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Study Protocol: A Randomised Controlled Trial of Nortriptyline Added to a Smoking Cessation Intervention Conducted among Prisoners

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Authors' contributions

All authors contributed to the design of the study and developed the protocol. Author RLR gained ethical approval from the Human Research Ethics Committees of the University of New South Wales, Justice Health NSW, the NSW Department of Corrective Services, the Aboriginal Health and Medical Research Council of NSW and the Queensland Corrective Services Research Committee. All authors contributed to manuscript preparation, and approved the final manuscript.

Study Protocol

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ABSTRACT

Background: Prisoners endure some of the worst health outcomes of any population group in the community. Smoking rates among prisoners remain high despite a significant reduction in smoking rates among the general public. This protocol describes a study in which we will assess the effectiveness of a smoking cessation intervention conducted among male prisoners.
Methods/Design: 425 male smoking prisoners will be recruited. After completion of a baseline assessment, participants will receive a multi-component smoking cessation intervention comprising two half hour individual sessions of cognitive behavioural therapy and nicotine replacement therapy with either active Nortriptyline or placebo. Blinded follow up assessments will be conducted at 3, 6 and 12 months.
Discussion: This study will provide data on the efficacy of Nortriptyline as a smoking cessation aid for male prisoners in combination with a multi-component smoking cessation intervention. No other smoking cessation randomised controlled trials on male

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prisoners has been published.
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Keywords: Prisoners; smoking cessation; cognitive therapy; nicotine dependence; nicotine patch; nortriptyline.

1. INTRODUCTION

While tobacco control strategies have decreased tobacco use in the Australian general population from 28% in 1998 to 16% in 2010 among men and from 22% to 14% among women [1], smoking rates remain high in disadvantaged populations such as prisoners (85%), people with a mental illness (50% - 80%), Aboriginal Australians (48%) and illicit drug users (71%) [2-9]. Most prisoners come from populations with high smoking rates in Australia: Aboriginal people, people with mental illnesses and people with severe alcohol and drug problems [7,8,10]. Aboriginal people represent approximately 2% of the general population but are as high as 21% in NSW and 30% in Queensland prison populations [11].

Surveys of prisoners in New South Wales (NSW), Queensland (QLD) and Victoria (VIC) found high levels of physical and mental ill health [7-10,12]. Depression is known to be associated with higher rates of smoking [13] and smoking cessation can trigger depression, thus diminishing the effectiveness of cessation interventions [14].

Prisoners have very high rates of smoking (85%), and most use 'roll-your-own' tobacco which has a higher nicotine and tar content than manufactured cigarettes [7]. Prison provides an opportunity for inmates to improve their health including smoking cessation.

Several studies describing the smoking and demographic characteristics of prisoners have been published, but only one describes a prison-based smoking cessation randomised controlled trial (RCT). Cropsey et al. [15-17] compared an intervention (mood management intervention and nicotine replacement therapy) and waitlist control group among female prisoners in one prison in southern USA and found that White smokers had higher smoking cessation rates than Black smokers (30% vs. 24% abstinent at 6 weeks; 13% vs. 10% abstinent at 12 months).

Our multicomponent intervention includes smoking cessation treatments recommended by the Cochrane database and by the Australian guidelines [18-22]. Studies conducted among US smokers reported benefits from adding Nortriptyline to a multicomponent intervention [23-25].

Our research team has conducted two preliminary smoking studies among male prisoners.

Study 1: Focus Group Study

In our first study, we conducted focus groups among Aboriginal and non-Aboriginal inmates to enable us to learn about tobacco use in prison and assist us in the development of the smoking cessation intervention and resource materials [26]. Information from these focus groups was used to develop a treatment manual for smoking cessation in prisons called the Inmate Quit Smoking Program [26]. The inmates developed a QUIT calendar and selected self-help resources that they felt would be appropriate for use in prison. The Quit calendar

covered the 12 weeks of the intervention with prompts on when to take the medication and begin the nicotine patches, comments on staying positive and suggestions for taking one's mind off quitting (e.g. exercising, deep breathing, walking), times when cravings might occur, and messages reminding participants how much money they had saved as a result of not smoking. These resources were then used in our second study which was a feasibility study of conducting a smoking cessation study in the prison system.

