BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-021326
Article Type:	Protocol
Date Submitted by the Author:	24-Dec-2017
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Keywords:	Clinical trials < THERAPEUTICS, PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

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Keywords

Randomised controlled trial; Prisoners; Tobacco Smoking; Smoking Ban

ABSTRACT

Introduction

Smoking remains the leading risk factor for disease burden and mortality worldwide. Heavy **S**moking is often associated with poor **N**utrition, **A**lcohol abuse and **P**hysical 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 multi-centre, 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

Australian New Zealand Clinical Trials Registry: ACTRN12617000217303.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The SNAP study is the first study in Australia to evaluate a brief intervention for smoking relapse after release from smoke-free prisons.
- This study will use 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 will measure 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 will conduct 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

In Australia, tobacco smoking is the leading risk factor for disease burden and deaths[1], causing around 15,000 deaths and costing AU$31.5 billion annually[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].

Indigenous Australians are among the most marginalised groups in Australia. Indigenous Australians smoke at three times the level of the general population (41% vs. 12%)[5], 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[6], they are significantly over-represented in the prison system, comprising about 27% of the Australian prisoner population[7] and approximately 33% of those released from prison[8].

The prevalence of tobacco smoking is much higher among prison entrants than in the general population in Australia (73% vs 13%)[7,9], largely due to the over-representation of vulnerable groups in prison, including Indigenous people[4]. Australia has one of the highest rates of smoking in prison internationally, following Malaysia (98.2%), Taiwan (89.1%) and Philippines (82.4%) in the Asia-Pacific region[10]. Elevated rates of smoking among prisoner populations contribute to the substantial rates of morbidity and mortality in this group[11]. For example, mortality rates from smoking-related cancers are doubled for those who have been imprisoned compared to the general population[12]. Effective and scalable interventions to reduce smoking among people who experience incarceration in Australia are needed.

The Northern Territory (NT) prison population comprises 84% Indigenous Australians prisoners[13], of whom 92% are current smokers[7]. 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 programs 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[5] 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 United States (the WISE Study) suggest that a smoking ban in prison alone had little impact on post-release smoking, with over 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 multi-centre, 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 Centre, which are the only two adult prisons in the Northern Territory, Australia, with a total population size of approximately 1,600 inmates.

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).

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 (i.e., 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 (*Supplementary 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 more than 100 cigarettes in lifetime;
2. Sentenced prisoners residing in one of the two NT correctional centres who will be released by January 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 (e.g. 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 pre-defined, computer-generated simple randomisation sequence stratified by study site. Treatment allocation will occur via telephone contact with a central allocation team. This will ensure allocation concealment, with security in place to ensure allocation data cannot be assessed or influenced by any person involved in the study. Participants will not be blinded because of the restricted environment and congregate living circumstances in the prison settings. The data analyst will be blind to group allocation.

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 programs are available to prevent smoking relapse upon 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 four 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 (*Supplementary 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 Royal Australian College of General Practitioners 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 planning and self-monitoring; (5) Arranging referral to Quitline or a tobacco treatment specialist after release.

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 for a healthy lifestyle (*Supplementary 3*).

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 one-day workshop followed by at least two sessions of two-hours 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 (*Supplementary 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 (HSI)[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 (ADG)[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 (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 (*Supplementary 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 Integrated Offender Management System.

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 (*Supplementary 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 re-incarcerated. 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 three-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 (ppm) 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 7 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 method (TFB)[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 sub-scores.

Alcohol consumption

Self-reported alcohol consumption after release will be measured using the AUDIT-C. The AUDIT-C comprises 3 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 include the MTSS score[33], EQ5D-5L score[37] and K6 score[38]. 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 U.S.[28], of those who had received six sessions of intensive intervention comprising motivational interviewing and cognitive behaviour therapy, 12% remained abstinent three months after release, compared to 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.

To achieve 80% power for the two-sided 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. High dropout rate is common in this hard to reach population[39]; therefore, we assume a 50% attrition rate 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[45]. Continuous smoking abstinence, the primary outcome, will be analysed in an unadjusted log binomial regression model comparing SNAP against usual care. We will use multiple imputation for missing follow-up responses of participants lost to follow-up[46].

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) Day 3-7; (4) Day 8-30; (5) Day 31-90. The number of cigarettes smoked will be analysed using a multilevel Poisson regression model[47]. 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 regression.

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. (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 to 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[48]. 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 de-identified 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 adverse events 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.

Ethics and dissemination

Ethics approval was first obtained in the University of New South Wales Human Research Ethics Committee (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.

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[49]. 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[50].

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 overrepresented in prisons. Although RCTs are widely recognized 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[51], 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[52]. Furthermore, there are very few published RCTs with incarcerated population that have sample sizes of 100 or more[53]. 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[54]. 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 learned from this study will inform policy makers 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.

OTHER INFORMATION

Acknowledgements

We would like to acknowledge the Northern Territory Correctional Services for their support of this project. We would like to thank Dr Cheneal Puljevic and Ms Rebecca Bosworth for their assistance in preparing the study. We would like to acknowledge Dr Etty Matalon for her clinical expertise in developing the brief intervention and staff training.

Funding

The SNAP study is supported by the Australian Commonwealth Government Department of Health Tackling Indigenous Smoking Grant (TIS H151G6012). The design, management, analysis and reporting of the study are entirely independent of the funding body.

The National Drug and Alcohol Research Centre at the University of New South Wales (UNSW), Australia is supported by funding from the Australian Government under the Substance Misuse Prevention and Service Improvements Grants Fund and by infrastructure support from the UNSW, Australia. ES is supported by an Australian National Health and Medical Research Centre (NHMRC) Early Career Fellowship (APP1104600). SK is supported by an NHMRC Senior Research Fellowship (APP1078168). RJC is supported by a Cancer Institute New South Wales Early Career Research Fellowship (GNT14/ECF/1-46). DP is supported by an Australian Research Council's Discovery Early Career Award (Project DE150100309).

Authors' contributions

KD, SK, RH conceived the study; KD, SK, RH, ES, RC, 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.

Competing interests

The authors declare that they have no competing interests.

Data sharing

Extra data is available by emailing Prof Kate Dolan (k.dolan@unsw.edu.au)

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FIGURE LEGEND

Figure 1. SNAP study planned flow chart

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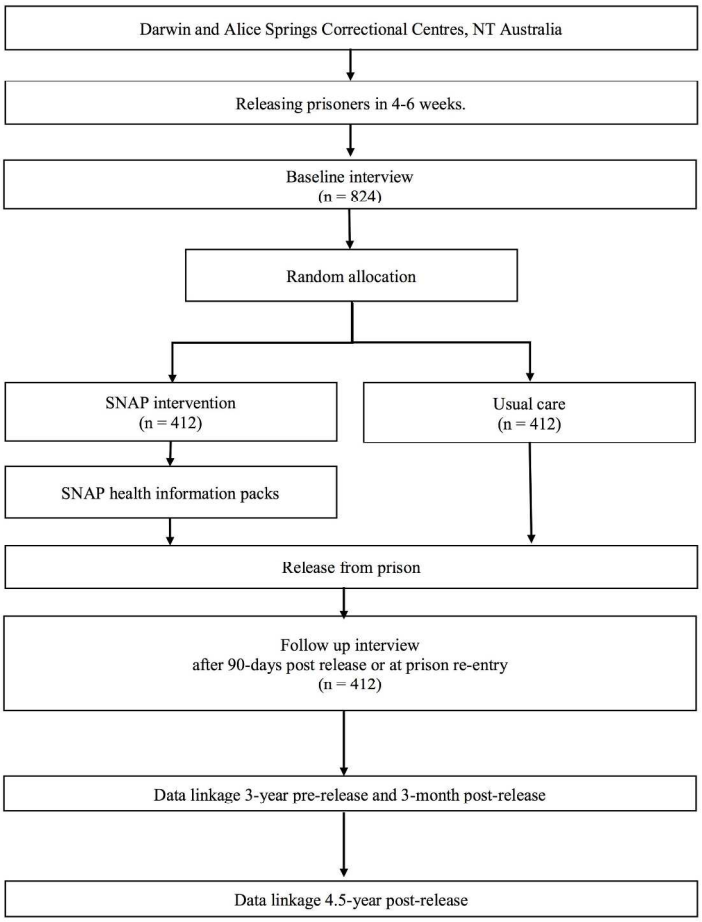


Figure 1. SNAP Study Planned Flowchart

209x297mm (300 x 300 DPI)

NDARC National Drug & Alcohol Research Centre

UNSW AUSTRALIA

SNAP

OFFICIAL USE ONLY

Study ID ☐☐☐☐

Consent Date ☐☐/☐☐/☐☐☐☐

CONSENT FORM

A Randomised Controlled Study of the Health Intervention "SNAP" in Northern Territory Prisons to Prevent Relapse to Smoking after Release from Prison

Chief Investigator: Professor Kate Dolan, Professor Stuart Kinner, Ms Robyn Hopkins, Dr Ryan Courtney, Dr Emily Stockings, Professor Anthony Shakeshaft, Dr Dennis Petrie, A/Prof Timothy Dobbins.

<u>This Means You Can Say NO</u>

Declaration by the participant

1. I understand I am being asked to agree to take part in this research project;
2. I have read the Participant Information Sheet or it has been explained to me in a language that I understand;
3. I provide my consent for the information collected about me to be used for the purpose of this research study only.
4. I agree to be contacted for future research by the SNAP study team.
5. I do attend a health centre on a regular basis, and allow the SNAP team to leave a message there for me so they can arrange an interview.
6. I agree if I come back to prison that the SNAP team can check and re-interview me in prison.
7. Any questions that I have asked have been answered to my satisfaction.
8. I understand that all research data will be treated as confidential and identifying information about me will only be provided to Commonwealth government bodies under strict conditions.
9. I agree that research data gathered for the study may be published provided that I cannot be identified as a subject.
10. I freely agree to participate in this research study as described and understand that I am free to leave the study at any time during the project and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
11. I understand that the study has been approved by the University of New South Wales Human Research Ethics Committee (UNSW-HREC), the Central Australia Human Research Ethics Committee (CAHREC) and the Menzies Human Research Ethic Committee (Menzies-HREC).
12. I understand that I will be given a signed copy of this document to keep.

I consent to being part of the SNAP Study

Name of Participant _____

Signature _____ Date _____/_____/_____

(OPTIONAL): I would like to receive a copy of the study results via email or post. I have provided my details below and ask that they be used for this purpose only;

Address: _____

Emails: _____

I* do NOT *wish to be part of the SNAP Study

Name of Participant _____

Signature _____ Date _____/_____/_____

Office Use Only

1. I, the researcher, have explained the study details and the implications of participation in the study to the above signed participant. I have enquired as to whether they have any questions regarding the study and have answered any that have been forthcoming.
2. I recognise the fact that the participant has the right to withdraw at any time.
3. I shall ensure that all the data and information collected in relation to the study is secure and remains confidential.

Name of researcher _____

Signature of researcher _____ Date _____/_____/_____

QUIT FOR A NEW LIFE "SNAP" (5 A's)
Treatment Manual

INSTRUCTION TO USE

- *Prior to the continuation of the session, calculate the amount smoked, together with the cost and write in the space provided*
- *Give the participants their client booklet and explain that you will go through the material together*
- *This guideline is meant to guide you through the process of 'motivational interviewing'.*
- *References to the Baseline Questionnaire or Client Booklet are underlined*
- *You will need to capture some information to give feedback in the interview, you could write the information in* _____
- *Example conversation scripts are given in double quotation marks, e.g.* **"This is an example."**
- *The wordings in the conversation scripts are given as examples only. You should use words at your own discretion. The interview should be an engaging conversation between you and the participants.*
- *The aims of the questions are given at the end of this clinical guidelines.*

1. ASK

1.1 "How do you feel about not smoking in the future?"

*What you are trying to assess is their level of motivation in relation to smoking after release. Request that they place a cross on the appropriate answer to the following question on **Page 2** of Client Booklet. You may ask them to elaborate further on their answer if you wish. You are also trying to engage in a conversation and establish some level of rapport.*

OK	NOT SURE	NOT GOOD

1.2 "What is the main reason you want to stay smoke free"

This question is to ascertain their main reason or motivation to stop which you may wish to reflect and support using motivational interviewing techniques.

*To further ascertain their level of motivation you will request that fill out rulers on the **Page 3** of Client Booklet.*

1.3 "On a scale of 0 to 10 how important is it for you to not smoke again?"

1	2	3	4	5	6	7	8	9	10

1.4 "How interested are you in not smoking again?"

1	2	3	4	5	6	7	8	9	10

1.5 "How confident are you that you won't smoke again?"

1	2	3	4	5	6	7	8	9	10

*Acknowledge their answer by saying **"Great"** Or **"OK"**, and thank them for their answers*

Refer to 3.1 and 3.4 of the Baseline Questionnaire and confirm

1.6 "Earlier you said that before coming into prison you smoked …… per day and that you started at age ……. and that it cost …… per week"

_____ **per week**
_____ **per year**
_____ **life time**

$_____ **per week**
$_____ **per year**
$_____ **life time**

Refer to 5.9 in the Baseline Questionnaire and confirm:

1.7 "You also said you smoked …… (amount joints/cones/ bongs cannabis) since the age of …… on a …… daily/weekly basis" –

NB more than twice a week is likely to be dependent

1.8 "How much did cannabis cost per week?" **$**_____

_____ **per week**
_____ **per year**
_____ **life time**

$_____ **per week**
$_____ **per year**
$_____ **life time**

1.9 "Do you mull up with tobacco?" **Y / N_**

"How much does that cost per week?" **$**_____

$_____ **per year**
$_____ **life time**

1.10 "Did you use Bush tobacco?" **Y / N_**

"How much did that cost?" **$_____**

ONLY If they spend more $$$ on bush calculate the cost: (tobacco, cannabis, bush)

$_____ per week

$_____ per year

$_____ life time

You will need this information to give feedback later

Quit Attempts

Referring to 3.7 of Baseline Questionnaire

You need to ask the following questions as a way of engaging further and obtaining valuable information about their quit attempts and relapses. You are looking for successful ways they have they have maintained abstinence. While these questions are answered, further elaboration is sought in a conversational style. You might want to reflect their answers if appropriate e.g. ***"That's interesting, why is that?"*** *or* ***"Was that a lot?"*** *or* ***"What happened then? How did this change?"***

1.11 "Earlier you said ……..… (quit attempts) – if appropriate … *how many times have you successfully done that?"*

"That's interesting ……." *or* ***"What happened then? ……. How did this change?"***

You will need this information to feedback later.

1.12 "Why did you start again?"

"That's interesting ……." *or* ***"What happened then? ……. How did this change?"***

You will need this information to feedback later.

1.13 "How was it for you the first couple of weeks in prison when you were in withdrawal?"

You are looking for something positive or someway in which they coped that can be used again when they leave

2. ASSESS

Request that they turn to ***Page 4*** *of Client Booklet and describe the lung/tree. Point out that there are both sides to this tree – there are some down sides to smoking as well as gains to maintaining a smoke free life. Ask them to look at the pictures and circle the ones that they can relate to, such as having arguments or not having enough money, on one side versus being able to afford a new car or becoming more involved with community activities. Please*

remember to elaborate on the benefits of remaining smoke free. Record them in the space below, then ask:

2.1 "What is not good about smoking?"

2.2 "What's going to be great about continuing to stay smoke free?"

2.3 "Are there any other things that you don't like about smoking?"

Future Goals

Preface this next section by saying ***"May I now ask you or talk to you about the next three months and any goals you may have? Thinking about 3 months from your release and using page 5 of your booklet"***

2.4 "What 3 things would you want to have or do?"

Ask them to write them down in their booklet, if they are unable then you should write them down for the participant. Discuss further if any relate to smoking in any way.

1.
2.
3.

Triggers

You may need to explain triggers and what they are, and explain the difference between internal and external triggers. ***"Internal triggers are emotional and external are people places, things."***

2.5 "What are some situations or feelings that would make you feel like a smoke or where you would find it difficult not to smoke?"

