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Brief intervention on Smoking, Nutrition, Alcohol and Physical (SNAP) inactivity for smoking relapse prevention after release from smoke-free prisons: a study protocol for a multicentre, investigator-blinded, randomised controlled trial

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ABSTRACT

Introduction Smoking remains the leading risk factor for disease burden and mortality worldwide. Heavy Smoking is often associated with poor Nutrition, Alcohol abuse and Physical inactivity (known as 'SNAP'). Australia's first prison smoking ban was introduced in the Northern Territory in July 2013. However, relapse to smoking after release from prison is normative. Holistic and cost-effective interventions are needed to maintain post-release abstinence to realise the potential public health impact of smoke-free prison policies. Rigorous, large-scale trials of innovative and scalable interventions are crucial to inform tobacco control policies in correctional settings.

Methods and analysis This multicentre, investigator-blinded, randomised parallel superiority trial will evaluate the effectiveness of a brief intervention on SNAP versus usual care in preventing smoking relapse among people released from smoke-free prisons in the Northern Territory, Australia. A maximum of 824 participants will be enrolled and randomly assigned to either SNAP intervention or usual care at a 1:1 ratio at baseline. The primary endpoint is self-reported continuous smoking abstinence three months after release from prison, verified by breath carbon monoxide test. Secondary endpoints include seven-day point prevalence abstinence, time to first cigarette, number of cigarettes smoked post release, Health Eating Index for Australian Adults, Alcohol Use Disorder Identification Test-Consumption and International Physical Activity Questionnaire scores. The primary endpoint will be analysed on an intention-to-treat basis using a simple log binomial regression model with multiple imputation for missing outcome data. A cost-effectiveness analysis of the brief intervention will be conducted subsequently.

Ethics and dissemination This study was approved by the University of New South Wales Human Research Ethics Committee (HREC), Menzies HREC and Central Australia HREC. Primary results of the trial and each of the secondary endpoints will be submitted for publication in a peer-review journal.

Trial registration number ACTRN12617000217303; Pre-results.

Strengths and limitations of this study

- The Smoking, Nutrition, Alcohol and Physical (SNAP) study uses a pragmatic randomised controlled trial design, which is rarely seen in research in people transitioning from prison to the community or ex-prisoners.
- This study directly measures actual smoking relapse rates after leaving smoking-free prisons, instead of measuring intention to stay abstinent as a proxy.
- This study measures continuous smoking abstinence verified with CO_{breath} test at three months after release as the primary outcome, which is a major predictor of long-term success in sustained abstinence.
- This study includes an associated economic evaluation to inform decisions about implementation of the brief intervention beyond the trial.
- The lack of blinding of the participants is a limitation of the study design.

INTRODUCTION

Tobacco smoking is a major cause of preventable diseases and deaths in most countries. Worldwide, >7 million deaths each year are attributable to tobacco smoking.[1] In some countries, smoking causes more deaths and hospitalisation than drugs and alcohol use combined.[2] In recent years, Australia has

been considered one of the world's most successful nations in effective tobacco control policy, reflected in the significant reduction in smoking prevalence among the general population from 24.3% in 1991 to 12.2% in 2016.[3] However, reductions in smoking have been much less apparent for disadvantaged populations.[4]

Internationally, the prevalence of tobacco smoking is much higher among prisoners than the general community, largely due to the over-representation of vulnerable groups in prison. A recent global systematic review found that smoking levels in prisoners over 50 countries were 1.7-fold to over 8-folds higher than the general population.[5] Australia has one of the highest rates of smoking in prison, following Malaysia (98.2%), Taiwan (89.1%) and the Philippines (82.4%) in the Asia-Pacific region.[6] Elevated rates of smoking among prisoner populations contribute to the substantial rates of morbidity and mortality in this group.[7] For example, mortality rates from smoking-related cancers are doubled for those who have been imprisoned compared with the general population.[8] Effective and scalable interventions to reduce smoking among people who experience incarceration worldwide are needed.