Study 2: Feasibility Study of the Smoking Cessation Intervention in Prison

In this study we recruited prisoners who wished to quit smoking through inmate-designed posters displayed in the clinics and word of mouth via prison delegates and Aboriginal elders. The aim of this study was to examine whether brief cognitive behavioural therapy, bupropion (an anti-depressant medication) and nicotine replacement therapy in the form of a patch would lead to smoking cessation among 30 male prisoners. This study was the first trial of smoking cessation among prisoners using combined pharmacotherapies. Our intervention was based on the study by Jorenby et al. [27] that found combined therapy (bupropion, NRT and bCBT) to be more effective than bupropion alone, NRT alone, or placebo in a group of smokers in the general community. This study revealed that inmates had a high or very high level of dependence upon tobacco. Most wanted to use their time in prison to get healthy.

At 6 months, the biochemically validated continuous and point prevalence abstinence rates were 22% and 26%, respectively [3]. Notwithstanding the stresses of prison life, these abstinence rates are high and provide evidence that smoking cessation programs in prison are well accepted, effective and feasible [3]. Reasons for relapse to smoking included: being transferred between prisons without notice (in prison this is considered to be a highly stressful event), boredom, lock-downs (prolonged periods of time where prisoners are locked in their cells), or family and legal stressors. Importantly, an overwhelming majority (95%) of inmates who relapsed during the trial indicated a willingness to try quitting again with our multi-component intervention. This information led us to develop the stressor pack (see below) to assist prisoners during these difficult times. Use of bupropion was deemed not feasible as it had to be given to participating prisoners twice daily.

As a consequence, we embarked upon our third study, a randomised controlled trial funded by a competitive research grant from the National Health and Medical Research Council of Australia (project ID 350829), as well as grants from NSW and Queensland Departments of Health, with NRT provided free of charge by GlaxoSmithKline. This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12606000229572). The protocol of the smoking cessation study is the focus of this paper.

2. METHODOLOGY

2.1 Study Aims

The aim of our research is to evaluate the efficacy of adding Nortriptyline (NOR) to a multi-component smoking cessation intervention involving brief cognitive behavioural therapy and nicotine transdermal patch (NRT) among male prisoners.

2.2 Study Design and Setting

This will be a randomised controlled trial and Fig. 1 shows the overall design. This research will be conducted in 17 prisons across NSW and 1 prison in Queensland.