Then ask the subject to tick or place a cross on the list on ***Page 6*** *of their booklet. While writing them below:*

Internal:

1.

2.

3.

External:

1.

2.

3.

You may now summaries and paraphrase ***"So what you are saying is …… and when …… you …… we will need to find better ways to cope with these rather than smoking"***

Effects of smoking on:

Their Health

Refer to 8.6 of Baseline Questionnaire

2.6 "Earlier you rated your health today as … /100, but how do you think your health has been affected as a result of your smoking?"

You may wish to add

"in general, do you think smoking affects people's health and in what way?"

Ask them to turn to ***Page 7*** *of their booklet and ask while pointing to the various pictures separately*

"You said that smoking has already affected …….
Now may I ask you how smoking has affected ……

Answer each in the space provided

Their future, family friends, community, spirit

2.7 "Your future?"

2.8 "What about your family and friends? How has it affected them?"

2.9 "Can you tell me how smoking has affected your community?"

2.10 "How about your spirit? Tell me how this has been affected by your smoking?"

Then ask

2.11 "What gives you strength? What makes you feel good? Something that will help you stay smoke free"

3. ADVISE

Now comes a very important part - the FEEDBACK – go back to page 1 – 6 of these Clinician Guidelines, and give a summary of what you have heard and been discussing so far. You may wish to say something like:

3.1 "Thank you so much for all this information it's great. I would like to just stop here for a minute and summarise what we have been discussing so far. Would that be ok?" What you have told me is that ……"

Go back and repeat the answers given from the beginning of the questionnaire

*Ask them to back to **Page 2** of their booklet: "How I feel about my smoking future".*

3.2 "You said …… You also said ……

*……. reflecting the scores on the rulers and using the questions on the rulers in the handout. Ask appropriate questions, e.g. **"What is stopping you from moving from a 5 to 10?",** or **"Why are you _____ interested/not interested and not a _____ in making this change?"**, etc. continue summarising the, costs and benefits lungs/tree, goals, triggers, effects on health, future, family, community, spirit etc….. then ……*

*Using **Page 8 of** their booklet, fill out (or request that they fill it out) while you are summarising and talking. Feedback the amount of tobacco they smoked; the cost of their smoking; how much cannabis they used and the costs per week, then per year, their lifetime, then total costs in a lifetime. Also request they write cost to family and community on page 8.*

$_____ per day/week

$_____ per year

$_____ life time

You may wish to discuss quit attempts - good reasons they have tried to quite before …. Only feedback successful times and praise the attempts and the length of abstinence (even if only for days). Suggest if they did it then they can do it again…if appropriate, use their first couple of weeks of being in prison and how they coped as an example

If appropriate reiterate the effect on their health and/or add ….

3.3 "Did you know ……."

*Read through relevant points on **Page 9** of their booklet and ask if they can relate to any of this information (give hand out on physical effect of smoking.)*

"ALSO" *……..*

*Using **Page 10** of their booklet, request they circle the appropriate answer to:*

3.4 "What might happen if I start smoking again because we need to be aware of what will happen if you start smoking again?"

Now ask "Do you have any questions at this point? Is there anything interesting or that sticks out for you?

Acknowledge and paraphrase. Then ask:

"What do you think of all this so far?"

Reiterate their answer in 1.13 of Baseline questionnaire

3.6 "Earlier you answered ……."

1) **I don't want to stop smoking**
2) **I think I should stop smoking but don't really want to**
3) **I want to stop smoking but haven't thought about it until coming to prison**
4) **I REALLY want to stop smoking and hope to stay smoke free after release**
5) **Don't know**

How do you feel now? has this changed?

3.7 "…Let's now discuss some ways to increase your chances of staying smoke free after you have left prison?"

*If the participant changed the answer or answered 1 or 2, you should still proceed with the interview and say something like **"even if you feel you may not be ready right now, we could still talk about ways to increase your chances if or when you change your mind"** or **"You never know you may at some later date use what we are going to talk about."***

Regardless of the answer, if they are unsure, you need to probe about what they see as the barriers to staying smoke free. If you suspect that they want to maintain abstinence, say "OK then let's talk about how we can we make that happen? let's give it a go."

4. ASSIST

*Using **Pages 11 – 14** of their booklet, fill out as appropriate, strategies such as good food and physical activity as substitutes for smoking – the strategies to each trigger need to be discussed at length and in detail in relation to plausibility)*

4. 1 write down triggers for them and develop strategies for them with the participant and write them in their booklet

Triggers	Strategies

4.2 Discuss and Agree on Other Strategies:

*Other strategies – **4 D's** on **Page 12** of their booklet which they need to write in*

Distract

"Distract myself e.g. …… or go for a walk"
"Ring quit line number ……" (*write it down for them)*
"Go to ……"
"Talk to ……"
"Imagine yourself as a non-smoker ask them to imagine it every day before they leave prison"

Deal with it – this involves self-talk – talking to themselves when they feel like smoking. It's related to self-motivation and changing mindset. They need to rehearse saying things like

"How long can I go without giving in?"
"I'm doing this because I want (tree)"
"How much better will I feel if I don't give in"
"This is not the worst thing in the world!"

Drink water

"Or eat a sugar free mint"

Delay or Destress

- **Suggest they do something else that reduces stress, something that needs them to move, eg walking, fishing, sport, deep breathing – using a method of relaxation (5 in, 5 hold, 5 out), etc.**
- **Suggest they delay giving in by doing something else until the craving goes away – usually 30 minutes**

4.3 Establish and Agree on The Other Rules

- **"Not smoke in the car"**
- **"Not smoke in the house"**
- **Stress that they should NOT entertain the idea that "just one won't hurt – as one will hurt"**

Inform them that the relapse rate is significantly increased should they not give up both cannabis and tobacco at the same time, rather than substitute one for the other.

4.4 Plan and Rewards

*Using and filling out **Page 14** of their booklet, and to finish on a positive note, discuss their immediate rewards and make sure they are achievable – plan with them the following and say*

"Let's talk about you remaining a non-smoker and what you will do to reward yourself with the money you will save."

Daily reward

Weekly reward

Monthly reward

5. ARRANGE

It is important to discuss support systems such as making an appointment with their medical practitioner or counsellor or anyone they see as helping them after release together with family members or other personal support people that they will turn to and discuss their success with.

5.1 NT Quitline (13 78 48)

5.2 Discuss family and friend support, to write in their booklet

5.3 Relapse Prevention

*Finally relapse prevention needs to be discussed as per **Page 15** of their booklet. However, before this you must discuss **the first 24 hours after release** in detail e.g. Who will pick them up? Where will they go? How will they avoid the first trigger to smoke? What will they do the next morning? What will they do to protect themselves against temptation? Then reiterate their answer to **"What gives you strength"** that was asked previously. Ask them to write on **Page 14** of their booklet who is going to be of great help to them.*

"What or who will keep you strong? how will they do that? "

END OF THE INTERVIEW

Thank the participants for their time. Reassure $5 reimbursement will be put into their accounts.

Explain to the participant that we expect to talk to them again 90-days after their release from prison and give $10 reimbursement for that.

Write down Study ID and expected follow-up date on the both follow-up cards, and give one to the participant and put the other one in the pre-release bag.

Give the pre-release bag to prison staff who are responsible to give it on release.

AIMS of the Questions in Motivational Interview

- How motivated are they about staying stopped?
- Main reason they want to stay stopped
- Howe important, interested and confident they are about staying stopped
- Assess amount and cost of tobacco for feedback
- Assess quit attempts – looking for successes and motivators for attempting change. Successful methods can be used again while avoiding unsuccessful methods
- Ascertaining reasons for relapses in order to stress the need to avoid them and/ or develop better ways to cope with them
- Using last time in prison as an example of the ability to stop and any benefits derived from this
- Decisional balance (tree) attempts to tip the balance towards change as it reinforces the costs and highlights the benefits i.e. gains to be made if they stay stopped
- Assess the impact smoking has on goal attainment. Goals are discussed in relations to how smoking either hinders or help in the attainment of these goals.
- Highlight High risk situations (triggers) in order to either Avoid or develop strategies to better aid the person when they are tempted - skills them development and mastery
- Highlight negative effects of smoking in order to reinforce the maintenance of change or increase readiness to change i.e. effects on health, future, family and friends, community, spirit
- Looking for ways/activities/people to support/maintain that change
- Summaries are very important ways to reinforce change through repetition. Hearing it all again helps reinforce the need for change or shifts motivation toward change, in particular the long-term health effects of smoking and/or financial costs of smoking
- 3.6 assess any shift in motivation to change after discussing smoking in these terms
- The development of strategies in relation to high risk situations is extremely important. The hope is, this will better equip the person when faced with a high-risk situation after release. Making sure these strategies are realistic. Look for previous ways people have successfully maintained change. Use the 4 D's as other suggestions to add to the strategies being developed.
- Rewards are critical to behaviour change, whether they are physical, emotional or tangible. Reward desired behaviour through use of supportive people or activities. Doing fun things with supportive people.
- Highlight the causes of relapse. Try to avoid High risk situation in order to avoid relapse. This can also be done by establishing rules e.g. one won't hurt.
- Preparation of first 24 hours will increase the chances of avoiding relapse.

  All the above is aimed at increasing awareness and reinforcing the need to maintain the change as well as giving people skills to avoid relapsing.

Supplementary 3. Education materials in the health promotion pack.

1. 'Don't make smokes your story' toolkit:
    a. 'Medicines to Help You Stop Smoking' A5 booklet
    b. 'Don't make smokes your story' sticker.
    c. Smoke free zone magnet.
    d. My QuitBuddy mobile app card.

(http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/stakeholder-toolkit)

2. 'Australian Guide to Healthy Eating: Food Plate' poster.

(https://www.eatforhealth.gov.au/guidelines/australian-guide-healthy-eating)

3. Reduce your risk: new national guidelines for alcohol consumption.

(http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/guide-adult)

4. 'Make your Move – Sit less – Be active for life!' brochure.

(http://www.health.gov.au/internet/main/publishing.nsf/content/health-pubhlth-strateg-phys-act-guidelines)

1. Basic Information

First, I'll ask some questions about your background.

1.1. Gender

Male ○ 1
Female ○ 2
Other ○ 3

1.2. What is your date of birth?

☐☐/☐☐/☐☐☐☐

1.3. Are you of Aboriginal or Torres Strait Islander origin?

Aboriginal ○ 1
Torres Strait Islander ○ 2
Aboriginal & Torres Strait Islander ○ 3
No ○ 4

2. Eligibility

2.1. Did you smoke daily before coming to prison?
(If they did not smoke daily ask whether they had smoked at least 100 cigarettes in their lifetime.)

No ○ 0
Yes ○ 1

2.2. Do you want to stay smoke-free after you get out of prison?

No ○ 0
Yes ○ 1
Unsure ○ 2

2.3. What is the expected date of discharge?
(Copy this information from the monthly prisoner list if already known.)

☐☐/☐☐/☐☐☐☐

2.4. Have you ever been diagnosed with a severe psychiatric disorder (e.g. Schizophrenia, Bipolar Disorder)?

No ○ 0
Yes ○ 1

2.5. In the last four weeks, have you thought about harming, injuring or killing yourself?

No ○ 0
Yes ○ 1

2.6. If Yes, please give details

_____

_____

2.7. Does the subject have impaired decision-making capacity?
(Use the Mini-Mental State Examination instrument to confirm if you suspect the subject has cognitive impairment.)

No ○ 0
Yes ○ 1

2.8. Is the subject eligible to enter the study?

No ○ 0
Yes ○ 1

(Interviewer: if Yes, present study information sheet and informed consent; if No, explain to the inmate why and end the interview)

2.9. Has signed informed consent been obtained?

No ○ 0
Yes (skip to 2.11) ○ 1

2.10. If No, please reason why signed informed consent was not obtained.

_____

_____

2.11. Has a copy of informed consent been given to the subject for a record?

No ○ 0
Yes ○ 1

3. Contact information

After you leave prison, we need to be able to contact you to ask you questions about your health. Please answer as much detail as you can.

3.1. What is your home address?

_____

_____

_____

3.2. What is your postal address? (if different from home address)

_____

_____

_____

3.3. What is your phone number?

_____

3.4. What is your mobile number?

_____

3.5. What is your email address?

_____

3.6. What is your Facebook name?

_____

3.7. What is your local Probation and Parole Office?

_____

_____

_____

3.8. What is the name of your local health centre?

_____

_____

_____

3.9. What is your local Centrelink Office?

_____

_____

_____

3.10. Who is your remote Drug and Alcohol worker and their contact numbers?

_____

3.11. Could you name an Elder in your community and give their telephone numbers?

_____

3.12. Could we contact you through the Central Australian Aboriginal Congress (the Congress) or the Top End Health Services?

No ○ 0
Yes ○ 1

3.13. Your follow up interview will be on ☐☐ / ☐☐ / ☐☐☐☐ (auto-calculated field), is there something that could remind you?

*(Follow up interview will be **90 days after release**. Write on the 1800 SNAP follow up card and present to the subject).*

_____

_____

4. Demographics

4.1. What is your marital status?

Never married ○ 1
Widowed ○ 2
Divorced ○ 3
Separated not divorced ○ 4
Married ○ 5
De-facto/regular partner ○ 6

4.2. How many children do you have?

Nil ○ 0
1 ○ 1
2 ○ 2
3 ○ 3
4 ○ 4
5 ○ 5
more than 5 ○ 6

4.3. What is your highest educational qualification?

No formal qualification (< year 10) ○ 1
School certificate ○ 2
NTCE/HSC/VCE/Leaving certificate ○ 3
College certificate/diploma ○ 4
Technical or trade certificate ○ 5
Degree/tertiary qualification ○ 6

4.4. Where were you living immediately before coming into prison?

Renting ○ 1
Own home or family own house ○ 2
Unsettled lodgings (squat, hostel, etc.) ○ 3
Sleeping rough (homeless) ○ 4
Hospital ○ 5
Other ○ 6
Please specify 'other': _____

4.5. In the last 12 months before custody were you working (including Work for the Dole)?

No ○ 0
Yes ○ 1

4.6. What was the total of all wages, government benefits, pensions and other income you usually received after tax before coming into prison?

