with nicotine gum, lozenge, or inhaler (77.55%,  $n = 55$ ), followed by nicotine patch alone (16.9%,  $n = 12$ ) and gum, lozenge or inhaler alone (5.6%,  $n = 4$ ). A total of 29 participants (27.9%) received supportive telephone counseling from the Quitline, with a mean of 1.2 calls received ( $SD = 1.7$ ). Only two participants (1.9%) attended the community-run smoking cessation groups during the intervention phase.

### Primary Outcomes

#### Continuous Abstinence

Biochemical validation confirmed 100% of self-reported continuous abstinence throughout the study period. Prevalence of continuous abstinence at the 1-week, 2-, 4-, and 6-month follow-ups were 1.0% (1), 0% (0), 0% (0), and 0% (0) for the control group and 5.8% (6), 2.9% (3), 1.9% (2), and 1.9% (2) for the



**Table 1.** Sociodemographic and Clinical Characteristics for Both Treatment Conditions at Baseline

Number of participants <sup>a,b</sup>	Control ( <i>n</i> = 101)	Intervention ( <i>n</i> = 104)	Total ( <i>n</i> = 205)
Unit admitted			
Mental health and substance use unit	54.5 (55)	54.8 (57)	54.6 (112)
General acute unit 1	25.7 (26)	26.9 (28)	26.3 (54)
General acute unit 2	19.8 (20)	18.3 (19)	19.0 (39)
Age	37.2 (10.8)	38.1 (11.0)	37.6 (10.9)
Gender			
Male	53.5 (54)	53.8 (56)	53.7 (110)
Female	46.5 (47)	46.2 (48)	46.3 (95)
Marital status			
Single	68.3 (69)	67.3 (70)	68.1 (139)
Current partner	15.8 (16)	19.2 (20)	17.6 (36)
Previously partnered	14.9 (15)	13.5 (14)	14.1 (29)
Total admission length	31.4 (37.9)	31.6 (39.2)	31.5 (38.5)
Days from admission to study consent	13.1 (24.3)	9.7 (13.1)	11.4 (19.5)
K10 total	28.6 (10.6)	30.1 (10.8)	29.4 (10.7)
K10 score			
Low to moderate distress (10–29)	54.5 (55)	50.0 (52)	52.2 (107)
Severe distress (30–50)	43.6 (44)	46.2 (48)	44.9 (92)
Education, % ( <i>n</i> )			
Less than year 12	58.0 (58)	60.0 (60)	57.6 (118)
Year 12 or greater	42.0 (42)	40.0 (40)	40.0 (82)
AUDIT-C categories			
Nonhazardous alcohol use	66.3 (67)	58.7 (61)	62.4 (128)
Hazardous alcohol use	33.7 (34)	41.3 (43)	37.6 (77)
Employment, % ( <i>n</i> )			
No paid employment	60.4 (61)	68.3 (71)	64.4 (132)
Paid employment	35.6 (36)	27.9 (29)	31.7 (65)
Receives government pension			
No	18.8 (19)	12.5 (13)	15.6 (32)
Yes	78.2 (79)	85.6 (89)	82.0 (168)
Primary mental health diagnosis			
Schizophrenia and related psychosis	34.7 (35)	32.7 (34)	33.7 (69)
Substance-related disorders	20.8 (21)	22.1 (23)	21.5 (44)
Unipolar depressive disorders	20.8 (21)	16.3 (17)	18.5 (38)
Bipolar disorders	9.9 (10)	18.3 (19)	14.1 (29)
Anxiety and stress-related disorders	6.9 (7)	2.9 (3)	4.9 (10)
Personality disorders	2.0 (2)	3.8 (4)	2.9 (6)
Other	5.0 (5)	3.8 (4)	4.4 (9)
Abstained from smoking during admission			
No	82.2 (83)	83.7 (87)	82.9 (170)
Yes	17.8 (18)	16.3 (17)	17.1 (35)
Used NRT during admission <sup>c</sup>			
No	16.7 (13)	17.1 (13)	16.9 (26)
Yes	83.3 (65)	82.9 (63)	83.1 (128)
Received advice to quit during admission <sup>c</sup>			
No	70.7 (53)	65.5 (49)	66.2 (102)
Yes	32.0 (25)	35.5 (27)	33.8 (52)

<sup>a</sup>Numbers vary due to missing data.<sup>b</sup>Data are means (*SD*) or numbers (%).<sup>c</sup>Data collected during the 1-week follow-up assessment to account for the whole admission (*n* = 154).

intervention group. Fisher's exact tests revealed no significant differences between conditions at the 1 week ( $p = .06$ ), 2 months ( $p = .13$ ), 4 months ( $p = .26$ ), or 6 month assessments ( $p = .26$ ).

