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Acronym	APPRAISE
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Impact of COVID-19 and changes to protocol

Overview

We halted recruitment and ongoing intervention delivery on the 13th of March 2020 as a result of COVID-19 restrictions across the prison estates and wider community. We also had to stop delivery of the 'in-prison' intervention sessions due to the restrictions in the prison. It was agreed on the 12th of June that no further recruitment would occur at HMP Edinburgh.

Lack of access to the prison also meant we were unable to deliver post-intervention sessions because it was not possible to determine when participants were released. Access to HMP Edinburg was reinstated albeit with limitations on the 6th of July. No access to HMP Durham was reinstated.

The table below outlines all changes made to the original protocol with most changes being made as a response to COVID-19.

	Original Aim	**Changes to Protocol**
Changes to recruitment	Our original aim was to recruit 180 participants across two prison sites (Edinburgh [N=90] and Durham [N=90). Recruitment began in Durham on the 2nd of December 2019 and was completed on the 28th of February 2020 (N=90). Recruitment began in Edinburgh on the 15th of January 2020 and was halted due to COVID 19 restrictions on 13th of March 2020 (N=44).	Recruitment at HMP Edinburgh was halted on the 13th of March and a decision to stop any further recruitment was made on the 12th of June. Total Consented: 134 Total included: 132 (90 in Durham, 42 in Edinburgh). N.B. This change was approved on the 16th of July 2020.
Changes to intervention delivery	Our original aim was to deliver a face-to-face intervention session within the prison to all participants in the intervention condition. It was also our aim to deliver 3 x 20-minute telephone sessions to those who received the first intervention session and were subsequently released from prison. Our aim was to deliver the post release sessions on or as close to day 3, 7, and 21 post release.	Unfortunately, due to COVID-19 restrictions, outstanding interventions at Edinburgh (N=5) were not possible and post release intervention sessions at both sites were halted. Post-release intervention sessions had to be halted because we were unable to access release data in the prisons. This meant that intervention sessions could not be

		delivered on or as close to days 3 (Session 2),7 (Session 3), and 21 (Session 4) post-release. It was agreed that post-release intervention sessions should still be attempted where possible and that the originally intended interval between them should be maintained (4 days between sessions 2 and 3, and 14 days between sessions 3 & 4).
Changes to 6 & 12 month follow up timing.		Due to the impact of COVID-19, we extended the possible follow up window from 8 weeks to 12-weeks. This was to allow for both post-release intervention delivery and 6- & 12-month data collection N.B. This change was approved on the 21st of September 2020.
Changes to 6 & 12 month follow up procedures.		Due to the impact of Covid-19, face to face follow ups are no longer appropriate. Therefore, an amendment was sought to allow hard copies and electronic copies of the survey to be sent to participants. N.B. This change was approved on the 21st of September 2020.
Changes to 6 & 12-month CRFs		To allow for the self-completion of questionnaires, a number of changes were required. N.B. These changes were approved on the 21st of September 2020. - The Time Line Follow Back-28 (TLFB-28) has

		been removed from the follow up CRFs. This is because this is not an appropriate self-completion tool. - The Negative Alcohol Expectancy Questionnaire includes 3 sub-sections. The final sub-section has been removed as the project management group identified it as having the potential to cause distress. - The layout of the Service Use Questionnaire has been simplified to support self-completion.
Changes to Interview Schedules		To explore the unique impact of COVID-19 on the feasibility of this and any future project, additional questions have been added to our interview guides. The questions will allow us to identify whether changes to service utilization and delivery have occurred as a result of COVID-19 and establish there are likely to be long term impacts and changes as a result. This will help inform the feasibility of any future trial. N.B. This change was approved on the 04th of September 2020.
Inclusion of a survey		We have proposed designing and distributing a short survey to all UK prisons with a male remand population to ask what their current ABI delivery process is, how this has been impacted by COVID-19, and whether they would be willing to work with us on a

		potential future RCT to explore the efficacy of a self-efficacy enhancing psychosocial alcohol intervention. This information would inform the feasibility of a future RCT.
Changes to proposed end date		We have requested a 9-month extension which would change the end date from 31/03/2020 to 31/12/2020. N.B. This change was approved on the 04th of September 2020.

Trial summary

Trial title	A two-arm parallel group individually randomised Prison Pilot study of a male Remand Alcohol Intervention for Self-efficacy Enhancement: the APPRAISE study
Acronym	APPRAISE
Summary of trial design	Pilot feasibility randomised control trial
Summary of participant population	Remand prisoners in England and Scotland, aged 18 years or older, who screen positive for at-risk drinking (score of 8 or more on the AUDIT screening tool)
Planned sample size	**Intervention** 90 cases and controls in England site 90 cases and controls in Scotland site **Process evaluation** 20% of intervention cases audio recorded 20% of control cases audio recorded 32 1:1 interviews with men on remand in both conditions 4 1:1 interviews with interventionists 4 1:1 interviews with non-interventionists 8 stakeholder interviews (prison staff, healthcare staff, commissioners; policy makers and third sector partners)
Number of sites	2 (Durham and Edinburgh)
Intervention duration	4 sessions (1st 40 minutes; remainder 20 minutes)
Follow up duration	6 and 12 months
Planned study period	28 months
Intervention arms	1 active intervention arm: • 1 session face to face • 3 booster sessions post liberation by phone (approx. 3 days, 1 week and 3 weeks after release) • All intervention sessions delivered by Change Grow Live
Control arm	Care as usual delivered