Nil income ○ 1
$1 - $200 per week ○ 2
$201 - $400 per week ○ 3
$401 - $600 per week ○ 4
$601 - $800 per week ○ 5
$801 - $1,000 per week ○ 6
> $1,000 per week ○ 7

4.7. In the 12 months before coming into custody were you receiving a pension or allowance?

No ○ 0
Yes ○ 1

5. Smoking

Next, I am going to ask a few questions about your smoking before you coming to prison

5.1. How old were you when you first started smoking cigarettes?

☐☐ years

5.2. When was your last cigarette before coming to prison?

≤ 1 week before prison ○ 1
> 1 week and ≤ 1 month before prison ○ 2
> 1 month and ≤ 6 months before prison ○ 3
> 6 months before prison ○ 4

5.3. Did you typically smoke in the following places? *(multiple response)*

In cars ☐ 1
In your house ☐ 2
In community buildings, (e.g. church/school) ☐ 3
Outdoor dining area ☐ 4

Next, I am going to ask a few questions about your smoking habit during the 12 months before coming into prison

5.4. On the days that you used to smoke, about how many cigarettes do you usually smoke? (including both factory-made and roll-your-own cigarettes)

10 or less ○ 1
11 - 20 ○ 2
21 - 30 ○ 3
more than 30 ○ 4

5.5. How soon after waking do you smoke your first cigarette?

More than 60 minutes ○ 1
31 - 60 minutes ○ 2
5 - 30 minutes ○ 3
Within 5 minutes ○ 4

5.6. On average, how much money do you usually spend on cigarettes each week?

AUD ☐☐☐

5.7. Which of the following describes you?

I don't want to stop smoking ○ 1
I think I should stop smoking but don't really want to ○ 2
I want to stop smoking but haven't thought about until coming to prison ○ 3
I REALLY want to stop smoking and hope to stay smoke free after release ○ 4

Don't know ○ 5

5.8. On a scale from 0 – 100, how likely is that you will stay off cigarettes after you leave prison? ☐☐☐

5.9. Have you ever tried to quit smoking and succeed in not smoking for at least 24 hours before coming into prison?

No (skip to 5.11) ○ 0
Yes ○ 1

5.10. Have you taken any of the following measures regarding smoking? *(multiple response)*

Changed to a lower tar or nicotine content cigarette brand ☐ 1
Reduced the amount of tobacco you smoke in a day ☐ 2
Used nicotine replacement therapy (e.g. patches, lozenges) ☐ 3
Spoke to the Quitline ☐ 4
Attended a QUIT smoking program ☐ 5
Other ☐ 6
Please specify 'other' _____

5.11. Do you agree that prison should have smoking bans?

No ○ 0
Yes ○ 1
Unsure ○ 2

5.12. Who else smoke(s) in your family? *(multiple response)*

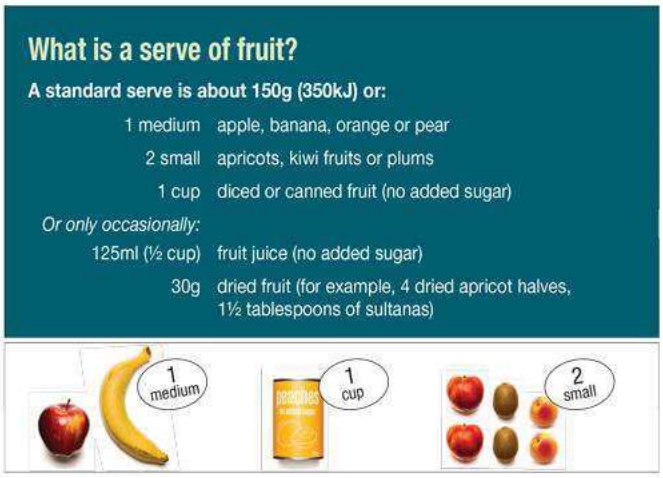
Mother ☐ 1
Father ☐ 2
Husband/wife/partner ☐ 3
Children ☐ 4
Brothers/sisters ☐ 5
Other family members ☐ 6

6. Nutrition

Next, I am going to ask a few questions about your eating on a typical day in prison

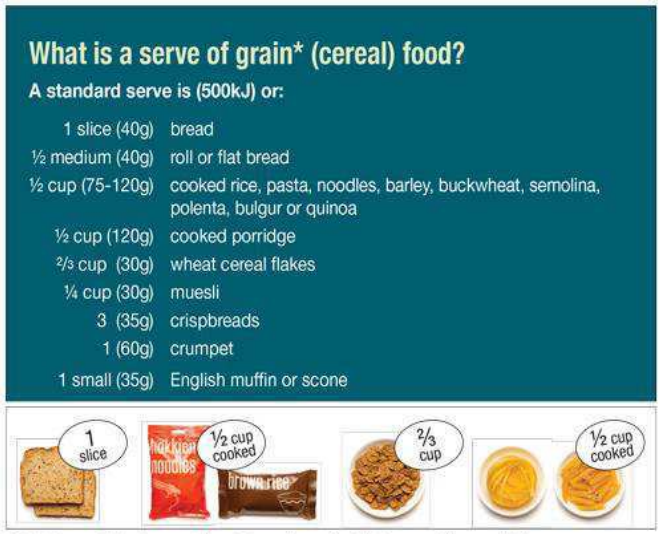
6.1. How many servings of fruit do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.2. How many servings of grains do you eat?

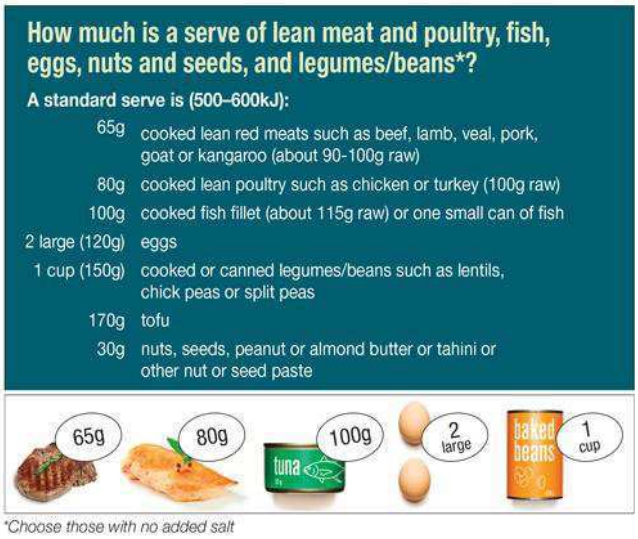
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



*Grain (cereal) foods, mostly wholegrain and/or high cereal fibre varieties

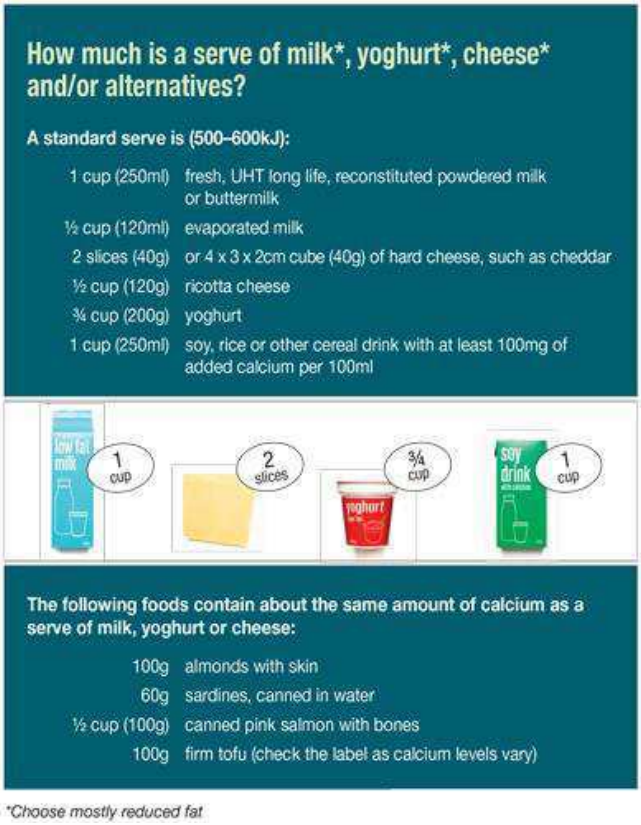
6.3. How many servings of lean meats, poultry, fish, eggs, beans, nuts and seeds do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.4. How many servings of milk, yoghurt and cheese do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.5. How many servings of vegetables or salad do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3

Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6

6.6. Would you say that you are?

Very overweight ○ 1
Overweight ○ 2
Normal weight ○ 3
Underweight ○ 4
Very underweight ○ 5
Don't know ○ 6

7. Alcohol and drugs

Next, I am going to ask a few questions about your personal drinking habit during the last 12 months before coming into prison

7.1. How often did you drink?

Never ○ 0
Monthly or less ○ 1
2 to 4 times a month ○ 2
2 to 3 times a week ○ 3
4 or more times a week ○ 4

7.2. When you have a drink, how many do you usually have in one day?

1 or 2 ○ 1
3 or 4 ○ 2
5 or 6 ○ 3
7 to 9 ○ 4
10 or more ○ 5
If '10 or more', please specify _____ units
(check card to calculate units)

7.3. How often did you have 6 or more drinks on one day?

Never ○ 0
Less than monthly ○ 1
Monthly ○ 2
Weekly ○ 3
Daily or almost daily ○ 4

7.4. How many times have you got into any fight because of your drinking?

☐☐

7.5. Have you received any treatment for your alcohol use?

No (skip to 7.7) ○ 0
Yes ○ 1

7.6. Please specify what kind of alcohol treatment. *(multiple response)*

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Alcoholics Anonymous) ☐ 5
Other ☐ 6
Please specify 'other': _____

7.7. Have you ever felt that any of the following people ever had problems such as family, health, work or the law due to their use of alcohol? *(multiple response)*

Mother ☐ 1
Father ☐ 2
Husband/wife/partner ☐ 3
Children ☐ 4
Brothers/sisters ☐ 5
Other family members ☐ 6

7.8. Have you ever used cannabis/ganja?

No (Skip to 7.13) ○ 0

Yes ○ 1

7.9. How old were you when you first used cannabis/ganja?

☐☐

7.10. Have often have you used cannabis/ganja <u>in the last 3 months</u>?

Never ○ 0
Less than monthly ○ 1
Monthly ○ 2
Weekly ○ 3
Daily or almost daily ○ 4

7.11. Do you mull up cannabis/ganja with tobacco?

No ○ 0
Yes ○ 1

7.12. On average, how much money do you spend on cannabis each week?

AUD ☐☐☐

7.13. Have you ever injected a drug, such as heroin, amphetamines, cocaine, methamphetamine?

No (Skip to8.1) ○ 0
Yes ○ 1

7.14. How old were you when you first injected any illicit drug?

☐☐

8. Physical activity

Next, I'd like to ask you a few questions related to your physical activity.

8.1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?
(Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.3 if zero)

8.2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.3. During the **last 7 days**, on how many days did you do **moderate** physical activities?
(Moderate activities make you breathe somewhat harder than normal and may include light lifting, regular bicycling or doubles tennis. Do not include walking Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.5 if zero)

8.4. How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.5. During the **last 7 days**, on how many days did you walk for at least 10 minutes?

☐ days per week
(Skip to 8.7 if zero)

8.6. How much time did you usually spend **walking** on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.7. During the **last 7 days**, how much time did you spend **sitting** on week day?

☐☐ hours
☐☐☐ minutes
per day

8.8. In the 12 months before you came into prison, would you describe yourself as?

Very active ○ 1
Fairly active ○ 2
Not very active ○ 3
Not at all active ○ 4
Don't know ○ 5

8.9. Compared with before you came into prison, would you say that you are now?

More active ○ 1
About as active ○ 2
Less active ○ 3
Don't know ○ 4

9. Mental Health

9.1. How often during the past **4 weeks** did you feel nervous?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.2. How often during the past **4 weeks** did you feel hopeless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.3. How often during the past **4 weeks** did you feel restless or fidgety?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.4. How often during the past **4 weeks** did you feel so sad that nothing could cheer you up?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.5. How often during the past **4 weeks** did you feel everything was an effort?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.6. How often during the past **4 weeks** did you feel worthless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

10. Quality of life

*Now, I am going to ask you about your general well-being. I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes you **TODAY**.*

10.1. First, I'd like to ask you about mobility, would you say you have…?

No problems in walking about ○ 1
Slight problems in walking about ○ 2
Moderate problems in walking about ○ 3
Severe problems in walking about ○ 4
Unable to walk about ○ 5

10.2. Next, I'd like to ask you about self-care, would you say you have…?

No problems in washing or dressing yourself ○ 1
Slight problems in washing or dressing yourself ○ 2
Moderate problems in washing or dressing yourself ○ 3
Severe problems in washing or dressing yourself ○ 4
Unable to wash or dress yourself ○ 5

10.3. Next, I'd like to ask you about usual activities, such as work, study, housework, family or leisure activities, would you say you have…?

No problems in doing your usual activities ○ 1
Slight problems in doing your usual activities ○ 2
Moderate problems in doing your usual activities ○ 3
Severe problems in doing your usual activities ○ 4
Unable to do your usual activities ○ 5

10.4. Next, I'd like to ask you about pain or discomfort, would you say you have…?

No pain or discomfort ○ 1
Slight pain or discomfort ○ 2
Moderate pain or discomfort ○ 3
Severe pain or discomfort ○ 4
Extreme pain or discomfort ○ 5

10.5. Next, I'd like to ask you about anxiety or depression, would you say you are…?

Not anxious or depressed ○ 1
Slightly anxious or depressed ○ 2
Moderately anxious or depressed ○ 3
Severely anxious or depressed ○ 4
Extremely anxious or depressed ○ 5

10.6. How good or bad is your health today on a scale from 0 to 100?
(0 means the **worst** health you can imagine; 100 means the **best** health you can imagine)

☐☐☐

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the SNAP Study: A Randomised Controlled Study of the Health Intervention "SNAP" in Northern Territory Prisons to Prevent Relapse to Smoking after Release from Prison

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the SNAP Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☐ Medicare & PBS claims history

for the period* 01/01/2014 to: 30/12/2022 to the SNAP Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Benefit paid	Patient out of pocket
20/04/09	00023	Level B consultation	$38.30	$34.30	$4.00
22/06/09	11700	ECG	$29.50	$29.50	

Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode
999999A		2300
999999A	20/04/09	2300

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012

Version: 20-07-2017

UNSW THE UNIVERSITY OF NEW SOUTH WALES SYDNEY · CANBERRA · AUSTRALIA

Australian Government
Department of Health

NDARC National Drug & Alcohol Research Centre

Smoking Nutrition Alcohol Physical activity (SNAP) Study

SNAP

Follow-up Questionnaire

Randomisation ID: ☐☐☐☐

Interviewer initials: ☐☐

Date of interview: ☐☐ / ☐☐ / ☐☐☐☐

Method of follow-up contact:
Direct telephone call ○1
1800 SNAP hotline ○2
Prison re-entry ○3
By parole officer ○4
By local health service ○5
Other ○6

Please specify 'other'_____

1. Banking information

Thank you for agreeing to complete this follow up interview, you will receive $10 reimbursement after completing this questionnaire. To allow us to reimburse you correctly, please provide your banking account details below. If you do not have a banking account, please provide the nearest post office to your home, we will send you the reimbursement via Western Union money order.