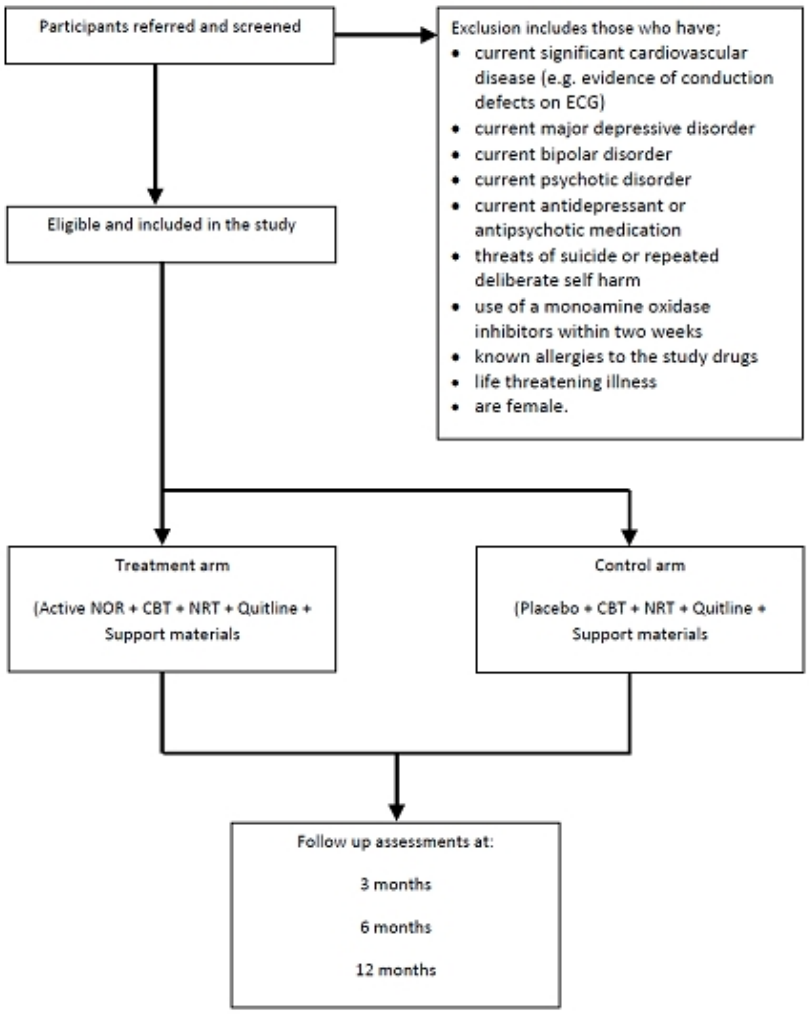

Fig. 1. Flowchart of recruitment and retention of participants through the trial

This research is approved by the Human Research Ethics Committees of the University of New South Wales, Justice Health NSW, the NSW Department of Corrective Services, the Aboriginal Health and Medical Research Council of NSW and the Queensland Corrective Services Research Committee.

2.3 Participants

The sample size is based on the ability to detect a difference of 14% in the continuous abstinence rate at one year between the two groups. The required sample size to detect this

difference with a power of 0.8 and significance of 0.05 is n=178 in each group. With an anticipated an attrition rate of 20%, we aim to recruit 425 inmates to the study.

As many inmates have low levels of literacy, the Consent forms will be tailored to ensure clarity and ease of comprehension by prisoners. Trained nurses experienced in working with prisoners will read the consent forms to the participants and inform them that participation is voluntary and withdrawal without consequence is an option at any time. Inmates who experience side-effects during the course of the trial will be referred to prison medical services for further assessment.

Participants will be recruited from prisons in NSW and Queensland. Prison delegates, prison Aboriginal elders, word of mouth, clinic staff, and flyers and posters developed as a result of our first study and trialled in our second study will be used to recruit inmates to the randomised controlled trial. To advertise the study, signs and flyers will be distributed through prison clinics, prison shops and accommodation areas. These strategies were trialled in our second study (the feasibility study) and found to be effective.

Female prisoners will not be included in this study as they constitute a small minority of the Australian prison population and in NSW and Queensland the percentage is less than 5%. Further, the median sentence length for female prisoners is less than a year. As the length of follow-up for the trial is 12 months and the numbers of women in the system is small, female prisoners will not be included in the study.

2.3.1 Inclusion criteria

Each participant will be required to satisfy all of the following criteria to be eligible for the trial: $\geq$18 years; has been incarcerated for $\geq$1 month with $\geq$6 months of the current sentence remaining; English speaker; consumes $\geq$30 grams of tobacco per day; scores $\geq$6 on the Fagerström Test for Nicotine Dependence (indicates moderate to high nicotine dependence); and readiness to quit smoking [28,29]. They must also be willing to provide the investigators with the contact details of family or friends to enable community follow-up should they be released.

2.3.2 Exclusion criteria

Female; current significant cardiovascular disease (e.g. evidence of conduction defects on ECG); current major depressive disorder; bipolar disorder; current antidepressant or antipsychotic medication; threats of suicide or repeated deliberate self harm; current psychotic disorder; use of a monoamine oxidase inhibitors within two weeks; known allergies to the study drugs; life threatening illness.