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Abbreviations

AUDIT	Alcohol Use Disorders Identification Test
CGL	Change Grow Live
GDP	Gross domestic product
MRC	Medical Research Council
TLFB-28	Timeline follow-back (28 days)
PNC	Police National Computer
DRSEQ-R	Drinking Refusal Self-Efficacy Questionnaire – Revised
NAEQ	Negative Alcohol Expectancy Questionnaire
RCT	Randomized control trial
ECTU	Edinburgh Clinical Trials Unit
PRISM-A	Alcohol Brief Interventions (ABIs) for male remand prisoners: protocol for development of a complex intervention and feasibility study (PRISM-A)
SPS	Scottish Prison Service
HMPS	Her Majesty's Prison Service
NICE	National Institute for Health and Care Excellence
WEMWBS	Warwick-Edinburgh Mental Well-being Scale
SIPS	Screening and Intervention Programme for Sensible drinking
PPI	Patient and Public Involvement
NOMS	National Offender Management Service
NIHR	National Institute for Health Research
CI	Confidence Interval

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1.0 Background

The prevalence of at-risk drinking, that includes drinking at levels that harm a person's health, is far higher amongst those in contact with the criminal justice system (73%) (1-5) than the general population (35%) (6). In the United Kingdom (UK), between 51-83% of incarcerated people are classified as risky drinkers (7). For those on remand in prison, the prevalence is between 62-68% (5). Furthermore, rates of alcohol dependence among those who are incarcerated (43%) are 10 times higher than for the general population (5). There is robust evidence from systematic reviews and meta-analyses to indicate that short alcohol interventions are effective in reducing alcohol consumption amongst risky drinkers in health care settings (8, 9). There is very little evidence of efficacy or effectiveness of alcohol interventions in reducing risky drinking amongst those in the criminal justice system including the prison system (10, 11) and in particular remand prisoners. However, there has recently been evidence in the UK that alcohol (and drug) interventions can have an effect on reduced recidivism (12). Furthermore, short alcohol interventions have been shown to reduce recidivism in the probation setting (4). Nevertheless, there is limited evidence for the optimum timing of delivery, recommended length, content, implementation and economic benefit of an extended alcohol intervention in the prison setting. Likewise, there are weaknesses within the current evidence base with regards the theoretical underpinnings of such interventions. This risks an intervention with a weak theoretical base, poorly specified 'active' ingredients and less likely to deliver the desired outcomes. This study will therefore provide vital evidence that will inform a future definitive randomised controlled trial (RCT).

Our systematic review of the efficacy of psychosocial alcohol interventions for incarcerated people (10) found that interventions in the prison setting have the potential to positively impact their relationship with and use of alcohol; however, because of small numbers and the use of different outcome measures we could not conduct a meta-analysis or generalise findings. Notably, none of the studies focused on men on remand, as compared with other subgroups within prisons. Remand refers to those who are either unconvicted, or convicted and unsentenced, held in custody awaiting trial and/or sentencing. This proposed study is working with men on remand. We acknowledge that there are also women prisoners who have alcohol use disorders. There is evidence that women face different issues and barriers to services which are important to note (13).

The intervention in this proposed study (the APPRAISE study) builds on previous research which has explored the theoretical validity of a self-efficacy enhancing alcohol intervention (14, 15) and was originally tested as part of a pilot cluster-RCT in a general hospital setting with evidence of a potential effect (14). In our recently completed Medical Research Council Public Health Intervention Development (MRC-PHIND) funded PRISM-A study, we undertook development and refinement of this self-efficacy enhancing alcohol intervention within the prison setting, working with men on remand to include a synthesis of their views, with reviews of the evidence base and theoretical underpinnings (16).

The PRISM-A study, carried out in two prisons in the UK, showed a high prevalence of risky drinking (82% scored $\geq$8 on the Alcohol Use Disorders Test (AUDIT). These numbers are comparable to other findings in the prison system in the UK (1-5) but more than three times as high as in primary care settings (6). We were able to access, recruit, consent and identify those who were risky drinkers. We also found high levels of willingness of staff and participants to engage with the self-efficacy enhancing intervention we tested for acceptability, and a willingness to participate in a trial that would involve follow-up at 6 and 12 months. Analysis of 24 in-depth interviews with male remand participants, demonstrated strong support that the intervention could help men on remand to develop skills and strategies that would be particularly useful on liberation. We also identified through the interviews, a stronger preference amongst the participants for interventions of longer duration and that such interventions should incorporate a post-liberation component.

Using the results from the PRISM-A study, the MRC framework suggests that the next step is to conduct a pilot study to assess feasibility and acceptability of the intervention (17). We will do this by conducting a pilot study to assess feasibility and acceptability of a psychosocial alcohol intervention delivered to men on remand with the aim of enhancing self-efficacy in comparison to usual care, and to explore potential effectiveness on the key parameters related to a trial (17). This will provide the information required to

design a future definitive RCT.