1.1. Name of account

_____

1.2. BSB

_____

1.3. Account number

_____

1.4. Nearest post office

_____

2. Smoking

Next, I am going to ask a few questions about your smoking after being released from prison

2.1. When was your first cigarette after being released from prison?

On the day of release (skip to 2.5 after Q2.2) ○ 1
On the second day after release (skip to 2.5 after Q2.2) ○ 2
Not the first two days but within a week after release (skip to 2.5 after Q2.2) ○ 3
Not the first week but within a month after release (skip to 2.5 after Q2.2) ○ 4
Not the first month but within three months after release (skip to 2.5 after Q2.2) ○ 5
I did not smoke after release ○ 6

2.2. Just to confirm, have you smoked any tobacco, even a part of a cigarette in the last 7 days?

No ○ 0
Yes ○ 1

2.3. What is the most important reason for you to stay smoke-free after release?

I wanted to improve my health ○ 1
I wanted to save money ○ 2
I wanted to stay abstinent for my children ○ 3
I wanted to break free of a habit ○ 4
I did not like the smell of smoking ○ 5
Other ○ 6
Please specify 'other'_____

2.4. On a scale from 0 – 100, how likely is that you will stay off cigarettes in the next 30 days? (skip to 2.16)

☐☐☐

2.5. Have you smoked more than five (5) cigarettes in total after your release?

No ○ 0
Yes ○ 1

2.6. How many cigarettes did you smoke on the day of release? (including both factory-made and roll-your-own cigarettes)

☐☐

2.7. How many cigarettes did you smoke on the 2nd day after release?

☐☐

2.8. How many cigarettes in total did you smoke in the first week (including the first two days) after release?

☐☐☐

2.9. How many cigarettes on average did you smoke daily in the first month after release?

☐☐☐

2.10. How many cigarettes on average did you smoke daily in the first three months after release?

☐☐☐

2.11. How many cigarettes on average did you smoke daily in the last 7 days?

☐☐☐

2.12. On a typical day, how soon after waking do you smoke your first cigarette?

More than 60 minutes ○ 0
31 - 60 minutes ○ 1
5 - 30 minutes ○ 2
Within 5 minutes ○ 3

2.13. Did you smoke in the following places after you leave prison? *(multiple response)*

In cars ☐ 1
In your house ☐ 2
In community buildings (e.g. church, school) ☐ 3
Outdoor dining area ☐ 4
None of above ☐ 5

2.14. If you had to give one reason for why you returned to smoking, what reason would you say?

I was celebrating freedom ○ 1
I was with someone who was a smoker ○ 2
I was feeling stressed ○ 3
I was bored ○ 4
I used it as self-medication ○ 5
Other ○ 6
Please specify 'other'_____

2.15. Which of the following describes you now?

I don't want to stop smoking ○ 1
I think I should stop smoking but don't really want to ○ 2
I want to stop smoking but haven't thought about when ○ 3
I REALLY want to stop smoking but I don't know when I will ○ 4
I want to stop smoking and hope to soon ○ 5
I REALLY want to stop smoking and intend to in the next 3 months ○ 6
I REALLY want to stop smoking and intend to in the next month ○ 7

2.16. Have you ever taken any measures to quit smoking since leaving prison?

No (skip to3.1) ○ 0
Yes ○ 1

2.17. Have you taken any of the following measures regarding smoking? *(multiple response)*

Changed to a lower tar or nicotine content cigarette brand ☐ 1
Reduced the amount of tobacco you smoke in a day ☐ 2
Used nicotine replacement therapy (e.g. patches, lozenges) ☐ 3
Spoke to the Quitline ☐ 4
Attended a QUIT smoking program ☐ 5
Other ☐ 6
Please specify 'other'_____

2.18. How many of your close friends and immediate family members smoke?

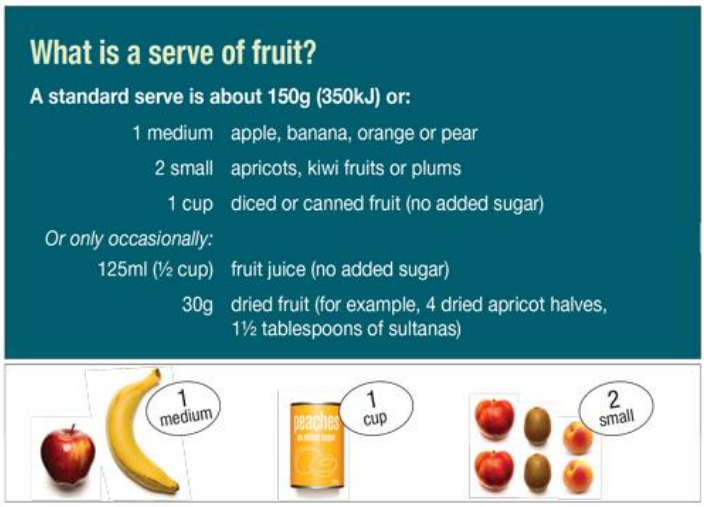
None ○ 0
Some ○ 1
About half ○ 2
Most ○ 3
All ○ 4

3. Nutrition

Next, I am going to ask a few questions about your eating on a typical day after leaving prison.

3.1. How many servings of fruit do you eat?

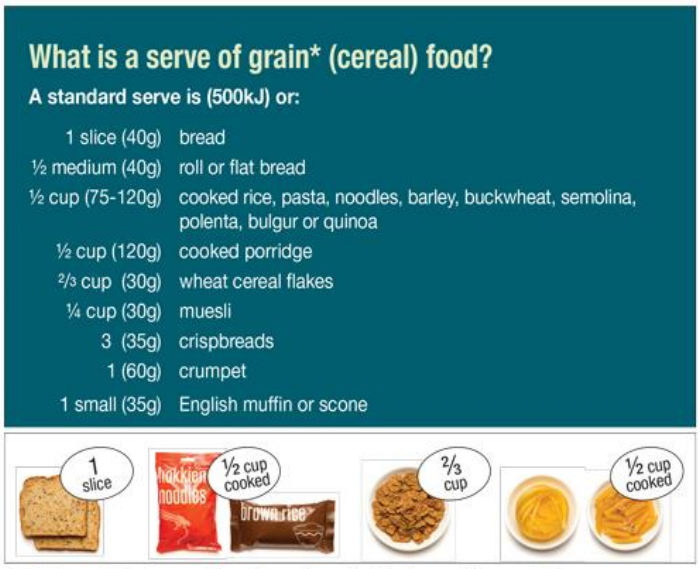
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



3.2. How many servings of grains do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5

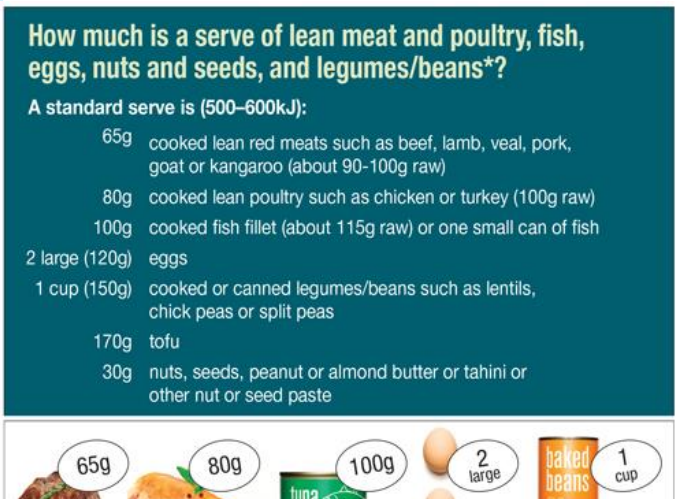
Six serves or more ○ 6



*Grain (cereal) foods, mostly wholegrain and/or high cereal fibre varieties

3.3. How many servings of lean meats, poultry, fish, eggs, beans, nuts and seeds do you eat?

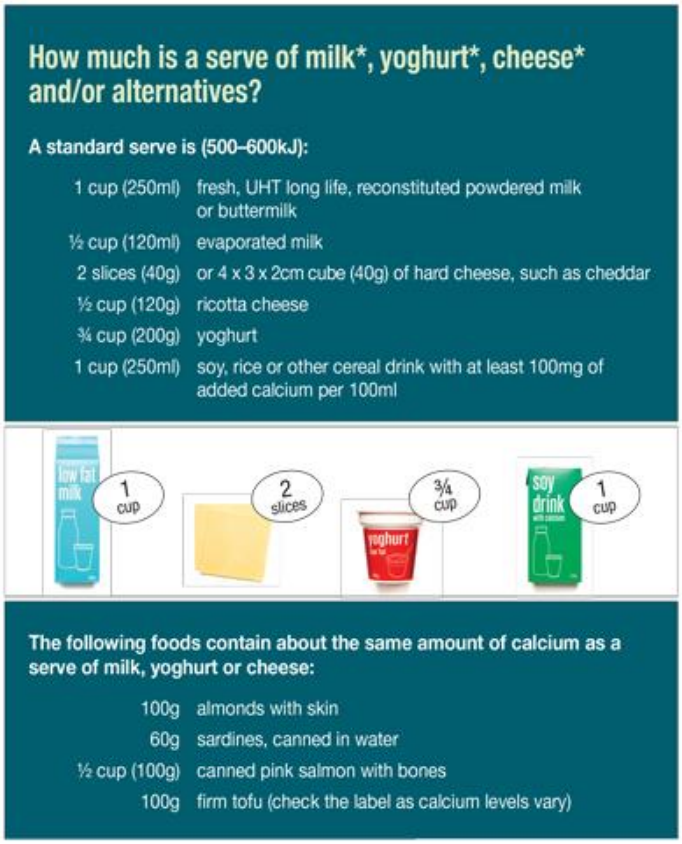
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



*Choose those with no added salt

3.4. How many servings of milk, yoghurt and cheese do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



*Choose mostly reduced fat

3.5. How many servings of vegetables or salad do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6

*With canned varieties, choose those with no added salt

3.6. Would you say that you are?

Very overweight ○ 1
Overweight ○ 2
Normal weight ○ 3
Underweight ○ 4
Very underweight ○ 5

Don't know ○ 6

4. Alcohol and drugs

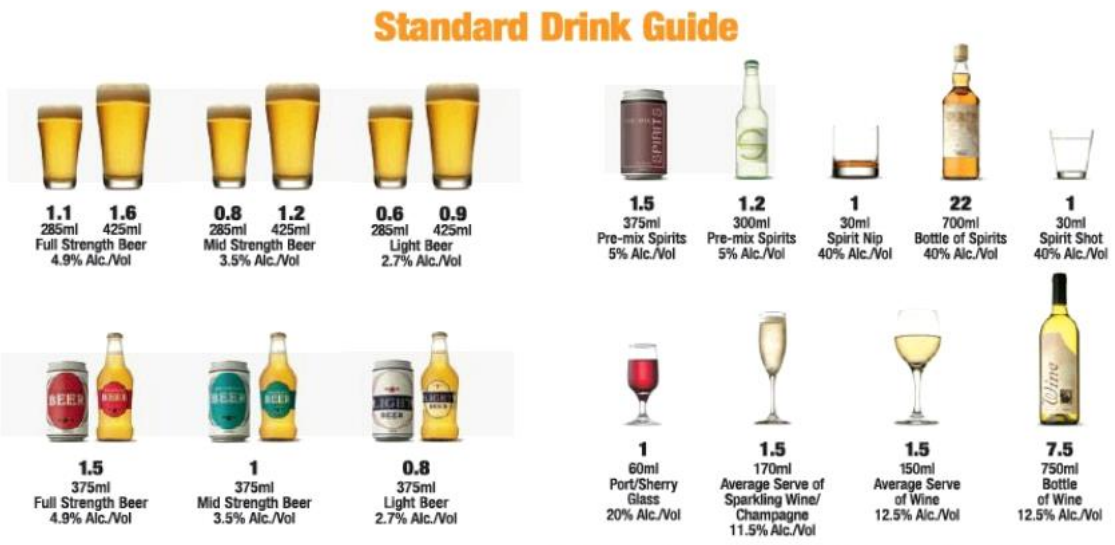
Next, I am going to ask a few questions about your drinking habit <u>after leaving prison</u>

4.1. How often did you have a drink containing alcohol since leaving prison?

Never ○ 0
Monthly or less ○ 1
2 to 4 times a month ○ 2
2 to 3 times a week ○ 3
4 or more times a week ○ 4

4.2. How many standard drinks containing alcohol did you have on a typical day when you were drinking?

1 or 2 ○ 1
3 or 4 ○ 2
5 or 6 ○ 3
7 to 9 ○ 4
10 to 14 ○ 5
15 to 19 ○ 6
20 or more ○ 7
(check card to calculate units)



4.3. How often did you have 6 or more standard drinks on one occasion?

Never ○ 1
Less than monthly ○ 2
Monthly ○ 3
Weekly ○ 4
Daily or almost daily ○ 5

4.4. Have you received any treatment for your alcohol use after leaving prison?

No (skip to 3.7) ○ 0
Yes ○ 1

4.5. Please specify what kind of alcohol treatment. *(multiple response)*

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Alcoholics Anonymous) ☐ 5
Other ☐ 6
Please specify 'other': _____

4.6. Have you used cannabis/ganja since leaving prison?

No (Skip to 3.9) ○ 0
Yes ○ 1

4.7. Have often have you used cannabis/ganja since leaving prison?

Never ○ 1
Once or twice ○ 2
Monthly ○ 3
Weekly ○ 4
Daily or almost daily ○ 5

4.8. Have you ever injected an illicit drug, such as heroin, amphetamines, cocaine, methamphetamine, after leaving prison?

No ○ 0
Yes ○ 1

4.9. Have you received any treatment for your drug use?

No (Skip to 5.8) ○ 0
Yes ○ 1

4.10. Please specify what kind of treatment for your drug use.

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Self-Help Addition Resource Centre) ☐ 5
Other ☐ 6
Please specify 'other': _____

5. Physical activity (IPAQ)

Next, I'd like to ask you a few questions related to your physical activity.

5.1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?
(Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.3 if zero)

5.2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.3. During the **last 7 days**, on how many days did you do **moderate** physical activities?
(Moderate activities make you breathe somewhat harder than normal and may include light lifting, regular bicycling or doubles tennis. Do not include walking Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.5 if zero)

5.4. How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.5. During the **last 7 days**, on how many days did you walk for at least 10 minutes?

☐ days per week
(Skip to 8.7 if zero)

5.6. How much time did you usually spend **walking** on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.7. During the **last 7 days**, how much time did you spend **sitting** on week day?

☐☐ hours
☐☐☐ minutes
per day

5.8. Would you describe yourself as?

Very active ○ 1
Fairly active ○ 2
Not very active ○ 3
Not at all active ○ 4
Don't know ○ 5

5.9. Compared with when you are in prison, would you say that you are now?

More active ○ 1
About as active ○ 2
Less active ○ 3
Don't know ○ 4

6. Mental Health (K6)

6.1. How often during the past **4 weeks** did you feel nervous?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.2. How often during the past **4 weeks** did you feel hopeless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.3. How often during the past **4 weeks** did you feel restless or fidgety?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.4. How often during the past **4 weeks** did you feel so sad that nothing could cheer you up?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.5. How often during the past **4 weeks** did you feel everything was an effort?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.6. How often during the past **4 weeks** did you feel worthless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4

7. Quality of life (EQ-5D)

Now, I am going to ask you about your general well-being. I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes you TODAY.

7.1. First, I'd like to ask you about mobility, would you say you have…?

No problems in walking about ○ 1
Slight problems in walking about ○ 2
Moderate problems in walking about ○ 3
Severe problems in walking about ○ 4
Unable to walk about ○ 5

7.2. Next, I'd like to ask you about self-care, would you say you have…?

No problems in washing or dressing yourself ○ 1
Slight problems in washing or dressing yourself ○ 2
Moderate problems in washing or dressing yourself ○ 3
Severe problems in washing or dressing yourself ○ 4
Unable to wash or dress yourself ○ 5

7.3. Next, I'd like to ask you about usual activities, such as work, study, housework, family or leisure activities, would you say you have…?

No problems in doing your usual activities ○ 1
Slight problems in doing your usual activities ○ 2
Moderate problems in doing your usual activities ○ 3
Severe problems in doing your usual activities ○ 4
Unable to do your usual activities ○ 5

7.4. Next, I'd like to ask you about pain or discomfort, would you say you have…?

No pain or discomfort ○ 1
Slight pain or discomfort ○ 2
Moderate pain or discomfort ○ 3
Severe pain or discomfort ○ 4
Extreme pain or discomfort ○ 5

7.5. Next, I'd like to ask you about anxiety or depression, would you say you are…?

Not anxious or depressed ○ 1
Slightly anxious or depressed ○ 2
Moderately anxious or depressed ○ 3

Severely anxious or depressed ○ 4
Extremely anxious or depressed ○ 5

7.6. How good or bad is your health today on a scale from 0 to 100?
(0 means the **worst** health you can imagine; 100 means the **best** health you can image)

☐☐☐

8. Carbon monoxide (CO) breathing test

This machine allows us to determine the amount of carbon monoxide in your lungs. Carbon monoxide is present in cigarettes, so the more cigarettes you smoke, the more carbon monoxide is present in your lungs and the higher the number. Generally, a reading between 0 and 6 indicates that you haven't smoked in the last 24 hours. However, these numbers can be higher due to many reasons, including environmental carbon monoxide, age, and how many years you have been a smoker.