#### Point Prevalence Abstinence

Biochemical validation confirmed 96.6% of self-reported 7-day point prevalence abstinence throughout the study period. Prevalence of biochemically validated 7-day point prevalence abstinence varied between 2.0% and 5.9% for the control group

and 6.7% and 11.5 % for the intervention group for each of the four follow-up points, with no significant main effect of condition ( $F[1, 206] = 3.78, p = .05$ ; Table 3). However, at the 4-month follow-up (end of treatment), 7-day point prevalence abstinence was significantly higher in the intervention (11.5%) than control (2.0%) condition ( $OR = 6.46, 95\% CI = 1.50–32.77$ ). Demographic variables, use of the intervention components, psychological distress, and alcohol and cannabis use did not predict 7-day point prevalence abstinence at any time

**Table 2.** Smoking-Related Characteristics at Baseline

Number of participants <sup>a,b</sup>	Control (n = 101)	Intervention (n = 104)	Total (n = 205)
Age began smoking regularly	15.7 (4.3)	16.4 (4.5)	16.1 (4.4)
Cigarettes per day	23.7 (15.0)	22.2 (10.8)	23.0 (13.0)
FTND total	5.6 (2.2)	5.7 (2.1)	5.7 (2.1)
Nicotine dependent (FTND ≥ 6)			
No	49.0 (48)	43.7 (45)	46.3 (93)
Yes	51.0 (50)	56.3 (58)	53.7 (108)
Previous quit attempts (lifetime)			
Never	16.8 (17)	14.6 (15)	15.7 (32)
Once	18.8 (19)	12.6 (13)	15.7 (32)
2–3	32.7 (33)	33.0 (34)	32.8 (67)
>3	31.7 (32)	39.8 (41)	35.8 (73)
Previous quit attempts (12 months)			
No attempt	47.8 (44)	42.1 (40)	44.9 (84)
One or more	52.2 (48)	57.9 (55)	55.1 (103)
Stage of change for quitting			
Precontemplation	58.0 (58)	48.1 (50)	52.9 (108)
Contemplation	30.0 (30)	34.6 (36)	32.4 (66)
Preparation for action	12.0 (12)	17.3 (18)	14.7 (30)
Pre-hospitalization NRT use (lifetime)			
No	34.7 (35)	30.8 (32)	32.7 (67)
Yes	65.3 (66)	69.2 (72)	67.3 (138)
Cannabis use (12 months)			
No	42.6 (43)	40.4 (42)	41.5 (85)
Yes	57.4 (58)	59.6 (62)	58.5 (120)
Mix cannabis with tobacco			
No	13.8 (8/58)	12.9 (8/62)	13.3 (16/120)
Yes	86.2 (50/58)	87.1 (54/62)	86.7 (104/120)

<sup>a</sup>Numbers vary due to missing data.

<sup>b</sup>Data are means (SD) or numbers (%).

point (all  $p$ s > .37). However, at the 4-month follow-up, use of NRT was significantly associated with point prevalence abstinence. Of the 12 participants in the intervention condition with validated abstinence at this time point, 11 (91.7%) reported using NRT at this time point, and of the two participants in the control condition with validated abstinence, none (0%) were using NRT at the time of the 4-month follow-up ( $\chi^2$  (3) = 6.8,  $p$  = .009).