2.0 Rationale for current study

Our prison populations are disproportionately drawn from some of our most deprived and underserved communities. They frequently suffer from multiple short and long term physical and mental health issues (18). Adverse childhood experiences are often compounded by poor educational experiences and associated with subsequent social and financial exclusion.

The Scottish Parliament Health and Sports Committee recently held an inquiry into prisoner healthcare to consider how health and social care and medicines in prison are accessed and the effectiveness of health and social care in prison. The Inquiry report set out recommendations for Scottish Government to prepare a strategic plan to address prison social and healthcare (19). Furthermore, recent National Institute for Health and Care Excellence (NICE) Guidelines [NG57] (20) for people in prison acknowledge that adequate healthcare provision for prisoners would reduce pressure on community services later.

It has been shown that there is a complex interplay between individual and contextual factors and risky drinking behaviours and alcohol-related crime (21). Eleven percent of the prison population in England and Wales and 19% in Scotland are remand prisoners (22). This equated in 2015/2016 to around 7,500 males in England and Wales and approximately 1,400 in Scotland (22). Rates of risky drinking are higher (62-68%) amongst those on remand than in the general population (35%) (5). Harmful use of alcohol has been identified as a causal factor in more than 200 diseases and injuries, with alcohol contributing to 5.1% of the global burden of disease and injury, as measured by Disability-Adjusted Life Years (DALYS) (23). The impacts of risky drinking are significant, resulting in a significant health, economic and social burden on individuals, families and society as a whole (23). In the case of men who have been in prison, standardized mortality ratios (SMR) for causes of death related to alcohol are significantly higher than the general population (SMR = 2.8) in a recent Scottish survey (24).

Addressing alcohol harm in prisons, at what can be considered a 'teachable moment', where there is an opportunity for reflection on their risky drinking and their current position, could potentially reduce the risk of re-offending, costs to society, whilst helping address health inequalities (25). While there is an inevitable uncertainty in estimating the costs of alcohol-related crime and disorder, most estimates suggest it represents a considerable economic burden. A Cabinet Office estimate in 2004 reported that alcohol-related crime in England cost society £11 billion (26). However, this estimate is outdated and there are concerns regarding the assumptions and methodological judgements used in deriving this estimate (27). Better quality estimates from four high income countries placed the total costs of alcohol at 2.6% of gross domestic product (GDP) in 2007, of which 3.5% was made up of law enforcement costs (28, 29). Evidence estimates that health savings of £4.3m and crime savings of £100m per year can be made as a result of appropriate alcohol intervention (30).

A systematic review of alcohol interventions for offenders in the criminal justice setting identified a lack of evidence-based intervention strategies, highlighted the paucity of knowledge in this area, and in particular the lack of UK based studies and absence of rigorous studies focusing on men on remand (5, 10). Data shows that approximately 25% of individuals who are held on remand in prison will not receive a custodial sentence (31). People held in custody on remand spend an average often weeks in prison (32) and many do not have the opportunity to access mainstream prison health/public health services (33). The use of alcohol interventions for male remand prisoners is an under-researched area with large gaps in knowledge. The proposed work will address existing evidence gaps on extended alcohol interventions men on remand.

Given the limited evidence on the effectiveness of psychosocial alcohol interventions for men on remand, we propose a two-arm individually randomised pilot study to assess the feasibility and acceptability of a self-efficacy enhancing intervention developed during the PRISM-A study (16). The proposed research aims to develop an extended alcohol intervention that is based on evidence based behavioural change concepts and is acceptable for delivery to men on remand who have been identified as drinking alcohol at a level that is

or has caused them harm (harmful or hazardous consumption) with aim of reducing harmful or hazardous drinking (34). The study will also measure how feasible it is to deliver this intervention in the prison setting and on liberation to male remand prisoners. The work is of importance to fill existing gaps in this area. Furthermore, we currently do not know what the 'active' ingredients are of an extended alcohol intervention with this population. The results from this study will enable us to undertake a future definitive RCT evaluating its effectiveness and cost-effectiveness.

3.0 Study aims and research objectives

The study aims to undertake a two-arm, parallel group, individually randomised, pilot study of a self-efficacy enhancing psychosocial alcohol intervention for men on remand in prison. If the pilot study is successful, it will provide the evidence to support the design of a future definitive multi-centre RCT for which new funding would be sought.

OBJECTIVE 1: To pilot the study measures and evaluation methods to assess the feasibility of conducting a future definitive multi-centre, pragmatic, parallel group, RCT.

1a) Is it feasible to conduct a future multi-centre RCT of a self-efficacy enhancing psychosocial alcohol intervention for men on remand?

1b) Can we obtain reasonable estimates of the parameters necessary to inform the design and sample size calculation for a future definitive multi-centre RCT? This includes standard deviations of potential continuous primary outcomes and estimates of recruitment, retention and follow-up rates.

1c) How well do participants complete the questionnaires necessary for a future definitive RCT?

1d) Can we collect economic data needed for a future definitive RCT?

1e) Can we access recidivism data from the Police National Computer (PNC) databases for trial participants?

1f) Can we access health data from routine NHS data sources for trial participants?