In Australia, Indigenous Australians are among the most socioeconomic disadvantaged groups. Indigenous Australians smoke at three times the level of the general population (41% vs 12%)[9] and are two to seven times more likely than non-Indigenous people to die from a tobacco-related disease. Although Indigenous Australians represent 2.8% of the Australian population,[10] they are significantly over-represented in the prison system, comprising about 27% of the Australian prisoner population[11] and approximately 33% of those released from prison.[12]

The Northern Territory (NT) prison population comprises 84% Indigenous Australians prisoners,[13] of whom 92% are current smokers.[11] In July 2013, the Northern Territory Corrective Services (NTCS) introduced Australia's first smoking ban in prison.[14] While smoking bans may have potential health benefits for people in prison[15] and may increase desire to quit,[16] reports suggest that the vast majority of people typically relapse to smoking shortly after release from prison.[17–19] A recent systematic review of smoking cessation programmes in prisons highlighted the need for effective interventions to maintain abstinence post-release when prison smoking bans are in place.[20]

Rationale

Health risk behaviours often co-occur. There is a strong relationship between heavy smoking and other risk factors, such as poor nutrition, alcohol abuse and physical inactivity (also known as 'SNAP').[21] The prevalence of risky drinking,[22] poor nutrition[23] and physical inactivity[9] is also high in Indigenous Australians. Therefore, it is crucial to take a holistic approach to address smoking and other health risk behaviours together in order to reduce smoking relapse rates among this group.[24] The SNAP intervention, originally developed by the Royal Australian College of General Practitioners (RACGP),[25] has been demonstrated to be effective in reducing health risk behaviours in community samples[26] and feasible in diverse settings.[27] However, there is a need for more rigorous evaluations of the SNAP interventions among Indigenous Australians.[24]

There have been few randomised controlled trials (RCTs) of smoking cessation interventions in prison settings. Data from an RCT in the USA (the WISE study) suggest that a smoking ban in prison alone had little impact on post-release smoking, with >93% relapsing to smoking within three weeks of release in the control group. However, the study also showed that, when the smoking ban was followed by a behavioural intervention combining motivational interviewing and cognitive behavioural therapy prior to prison release, it significantly increased sustained smoking abstinence at week 3 (25% vs 7%) and week 12 (12% vs 2%) after release.[28] There have been no such studies conducted in Australian prisons.

This protocol describes a modified SNAP intervention targeting smoking relapse after release from prisons where smoking is banned and proposes an RCT to evaluate the effectiveness of the intervention in extending smoking abstinence and improving healthy lifestyle among Indigenous and non-Indigenous adults released from prisons in NT, Australia.[29]

OBJECTIVES

Primary objective

The primary objective of the study is to determine if the SNAP intervention, delivered in the four weeks prior to release from prison, could increase continuous smoking abstinence rate for three months after release.

Secondary objectives

The secondary objectives are to determine if the SNAP intervention could

1. Increase seven-day point prevalence.
2. Delay the time to first cigarette.
3. Reduce the number of cigarettes smoked.
4. Improve healthy eating habits.
5. Reduce alcohol consumption.
6. Increase physical activity after release from prison.

METHODS AND ANALYSIS

Study design and setting

The SNAP study is a multicentre, investigator-blinded, randomised parallel superiority trial. The study will compare the effectiveness of a modified SNAP intervention versus usual care in the prevention of smoking relapse among people released from two smoke-free prisons in NT, Australia. An overview of the trial process is shown in figure 1. The study will be conducted in Alice Springs Correctional Centre and Darwin Correctional