## Secondary Outcomes

### *Quit Attempts, Cigarette Consumption, and Nicotine Dependence*

A significant main effect of condition was found for quit attempts, with significantly greater proportions of participants in the intervention condition making a quit attempt at 2 months (48.1% vs. 27.7%), 4 months (46.2% vs. 24.8%), and 6 months (31.7% vs. 13.9%) relative to controls ( $F$ [1, 202.5] = 15.23,  $p$  = .0001). A significant main effect of condition was found for 50% reduction in cigarettes per day, with greater proportions of participants in the intervention condition having reduced their cigarette consumption by 50% or more at 1 week (26.0% vs. 9.9%), 2 months (29.8% vs. 12.9%), 4 months (33.7% vs. 8.9%), and 6 months (36.5% vs. 8.9%) relative to controls ( $F$ [1, 204.6] = 25.28,  $p$  < .0001, Table 3).

Time-by-condition interactions were significant for daily cigarette consumption ( $F$ [4, 586] = 6.5,  $p$  = .001) and nicotine dependence ( $F$ [3, 406] = 8.5,  $p$  < .0001), with greater

reductions in each outcome for participants in the intervention condition relative to controls (Table 4). For psychological distress, we found no significant condition-by-time interaction ( $F$ [3, 621] = 1.48,  $p$  = .22) and no significant main effect of condition ( $F$ [1, 621] = .04,  $p$  = .85). The main effect of time was significant ( $F$ [3, 621] = 63.2,  $p$  < .0001) with K10 scores decreasing from baseline to the 2-month assessment and remaining constant from 2 months to 6 months for both conditions (Table 4).

## DISCUSSION

To the authors' knowledge, this is one of only two studies undertaken internationally to examine the efficacy of a smoking cessation intervention initiated in the inpatient psychiatric setting and continued postdischarge for smokers with a mental disorder, and the first such study undertaken in Australia. Moreover, this study is unique in examining the effect of providing smoking cessation support immediately upon discharge, facilitating a continuation of NRT use from the inpatient setting and proactively encouraging all smokers to accept the offer of cessation support irrespective of any stated desire to quit at that time or request for assistance. While we found no significant difference between the intervention and control conditions on rates of continuous or 7-day point prevalence abstinence at the 6-month follow-up, numeric group differences were in the expected direction, indicating this study may have been

**Table 3.** Results of Generalized Linear Mixed Models for Categorical Outcomes Point Prevalence Abstinence, Quit Attempts, and 50% Reduction in Cigarette Consumption for the Intervention and Control Groups at the 1-Week, 2-, 4-, and 6-Month Follow-Up Assessments<sup>a</sup>

Measure/groups	1 week			2 months			4 months			6 months		
	% (n)	OR	95% CI	% (n)	OR	95% CI	% (n)	OR	95% CI	% (n)	OR	95% CI
Point prevalence abstinence <sup>b</sup>												
Control (n = 101)	5.0 (5)	1		5.0 (5)	1		2.0 (2)	1		5.9 (6)	1	
Intervention (n = 104)	6.7 (7)	1.37	0.45–4.98	10.6 (11)	2.27	0.81–7.52	11.5 (12)	6.46	1.50–32.77	7.7 (8)	1.32	0.47–4.36
Quit attempts <sup>c,d</sup>												
Control (n = 101)	12.9 (13)	n/a	n/a	27.7 (28)	1		24.8 (25)	1		13.9 (14)	1	
Intervention (n = 104)	23.1 (24)	n/a	n/a	48.1 (50)	2.41	1.35–4.44	46.2 (48)	2.61	1.44–4.85	31.7 (33)	2.89	1.43–5.98
50% reduction in cigarettes per day <sup>e</sup>												
Control (n = 101)	9.9 (10)	1		12.9 (13)	1		8.9 (9)	1		8.9 (9)		
Intervention (n = 104)	26.0 (27)	3.19	1.57–8.18	29.8 (31)	2.88	1.51–6.88	33.7 (35)	5.19	2.53–13.47	36.5 (38)	5.90	2.89–15.25

Note. OR = odds ratio (unadjusted); CI = confidence interval.

<sup>a</sup>Missing data were classified as nonabstinent, as not having made a quit attempt, or as failing to achieve the specified rate of reduction.

<sup>b</sup>Validated with CO test <10 ppm. No significant condition-by-time interaction ( $F[3,641.7] = 1.63, p = .18$ ). No significant main effect of condition ( $F[1, 206] = 3.78, p = .05$ ) or time ( $F[3, 641.7] = 0.49, p = .69$ ).