OBJECTIVE 2: To assess intervention fidelity

2a) What proportion of the interventions are delivered as per protocol?

2b) Is there any evidence of contamination between the two conditions and/or between those workers delivering the intervention

2c) To what extent was the intervention changing process variables consistent with the underpinning theory?

OBJECTIVE 3: To qualitatively explore the feasibility and acceptability of a self-efficacy enhancing psychosocial alcohol intervention and study measures to staff and for men on remand and on liberation

3a) How acceptable are the trial and intervention procedures (including context and any barriers and facilitators) to the following key stakeholders: men on remand in prison and on liberation; prison staff (including healthcare staff); commissioners; policy makers and third sector partners?

OBJECTIVE 4: To assess whether operational progression criteria for conducting a future definitive RCT are met across trial arms and study sites and if so, develop a protocol for a future definitive trial. *Operational progression criteria are based on previous research results (4)*

4a) Do the 2 prisons invited to the study agree to take part?

4b) Based on knowledge from previous data, do at least 90 eligible participants consent to take part and be randomised across the trial arms?

4c) Do at least 70% of participants who consent to the trial and are allocated to intervention condition go on to receive at least one intervention session?

4d) Do at least 60% of those who consent to the trial contribute to follow up assessments at 12 months across trial arms and study sites?

4.0 Research Design

4.1 Study design

The study aligns to the MRC framework (17), using mixed methods with two linked phases conducted in two sites in the UK: Scotland and the North East of England.

Phase I will involve a 2-arm, parallel group, individually randomised pilot study (Objectives 1 and 4). The pilot evaluation will provide data on feasibility and an assessment on the likely impact of the APPRAISE intervention to inform the feasibility of a future definitive multi-centre RCT.

Phase II will comprise a process evaluation (Objective 2 and 3). We have drawn on the new MRC framework for process evaluation to guide the planning, design and proposed conduct of the process evaluation (35). The aim of the process evaluation is threefold: first, to assess how the intervention was implemented, second, to undertake some preliminary exploration of change mechanism underpinning the intervention and third, to assess the context within which the intervention is delivered.

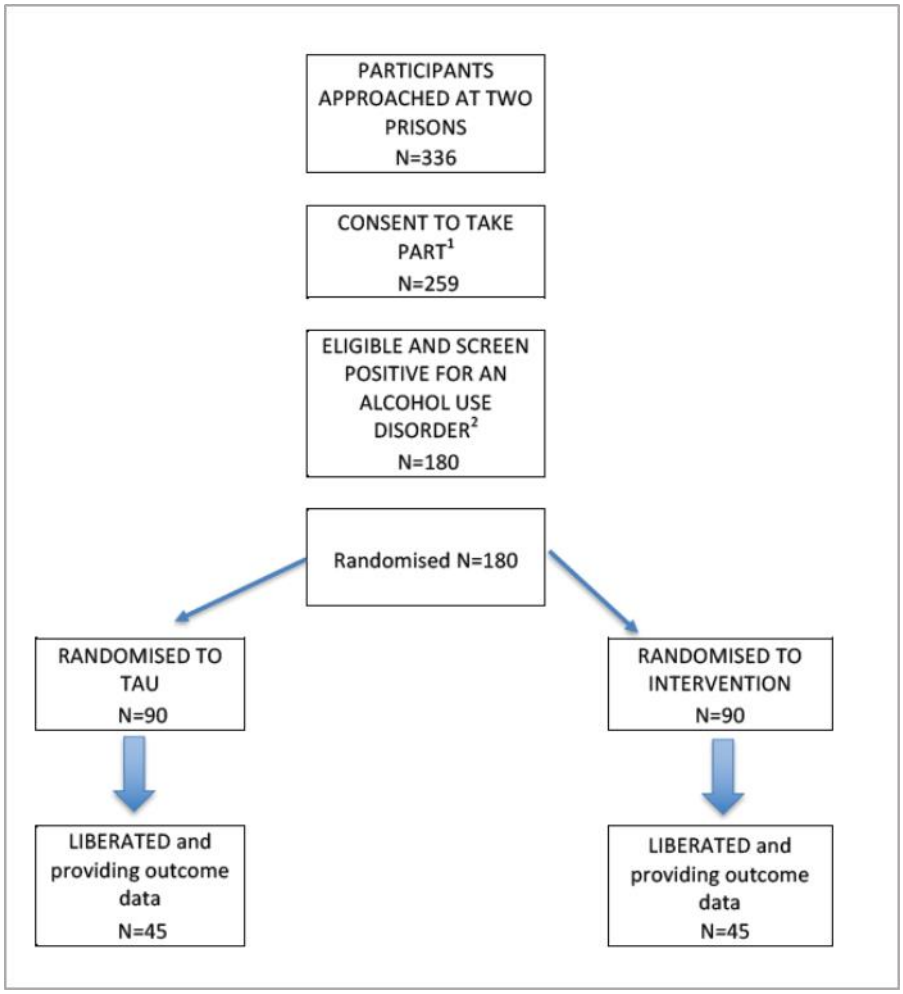


Figure 1: Study Flow Chart

5.0 Study population

5.1 Study group

A total of 180 adult men on remand will be recruited from two prisons that hold men on remand; one within the SPS prison estates (n=90) and one from Her Majesty's (HM) Prison and Probation Service (England) (n=90). We have used the knowledge gained from our previous study (PRISM-A) to purposively select two prison sites offering geographical, socio-economic and ethnic diversity. We have selected prisons that provide alcohol services from external agencies who engage with those in prison and following liberation. We have also selected sites that have different procedures and structures. Prison settings also have a variety of induction procedures, communication mechanisms and processes as well as available secure space to engage with those incarcerated. The range of categories of prisoners within any establishment also impacts on the logistics of conducting research due to procedures for movement around the prison. Understanding these different approaches and dynamics in relation to the feasibility of conducting a future definitive multi-centre RCT cognisant of these complexities is an important component of objective 4 of the study.