2.3.3 Screening

Prisoners who express interest in participating in the study will be screened for suitability by the prison doctor using a modified version of the screening checklist used in study 2, and include an ECG. The medical screening checklist includes a list of 9 items corresponding to key exclusion criteria (e.g., life threatening illness, current significant cardiovascular disease, current antidepressant or antipsychotic medication) to ensure participant safety in the trial. If the medical staffs are uncertain whether an inmate should participate in the trial they will contact one of the investigators who are medical practitioners (AW or KW) for advice.

2.3.4 Personnel

Prison nurses will be trained by the investigators to conduct the intervention and the assessment procedures. Prison doctors will be responsible for prescribing the medication. The medications will be administered by prison clinic nurses as part of daily routine and a record of medications will be recorded in the prisoner's medical records. Blinded assessment of outcomes will be conducted by nurses not participating in the baseline assessments or interventions and they will be conducted at 3, 6 and 12 months.

2.3.5 Content of the multicomponent smoking cessation interventions

Eligible subjects will be randomised to either the active or placebo study groups. Inmates will be randomly assigned to one of two multi-component smoking cessation interventions. Both groups will receive brief cognitive behavioural therapy (CBT), the nicotine transdermal patch, a prison stressor package (developed in response to Study 1) and access to the Quitline (initiated for this study). Group 1 will receive active Nortriptyline (NOR) and group 2 will receive placebo Nortriptyline.

The stop smoking date will be set for the third week following the commencement of Nortriptyline (or placebo) treatment. This date coincides with commencing NRT (see timeline in Table 1). Upon quitting, clinic nurses will instruct participants on the correct use of NRT, and emphasise that they should not smoke any cigarettes whilst wearing nicotine patches. The timeline of delivery of the components of the smoking cessation intervention are outlined in Table 1.

Table 1. Study procedure for the intervention and study group

Week	Notes	NOR	Placebo	NRT	CBT
	Recruitment				
-2	Baseline screening				
-1	Randomisation				
1	Begin NOR or placebo	Tapered dose[1]	✓		
2		✓	✓		
3	Quit week	✓	✓	✓	✓
4		✓	✓	✓	✓[2]
5		✓	✓	✓	
6		✓	✓	✓	
7		✓	✓	✓	
8		✓	✓	✓	
9		✓	✓	✓	
10		✓	✓	✓	
11		✓	✓	✓	
12	First follow-up date	✓	✓	✓	
13		Tapered dose[3]			
26	Second follow-up date				
52	Final follow-up				

1) Dosage is 25mg/d (1 tablet) for 3 days and then 50mg/d (2 tablets) for 4 days.
2) Second bCBT session held during weeks 4-6. Specific date not set due to the logistics of working within prisons.
3) Dosage is 50mg/d (2 tablets) for 4 days and then 25mg/d (1 tablet) for 3 days.

2.3.6 Brief cognitive behavioural therapy (CBT)

Experience from our second study revealed that group sessions with prisoners were difficult to organise, requiring large numbers of custodial staff to escort prisoners and ensure investigator and inmate safety (some groups of prisoners cannot be in the same location as other inmates). Therefore, we decided that both of the CBT sessions will be conducted on an individual basis by Quitline counsellors trained in delivery of the smoking cessation interventions. Prisoners will receive two individual half-hour CBT sessions within a four-week period. These will be held in the quit week (week 3) and during weeks 4-6. The second session will be spread over a 3-week period as we found in our second study that some prisoners were unavailable to participate in the designated week due to lock-downs and lack of custodial staff.