<sup>c</sup>No significant condition-by-time interaction ( $F[2, 412.6] = 0.12, p = .89$ ). Significant main effect of condition ( $F[1, 202.5] = 15.23, p = .0001$ ), with more participants in the intervention condition having made a quit attempt at 2, 4, and 6 months relative to controls. Significant main effect of time ( $F[2, 412.7] = 9.66, p \leq .0001$ ), with more participants having made a quit attempt at 2 and 4 months relative to 6 months for both treatment conditions.

<sup>d</sup>Quit attempts defined as not smoking for a period of 24hr with the intent to quit (not including hospitalization).

<sup>e</sup>No significant condition-by-time interaction ( $F[3, 610.2] = 1.22, p = .31$ ). Significant main effect of condition ( $F[1, 204.6] = 25.28, p < .0001$ ), with more participants in the intervention condition having reduced their cigarette consumption by 50% since baseline at 1 week, 2, 4, and 6 months relative to controls. No significant main effect of time ( $F[3, 613.2] = 0.43, p = .73$ ).

**Table 4.** Results of Generalized Linear Mixed Models Examining Differences in Continuous Outcomes Cigarettes Smoked per Day, Nicotine Dependence, and Psychological Distress Between the Treatment Conditions at the 1-Week, 2-, 4-, and 6-Month Follow-Up Assessments

Variable/time point	Control	Intervention	Mean difference (95% CI) <sup>a</sup>		<i>p</i> <i>value</i>
Cigarettes per day <sup>b</sup>					
Baseline	23.7 (1.4)	22.2 (1.4)	−1.5	(−5.4 to 2.4)	.404
1 week	18.8 (1.4)	14.0 (1.2)	−4.8	(−8.3 to −1.2)	.006
2 months	18.2 (1.4)	12.1 (1.2)	−6.0	(−9.4 to −2.6)	.002
4 months	19.2 (1.4)	11.3 (1.1)	−7.9	(−11.4 to −4.4)	<.0001
6 months	19.0 (1.5)	11.9 (1.1)	−7.1	(−10.7 to −3.5)	<.0001
Nicotine dependence (FTND) <sup>c,d</sup>					
Baseline	5.6 (0.2)	5.7 (0.2)	0.1	(−0.6 to 0.8)	.779
1 week	—	—	—	—	—
2 months	5.2 (0.3)	4.4 (0.3)	−0.8	(−1.5 to −0.1)	.036
4 months	5.5 (0.3)	4.1 (0.3)	−1.3	(−2.1 to −0.6)	<.0001
6 months	5.7 (0.3)	4.2 (0.3)	−1.6	(−2.3 to −0.8)	.0001
Psychological distress (K10) <sup>e</sup>					
Baseline	28.6 (1.1)	30.1 (1.1)	1.5	(−1.6 to 4.6)	.337
1 week	—	—	—	—	—
2 months	21.0 (1.0)	21.0 (1.0)	0.1	(−2.8 to 2.9)	.960
4 months	22.6 (1.1)	21.2 (1.0)	−1.4	(−4.3 to 1.6)	.355
6 months	22.0 (1.1)	21.3 (1.1)	−0.7	(−3.7 to 2.3)	.642

Note. (—) = data not collected at this time point; CI = confidence interval.

<sup>a</sup>Data are mean score (SE) or mean change score.

<sup>b</sup>Significant condition-by-time interaction ( $F[4, 586] = 6.5, p = .001$ ) for baseline vs. 1 week, 2, 4, and 6 months. Significant main effect of time for baseline vs. 1 week, 2, 4, and 6 months ( $F[4, 586] = 31.1, p < .0001$ ). Significant main effect of condition for intervention vs. control ( $F[1, 205] = 16.6, p < .0001$ ).

<sup>c</sup>Significant condition-by-time interaction ( $F[3, 406] = 8.5, p < .0001$ ) for baseline vs. 1 week, 2, 4, and 6 months. Significant main effect of time ( $F[3, 406] = 10.9, p < .0001$ ) for baseline vs. 1 week, 2, 4, and 6 months. Significant main effect of condition ( $F[1, 215] = 9.8, p = .002$  for intervention vs. control).