The target population for the study is adult men (18 years and over) on remand in prisons who have been in prison for three months or less. The average time on remand is approximately ten weeks (32).

6.0 Inclusion/Exclusion criteria

6.1 Inclusion

Men detained on remand will be included in the pilot feasibility trial if they meet all of the following inclusion criteria:

- Informed consent given
- Men aged 18 years and over
- Have been in the prison setting for three months or less
- ≥8 on the AUDIT screening tool (34)
- Detained in either the Scottish Prison Service (SPS) Scottish study site or Her Majesty's Prison Service (HMPS) North East England study site

6.2 Exclusion

The following exclusion criteria were used in the PRISM-A study and were found to be appropriate. Men on remand will be excluded from the pilot feasibility trial if they meet any of the following exclusion criteria:

- Previously recruited to the study
- Unable to give informed consent or deemed incompetent/unable to make an informed decision regarding consent
- Identified as a risk to self and/or others by prison staff
- Judged to be under the influence of an illicit substance by prison or research staff.[1]
- Currently taking Antabuse
- On a segregative rule under the prison rules
- Not able to understand the documents, which are in the English language or agree to the Research Assistant (RA) working with them to understand them

7.0 Recruitment strategy

7.1 Identification of study participants

The process of participant identification that we will use for APPRAISE was established and successful in our recent PRISM-A study (16). The Prison Induction team (consisting of prison officers and peer prisoners) will provide potential study participants with a verbal account of the study together with copies of the Participant Information Sheet during their Induction session into the prison. The RAs will liaise with prison officers from the Induction team each week to identify potential participants. Potential participants will be located and those willing, will meet with the RA in an area of the prison in which they can discuss issues in private, without risk of being overheard, and without risk to the interviewer or undue disruption to the prisons' daily running. The RA will review the Participant Information Sheet with them, providing a written and verbal description of the study, answer any questions or queries and will then invite them to consider participating. The RA will obtain informed consent from those willing to participate. Those who do not wish to participate at this point will receive no further interaction with regards participating in the study.

7.2 Consent

We are aware that freedom of consent can easily be undermined for prisoners and those in the criminal justice system, which means these individuals may be more vulnerable to exploitation or abuse by researchers: learning disabilities, illiteracy and language barriers are prevalent within these populations. The prevalence of these characteristics alongside the power differential between researcher and potential participant means that particular care will be needed to ensure that valid, freely given and fully informed consent can be achieved. For the purposes of this research we consider that valid consent is underpinned by

[1] Prison and/or research staff will be responsible for making a subjective judgment as to whether or not a remand person is under the influence of an illicit substance and whether the level of intoxication is likely to have an influence on risk or capacity to understand/consent.

adequate information being provided to the potential study participant and that they have the capacity to decide for themselves. A capable person will:

- Understand the purpose and nature of the research.
- Understand what the research involves, its benefits (or lack of benefits), risks and burdens.
- Understand the alternatives to taking part.
- Be able to retain the information long enough to make an effective decision.
- Be able to make a free choice.
- Be capable of making *this particular decision* at the time it needs to be made.

We will use and train the RAs to use the Offender Health Research Network Toolkit which outlines a clear pathway to successfully undertake health research in the criminal justice system http:www.ohrn.nhs.uk/toolkit/. The Expert Advisory Group will also provide support, whilst Professional codes of ethics (Nursing & Midwifery Council) will guide the team to safeguard the civil rights of participants. The team has experience of undertaking research in criminal justice settings i.e. probation and prisons (4, 36, 37). We are cognisant of the issues related to possible coercion and informed consent in research involving prisoners, whilst mindful of the evidence from other studies which have identified that prisoners who were considered particularly vulnerable demonstrated adequate capacity to consent in research (25, 30).

We will be asking participants to consent to their data being used for the present study as well as consenting to long-term follow-up (beyond this study) and for appropriate linkage to be conducted.

7.3 Proposed sample size

We will aim to recruit at least 180 participants in total comprising 90 participants per study arm across the 2 study sites. From prison data obtained from correspondence with the Scottish Prison Service and the Ministry of Justice, we estimate that approximately 50% of participants will be liberated while the rest will remain incarcerated; leaving 45 participants per study arm (90 in total) across the 2 study sites.