The CBT sessions are based upon the *Inmate Quit Smoking Program* treatment manual developed by the chief investigators and trialled in the feasibility study (Study 2). This cognitive behavioural intervention is designed to facilitate attitude and behaviour change among smokers. It comprises 2 individual visits and booklets which will be distributed during the first visit. Topics covered in the CBT and reinforced in the booklets include: setting a quit date; cognitive-behavioural strategies for cessation such as dealing with smoking triggers; benefits of quitting; dealing with withdrawal symptoms; overcoming obstacles; dealing with stress and boredom; dealing with weight gain; goal setting; and staying in control. It incorporates the framework of stage of readiness to quit. A booklet called *Breakfree* was developed specifically for and by prison inmates resulting from information we gained in our first study [30]. A QUIT calendar developed by inmates for our second study will also be distributed as part of the intervention. We believe that it is important for the consumer (in this case, the prisoner) to participate in the resource development. All resources assume a reading age of 10 years. The focus group study (Study 1) highlighted the need for us to develop a stressor package (see below) for prisoners who will be transferred to other prisons during their incarceration. Prisoners reported that this is a very stressful time.

2.3.7 Stressor package

During the second CBT session inmates will be provided with a prison specific 'coping with change' package in the event that they are transferred to a different correctional facility. This package was developed by chief investigator Wilhelm and is aimed to address issues of concern raised during our first study in which focus groups identified transferral to another prison as a key stressor linked to relapse to cigarette smoking. We found in Study 2 that a high rate of relapse occurred among prisoners who were transferred between facilities [3].

2.3.8 Transferrals

There are approximately 150,000 prisoner movements in NSW every year [7]. If a prisoner is transferred to another prison, his medication will be transferred to the destination prison as per routine clinical practice with other medications within the correctional system.

2.3.9 Nicotine transdermal patch

Beginning in week 3, a 24-hour transdermal nicotine patch will be distributed daily to each subject. Over the 10-week course of patch therapy, a structured tapering system will be employed: 21mg of nicotine per day for the first 6 weeks, followed by 14mg/d over the next 2 weeks and 7mg/d in the final 2 weeks of therapy. Prisoners in both study groups will receive

the nicotine transdermal patch. Due to the nature of the prison system patches will be distributed on a daily basis (rather than weekly) in order to prevent their use as a form of currency. The focus groups in Study 1 revealed that all types of drugs are traded in prison [26].

2.3.10 Nortriptyline

Participants will commence their Nortriptyline anti-smoking medication (active or placebo) 2 weeks prior to the quit date to ensure therapeutic levels are reached. Subsequent therapy will last for a further 10 weeks. Prisoners will receive Nortriptyline at 25mg/d for 3 days, then 50mg/d for 4 days and 75mg/d for the remaining 11 weeks. After this period subjects will decrease to 50mg/d for 4 days, then 25mg/d for 3 days before ceasing to take Nortriptyline or placebo therapy. The treatment schedule is based on the study of Prochazka et al. [31]. The study medication (and identical placebo tablets) will be provided in 25mg tablet form. Prisoners will receive their medication on a once daily basis from the prison clinic nurses. Nortriptyline is a supervised medication and prisoners will take it under clinic nurse supervision.

We selected Nortriptyline for two reasons. Firstly, abstinence from tobacco increases depression and depression increases relapse suggesting that an antidepressant may be a useful smoking cessation aide. Depression is common in prisoner populations. Several meta-analyses have shown Nortriptyline to be effective for smoking cessation [21,25]. Secondly, Nortriptyline is a generic medication and off patent and, as such, is significantly less expensive than alternatives. We surmise that in a disadvantaged population with limited means, the cost of treatment is likely to be a consideration for individuals wishing to quit and for prison medical services who are likely to be more amenable to lower cost treatments.

2.3.11 Quitline

All prisoners will receive information about the Quitline. Quitline is a telephone counselling service provided to all Australians in the community. Quitline offers access to self-help resources, advice, support and telephone counselling for people wanting to quit smoking. Chief investigator Wodak is the director of the NSW Quitline and has initiated access for all NSW prisoners to this service.