<sup>d</sup>FTND not administered if participant reported abstinence.

<sup>e</sup>No significant condition-by-time interaction ( $F[3, 621] = 1.48, p = .22$ ). No significant main effect of condition ( $F[1, 621] = .04, p = .85$ ). Significant main effect of time ( $F[3, 621] = 63.2, p < .0001$ ), with K10 scores decreasing from baseline to 2 months and remaining constant from 2 to 6 months for both conditions.

underpowered to detect the effect of the intervention. Point prevalence abstinence was higher among intervention participants than controls at 4 months (end of treatment), but not at 6 months postdischarge (2 months posttreatment), suggesting that the intervention was effective for some, but relapse was high when treatment ended. Participants in the intervention condition were also more likely to have made a quit attempt, to have reduced their daily cigarette consumption by 50% or more since baseline, and had lower levels of nicotine dependence than controls, and these effects were sustained beyond end of treatment. Psychological distress did not differ between treatment conditions over time. We did not identify any significant predictors of successful abstinence at any time point; however, use of NRT was significantly associated validated point prevalence at the 4-month assessment. These results demonstrate the potential for an integrated approach to smoking cessation intervention to address the currently unmet needs for smoking cessation care among people with an acute mental disorder. Further research is required to extend the benefits of such care.

Despite the significant proportion of smokers with a mental disorder, they are often excluded from studies examining the efficacy of smoking cessation interventions. Consequently, there remains little rigorous evidence regarding effective smoking cessation treatments among this group, and only one systematic review—containing eight trials—has been published to

date (Banham & Gilbody, 2010). Such studies have primarily focused on clinically stable community-residing patients with schizophrenia or schizoaffective disorders, who were required to report a willingness to quit at study intake (Banham & Gilbody, 2010).

At 6- to 8-month follow-up, 7-day point prevalence abstinence in such studies has ranged from 0% to 17.6% for control groups and between 4.0% and 18.8% for intervention groups (Baker et al., 2006; Evins et al., 2005; George et al., 2000, 2002, 2008), with just one producing significant differences between treatment conditions (George et al., 2008). Aside from the current study, the recently published study of Prochaska and colleagues is the only other randomized controlled trial conducted among a diagnostically heterogeneous sample of inpatient psychiatric patients who were not required to express a willingness to quit for study entry (Prochaska et al., 2013). In their study, rates of 7-day point prevalence abstinence at 6-month follow-up were 6.5% and 14.4% for the control and intervention groups respectively, however many instances of reported abstinence were not directly validated with CO, but often consisted of collateral contact reports of participants' nonsmoking status. Results of secondary outcomes in the present study including significantly higher rates of 50% reduction in cigarette consumption, and significant declines in nicotine dependence levels are also comparable to those found previously (Baker et al.,



2006; Evins et al., 2007). These findings suggest that additional strategies which enhance cessation effects may be required for smokers with an acute mental disorder who have been recently discharged from an inpatient psychiatric facility.

More intensive intervention involving more frequent contacts has previously been suggested to be efficacious in reducing smoking-related behaviors, with a strong dose–response relation between counseling intensity (minutes of contact) and effectiveness (Baker et al., 2006; Fiore et al., 2008; McFall et al., 2010). In this study, the interventions did not involve intensive intervention modalities, particularly as participants received on average just under 1 hr and a half of individual cessation counseling and only two participants attended the smoking cessation groups throughout the 4-month intervention phase. Future studies may focus on further enhancing individual-based telephone, computer or face-to-face counseling with evidence-based behavioral therapies such as motivational interviewing and cognitive behavioral therapy, which have demonstrated efficacy in reducing smoking behavior among smokers with a serious mental disorder (Baker et al., 2006; Evins et al., 2007). A recent systematic review and meta-analysis identified a modest, but positive effect of behavioral mood management in increasing cessation rates among smokers with depression (Gierisch, Bastian, Calhoun, McDuffie, & Williams, 2012). Further, while we found no evidence that alcohol and cannabis use were associated with cessation outcomes, the high rate of comorbid substance use identified in this sample suggests that interventions concurrently targeting tobacco and other drug use may also assist in improving long-term abstinence in this population (Prochaska, Delucchi, & Hall, 2004).