This sample size:

i) will enable us to calculate two-sided 95% confidence intervals around proportions recruited, liberated, and drop-out in each study arm with half-widths of less than 0.15

ii) exceeds the 30 per group recommendation of Lancaster et al (2004) (38) and 35 participants per group recommendation of Teare et al (2014) (39) for estimating key unknown design parameters e.g. standard deviation with sufficient precision when the primary outcome is continuous

iii) will ensure that within each study arm within each site we are satisfying the minimum 12 per group rule of thumb of Julious (2005) for pilot trials (40).

7.4 Screening

Questions regarding alcohol use are part of the initial health assessment for those entering prison, however, there is no standardization of the tools used. As such, and after informed consent has been obtained, the RA will undertake screening of all study participants using the AUDIT tool. The AUDIT has been used previously in the criminal justice system (1) and is considered the 'gold standard' alcohol screening instrument (34). Moreover, we have used the AUDIT with men on remand and it was found to be feasible and acceptable. Those scoring <8 on AUDIT will be thanked for their time and will take no further part in the study. Those with an AUDIT score of ≥ 8 who are eligible for the study will complete the baseline measures.

7.5 Randomisation

The randomization process will be supported by the Edinburgh Clinical Trials Unit (ECTU). Due to the restriction of the use of electronic equipment and no access to mobile phones by the research team and RAs whilst in the prison setting, we are unable to use a randomization system such as an Interactive Voice Response telephone system or one accessed over the web. Allocation will be conducted at the level of the

participant using stratified block randomisation (4-6) by site, via sealed envelopes, based on a predetermined random number allocation carried out independently by ECTU (41, 42).

7.6 Proposed outcome measures

The aim of this pilot study will be to: Estimate rates of recruitment, consent, retention and response; logistics of methodology and resource utilisation. In addition, estimation of the parameters of the primary outcome would allow the sample size of a definitive trial to be determined.

7.7 Primary outcome measure

The proposed primary outcome measure for a future definitive study is total alcohol consumed (in units) in a 28-day period. This is ascertained using the 28 day time line follow back questionnaire (TLFB-28) (43). Three other variables can be derived from the data: percent days abstinent, drinks per drinking day (secondary outcome measures) and total number of days where alcoholic drinks are consumed. The TLFB-28 will be conducted by the RA at TP 1 and 2 and takes approximately 20 minutes to complete.

7.8 Self-report secondary outcomes measures

Secondary outcome measures will be completed at TP0, TP1 and TP2. Alcohol use frequency, quantity (on a typical occasion) and binge drinking will be assessed using the Alcohol Use Disorder Identification Test (AUDIT) (34). The AUDIT can be scored between 0 and 40. A score of 8+ is referred to as a 'positive screen' and indicates an alcohol use disorder; hazardous drinking/increasing risk drinking (score of 8–15), harmful drinking/high risk drinking (16–19) or probable dependent drinking (20+). A score of 8 or more out of a possible 40 on the AUDIT has an established sensitivity of 92% and specificity of 94% (34) to detect those at-risk of harm from alcohol use. In order to assess the utility of using Average Drinks per Day derived from the AUDIT at 12 months as a primary outcome measure we will randomise the order of presentation of TLFB-28 and AUDIT and conduct a levels of agreement analysis, using TLFB-28 as a gold standard, to explore whether AUDIT is an acceptable proxy for TLFB-28. The order of presentation of TLFB and AUDIT will be randomised in advance by a secure remote randomisation service.

The Warwick-Edinburgh Mental Well-being scale (WEMWBS) will be used to assess mental well-being (44). This tool uses a 5-point Likert scale which gives a score of one to five per question giving a minimum score of 14 and maximum score of 70. A higher WEMWBS score indicates a higher level of mental well-being (44).

Readiness to change will be measured using the Readiness to Change Ruler which measures readiness to change drinking behaviour (7).

We will measure self-reported alcohol self-efficacy, using the Drinking Refusal Self-efficacy Questionnaire – revised (DRSEQ-R)(45) and alcohol expectancy, using the Negative Alcohol Expectancy Questionnaire (NAEQ) (46).

Furthermore, we will use the Euroqol EQ-5D -5L, which is a measure of health-related quality of life. EQ-5D-5L has a ceiling of 1.0, which represents full quality of life, and the higher the score (max 1.0) the greater the quality of the individual' s life (49).

A tailor made service use questionnaire will be adapted based on the economic form 90 (50) to determine social costs including in the domains of health and social care use, criminal justice involvement, unemployment, and welfare.

7.9 Other secondary outcome measures

We will look to understand whether we can obtain individual level data on recidivism rates over a 12-month period since time TP0 derived from PNC data and use of health and social services measured by data derived from Community Health Index (CHI)/NHS number. This data will be obtained at TP3. We will also look to determine the number of participants who are incarcerated at TP1 and TP2. Furthermore, we will collect

data on time spent by researchers and practitioners on the study to inform the tools needed for a definitive study.

7.10 Assessment of outcomes

Baseline data (TP0) will be collected in the prison setting with follow-up data at TP1 and TP2 being collected by telephone interview or in person (including in the prison setting). RAs will carry out these at all-time points.

The readiness to change ruler will also be completed immediately prior to and immediately following the initial intervention session. This will be carried out by the interventionist as part of the initial intervention delivery. Once the first intervention session is complete, this data will be given to the RAs who will be responsible for its management.