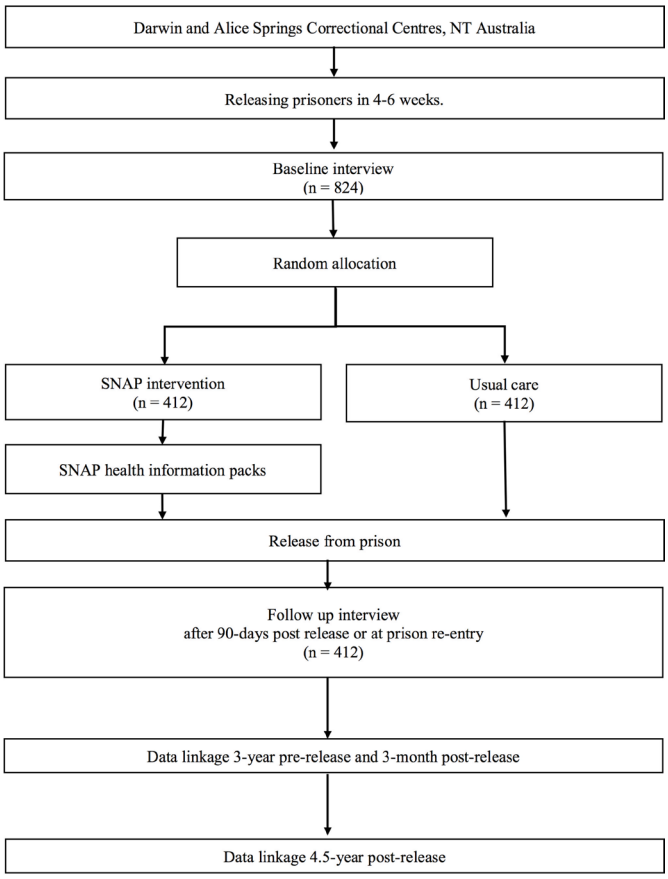

Figure 1 Smoking, Nutrition, Alcohol and Physical (SNAP) study planned flow chart. NT, Northern Territory.

Centre, which are the only two adult prisons in the NT, Australia, with a total population size of approximately 1600 inmates.

Participants and eligibility criteria

A list of potential participants will be drawn from the Integrated Offender Management System (IOMS) 4–6 weeks prior to their earliest expected release date. Inmates expecting to be released on parole (ie, before completion of full sentence) will be eligible for inclusion. Both men and women will be eligible. Potential participants will be informed about the study and screened individually for eligibility by trained research assistants (RAs) who are independent of NTCS. Participation in the study is voluntary and does not affect sentence or parole status. Eligible participants must provide written informed consent (online supplementary file 1) before inclusion in the study.

Inclusion criteria

Participants eligible for inclusion in the study will meet all of the following criteria:

1. Smoked daily before incarceration or smoked >100 cigarettes in lifetime.
2. Sentenced prisoners residing in one of the two NT correctional centres who will be released by June 2018.
3. Expected to be released from prison in 4–6 weeks after screening.

Exclusion criteria

People will be excluded from the trial if they have

1. Express no interest in remaining abstinent from tobacco smoking after release from prison.
2. A self-reported diagnosis of a severe psychiatric disorder (eg, schizophrenia, bipolar disorder).
3. Recent self-harm ideation assessed by a screening question 'In the last four weeks, have you thought about harming, injuring or killing yourself?'.
4. Impaired decision-making capacity assessed using the Mini Mental State Examination (score <5).[30]

Randomisation

After informed consent is obtained and the baseline interview is completed, participants will be assigned to either the intervention or control group with equal probability according to a predefined, computer-generated simple randomisation sequence stratified by study site. Treatment allocation will occur via telephone contact with a central allocation team. Allocation concealment will be ensured by a central automated allocation procedure that is independent of the investigators and trial coordinator. Participants will not be blinded because of the restricted environment and congregate living circumstances in the prison settings. Treatment assignment data will be stored separately and will be masked from the investigators and data analyst and maintained until all data are collected and cleaned, and statistical analyses are performed.

Intervention

Usual care

Control group participants will receive standard prison care. Smoking is banned in the two correctional centres. At the time of the study, no specific programmes are available to prevent smoking relapse on release from NT prisons. NT prisons ceased providing nicotine replacement therapy (NRT) in July 2014, therefore participants will not receive NRT before release.[14] Participants could have unmonitored access to Quitline, which is a free and confidential telephone advice service for people in NT who want to quit smoking.

SNAP

In addition to usual care, the intervention group will receive one session of the SNAP intervention within 4 weeks prior to release, delivered by RAs who have completed training in the SNAP intervention. The sessions will last between 45 and 60 minutes depending on the participant's readiness to change and comprehension level. An illustrated SNAP pamphlet will be provided to participants to facilitate the intervention session. The pamphlet was culturally appraised by an Aboriginal Cultural Advisor, and the language used in the pamphlet was matched to the average reading levels of the prison population.

The SNAP intervention manual (online supplementary file 2) was developed based on the principles of motivational interviewing[31] with a focus on eliciting the person's own desire to quit smoking, developing discrepancy between values and current behaviours, building self-efficacy and strengthening a person's commitment to maintaining smoking abstinence post release. The SNAP intervention follows the '5As' structure recommended by the RACGP guidelines of effective tobacco cessation counselling.[25] The RAs will apply the following processes: (1) asking participants about their tobacco use and affirming a decision to quit; (2) assessing stage of change and willingness to quit; (3) advising to quit; (4) assisting with relapse prevention goal setting, planning and self-monitoring; and (5) arranging referral to Quitline or a tobacco treatment specialist after release. During the assisting phrase of the interview, depending on the participant's circumstance, the RAs will also suggest eating good food, reducing alcohol drinking and doing physical activity as aiding strategies to avoid smoking triggers.