2.3.12 Outcomes

The primary outcomes are: continued abstinence and point prevalence abstinence at 12 months. Continuous abstinence is defined as abstinence between quit day and a specified follow-up period [32]. Point prevalence is defined as the proportion of subjects who have not smoked for the past 7 days [32]. Continuous abstinence and point prevalence cessation will also be reported for the 3, 6 and 12 month follow-ups. Outcomes will be determined on an intention to treat basis. That is, participants who miss a follow-up assessment will be regarded as continuing smokers at that time period. Secondary outcomes are depression score (as per the Beck depression Inventory) and psychological distress (as measured by the K10).

2.3.13 Measures

We will use measures that are widely used in smoking cessation research and treatment. All follow-up assessments will be conducted by trained nurses who have worked in prisons who

are blind to treatment allocation of prisoners. The measures that will be used at baseline and during follow-up visits are in Table 2.

Table 2. Measures used at baseline and 12, 26 and 52-week follow-ups

Measure	Follow-up			
	Baseline interview	12 weeks	26 weeks	52 weeks
Demographics (includes education and postcode prior to incarceration)	✓			
Smoking history	✓			
Nicotine dependence [28]	✓			
Readiness to quit smoking [29]	✓			
CO measurement	✓	✓	✓	✓
Abstinence (biochemically validated)		✓	✓	✓
Minnesota Nicotine Withdrawal Scale [33,34]	✓	✓		
Anxiety & depression (BDI[35], K-10[36])	✓	✓	✓	✓
Physical and mental morbidity (SF-36[37])	✓	✓	✓	✓
Self reported drug use[38]	✓	✓	✓	✓
Weight (kg)	✓	✓	✓	✓
Adverse side effects		✓		
Information on smoking status of cell mate	✓	✓	✓	✓

Questions about smoking history will ascertain the number of cigarettes smoked, years of regular smoking and prior quit attempts. Readiness and motivation to quit smoking will be assessed using the Crittenden criteria at baseline [29]. Reasons for quitting will be documented. Nicotine dependence will be assessed using the Fagerström Test for Nicotine Dependence, which has good internal consistency and construct validity, and is used routinely in smoking cessation research [28]. This 6 item instrument measures smoking behaviours indicative of physical dependence on a scale from 0 to 10; scores of six and above indicate a moderate to high level of dependence [28]. We will also administer the Minnesota Nicotine Withdrawal Questionnaire [33,34]. This is an 8-item measure consisting of the following items: craving for cigarettes, irritability, frustration or anger, anxiety, difficulty concentrating, restlessness, increased appetite or weight gain, depressed or sad mood, and insomnia. Anxiety and depression will be assessed using the following: the Beck Depression Inventory (BDI) and the K-10. The BDI is a self-evaluating indicator of depression comprising of 21 items measuring the cognitive, vegetative, mood, social, and irritability components of depression in the past week [35]. The K-10 scale is a 10-item questionnaire designed to maximise the ability to discriminate cases of serious mental illness from non-cases [36]. Physical and mental well-being will be measured with the SF-36. This contains 36 items that are combined to form eight scales to measure physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning and mental health [37]. Adverse events from the use of the patch and Nortriptyline will be documented at 12 weeks by a checklist. Self-report has been shown to be a reliable and valid measure of illicit drug use [38].

2.3.14 Follow-up

Prisoners will be followed up at 3, 6 and 12 months. The dates of follow up will be based upon the quit date (week 3). Prisoners will be followed-up at other prisons, if transferred, and also in the community, if released. Prison nurses will be trained to conduct follow up

assessments and take expired carbon monoxide readings using a smokerlyzer. In the event of release, the research assistant will locate the ex-prisoner in the community with the assistance of the Correctional Centre Release and Treatment Scheme (CCRTS). The CCRTS provides inmates with support in the post-release period and has a 90% follow-up rate. CCRTS staff has developed a unique set of skills necessary for locating clients on release and have agreed to support this project.