The Trial Steering Committee (TSC) will review the pre-stated operational progression criteria to assess formally the optimal design and progression to main trial phase.

7.11 Baseline assessment

Baseline assessment data will be collected via researcher led completion of hard copy questionnaires (TP0). Due to restrictions in the use of electronic equipment in the prison estate, we will be unable to take and use electronic devices to record study data. The RA will be able to answer any questions and offer clarifications if needed. The baseline assessment will take approximately 20-30 minutes. Immediately after, participants will be randomised and informed of their allocation (51). For those randomised to the intervention, an appointment to meet with their intervention worker for their one-to-one face-to-face session will be made. This is the process used by the current providers, Change, Grow, Live (CGL) when engaging with this client group in the prison setting. The additional 3 telephone booster sessions will be delivered on liberation by the same CGL intervention workers. All participants will be thanked for their time. As well as the outcome measures detailed below we will collect data on age, gender, marital status, educational status, and contact details.

7.12 Follow-up assessments

Follow-up assessments will be conducted at 6 months (TP1) and 12 months (TP2). These will be conducted either in person or over the phone by the RA at each study site. Where study participants are identified as being incarcerated at follow up, we will make appropriate arrangements with the relevant prison establishment to visit and undertake the follow-up assessment. Both 6 and 12-month assessments will be similar to the baseline assessment. From data gathered from our PRISM-A study, the majority (73%) of male remand prisoners stated their preference for follow-up contact would be by telephone so we will ensure this option is available to them. We will attempt to contact participants in multiple ways including telephone calls, text messages, and e-mails, based on participants preferred methods of contact, at varying times and days of the week. This approach was found to be successful in the SIPS probation study of Alcohol Screening and Brief Interventions (4). We will record and measure the number of participants who were: invited to participate; responded; eligible; recruited; transferred; subsequently sentenced; liberated; and lost to follow-up; and who returned to a criminal justice setting during the 12-month period and who completed the trial.

From our PRISM-A study, 88% of men on remand said they would be willing to take part in a research study such as this and to be followed up. We know that attrition at follow-up is a particular problem for hard to reach groups, such as those who have been involved in criminal justice system, whose characteristics and lifestyles can increase the likelihood of attrition. We also know that several participant engagement strategies to improve follow-up rates have been identified (52). We have adopted some of these e.g. using a comprehensive locator form, engaging with health and social care support services/3rd sector services, being available out of normal business hours to carry out follow-up interviews, including study contact details in the liberation packs that are provided by CGL. The feasibility and success of these will be measured as part of this pilot study. We have worked with Sharon Mercardo (SM), our PPI Co-applicant and former

Community Justice Mentor, who mentored men in prison and on liberation, to advise on the strategies that we will use in this study to maximise retention and follow-up. The strategies we will use are based on her own experiences of following up her mentees on liberation. These are also the strategies used by CGL community justice workers.

Mirroring the process that already operates by CGL when obtaining additional contact information, when we consent participants, we will request the following additional contact information from them: mobile and landline phone numbers for themselves, a significant other (e.g. family member, support network, other service that they have an established relationship with) and address details of the significant other that they are most likely to stay in contact with during their prison stay and on liberation. This approach has been used successfully in previous criminal justice studies (4). This information will be used to populate an individual locator form for each participant.

We will seek consent from the study participant to:

1) document and use mobile and land line phone numbers of participant and a significant other (e.g. family member, support worker) who may know the whereabouts of the participant.
2) write to an identified significant other at follow-up with contact verification cards (using reply paid envelopes).
3) use text messaging to send follow-up reminders to participants (using study mobile phones).
4) document and use social media account information and e-mail address to make contact upon liberation. Contact via social media will occur only once at each time point.
5) trace the whereabouts of the participant through professionals actively involved in their care following liberation (e.g. criminal justice mentors, probation staff, addiction staff, social workers).
6) obtain participants unique prisoner identification number. By checking prison identification numbers, we will record and measure the number of participants lost to follow-up due to return to prison/criminal justice setting. In such cases, we will attempt to record whether these are as a result of alcohol-related incidents/crimes.

7.13 Blinding

The RAs will not be involved in the delivery of the active and control interventions but will be aware of study allocation of participants as the trial progresses. Allocation concealment will be used whereby neither the person delivering the interventions nor the participant will be aware of the study allocation until they are irrevocably entered into the trial. Both the trial statistician (RP) and health economist (JB) will be blind to group allocation and will only have details of study participants by study number.

7.14 Unblinding

The trial statistician and health economist will only be unblinded if requested to do so by the Data Monitoring and Ethics Committee Project Steering Group (DMEC), due to safety concerns, otherwise unblinding will take place after the final analysis.

7.15 Stopping rule/discontinuation/withdrawal criteria

Participants will be reminded during the trial that they are free to withdraw at any time without having to give a reason and without it affecting their care in the prison setting or on liberation. Where a participant wishes to withdraw, we will honor their wish and try to ascertain and document the reason for withdrawal, recording this within a Case Report Form. Participants who request withdrawal from the study intervention will be asked if they would be willing to remain in the study for the purposes of follow-up data collection. Data provided to the point of withdrawal will be retained and used in the study analysis provided that the patient consents to this.