On the day of release, participants in the intervention group will receive a health promotion pack with education materials on tobacco smoking, alcohol, nutrition and physical activity (online supplementary file 3). The education materials are expected to reinforce the messages delivered in SNAP intervention and assist the participants to stay smoke-free via a healthier lifestyle overall. While the health promotion pack may influence smoking relapse prevention, we believe the SNAP intervention carries the major treatment effect.

Treatment quality assurance

The RAs will receive intensive training in the specialised SNAP intervention, delivered by a clinical psychologist with 25 years' experience in the drug and alcohol field. The training will include a 1-day workshop followed by at least two sessions of 2-hour roleplay practice. After the training, the RAs must pass an assessment of their therapeutic skills, motivational interviewing skills and protocol compliance before they can deliver the SNAP intervention. The assessment is conducted in the format of a roleplay simulation and is audiotaped. The audiotapes will be evaluated independently by the clinical psychologist and a research fellow based on a predefined scoring system. RAs who fail the assessment will be provided with further training and then reassessed.

Measures

Baseline interviews

Eligible participants will complete a baseline questionnaire (online supplementary file 4) administered by the RAs. The baseline questionnaire takes approximately 30 minutes to administer and includes demographic variables, smoking history, nicotine dependence prior to incarceration (assessed by the Heaviness of Smoking Index[32]) and readiness to change assessed by a modified Motivation to Stop Scale (MTSS).[33] Nutrition intake will be evaluated by measuring the consumption of five food groups in the 2013 Australian Dietary Guidelines.[34] Alcohol consumption prior to incarceration will be measured using the Alcohol Use Disorder Identification Test—Consumption (AUDIT-C).[35] Physical activity will be measured using the International Physical Activity Questionnaire - Short Form (IPAQ-SF).[36] Other measures include quality of life using EQ5D-5L[37] and psychological distress using Kessler Psychological Distress Scale 6 (K6).[38] Individual consent (online supplementary file 5) will be sought to link data collected by the national *Pharmaceutical Benefits Scheme (PBS)* and *Medicare Benefits Schedule (MBS)*. The length of stay in prison before release as well as the number of prior incarceration episodes will be obtained from the prison records.

Follow-up interviews

On the day of release, all participants will be given a backpack which contains a follow-up reminder, a change of contact form with a reply-paid envelope and a toll-free 1800 number for participants to call for follow-up interviews. The RAs will attempt to contact the participants for a face-to-face follow-up interview approximately three months after release from prison. The NT has a total area of 1 349 129 km², such that a face-to-face interview is sometimes infeasible because of geographic distance. In such cases, the interview will be conducted over the telephone. A follow-up questionnaire (online supplementary file 6) will be administered by the RAs to assess tobacco use after release as well as the reasons for abstinence or relapse. The follow-up questionnaire will also include the same instruments to measure nutrition, alcohol consumption and physical activity as per baseline interviews.

We will use multiple strategies to contact participants for the follow-up interview, including interviewer-initiated phone calls, participant-initiated calls to the toll-free 1800 number, interviewer visits to community corrections, home visits in company with parole officers, referral calls from local health clinics and mail-out letters to participants' postal addresses. Multiple follow-up attempts will be made periodically until the end of the study as previous research has documented a dose–response relationship between the number of follow-up attempts made and retention in studies of adults released from prison in Australia.[39] IOMS will be checked every three weeks to identify participants who have been reincarcerated. Reincarcerated participants will be followed up in custody as soon as they have been identified.