8.1. Test date

☐☐/☐☐/☐☐☐☐

8.2. Place where the test is taken

_____

8.3. Just to confirm, have you smoked any tobacco, even a part of a cigarette in the last 7 days?

No ○ 0
Yes ○ 1

8.4. Have you smoked cannabis in the last 7 days?

No ○ 0
Yes ○ 1

8.5. Carbon monoxide (CO) level (reading 1)

☐☐☐ ppm

8.6. Carbon monoxide (CO) level (reading 2)

☐☐☐ ppm

8.7. Carbon monoxide (CO) level (reading 3, if difference in previous reading is >5)

☐☐☐ ppm

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2; 6; 14
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 16
	5b	Name and contact information for the trial sponsor	16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	13-14

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5-6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig. 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11-12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9, 13

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11-12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	14
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	6; 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	8
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Suppl. 1; Suppl. 5
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-021326.R1
Article Type:	Protocol
Date Submitted by the Author:	17-May-2018
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Primary Subject Heading:	Smoking and tobacco
Secondary Subject Heading:	Public health, Smoking and tobacco, Evidence based practice
Keywords:	Clinical trials < THERAPEUTICS, PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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

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Keywords

Randomised controlled trial; Prisoners; Tobacco Smoking; Smoking Ban

ABSTRACT

Introduction

Smoking remains the leading risk factor for disease burden and mortality worldwide. Heavy **S**moking is often associated with poor **N**utrition, **A**lcohol abuse and **P**hysical 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 multi-centre, 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

Australian New Zealand Clinical Trials Registry: ACTRN12617000217303.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The 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 smoking abstinence 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, more than seven 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 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 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 to 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 disvatnaged 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 programs 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 United States (the WISE Study) suggest that a smoking ban in prison alone had little impact on post-release smoking, with over 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 multi-centre, 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 Centre, which are the only two adult prisons in the Northern Territory, Australia, with a total population size of approximately 1,600 inmates.

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).

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 (i.e., 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 (*Supplementary 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 more than 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 (e.g. 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 pre-defined, 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 programs are available to prevent

smoking relapse upon 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 four 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 (*Supplementary 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 Royal Australian College of General Practitioners 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; (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 (*Supplementary 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 one-day workshop followed by at least two sessions of two-hours 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 (*Supplementary 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 (HSI)[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 (ADG)[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 (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 (*Supplementary 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 Integrated Offender Management System.

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 (*Supplementary 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 re-incarcerated. 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 three-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 (ppm) 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 7 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 method (TFB)[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 sub-scores.

Alcohol consumption

Self-reported alcohol consumption after release will be measured using the AUDIT-C. The AUDIT-C comprises 3 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 U.S.[28], of those who had received six sessions of intensive intervention comprising motivational interviewing and cognitive behaviour therapy, 12% remained abstinent three months after release, compared to 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]. Previous study suggested a follow-up rate of 48% in remote regions in the Northern Territory[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 (MCAR). If Missing At Random (MAR), 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) Day 3-7; (4) Day 8-30; (5) Day 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 pariticipant 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. (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 to 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 de-identified 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 adverse events 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 Northern Territory Correctional Services, community correction managers, representatives of local health services and Indigenous interviewers. It was not possible to involve patients in prison settings in the design and conduct of the study. Qualitative feedback on the intervention was 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 Northern Territory Correction Services. The results will also be available on the National Drug and Alcohol Research Centre website: https://ndarc.med.unsw.edu.au/project/snap.

ETHICS AND DISSEMINATION

Ethics approval was first obtained in the University of New South Wales Human Research Ethics Committee (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 9th 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 overrepresented in prisons. Although RCTs are widely recognized 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]. Furthermore, 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 learned from this study will inform policy makers 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.

OTHER INFORMATION

Acknowledgements

We would like to acknowledge the Northern Territory Correctional Services for their support of this project. We would like to thank Dr Cheneal Puljevic and Ms Rebecca Bosworth for their assistance in preparing the study. We would like to acknowledge Dr Etty Matalon for her clinical expertise in developing the brief intervention and staff training. We would also like to acknowledge Ms Jody Clarke for her help with assessing the cultural appropriateness of the study design and research documents.

Funding

The SNAP study is supported by the Australian Commonwealth Government Department of Health Tackling Indigenous Smoking Grant (TIS H151G6012). The design, management, analysis and reporting of the study are entirely independent of the funding body.

The National Drug and Alcohol Research Centre at the University of New South Wales (UNSW), Australia is supported by funding from the Australian Government under the

Substance Misuse Prevention and Service Improvements Grants Fund and by infrastructure support from the UNSW, Australia. ES is supported by an Australian National Health and Medical Research Centre (NHMRC) Early Career Fellowship (APP1104600). SK is supported by an NHMRC Senior Research Fellowship (APP1078168). RJC is supported by a Cancer Institute New South Wales Early Career Research Fellowship (GNT14/ECF/1-46). DP is supported by an Australian Research Council's Discovery Early Career Award (Project DE150100309).

Authors' contributions

KD, SK, RH conceived the study; KD, SK, RH, ES, RC, 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.

Competing interests

The authors declare that they have no competing interests.

Data sharing

Extra data is available by emailing Prof Kate Dolan (k.dolan@unsw.edu.au)

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FIGURE LEGEND

Figure 1. SNAP study planned flow chart

Figure 1. SNAP study planned flow chart

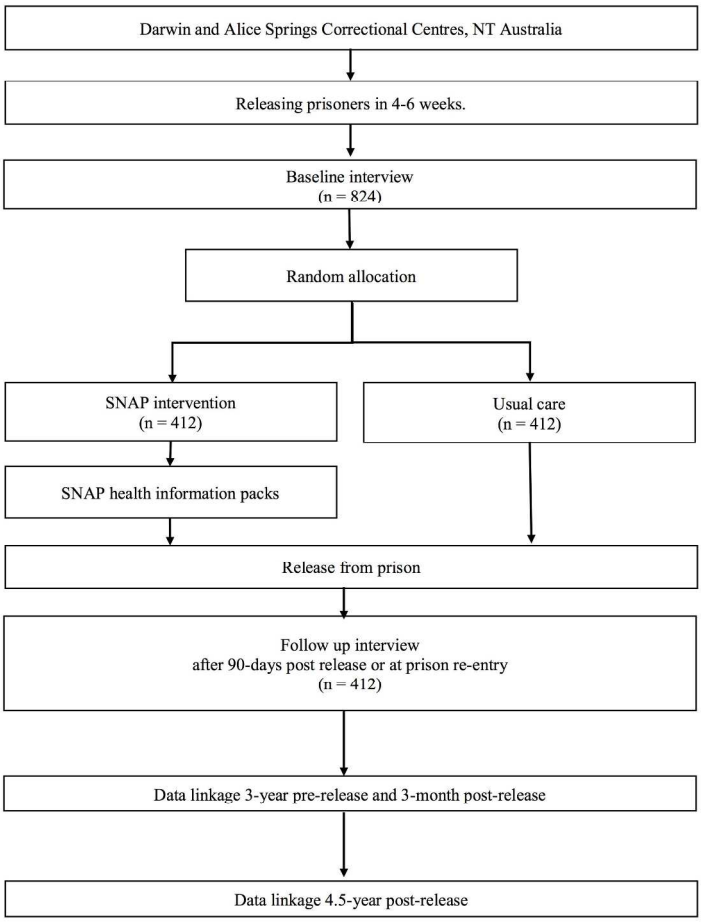


Figure 1. SNAP Study Planned Flowchart

209x297mm (300 x 300 DPI)

NDARC National Drug & Alcohol Research Centre

UNSW AUSTRALIA

SNAP

OFFICIAL USE ONLY

Study ID ☐☐☐☐

Consent Date ☐☐/☐☐/☐☐☐☐

CONSENT FORM

A Randomised Controlled Study of the Health Intervention "SNAP" in Northern Territory Prisons to Prevent Relapse to Smoking after Release from Prison

Chief Investigator: Professor Kate Dolan, Professor Stuart Kinner, Ms Robyn Hopkins, Dr Ryan Courtney, Dr Emily Stockings, Professor Anthony Shakeshaft, Dr Dennis Petrie, A/Prof Timothy Dobbins.

This Means You Can Say NO

Declaration by the participant

1. I understand I am being asked to agree to take part in this research project;
2. I have read the Participant Information Sheet or it has been explained to me in a language that I understand;
3. I provide my consent for the information collected about me to be used for the purpose of this research study only.
4. I agree to be contacted for future research by the SNAP study team.
5. I do attend a health centre on a regular basis, and allow the SNAP team to leave a message there for me so they can arrange an interview.
6. I agree if I come back to prison that the SNAP team can check and re-interview me in prison.
7. Any questions that I have asked have been answered to my satisfaction.
8. I understand that all research data will be treated as confidential and identifying information about me will only be provided to Commonwealth government bodies under strict conditions.
9. I agree that research data gathered for the study may be published provided that I cannot be identified as a subject.
10. I freely agree to participate in this research study as described and understand that I am free to leave the study at any time during the project and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
11. I understand that the study has been approved by the University of New South Wales Human Research Ethics Committee (UNSW-HREC), the Central Australia Human Research Ethics Committee (CAHREC) and the Menzies Human Research Ethic Committee (Menzies-HREC).
12. I understand that I will be given a signed copy of this document to keep.

I consent to being part of the SNAP Study

Name of Participant _____

Signature _____ Date _____/_____/_____

(OPTIONAL): I would like to receive a copy of the study results via email or post. I have provided my details below and ask that they be used for this purpose only;

Address: _____

Emails: _____

I* do NOT *wish to be part of the SNAP Study

Name of Participant _____

Signature _____ Date _____/_____/_____

Office Use Only

1. I, the researcher, have explained the study details and the implications of participation in the study to the above signed participant. I have enquired as to whether they have any questions regarding the study and have answered any that have been forthcoming.
2. I recognise the fact that the participant has the right to withdraw at any time.
3. I shall ensure that all the data and information collected in relation to the study is secure and remains confidential.

Name of researcher _____

Signature of researcher _____ Date _____/_____/_____

QUIT FOR A NEW LIFE "SNAP" (5 A's) Treatment Manual

INSTRUCTION TO USE

- *Prior to the continuation of the session, calculate the amount smoked, together with the cost and write in the space provided*
- *Give the participants their client booklet and explain that you will go through the material together*
- *This guideline is meant to guide you through the process of 'motivational interviewing'.*
- *References to the Baseline Questionnaire or Client Booklet are underlined*
- *You will need to capture some information to give feedback in the interview, you could write the information in* _____
- *Example conversation scripts are given in double quotation marks, e.g.* **"This is an example."**
- *The wordings in the conversation scripts are given as examples only. You should use words at your own discretion. The interview should be an engaging conversation between you and the participants.*
- *The aims of the questions are given at the end of this clinical guidelines.*

1. ASK

1.1 "How do you feel about not smoking in the future?"

*What you are trying to assess is their level of motivation in relation to smoking after release. Request that they place a cross on the appropriate answer to the following question on **Page 2** of Client Booklet. You may ask them to elaborate further on their answer if you wish. You are also trying to engage in a conversation and establish some level of rapport.*

OK	NOT SURE	NOT GOOD

1.2 "What is the main reason you want to stay smoke free"

This question is to ascertain their main reason or motivation to stop which you may wish to reflect and support using motivational interviewing techniques.

*To further ascertain their level of motivation you will request that fill out rulers on the **Page 3** of Client Booklet.*

1.3 "On a scale of 0 to 10 how important is it for you to not smoke again?"

1	2	3	4	5	6	7	8	9	10

1.4 "How interested are you in not smoking again?"

1	2	3	4	5	6	7	8	9	10

1.5 "How confident are you that you won't smoke again?"

1	2	3	4	5	6	7	8	9	10

*Acknowledge their answer by saying **"Great"** Or **"OK"**, and thank them for their answers*

Refer to 3.1 and 3.4 of the Baseline Questionnaire and confirm

1.6 "Earlier you said that before coming into prison you smoked …… per day and that you started at age ……. and that it cost …… per week"

_____ **per week**
_____ **per year**
_____ **life time**

$_____ **per week**
$_____ **per year**
$_____ **life time**

Refer to 5.9 in the Baseline Questionnaire and confirm:

1.7 "You also said you smoked …… (amount joints/cones/ bongs cannabis) since the age of …… on a …… daily/weekly basis" –

NB more than twice a week is likely to be dependent

1.8 "How much did cannabis cost per week?" **$**_____

_____ **per week**
_____ **per year**
_____ **life time**

$_____ **per week**
$_____ **per year**
$_____ **life time**

1.9 "Do you mull up with tobacco?" **Y / N_**

"How much does that cost per week?" **$**_____

$_____ **per year**
$_____ **life time**

1.10 "Did you use Bush tobacco?" **Y / N_**

"How much did that cost?" **$_____**

ONLY If they spend more $$$ on bush calculate the cost: (tobacco, cannabis, bush)

$_____ per week

$_____ per year

$_____ life time

You will need this information to give feedback later

Quit Attempts

Referring to 3.7 of Baseline Questionnaire

You need to ask the following questions as a way of engaging further and obtaining valuable information about their quit attempts and relapses. You are looking for successful ways they have they have maintained abstinence. While these questions are answered, further elaboration is sought in a conversational style. You might want to reflect their answers if appropriate e.g. ***"That's interesting, why is that?"*** *or* ***"Was that a lot?"*** *or* ***"What happened then? How did this change?"***

1.11 "Earlier you said ……..… (quit attempts) – if appropriate … *how many times have you successfully done that?"*

"That's interesting ……." *or* ***"What happened then? ……. How did this change?"***

You will need this information to feedback later.

1.12 "Why did you start again?"

"That's interesting ……." *or* ***"What happened then? ……. How did this change?"***

You will need this information to feedback later.

1.13 "How was it for you the first couple of weeks in prison when you were in withdrawal?"

You are looking for something positive or someway in which they coped that can be used again when they leave

2. ASSESS

Request that they turn to ***Page 4*** *of Client Booklet and describe the lung/tree. Point out that there are both sides to this tree – there are some down sides to smoking as well as gains to maintaining a smoke free life. Ask them to look at the pictures and circle the ones that they can relate to, such as having arguments or not having enough money, on one side versus being able to afford a new car or becoming more involved with community activities. Please*

remember to elaborate on the benefits of remaining smoke free. Record them in the space below, then ask:

2.1 "What is not good about smoking?"

2.2 "What's going to be great about continuing to stay smoke free?"

2.3 "Are there any other things that you don't like about smoking?"

Future Goals

Preface this next section by saying ***"May I now ask you or talk to you about the next three months and any goals you may have? Thinking about 3 months from your release and using page 5 of your booklet"***

2.4 "What 3 things would you want to have or do?"

Ask them to write them down in their booklet, if they are unable then you should write them down for the participant. Discuss further if any relate to smoking in any way.

1.
2.
3.

Triggers

You may need to explain triggers and what they are, and explain the difference between internal and external triggers. ***"Internal triggers are emotional and external are people places, things."***

2.5 "What are some situations or feelings that would make you feel like a smoke or where you would find it difficult not to smoke?"

Then ask the subject to tick or place a cross on the list on ***Page 6*** *of their booklet. While writing them below:*

Internal:

1. _____
2. _____
3. _____

External:

1. _____
2. _____
3. _____

You may now summaries and paraphrase ***"So what you are saying is …… and when …… you …… we will need to find better ways to cope with these rather than smoking"***

Effects of smoking on:

Their Health

Refer to 8.6 of Baseline Questionnaire

2.6 "Earlier you rated your health today as … /100, but how do you think your health has been affected as a result of your smoking?"

_____

You may wish to add

"in general, do you think smoking affects people's health and in what way?"

Ask them to turn to ***Page 7*** *of their booklet and ask while pointing to the various pictures separately*

"You said that smoking has already affected …….
Now may I ask you how smoking has affected ……

Answer each in the space provided

Their future, family friends, community, spirit

2.7 "Your future?"

_____

2.8 "What about your family and friends? How has it affected them?"

_____

2.9 "Can you tell me how smoking has affected your community?"

_____

2.10 "How about your spirit? Tell me how this has been affected by your smoking?"