2.3.15 Quality Assurance

As this study will be conducted in many prisons and due to the nature of the incarcerated study population, all aspects of the trial will have ongoing quality assurance overseen by the project officer and chief investigators.

2.3.16 Statistical Analysis

Data will be analysed using SAS version 9.2. The baseline characteristics of the participants will be compared using analysis of variance for continuous variables and chi-square analysis for categorical variables. The efficacy of the active Nortriptyline treatment will be evaluated using logistic-regression modelling using smoking status (as confirmed by self-report and carbon monoxide measurement) as the dependent variable. The independent variables are active or placebo Nortriptyline. The primary outcomes will be continued abstinence and point prevalence abstinence at 12 months. A secondary outcome will be 50% reduction in smoking amount at 12 months. We will perform subgroup analyses to investigate differences in the intervention between ≥75% compliance compared with < 75% compliance with medications, as well as Indigenous versus non indigenous heritage.

Depression and anxiety scores will be analysed in terms of change from baseline. For each group, the mean change in the score will be compared with zero by the one-sample t-test. The effect of treatment will be evaluated with a two-factor repeated measures analysis of variance model. Change in the depression score will be the independent variable. The repeated factors are treatment group, the independent cross-classification factor, and time. Fisher's exact test will be used to compare the rates of adverse events for each study group. Analyses will be based on intention to treat. Subjects who are lost to follow-up or miss a follow-up visit will be considered as continuing smokers. Odds ratios and associated 95% confidence intervals (CI) will be reported with the control group as the reference point (odds ratio = 1.00). The threshold for statistical significance will be $p \leq 0.05$. If the Type 1 error rate is larger than 5%, a Bonferroni correction will be applied to account for multiple hypothesis testing.

3. DISCUSSION

This study will evaluate, using a randomised control trial, a smoking cessation intervention delivered in the prison system. This is the first RCT of a smoking cessation intervention delivered to male prisoners. If successful, it will have major benefits for addressing smoking among this marginalised population identified as a group at high risk in the Australian Guidelines for Smoking Cessation [39].

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

3.1 Intervention Delivery

The multiple prisons participating in this trial will require close attention to staff training and supervision. All people involved in the assessment and follow up will have prior experience working with prisoners. A manual developed specifically for the research assistants of this study will be used to guide the study procedures [40]. The Project Officer (VA) will train the participant staff at each prison and discuss the procedures with the departments of pharmacy at each participating prison. The multi-component nature of our smoking cessation intervention will not enable us to assess the contributions of specific intervention components. The Quitline smoking cessation service has been introduced into the prison system (by AW).

3.2 Recruitment and Retention

Recruiting prisoners who are smokers and who are prepared to quit their tobacco use requires persistence and flexibility from the research staff. The stringent eligibility criteria (e.g.; if currently using anti-depressant or on anti-psychotic medication) will cause many smokers to be excluded from our study, and we will have to explain to such prisoners why they cannot participate. Prisons frequently implement lock-downs which will mean that access to the study population will be impossible as prisoners will be locked in their cells. We will not learn about lock-downs until we arrive at the prison to conduct assessments or interventions. This means that a day or half a day will be wasted, requiring research staff to return the following day. In the early stages of study 2, and for reasons unrelated to the study, a riot erupted in the prison, and with prisoners locked in their cells for days, we did not have access to them for some time. Again, we will not learn whether a prisoner has been transferred to another prison until we arrive to deliver the treatment or follow up assessment. This will require making additional arrangements to visit him in the other prison. Engagement in the two treatment sessions requires flexibility during circumstances when the prisoner is locked in his cell in a lock-down or transferred to another prison. As literacy skills in this population may be low, we have reduced the number of words and included pictures in the *Breakfree* booklet [30].

Notwithstanding these potential barriers, we envisage that the study will be a worthwhile endeavour and result in benefits to the health of this disadvantaged group of people.

CONSENT

Not applicable.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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the Queensland Department of Health. GlaxoSmithKline provided NRT free of charge for this study.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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