Primary outcome

The primary outcome will be continuous smoking abstinence three months after release from prison. Smoking abstinence is defined as biochemically verified smoking abstinence, allowing up to five cigarettes in total from the date of release to the 3-month follow-up. For participants who return to prison before the expected follow-up date, the primary outcome will be self-reported smoking abstinence between the two incarceration episodes. Biochemical verification will be an exhaled carbon monoxide

(CO_{breath}) test using a Bedfont Micro Smokerlyzer CO monitor. A reading of less than five parts per million will be defined as verified abstinence.[40]

Secondary outcomes

Seven-day point prevalence

Seven-day point prevalence abstinence will be measured by the question 'Have you smoked any tobacco, even a part of a cigarette, in the last seven days?' during the follow-up interview. Evidence suggests that point prevalence abstinence and continuous abstinence are closely related and both should be reported across studies.[41]

Time to first cigarette after release

The time to first cigarette after release will be asked in a multiple-choice question with the following choices: (1) 'on the day of release'; (2) 'on the second day after release'; (3) 'not the first two days but within a week after release'; (4) 'not the first week but within a month after release'; (5) 'not the first month but within three months after release'; and (6) 'I did not smoke after release'.

Number of cigarettes smoked post release

The number of cigarettes smoked on day 1 and 2 post release, as well as the average daily number of cigarettes smoked by day 7, 30 and 90 after release, will be captured using a modified Timeline Follow-Back (TLFB) method.[42]

Healthy dietary habits

Adherence to the 2013 Australian Dietary Guideline[34] after release will be assessed using a modified version of the Healthy Eating Index for Australian Adults (HEIFA-2013).[43] A score ranging from 0 to 10 is calculated for each of the five core food groups (fruit, grains, meat/poultry, dairy and vegetables) according to how closely an individual's daily intake matches the recommended number of servings for their age and sex. In each food group, when the recommended number of servings is achieved, no further credit will be given for additional servings, nor will any points be deducted for being beyond a certain number of servings. An overall index score ranging from 0 to 50 will be calculated as the sum of the five subscores.

Alcohol consumption

Self-reported alcohol consumption after release will be measured using the AUDIT-C. The AUDIT-C comprises three questions (each scored 0–4), and the test score is the sum of item scores, with a range from 0 to 12.

Physical activity

Self-reported physical activity after release will be measured using the IPAQ-SF, which will ask the participants about the time spent for vigorous and moderate activities, as well as for walking and sitting in the last seven days before follow-up. The data will be converted to a continuous measure of Metabolic Equivalence of Task (MET) minutes per week according to the IPAQ Data Processing Guidelines.[44] MET for vigorous and moderate physical activities, walking, as well as a total MET score will be calculated.

Other outcome measures

Other outcome measures after leaving prison include the MTSS score[33] for motivation level to quit smoking, EQ5D-5L score[37] for quality of life and K6 score[38] for psychological distress, as these outcomes have been reported to have a negative relationship with smoking and they are inversely associated with smoking cessation success.[45 46] Prospective linkage with PBS and MBS data will be conducted to measure health service utilisation, medicine use and related costs among participants after release. A subsequent cost-effectiveness analysis will be performed as outlined in the statistical analysis plan below.

Sample size

The sample size is calculated on the basis of post-release continuous smoking abstinence, which is the primary outcome measure. In a comparable RCT in the USA,[28] of those who had received six sessions of intensive intervention comprising motivational interviewing and cognitive–behavioural therapy, 12% remained abstinent three months after release, compared with 2% in the control group (OR 5.3). The SNAP intervention is less intensive; therefore, we estimate a smoking abstinence rate of 8% in the intervention group versus 2% in the control group at three months post release (OR 4.26).

To achieve 80% power for the two-sided Cohen's independent two-sample proportion test at a significance level of 0.05, a sample size of 412 is required to detect the proposed difference, with 206 in each group. Given the highly mobile nature of this population, high dropout rate is common.[39] A previous study suggested a follow-up rate of 48% in remote regions in the NT.[47] The overall reimprisonment rate in Australia was 39%[48]; therefore, we assume a 50% follow-up rate (34% at prison re-entry and 16% in the community) and aim to recruit 824 participants at baseline.