Then ask

2.11 "What gives you strength? What makes you feel good? Something that will help you stay smoke free"

3. ADVISE

Now comes a very important part - the FEEDBACK – go back to page 1 – 6 of these Clinician Guidelines, and give a summary of what you have heard and been discussing so far. You may wish to say something like:

3.1 "Thank you so much for all this information it's great. I would like to just stop here for a minute and summarise what we have been discussing so far. Would that be ok?" What you have told me is that ……"

Go back and repeat the answers given from the beginning of the questionnaire

*Ask them to back to **Page 2** of their booklet: "How I feel about my smoking future".*

3.2 "You said …… You also said ……

*……. reflecting the scores on the rulers and using the questions on the rulers in the handout. Ask appropriate questions, e.g. **"What is stopping you from moving from a 5 to 10?",** or **"Why are you _____ interested/not interested and not a _____ in making this change?"**, etc. continue summarising the, costs and benefits lungs/tree, goals, triggers, effects on health, future, family, community, spirit etc….. then ……*

*Using **Page 8 of** their booklet, fill out (or request that they fill it out) while you are summarising and talking. Feedback the amount of tobacco they smoked; the cost of their smoking; how much cannabis they used and the costs per week, then per year, their lifetime, then total costs in a lifetime. Also request they write cost to family and community on page 8.*

$_____ per day/week

$_____ per year

$_____ life time

You may wish to discuss quit attempts - good reasons they have tried to quite before …. Only feedback successful times and praise the attempts and the length of abstinence (even if only for days). Suggest if they did it then they can do it again…if appropriate, use their first couple of weeks of being in prison and how they coped as an example

If appropriate reiterate the effect on their health and/or add ….

3.3 "Did you know ……."

*Read through relevant points on **Page 9** of their booklet and ask if they can relate to any of this information (give hand out on physical effect of smoking.)*

"ALSO" *……..*

*Using **Page 10** of their booklet, request they circle the appropriate answer to:*

3.4 "What might happen if I start smoking again because we need to be aware of what will happen if you start smoking again?"

Now ask "Do you have any questions at this point? Is there anything interesting or that sticks out for you?

Acknowledge and paraphrase. Then ask:

"What do you think of all this so far?"

Reiterate their answer in 1.13 of Baseline questionnaire

3.6 "Earlier you answered ……."

1) **I don't want to stop smoking**
2) **I think I should stop smoking but don't really want to**
3) **I want to stop smoking but haven't thought about it until coming to prison**
4) **I REALLY want to stop smoking and hope to stay smoke free after release**
5) **Don't know**

How do you feel now? has this changed?

3.7 "…Let's now discuss some ways to increase your chances of staying smoke free after you have left prison?"

*If the participant changed the answer or answered 1 or 2, you should still proceed with the interview and say something like **"even if you feel you may not be ready right now, we could still talk about ways to increase your chances if or when you change your mind"** or **"You never know you may at some later date use what we are going to talk about."***

Regardless of the answer, if they are unsure, you need to probe about what they see as the barriers to staying smoke free. If you suspect that they want to maintain abstinence, say "OK then let's talk about how we can we make that happen? let's give it a go."

4. ASSIST

*Using **Pages 11 – 14** of their booklet, fill out as appropriate, strategies such as good food and physical activity as substitutes for smoking – the strategies to each trigger need to be discussed at length and in detail in relation to plausibility)*

4. 1 write down triggers for them and develop strategies for them with the participant and write them in their booklet

Triggers	**Strategies**

4.2 Discuss and Agree on Other Strategies:

*Other strategies – **4 D's** on **Page 12** of their booklet which they need to write in*

***D**istract*

"Distract myself e.g. …… or go for a walk"
"Ring quit line number ……" (*write it down for them)*
"Go to ……"
"Talk to ……"
"Imagine yourself as a non-smoker ask them to imagine it every day before they leave prison"

***D**eal with it* *– this involves self-talk – talking to themselves when they feel like smoking. It's related to self-motivation and changing mindset. They need to rehearse saying things like*

"How long can I go without giving in?"
"I'm doing this because I want (tree)"
"How much better will I feel if I don't give in"
"This is not the worst thing in the world!"

***D**rink water*

"Or eat a sugar free mint"

***D**elay or **D**estress*

- **Suggest they do something else that reduces stress, something that needs them to move, eg walking, fishing, sport, deep breathing – using a method of relaxation (5 in, 5 hold, 5 out), etc.**
- **Suggest they delay giving in by doing something else until the craving goes away – usually 30 minutes**

4.3 Establish and Agree on The Other Rules

- **"Not smoke in the car"**
- **"Not smoke in the house"**
- **Stress that they should NOT entertain the idea that "just one won't hurt – as one will hurt"**

Inform them that the relapse rate is significantly increased should they not give up both cannabis and tobacco at the same time, rather than substitute one for the other.

4.4 Plan and Rewards

*Using and filling out **Page 14** of their booklet, and to finish on a positive note, discuss their immediate rewards and make sure they are achievable – plan with them the following and say*

"Let's talk about you remaining a non-smoker and what you will do to reward yourself with the money you will save."

Daily reward

Weekly reward

Monthly reward

5. ARRANGE

It is important to discuss support systems such as making an appointment with their medical practitioner or counsellor or anyone they see as helping them after release together with family members or other personal support people that they will turn to and discuss their success with.

5.1 NT Quitline (13 78 48)

5.2 Discuss family and friend support, to write in their booklet

5.3 Relapse Prevention

*Finally relapse prevention needs to be discussed as per **Page 15** of their booklet. However, before this you must discuss **the first 24 hours after release** in detail e.g. Who will pick them up? Where will they go? How will they avoid the first trigger to smoke? What will they do the next morning? What will they do to protect themselves against temptation? Then reiterate their answer to **"What gives you strength"** that was asked previously. Ask them to write on **Page 14** of their booklet who is going to be of great help to them.*

"What or who will keep you strong? how will they do that? "

END OF THE INTERVIEW

Thank the participants for their time. Reassure $5 reimbursement will be put into their accounts.

Explain to the participant that we expect to talk to them again 90-days after their release from prison and give $10 reimbursement for that.

Write down Study ID and expected follow-up date on the both follow-up cards, and give one to the participant and put the other one in the pre-release bag.

Give the pre-release bag to prison staff who are responsible to give it on release.

AIMS of the Questions in Motivational Interview

- How motivated are they about staying stopped?
- Main reason they want to stay stopped
- Howe important, interested and confident they are about staying stopped
- Assess amount and cost of tobacco for feedback
- Assess quit attempts – looking for successes and motivators for attempting change. Successful methods can be used again while avoiding unsuccessful methods
- Ascertaining reasons for relapses in order to stress the need to avoid them and/ or develop better ways to cope with them
- Using last time in prison as an example of the ability to stop and any benefits derived from this
- Decisional balance (tree) attempts to tip the balance towards change as it reinforces the costs and highlights the benefits i.e. gains to be made if they stay stopped
- Assess the impact smoking has on goal attainment. Goals are discussed in relations to how smoking either hinders or help in the attainment of these goals.
- Highlight High risk situations (triggers) in order to either Avoid or develop strategies to better aid the person when they are tempted - skills them development and mastery
- Highlight negative effects of smoking in order to reinforce the maintenance of change or increase readiness to change i.e. effects on health, future, family and friends, community, spirit
- Looking for ways/activities/people to support/maintain that change
- Summaries are very important ways to reinforce change through repetition. Hearing it all again helps reinforce the need for change or shifts motivation toward change, in particular the long-term health effects of smoking and/or financial costs of smoking
- 3.6 assess any shift in motivation to change after discussing smoking in these terms
- The development of strategies in relation to high risk situations is extremely important. The hope is, this will better equip the person when faced with a high-risk situation after release. Making sure these strategies are realistic. Look for previous ways people have successfully maintained change. Use the 4 D's as other suggestions to add to the strategies being developed.
- Rewards are critical to behaviour change, whether they are physical, emotional or tangible. Reward desired behaviour through use of supportive people or activities. Doing fun things with supportive people.
- Highlight the causes of relapse. Try to avoid High risk situation in order to avoid relapse. This can also be done by establishing rules e.g. one won't hurt.
- Preparation of first 24 hours will increase the chances of avoiding relapse.

All the above is aimed at increasing awareness and reinforcing the need to maintain the change as well as giving people skills to avoid relapsing.

Supplementary 3. Education materials in the health promotion pack.

1. 'Don't make smokes your story' toolkit:
    a. 'Medicines to Help You Stop Smoking' A5 booklet
    b. 'Don't make smokes your story' sticker.
    c. Smoke free zone magnet.
    d. My QuitBuddy mobile app card.

(http://www.quitnow.gov.au/internet/quitnow/publishing.nsf/Content/stakeholder-toolkit)

2. 'Australian Guide to Healthy Eating: Food Plate' poster.

(https://www.eatforhealth.gov.au/guidelines/australian-guide-healthy-eating)

3. Reduce your risk: new national guidelines for alcohol consumption.

(http://www.alcohol.gov.au/internet/alcohol/publishing.nsf/Content/guide-adult)

4. 'Make your Move – Sit less – Be active for life!' brochure.

(http://www.health.gov.au/internet/main/publishing.nsf/content/health-pubhlth-strateg-phys-act-guidelines)

1. Basic Information

First, I'll ask some questions about your background.

1.1. Gender

Male ○ 1
Female ○ 2
Other ○ 3

1.2. What is your date of birth?

☐☐/☐☐/☐☐☐☐

1.3. Are you of Aboriginal or Torres Strait Islander origin?

Aboriginal ○ 1
Torres Strait Islander ○ 2
Aboriginal & Torres Strait Islander ○ 3
No ○ 4

2. Eligibility

2.1. Did you smoke daily before coming to prison?
(If they did not smoke daily ask whether they had smoked at least 100 cigarettes in their lifetime.)

No ○ 0
Yes ○ 1

2.2. Do you want to stay smoke-free after you get out of prison?

No ○ 0
Yes ○ 1
Unsure ○ 2

2.3. What is the expected date of discharge?
(Copy this information from the monthly prisoner list if already known.)

☐☐/☐☐/☐☐☐☐

2.4. Have you ever been diagnosed with a severe psychiatric disorder (e.g. Schizophrenia, Bipolar Disorder)?

No ○ 0
Yes ○ 1

2.5. In the last four weeks, have you thought about harming, injuring or killing yourself?

No ○ 0
Yes ○ 1

2.6. If Yes, please give details

_____

_____

2.7. Does the subject have impaired decision-making capacity?
(Use the Mini-Mental State Examination instrument to confirm if you suspect the subject has cognitive impairment.)

No ○ 0
Yes ○ 1

2.8. Is the subject eligible to enter the study?

No ○ 0
Yes ○ 1

(Interviewer: if Yes, present study information sheet and informed consent; if No, explain to the inmate why and end the interview)

2.9. Has signed informed consent been obtained?

No ○ 0
Yes (skip to 2.11) ○ 1

2.10. If No, please reason why signed informed consent was not obtained.

_____
_____

2.11. Has a copy of informed consent been given to the subject for a record?

No ○ 0
Yes ○ 1

3. Contact information

After you leave prison, we need to be able to contact you to ask you questions about your health. Please answer as much detail as you can.

3.1. What is your home address?

_____
_____
_____

3.2. What is your postal address? (if different from home address)

_____
_____
_____

3.3. What is your phone number?

_____

3.4. What is your mobile number?

_____

3.5. What is your email address?

_____

3.6. What is your Facebook name?

_____

3.7. What is your local Probation and Parole Office?

_____
_____
_____

3.8. What is the name of your local health centre?

_____
_____
_____

3.9. What is your local Centrelink Office?

_____
_____
_____

3.10. Who is your remote Drug and Alcohol worker and their contact numbers?

_____

3.11. Could you name an Elder in your community and give their telephone numbers?

_____

3.12. Could we contact you through the Central Australian Aboriginal Congress (the Congress) or the Top End Health Services?

No ○ 0
Yes ○ 1

3.13. Your follow up interview will be on ☐☐ / ☐☐ / ☐☐☐☐ (auto-calculated field), is there something that could remind you?

*(Follow up interview will be **90 days after release**. Write on the 1800 SNAP follow up card and present to the subject).*

_____

_____

4. Demographics

4.1. What is your marital status?

Never married ○ 1
Widowed ○ 2
Divorced ○ 3
Separated not divorced ○ 4
Married ○ 5
De-facto/regular partner ○ 6

4.2. How many children do you have?

Nil ○ 0
1 ○ 1
2 ○ 2
3 ○ 3
4 ○ 4
5 ○ 5
more than 5 ○ 6

4.3. What is your highest educational qualification?

No formal qualification (< year 10) ○ 1
School certificate ○ 2
NTCE/HSC/VCE/Leaving certificate ○ 3
College certificate/diploma ○ 4
Technical or trade certificate ○ 5
Degree/tertiary qualification ○ 6

4.4. Where were you living immediately before coming into prison?

Renting ○ 1
Own home or family own house ○ 2
Unsettled lodgings (squat, hostel, etc.) ○ 3
Sleeping rough (homeless) ○ 4
Hospital ○ 5
Other ○ 6
Please specify 'other': _____

4.5. In the last 12 months before custody were you working (including Work for the Dole)?

No ○ 0
Yes ○ 1

4.6. What was the total of all wages, government benefits, pensions and other income you usually received after tax before coming into prison?

Nil income ○ 1
$1 - $200 per week ○ 2
$201 - $400 per week ○ 3
$401 - $600 per week ○ 4
$601 - $800 per week ○ 5
$801 - $1,000 per week ○ 6
> $1,000 per week ○ 7

4.7. In the 12 months before coming into custody were you receiving a pension or allowance?

No ○ 0
Yes ○ 1

5. Smoking

Next, I am going to ask a few questions about your smoking before you coming to prison

5.1. How old were you when you first started smoking cigarettes?

☐☐ years

5.2. When was your last cigarette before coming to prison?

≤ 1 week before prison ○ 1
> 1 week and ≤ 1 month before prison ○ 2
> 1 month and ≤ 6 months before prison ○ 3
> 6 months before prison ○ 4

5.3. Did you typically smoke in the following places? *(multiple response)*

In cars ☐ 1
In your house ☐ 2
In community buildings, (e.g. church/school) ☐ 3
Outdoor dining area ☐ 4

Next, I am going to ask a few questions about your smoking habit during the 12 months before coming into prison

5.4. On the days that you used to smoke, about how many cigarettes do you usually smoke? (including both factory-made and roll-your-own cigarettes)

10 or less ○ 1
11 - 20 ○ 2
21 - 30 ○ 3
more than 30 ○ 4

5.5. How soon after waking do you smoke your first cigarette?

More than 60 minutes ○ 1
31 - 60 minutes ○ 2
5 - 30 minutes ○ 3
Within 5 minutes ○ 4

5.6. On average, how much money do you usually spend on cigarettes each week?

AUD ☐☐☐

5.7. Which of the following describes you?

I don't want to stop smoking ○ 1
I think I should stop smoking but don't really want to ○ 2
I want to stop smoking but haven't thought about until coming to prison ○ 3
I REALLY want to stop smoking and hope to stay smoke free after release ○ 4

Don't know ○ 5

5.8. On a scale from 0 – 100, how likely is that you will stay off cigarettes after you leave prison? ☐☐☐

5.9. Have you ever tried to quit smoking and succeed in not smoking for at least 24 hours before coming into prison?

No (skip to 5.11) ○ 0
Yes ○ 1

5.10. Have you taken any of the following measures regarding smoking? *(multiple response)*

Changed to a lower tar or nicotine content cigarette brand ☐ 1
Reduced the amount of tobacco you smoke in a day ☐ 2
Used nicotine replacement therapy (e.g. patches, lozenges) ☐ 3
Spoke to the Quitline ☐ 4
Attended a QUIT smoking program ☐ 5
Other ☐ 6
Please specify 'other'_____

5.11. Do you agree that prison should have smoking bans?

No ○ 0
Yes ○ 1
Unsure ○ 2

5.12. Who else smoke(s) in your family? *(multiple response)*

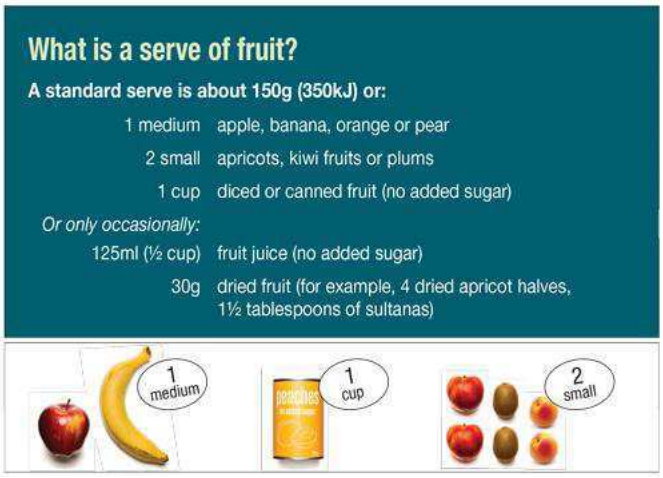
Mother ☐ 1
Father ☐ 2
Husband/wife/partner ☐ 3
Children ☐ 4
Brothers/sisters ☐ 5
Other family members ☐ 6

6. Nutrition

Next, I am going to ask a few questions about your eating on a typical day in prison

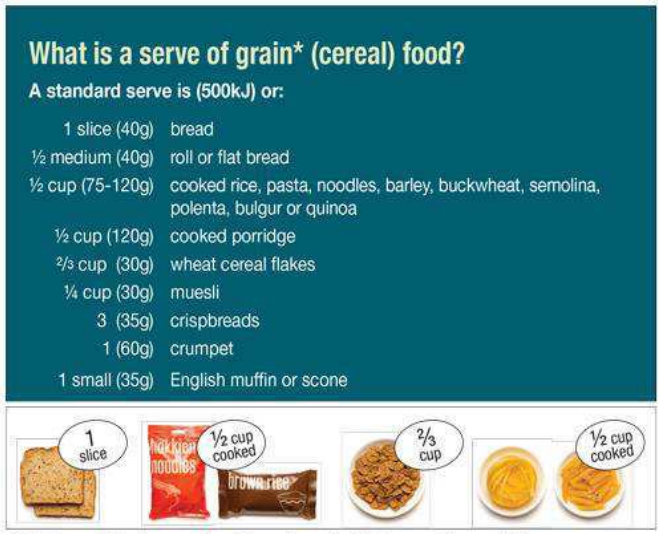
6.1. How many servings of fruit do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.2. How many servings of grains do you eat?