While the efficacy of all forms of NRT in increasing the likelihood of cessation has been established among general population smokers (Hartmann-Boyce, Stead, Cahill, & Lancaster, 2013), the efficacy of NRT among persons with a mental disorder has not been subject to large scale reviews or meta-analyses. Given that smokers with a mental disorder are more nicotine dependent (Australian Institute of Health and Welfare, 2007) and extract greater levels of nicotine from each cigarette (Williams et al., 2005), more intensive NRT therapies may be required to aid cessation among this group. Use of combination therapy whereby a transdermal patch is supplemented with fast acting forms of NRT such as sublingual lozenges, nicotine inhaler, and gum should likely continue beyond the typically recommended 8–12 weeks (Bittoun, 2006; Rigotti, 2012; Royal College of Physicians & Royal College of Psychiatrists, 2013), however further studies are needed to confirm the potential for extended use of higher dose NRT in increasing cessation rates among smokers with a mental disorder.

No smoking cessation intervention effect was observed in this study at 1 week postdischarge. Such a finding is consistent with previous studies showing no effect on postdischarge smoking cessation of admission to a smoke-free hospital (Jonas & Eagle, 1991; Prochaska et al., 2006). Such a pattern of results has been suggested to be a result, in part, of inadequate implementation of smoke-free policies and associated provision of smoking cessation care to patients in the inpatient psychiatric setting (Prochaska, 2009, 2010a). This explanation is likely to have been relevant to the findings in this study, given that the vast majority of participants continued to smoke during admission, and provision of nicotine dependence treatment was inconsistent. Evidence from general medical settings suggests that smokers who abstain from smoking during hospitalization have four times greater odds of remaining abstinent

up to 6 months post-hospitalization compared to those who do not abstain (Duffy, Scholten, & Karvonen-Gutierrez, 2010). Further, adding NRT to counseling during hospitalization significantly increases cessation rates (Rigotti et al., 2012). Strategies to improve smoke-free policy implementation in inpatient psychiatric settings, including consistent enforcement of smoking bans, cohesive leadership among staff, and systematic provision of nicotine dependence treatment are greatly needed (Lawn & Campion, 2010).

While this study was limited to a single Australian psychiatric facility, inpatient psychiatric facilities in most developed nations have some form of smoking ban in place (House of Commons Health Committee, 2005) and treat a diagnostically heterogeneous group of predominantly dependent smokers (Etter, Khan, & Etter, 2008; Prochaska et al., 2013; Ratschen, Britton, Doody, & McNeill, 2010), and as such there is no compelling reason to suggest our study findings are not generalizable to smoke-free psychiatric settings in other developed nations. However, the study was likely underpowered to detect the effect of the intervention and to identify factors predicting successful abstinence. Further, difficulty in contacting participants and variations in the onset of the intervention component meant that the 4-month outcome assessment may have occurred several weeks after the 4-month treatment period had ceased. Given the known high rate of relapse following treatment discontinuation in this population (George et al., 2000, 2002), rates of 7-day point prevalence abstinence may have been underestimated at this time point. Finally, while the use of biochemical validation of abstinence is a strength of the study, bias associated with the self-report of the secondary smoking-related outcomes cannot be ruled out.

For smokers with a mental disorder, cessation support provided post-hospitalization was effective in reducing cigarette consumption and nicotine dependence, and encouraging quit attempts at 6 months. Additional support strategies are required to facilitate longer term cessation benefits. This study represents a significant step forwards in the systematic treatment of smokers with a mental disorder through the platform of health care services. The unique methodology employed, whereby cessation treatment was initiated within the existing health service and provided to all smokers regardless of intent to quit, or psychiatric diagnosis, adds to its strength, and supports the feasibility and efficacy of initiating smoking cessation treatment in inpatient psychiatry.

## SUPPLEMENTARY MATERIAL

Supplementary Figure 1 can be found online at <http://www.ntr.oxfordjournals.org>

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## DECLARATION OF INTERESTS

*None declared.*

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