Statistical analysis plan

Primary analysis

Primary statistical analysis will be performed on an intention-to-treat (ITT) basis.[49] Between-group difference in the proportion of continuous smoking abstinence, the primary outcome, will be analysed in a log-binomial regression model comparing SNAP against usual care. The model will be adjusted for study site to compensate potential clustering effect. Missing data due to loss-to-follow-up will be tested for Missing Completely At Random. If Missing At Random, multiple imputations using chained equation will be employed.[50]

Secondary analyses

A number of secondary analyses will be conducted. Seven-day point prevalence abstinence will be analysed using simple log binomial regression. Time to first cigarette after release will be analysed in an interval-censored

survival analysis. Given the possibility of a floor effect on the abstinence outcomes, we will analyse the number of cigarettes smoked as a secondary smoking outcome. The number of cigarettes smoked will be extracted from the TLFB for the following time intervals: (1) day 1; (2) day 2; (3) days 3–7; (4) days 8–30; and (5) days 31–90. The number of cigarettes smoked will be analysed using a multilevel Poisson regression model.[51] The random intercept of the model will include participant ID and study site. The fixed effects of the model will include treatment allocation and the number of exposure days outside of prison as an offset in each interval. Other secondary outcomes including HEIFA-2013 score, AUDIT-C score, MET for physical activity, MTSS score, EQ5D-5L score and K6 score will be analysed using linear mixed models that include participant ID as random effect.

Sensitivity analyses

We will undertake the following sensitivity analyses: (1) comparing analysis results from biochemically verified abstinence versus self-reported abstinence; (2) comparing results from per-protocol and as-treated analyses with ITT analysis on the primary outcome to assess the impact of receipt of treatment in the trial; and (3) comparing results from a complete-case analysis with ITT analysis to assess the impact of missing data.

Planed cost-effectiveness analysis

The cost-effectiveness analysis will take a healthcare perspective and examine the additional cost per additional person who is smoke-free (as defined by the primary outcome) at the final follow-up from the SNAP intervention compared with usual care. It will consider the additional costs of the SNAP intervention compared with usual care in terms of the staff time needed to set-up, recruit and deliver the SNAP intervention in the prison setting, along with the material costs required. It will also estimate the cost impact of the SNAP intervention within the three months after release by comparing the government primary healthcare expenditure (including prescribed medication costs) in the SNAP intervention group and the usual care group using the linked MBS and PBS data. The estimated number of people who are smoke-free as a result of the SNAP intervention will match the estimated effect from the primary analysis. A probabilistic sensitivity analysis will be undertaken to examine the robustness of the conclusions.

Data integrity and management

All data will be collected and managed using the Research Electronic Data Capture (REDCap) platform.[52] Data will be kept strictly confidential and will be stored electronically on a REDCap MySQL database server that is securely hosted by the Medicine Computing Support Unit in University of New South Wales, Sydney. Only the principal investigator and the trial coordinator will have full access to the database. When the study is completed, research data will be transferred from the MySQL database to the University's shared drive which is only accessible to the research team. Research data will be deidentified and participants' identifying information will be stored in a separate location.

Withdrawal

If a participant wishes to withdraw, the reason and date of discontinuation will be recorded on a standard withdrawal form. The participant can choose whether the collected data could be retained to use for the study and whether any outstanding administrative data could be collected for research.

Safety and adverse event

An adverse event (AE) will be defined as any untoward medical occurrence regardless the possibility of a causal relationship with the intervention. All AEs occurring after signing the informed consent and until the follow-up interviews will be recorded. A serious adverse event (SAE) will be defined as any AE that is fatal or life-threatening, or that results in hospitalisation or persistent disability. The safety aspects of the study will be closely monitored by the trial coordinator and a SAE will be reported to the University of New South Wales Human Research Ethics Committee (UNSW HREC) immediately after it is identified.

Monitoring

The trial will be overseen by a steering committee that comprises the research investigators, the trial coordinator and an Indigenous cultural advisor. The steering committee will have a monthly meeting to monitor the progress of the trial. Important protocol amendments will need to be approved by the steering committee and submitted to the UNSW HREC by the principal investigator. Data quality will be checked by the trial coordinator on a weekly basis and reported to the principal investigator. The trial coordinator will visit the study sites once a year to examine trial procedures to ensure compliance with the trial protocol.

Patient and public involvement

The development of the research question and outcome measures were informed by community consultation with the NTCS community correction managers, representatives of local health services and Indigenous interviewers. It was not possible to involve inmates in prison settings in the design of the study. Qualitative feedback on the intervention will be gathered from the study participants at the end of intervention interview. The results of the study will be disseminated to study participants via the periodic newsletters published by the NTCS. The results will also be available on the National Drug and Alcohol Research Centre (NDARC) website: https://ndarc.med.unsw.edu.au/project/snap.