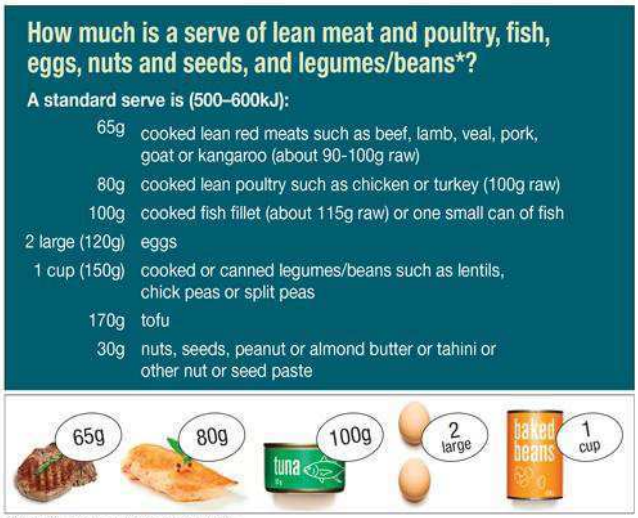
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



*Grain (cereal) foods, mostly wholegrain and/or high cereal fibre varieties

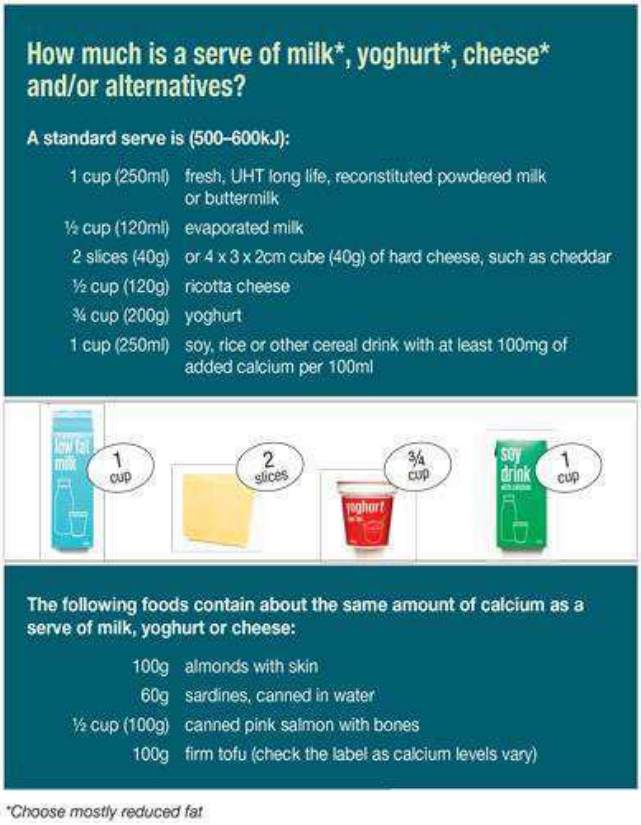
6.3. How many servings of lean meats, poultry, fish, eggs, beans, nuts and seeds do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.4. How many servings of milk, yoghurt and cheese do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



6.5. How many servings of vegetables or salad do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3

Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6

6.6. Would you say that you are?

Very overweight ○ 1
Overweight ○ 2
Normal weight ○ 3
Underweight ○ 4
Very underweight ○ 5
Don't know ○ 6

7. Alcohol and drugs

Next, I am going to ask a few questions about your personal drinking habit during the last 12 months before coming into prison

7.1. How often did you drink?

Never ○ 0
Monthly or less ○ 1
2 to 4 times a month ○ 2
2 to 3 times a week ○ 3
4 or more times a week ○ 4

7.2. When you have a drink, how many do you usually have in one day?

1 or 2 ○ 1
3 or 4 ○ 2
5 or 6 ○ 3
7 to 9 ○ 4
10 or more ○ 5
If '10 or more', please specify _____ units
(check card to calculate units)

7.3. How often did you have 6 or more drinks on one day?

Never ○ 0
Less than monthly ○ 1
Monthly ○ 2
Weekly ○ 3
Daily or almost daily ○ 4

7.4. How many times have you got into any fight because of your drinking?

☐☐

7.5. Have you received any treatment for your alcohol use?

No (skip to 7.7) ○ 0
Yes ○ 1

7.6. Please specify what kind of alcohol treatment. *(multiple response)*

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Alcoholics Anonymous) ☐ 5
Other ☐ 6
Please specify 'other': _____

7.7. Have you ever felt that any of the following people ever had problems such as family, health, work or the law due to their use of alcohol? *(multiple response)*

Mother ☐ 1
Father ☐ 2
Husband/wife/partner ☐ 3
Children ☐ 4
Brothers/sisters ☐ 5
Other family members ☐ 6

7.8. Have you ever used cannabis/ganja?

No (Skip to 7.13) ○ 0

Yes ○ 1

7.9. How old were you when you first used cannabis/ganja?

☐☐

7.10. Have often have you used cannabis/ganja <u>in the last 3 months</u>?

Never ○ 0
Less than monthly ○ 1
Monthly ○ 2
Weekly ○ 3
Daily or almost daily ○ 4

7.11. Do you mull up cannabis/ganja with tobacco?

No ○ 0
Yes ○ 1

7.12. On average, how much money do you spend on cannabis each week?

AUD ☐☐☐

7.13. Have you ever injected a drug, such as heroin, amphetamines, cocaine, methamphetamine?

No (Skip to8.1) ○ 0
Yes ○ 1

7.14. How old were you when you first injected any illicit drug?

☐☐

8. Physical activity

Next, I'd like to ask you a few questions related to your physical activity.

8.1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?
(Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.3 if zero)

8.2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.3. During the **last 7 days**, on how many days did you do **moderate** physical activities?
(Moderate activities make you breathe somewhat harder than normal and may include light lifting, regular bicycling or doubles tennis. Do not include walking Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.5 if zero)

8.4. How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.5. During the **last 7 days**, on how many days did you walk for at least 10 minutes?

☐ days per week
(Skip to 8.7 if zero)

8.6. How much time did you usually spend **walking** on one of those days?

☐☐ hours
☐☐☐ minutes
per day

8.7. During the **last 7 days**, how much time did you spend **sitting** on week day?

☐☐ hours
☐☐☐ minutes
per day

8.8. In the 12 months before you came into prison, would you describe yourself as?

Very active ○ 1
Fairly active ○ 2
Not very active ○ 3
Not at all active ○ 4
Don't know ○ 5

8.9. Compared with before you came into prison, would you say that you are now?

More active ○ 1
About as active ○ 2
Less active ○ 3
Don't know ○ 4

9. Mental Health

9.1. How often during the past **4 weeks** did you feel nervous?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.2. How often during the past **4 weeks** did you feel hopeless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.3. How often during the past **4 weeks** did you feel restless or fidgety?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.4. How often during the past **4 weeks** did you feel so sad that nothing could cheer you up?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.5. How often during the past **4 weeks** did you feel everything was an effort?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

9.6. How often during the past **4 weeks** did you feel worthless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

10. Quality of life

*Now, I am going to ask you about your general well-being. I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes you **TODAY**.*

10.1. First, I'd like to ask you about mobility, would you say you have…?

No problems in walking about ○ 1
Slight problems in walking about ○ 2
Moderate problems in walking about ○ 3
Severe problems in walking about ○ 4
Unable to walk about ○ 5

10.2. Next, I'd like to ask you about self-care, would you say you have…?

No problems in washing or dressing yourself ○ 1
Slight problems in washing or dressing yourself ○ 2
Moderate problems in washing or dressing yourself ○ 3
Severe problems in washing or dressing yourself ○ 4
Unable to wash or dress yourself ○ 5

10.3. Next, I'd like to ask you about usual activities, such as work, study, housework, family or leisure activities, would you say you have…?

No problems in doing your usual activities ○ 1
Slight problems in doing your usual activities ○ 2
Moderate problems in doing your usual activities ○ 3
Severe problems in doing your usual activities ○ 4
Unable to do your usual activities ○ 5

10.4. Next, I'd like to ask you about pain or discomfort, would you say you have…?

No pain or discomfort ○ 1
Slight pain or discomfort ○ 2
Moderate pain or discomfort ○ 3
Severe pain or discomfort ○ 4
Extreme pain or discomfort ○ 5

10.5. Next, I'd like to ask you about anxiety or depression, would you say you are…?

Not anxious or depressed ○ 1
Slightly anxious or depressed ○ 2
Moderately anxious or depressed ○ 3
Severely anxious or depressed ○ 4
Extremely anxious or depressed ○ 5

10.6. How good or bad is your health today on a scale from 0 to 100?
(0 means the **worst** health you can imagine; 100 means the **best** health you can imagine)

☐☐☐

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the SNAP Study: A Randomised Controlled Study of the Health Intervention "SNAP" in Northern Territory Prisons to Prevent Relapse to Smoking after Release from Prison

Important Information

Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the SNAP Study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information.

By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

☐ Medicare claims history OR

☐ PBS claims history OR

☐ Medicare & PBS claims history

for the period* 01/01/2014 to: 30/12/2022 to the SNAP Study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction), The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

☐ Power of attorney** ☐ Guardianship order**

** Please attach supporting evidence

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Benefit paid	Patient out of pocket
20/04/09	00023	Level B consultation	$38.30	$34.30	$4.00
22/06/09	11700	ECG	$29.50	$29.50	

Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode
999999A		2300
999999A	20/04/09	2300

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012

Version: 20-07-2017

UNSW THE UNIVERSITY OF NEW SOUTH WALES SYDNEY · CANBERRA · AUSTRALIA

Australian Government
Department of Health

NDARC National Drug & Alcohol Research Centre

Smoking Nutrition Alcohol Physical activity (SNAP) Study

SNAP

Follow-up Questionnaire

Randomisation ID: ☐☐☐☐

Interviewer initials: ☐☐

Date of interview: ☐☐ / ☐☐ / ☐☐☐☐

Method of follow-up contact:
Direct telephone call ○1
1800 SNAP hotline ○2
Prison re-entry ○3
By parole officer ○4
By local health service ○5
Other ○6

Please specify 'other'_____

1. Banking information

Thank you for agreeing to complete this follow up interview, you will receive $10 reimbursement after completing this questionnaire. To allow us to reimburse you correctly, please provide your banking account details below. If you do not have a banking account, please provide the nearest post office to your home, we will send you the reimbursement via Western Union money order.

1.1. Name of account

_____

1.2. BSB

_____

1.3. Account number

_____

1.4. Nearest post office

_____

2. Smoking

Next, I am going to ask a few questions about your smoking after being released from prison

2.1. When was your first cigarette after being released from prison?

On the day of release (skip to 2.5 after Q2.2) ○ 1
On the second day after release (skip to 2.5 after Q2.2) ○ 2
Not the first two days but within a week after release (skip to 2.5 after Q2.2) ○ 3
Not the first week but within a month after release (skip to 2.5 after Q2.2) ○ 4
Not the first month but within three months after release (skip to 2.5 after Q2.2) ○ 5
I did not smoke after release ○ 6

2.2. Just to confirm, have you smoked any tobacco, even a part of a cigarette in the last 7 days?

No ○ 0
Yes ○ 1

2.3. What is the most important reason for you to stay smoke-free after release?

I wanted to improve my health ○ 1
I wanted to save money ○ 2
I wanted to stay abstinent for my children ○ 3
I wanted to break free of a habit ○ 4
I did not like the smell of smoking ○ 5
Other ○ 6
Please specify 'other'_____

2.4. On a scale from 0 – 100, how likely is that you will stay off cigarettes in the next 30 days? (skip to 2.16)

☐☐☐

2.5. Have you smoked more than five (5) cigarettes in total after your release?

No ○ 0
Yes ○ 1

2.6. How many cigarettes did you smoke on the day of release? (including both factory-made and roll-your-own cigarettes)

☐☐

2.7. How many cigarettes did you smoke on the 2nd day after release?

☐☐

2.8. How many cigarettes in total did you smoke in the first week (including the first two days) after release?

☐☐☐

2.9. How many cigarettes on average did you smoke daily in the first month after release?

☐☐☐

2.10. How many cigarettes on average did you smoke daily in the first three months after release?

☐☐☐

2.11. How many cigarettes on average did you smoke daily in the last 7 days?

☐☐☐

2.12. On a typical day, how soon after waking do you smoke your first cigarette?

More than 60 minutes ○ 0
31 - 60 minutes ○ 1
5 - 30 minutes ○ 2
Within 5 minutes ○ 3

2.13. Did you smoke in the following places after you leave prison? *(multiple response)*

In cars ☐ 1
In your house ☐ 2
In community buildings (e.g. church, school) ☐ 3
Outdoor dining area ☐ 4
None of above ☐ 5

2.14. If you had to give one reason for why you returned to smoking, what reason would you say?

I was celebrating freedom ○ 1
I was with someone who was a smoker ○ 2
I was feeling stressed ○ 3
I was bored ○ 4
I used it as self-medication ○ 5
Other ○ 6
Please specify 'other'_____

2.15. Which of the following describes you now?

I don't want to stop smoking ○ 1
I think I should stop smoking but don't really want to ○ 2
I want to stop smoking but haven't thought about when ○ 3
I REALLY want to stop smoking but I don't know when I will ○ 4
I want to stop smoking and hope to soon ○ 5
I REALLY want to stop smoking and intend to in the next 3 months ○ 6
I REALLY want to stop smoking and intend to in the next month ○ 7

2.16. Have you ever taken any measures to quit smoking since leaving prison?

No (skip to3.1) ○ 0
Yes ○ 1

2.17. Have you taken any of the following measures regarding smoking? *(multiple response)*

Changed to a lower tar or nicotine content cigarette brand ☐ 1
Reduced the amount of tobacco you smoke in a day ☐ 2
Used nicotine replacement therapy (e.g. patches, lozenges) ☐ 3
Spoke to the Quitline ☐ 4
Attended a QUIT smoking program ☐ 5
Other ☐ 6
Please specify 'other'_____

2.18. How many of your close friends and immediate family members smoke?

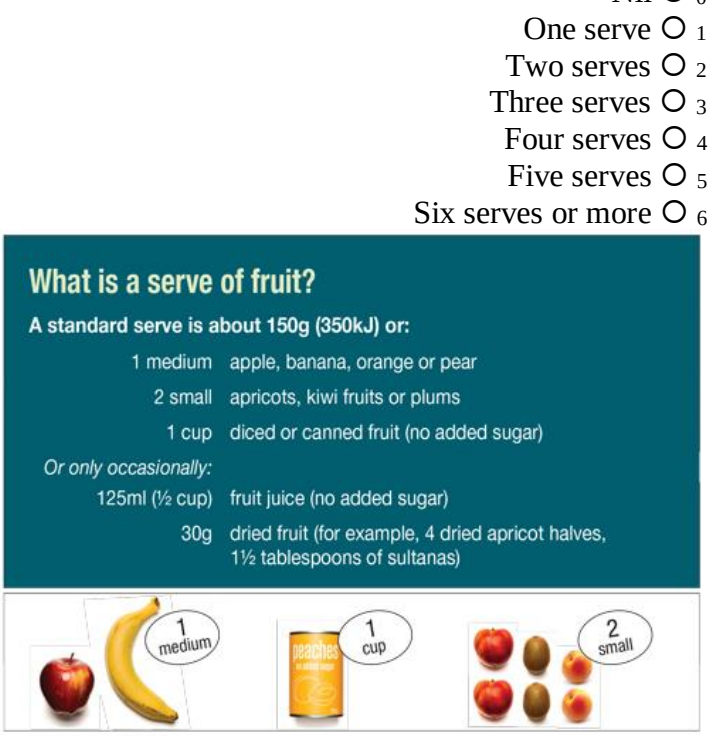
None ○ 0
Some ○ 1
About half ○ 2
Most ○ 3
All ○ 4

3. Nutrition

Next, I am going to ask a few questions about your eating on a typical day after leaving prison.

3.1. How many servings of fruit do you eat?

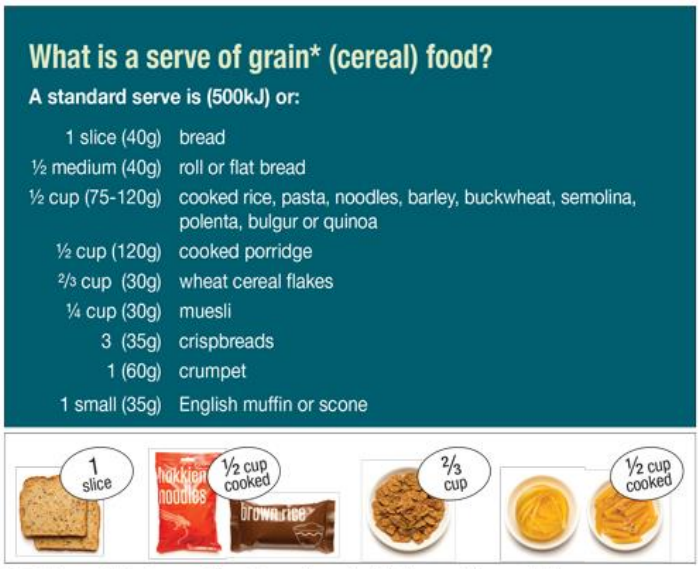
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



3.2. How many servings of grains do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5

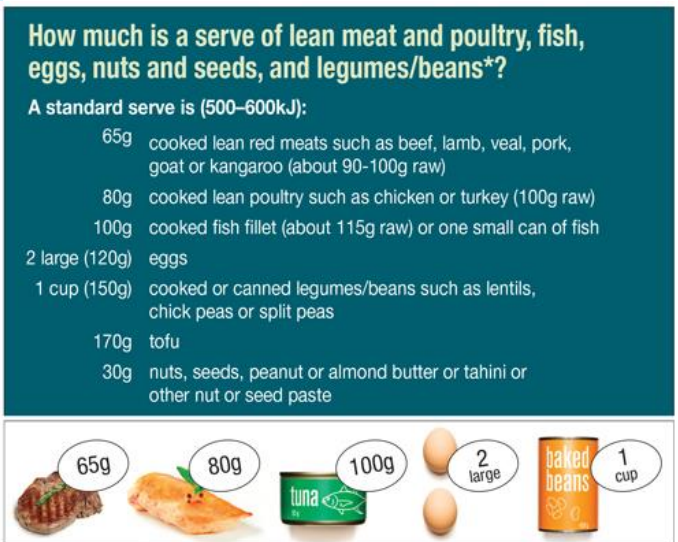
Six serves or more ○ 6



*Grain (cereal) foods, mostly wholegrain and/or high cereal fibre varieties

3.3. How many servings of lean meats, poultry, fish, eggs, beans, nuts and seeds do you eat?

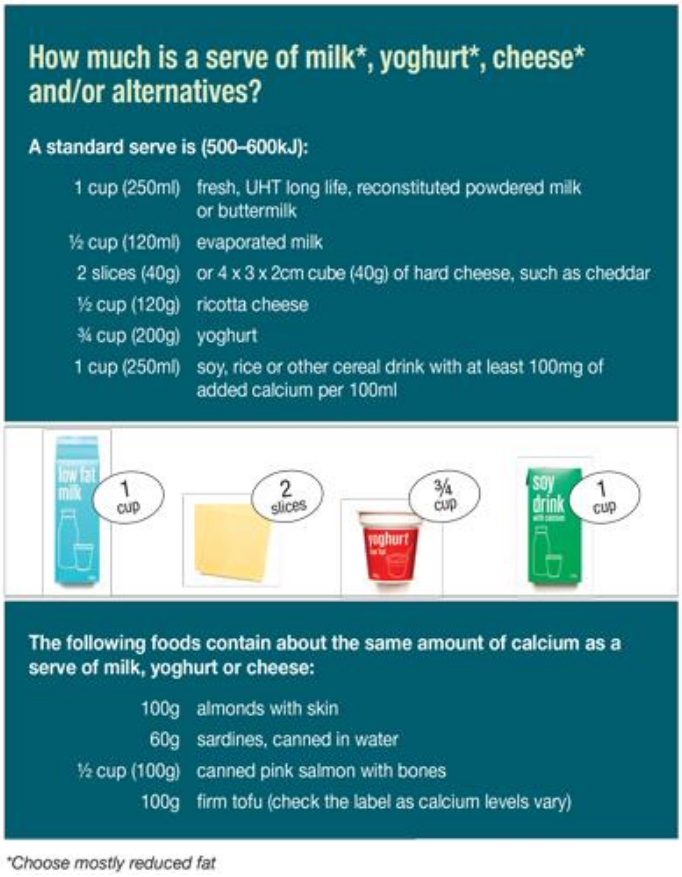
Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



*Choose those with no added salt

3.4. How many servings of milk, yoghurt and cheese do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6



3.5. How many servings of vegetables or salad do you eat?

Nil ○ 0
One serve ○ 1
Two serves ○ 2
Three serves ○ 3
Four serves ○ 4
Five serves ○ 5
Six serves or more ○ 6

3.6. Would you say that you are?

Very overweight ○ 1
Overweight ○ 2
Normal weight ○ 3
Underweight ○ 4
Very underweight ○ 5

Don't know ○ 6

4. Alcohol and drugs

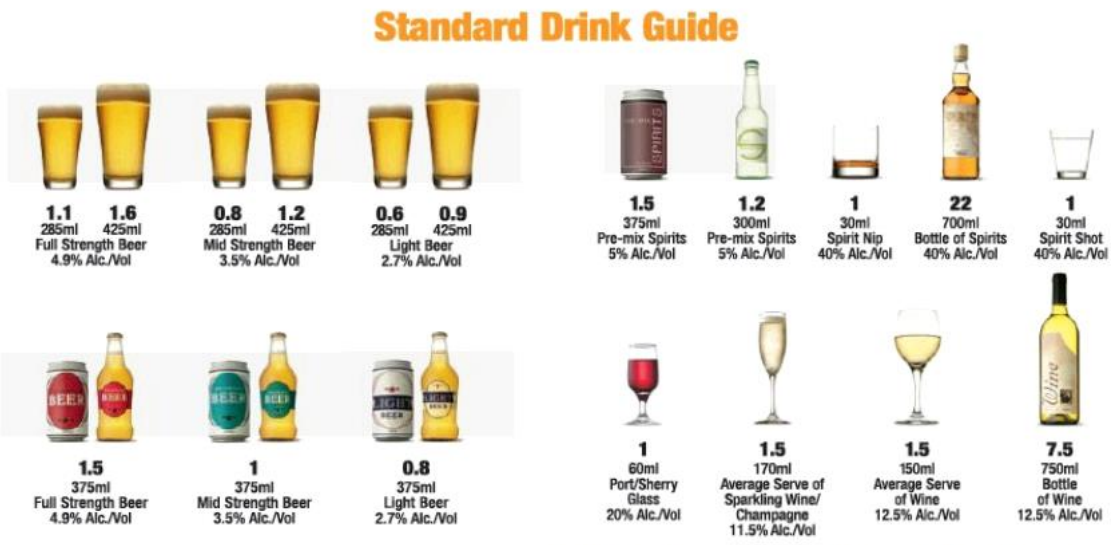
Next, I am going to ask a few questions about your drinking habit <u>after leaving prison</u>

4.1. How often did you have a drink containing alcohol since leaving prison?

Never ○ 0
Monthly or less ○ 1
2 to 4 times a month ○ 2
2 to 3 times a week ○ 3
4 or more times a week ○ 4

4.2. How many standard drinks containing alcohol did you have on a typical day when you were drinking?

1 or 2 ○ 1
3 or 4 ○ 2
5 or 6 ○ 3
7 to 9 ○ 4
10 to 14 ○ 5
15 to 19 ○ 6
20 or more ○ 7
(check card to calculate units)



4.3. How often did you have 6 or more standard drinks on one occasion?

Never ○ 1
Less than monthly ○ 2
Monthly ○ 3
Weekly ○ 4
Daily or almost daily ○ 5

4.4. Have you received any treatment for your alcohol use after leaving prison?

No (skip to 3.7) ○ 0
Yes ○ 1

4.5. Please specify what kind of alcohol treatment. *(multiple response)*

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Alcoholics Anonymous) ☐ 5
Other ☐ 6
Please specify 'other': _____

4.6. Have you used cannabis/ganja since leaving prison?

No (Skip to 3.9) ○ 0
Yes ○ 1

4.7. Have often have you used cannabis/ganja since leaving prison?

Never ○ 1
Once or twice ○ 2
Monthly ○ 3
Weekly ○ 4
Daily or almost daily ○ 5

4.8. Have you ever injected an illicit drug, such as heroin, amphetamines, cocaine, methamphetamine, after leaving prison?

No ○ 0
Yes ○ 1

4.9. Have you received any treatment for your drug use?

No (Skip to 5.8) ○ 0
Yes ○ 1

4.10. Please specify what kind of treatment for your drug use.

Withdrawal/ detoxification ☐ 1
Pharmacotherapy ☐ 2
Counselling ☐ 3
Rehabilitation ☐ 4
Peer support (e.g. Self-Help Addition Resource Centre) ☐ 5
Other ☐ 6
Please specify 'other': _____

5. Physical activity (IPAQ)

Next, I'd like to ask you a few questions related to your physical activity.

5.1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?
(Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.3 if zero)

5.2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.3. During the **last 7 days**, on how many days did you do **moderate** physical activities?
(Moderate activities make you breathe somewhat harder than normal and may include light lifting, regular bicycling or doubles tennis. Do not include walking Think only about those physical activities that you did for at least 10 minutes at a time.)

☐ days per week
(Skip to 8.5 if zero)

5.4. How much time did you usually spend doing **moderate** physical activities on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.5. During the **last 7 days**, on how many days did you walk for at least 10 minutes?

☐ days per week
(Skip to 8.7 if zero)

5.6. How much time did you usually spend **walking** on one of those days?

☐☐ hours
☐☐☐ minutes
per day

5.7. During the **last 7 days**, how much time did you spend **sitting** on week day?

☐☐ hours
☐☐☐ minutes
per day

5.8. Would you describe yourself as?

Very active ○ 1
Fairly active ○ 2
Not very active ○ 3
Not at all active ○ 4
Don't know ○ 5

5.9. Compared with when you are in prison, would you say that you are now?

More active ○ 1
About as active ○ 2
Less active ○ 3
Don't know ○ 4

6. Mental Health (K6)

6.1. How often during the past **4 weeks** did you feel nervous?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.2. How often during the past **4 weeks** did you feel hopeless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.3. How often during the past **4 weeks** did you feel restless or fidgety?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.4. How often during the past **4 weeks** did you feel so sad that nothing could cheer you up?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.5. How often during the past **4 weeks** did you feel everything was an effort?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4
All the time ○ 5

6.6. How often during the past **4 weeks** did you feel worthless?

None of the time ○ 1
A little of the time ○ 2
Some of the time ○ 3
Most of the time ○ 4

7. Quality of life (EQ-5D)

Now, I am going to ask you about your general well-being. I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes you TODAY.

7.1. First, I'd like to ask you about mobility, would you say you have…?

No problems in walking about ○ 1
Slight problems in walking about ○ 2
Moderate problems in walking about ○ 3
Severe problems in walking about ○ 4
Unable to walk about ○ 5

7.2. Next, I'd like to ask you about self-care, would you say you have…?

No problems in washing or dressing yourself ○ 1
Slight problems in washing or dressing yourself ○ 2
Moderate problems in washing or dressing yourself ○ 3
Severe problems in washing or dressing yourself ○ 4
Unable to wash or dress yourself ○ 5

7.3. Next, I'd like to ask you about usual activities, such as work, study, housework, family or leisure activities, would you say you have…?

No problems in doing your usual activities ○ 1
Slight problems in doing your usual activities ○ 2
Moderate problems in doing your usual activities ○ 3
Severe problems in doing your usual activities ○ 4
Unable to do your usual activities ○ 5

7.4. Next, I'd like to ask you about pain or discomfort, would you say you have…?

No pain or discomfort ○ 1
Slight pain or discomfort ○ 2
Moderate pain or discomfort ○ 3
Severe pain or discomfort ○ 4
Extreme pain or discomfort ○ 5

7.5. Next, I'd like to ask you about anxiety or depression, would you say you are…?

Not anxious or depressed ○ 1
Slightly anxious or depressed ○ 2
Moderately anxious or depressed ○ 3

Severely anxious or depressed ○ 4
Extremely anxious or depressed ○ 5

7.6. How good or bad is your health today on a scale from 0 to 100?
(0 means the **worst** health you can imagine; 100 means the **best** health you can image)

☐☐☐

8. Carbon monoxide (CO) breathing test

This machine allows us to determine the amount of carbon monoxide in your lungs. Carbon monoxide is present in cigarettes, so the more cigarettes you smoke, the more carbon monoxide is present in your lungs and the higher the number. Generally, a reading between 0 and 6 indicates that you haven't smoked in the last 24 hours. However, these numbers can be higher due to many reasons, including environmental carbon monoxide, age, and how many years you have been a smoker.

8.1. Test date

☐☐/☐☐/☐☐☐☐

8.2. Place where the test is taken

_____

8.3. Just to confirm, have you smoked any tobacco, even a part of a cigarette in the last 7 days?

No ○ 0
Yes ○ 1

8.4. Have you smoked cannabis in the last 7 days?

No ○ 0
Yes ○ 1

8.5. Carbon monoxide (CO) level (reading 1)

☐☐☐ ppm

8.6. Carbon monoxide (CO) level (reading 2)

☐☐☐ ppm

8.7. Carbon monoxide (CO) level (reading 3, if difference in previous reading is >5)

☐☐☐ ppm

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2; 6; 14
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 16
	5b	Name and contact information for the trial sponsor	16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	13-14

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5-6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig. 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11-12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9, 13

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11-12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	14
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	6; 14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	8
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	16
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Suppl. 1; Suppl. 5
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.