ETHICS AND DISSEMINATION

Ethics approval was first obtained in the University of New South Wales HREC (Sydney, Australia) as main

ethics committee. Additional regional approval was obtained from Menzies HREC and Central Australia HREC, which cover the Darwin Correctional Centre in the Top End region and the Alice Springs Correction Centre in the Central Australia region in Northern Territory, Australia, respectively. This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617000217303).

A manuscript with the results of the primary outcome and smoking-related secondary outcomes will be published in a peer-reviewed journal. Separate manuscripts will be written for other secondary outcomes and will also be submitted for publication in peer-reviewed journals.

On completion of the trial and after publication of the primary manuscript, data request can be submitted to the researchers at the National Drug and Alcohol Research Centre, University of New South Wales, Sydney, Australia.

CURRENT STATUS

The present study is an ongoing clinical trial for data collection. Participant recruitment was commenced in April 2017 and follow-up is planned to be completed in October 2018. As of 9 May 2018, we had assessed 790 inmates for eligibility, of whom 569 were eligible and 557 enrolled in the study. A total of 293 participants had been followed up post release.

DISCUSSION

Many people relapse to smoking within days of release from smoke-free prisons. The proposed RCT will add to the literature by rigorously evaluating the impact of a scalable, pre-release intervention on post-release smoking abstinence.

Behavioural interventions may be a cost-effective method of increasing the likelihood of abstinence post release.[20] However, limited research attention has been given to the high smoking rates and related health burden in prison populations.[53] There is only one published RCT (the WISE study)[28] that has evaluated a pre-release intervention for post-release smoking relapse. In addition, a Cochrane systematic review found that most studies on behavioural interventions did not use a robust experimental design and had insufficient power to detect the expected small difference in smoking relapse prevention.[54]

The SNAP study is designed to address these gaps in the literature. Firstly, the SNAP study is the first RCT in Australia to evaluate a brief intervention for smoking relapse after release from smoke-free prisons. Specially, this RCT will be conducted in the NT where Indigenous Australians are markedly over-represented in prisons. Although RCTs are widely recognised as the gold standard for evaluating the effectiveness of interventions, the use of an RCT design with people transitioning from prison to the community or ex-prisoners is rare,[55] possibly in part due to the transient nature of the population, the substantial requirements to monitor the movement of ex-prisoners, as well as the legal and ethical restrictions for researchers.[56] Secondly, there are very few published RCTs with incarcerated population that have sample sizes of 100 or more.[57] In the WISE study, the observed effect of an enhanced behavioural intervention at three months after release was 12% versus 2%. However, the study was powered based on the intervention effects at three weeks post release.[28] The sample size calculation in the SNAP study is based on a more conservative estimate of 8% versus 2% abstinence but at a longer term (three months) post release, which is a major predictor of long-term success in sustained abstinence.[58] Lastly, the SNAP study measures continuous smoking abstinence verified with CO_{breath} test as the primary outcome, which is rarely found in smoking research in prison settings with most studies relying on self-reported data.[20]

The SNAP study has the potential to benefit people released from prison, their communities, prison staff and Indigenous health clinics in remote areas in NT, Australia. If the SNAP intervention is found to be effective, it could be implemented as a pre-release treatment in NT prisons and similar settings. The lessons learnt from this study will inform policymakers about extending the smoking abstinence resulting from tobacco bans in similar correctional facilities worldwide.

In summary, there is a lack of innovative and potentially scalable interventions to maintain smoking abstinence after release from smoke-free prisons. Pre-release interventions for smoking relapse prevention need to be evaluated in trials with rigorous study design, and with an associated economic evaluation to inform decisions about implementation beyond the trial. The results of the SNAP study will inform future research and policies regarding tobacco control in people released from prison.

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Contributors KD, SAK and RH conceived the study; KD, SAK, RH, ES, RJC, AS, DP, TD and XJ participated in study design; KD and XJ conducted the sample size calculation; TD provided statistical expertise; preparing study design, data collection and management is the responsibility of XJ, the study coordinator. XJ drafted the manuscript; all authors revised the manuscript and gave the final approval of the version to be submitted.

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Patient consent Obtained.

Ethics approval This study was approved by the University of New South Wales Human Research Ethics Committee (HREC), the Menzies HREC and Central Australian HREC. The SNAP study is registered with the Australian New Zealand Clinical Trials Registry(ACTRN12617000217303).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Extra data are available by emailing Prof Kate Dolan (k.dolan@unsw.edu.au)

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