A decision may be made to discontinue a participant from the trial at any time if the RA considers it necessary for reasons including: participant withdrawal of consent; RA discretion that is in the best interest of the participant for withdraw; the RA has been informed by Prison, NHS or service staff that it is in the best

interest of the participant to withdraw; an adverse event requires discontinuation of participation in the trial; or termination of the trial by the sponsor.

8.0 Planned interventions

8.1 Control condition (care as usual)

Control condition will entail participants receiving care as they usually would within the existing service provision. We will record the nature of this at both study sites during the trial.

8.2 APPRAISE intervention

The intervention condition will be delivered by CGL staff. The APPRAISE intervention comprises of nine elements (10.2.1) to be delivered in 4 steps: Step 1 will comprise a 1 x 40-minute face-to-face session in which the 9 elements will be covered, delivered by a trained staff member from Change Grow Live (CGL) in the prison setting. Steps 2, 3 and 4 are 20-minute sessions conducted by phone, on or as close to day 3, 7, and 21 post liberation. Exact days will be recoded and will inform the process evaluation. The post liberation sessions will include elements 1 (preliminary discussion), 5 (situation-appraisal), 6 (goal setting), 7 (relapse), 8 (self-evaluation/self-reinforcement and 9 (culmination).

Table 1: Outline of APPRAISE Intervention

Element	Elements of intervention†	Enhancing Self-efficacy	Delivery method and location**
1	Preliminary discussion	Verbal persuasion	Face to Face (P)
2	Acquiring and providing information	Verbal persuasion	Face to Face (P)
3	Self-monitoring	Verbal persuasion	Face to Face (P)
4	Increasing awareness	Physiological state	Face to Face (P)
5	Situation-appraisal and appropriate coping strategies*	Vicarious experience	Face to Face (P) Mobile phone (L)
6	Goal setting*	Verbal persuasion	Face to Face (P) Mobile phone (L)
7	Relapse*	Performance attainment	Face to Face (P) Mobile phone (L)
8	Self-evaluation/self-reinforcement*	Performance attainment	Face to Face (P) Mobile phone (L)
9	Culmination	Performance attainment	Face to Face and mobile phone (L)

†(Holloway et al, 2006)
*Elements 5-8 highly rated by participants in the feasibility study (PRISM-A) and will form key focus of intervention delivery by mobile phone on liberation
** P = Prison; L = Liberation

Self-efficacy derives from Social Cognitive Theory and has been identified as an important determinant of health behaviour and health behaviour change (53). The four primary sources of self-efficacy information (that can be targeted through interventions) are: mastery experience; vicarious experience; verbal persuasion; and physiological state (14, 15, 53).The APPRAISE intervention is designed to increase levels of self-efficacy through development of self-regulative skills, self-management and self-belief, thus enabling an individual to address their alcohol consumption behaviour. Liberation then offers participants the ability to develop and build upon these skills and self-belief through success and mastery, with their efforts leading to the adoption and maintenance of reduced alcohol consumption (53, 54). Reducing alcohol consumption can

provide a sense of achievement and success with the overall effects of such an intervention a likely increase in the men's level of self-efficacy (54).

8.3 APPRAISE Intervention development

The APPRAISE intervention was modified to incorporate three booster sessions, on the basis of our learning from interviews with men on remand (n=24) as part of the MRC PHIND funded PRISM-A study. The aim of these interviews was to explore the acceptability of a self-efficacy enhancing alcohol brief intervention (16), including listening to feedback regarding the 9 elements of the intervention: i.e. 1) preliminary discussion, 2) acquiring and providing information, 3) self-monitoring, 4) increasing awareness, 5) situation-appraisal and appropriate coping strategies, 6) goal setting, 7) relapse, 8) self-evaluation/self-reinforcement, and 9) culmination (15). These intervention elements were found to be acceptable to participants who were interviewed. Feedback regarding frequency and intensity of contact identified a preference for more than one session, with a desire for additional sessions being delivered in the community following liberation to allow them to put skills gained as a result of the initial stage of the intervention into practice in real world situation in which alcohol is widely available to them.

8.4 Details of Intervention Elements

Element 1 Preliminary discussion: participants re-introduced to study and APPRAISE, made aware of the purpose of the engagement, emphasising confidentiality, consent and trust. Mirrored aspects of 'Opening strategies' (Rollnick, Heather and Bell, 1992).

Element 2 Acquiring and providing information: focus on participants reported level of alcohol consumption as per screening AUDIT score and their perception of the impact of alcohol on their health and life. Six key pieces of information provided: Standard units of alcohol; Recommended drinking levels; Alcohol-related health problems; Legal drink/drive limit; Tips on reducing consumption; Where to obtain information/support.

Element 3 Self-monitoring: participant provided with a diary card, encouraged to record when, where and with whom, if anyone, they consumed alcohol, why and what type of drink to enable self-monitoring, acts as source of self-evaluation and record of progress (Hartz et al 1990)

Element 4 Increasing awareness: Pros and cons of drinking recorded on a Balance Sheet of drinking. Physiological drinking sensations experienced discussed with strategies to identify and reduce with alternative appraisal of somatic sensations identified e.g alternative stress relieving strategies such as relaxation techniques rather than alcoholic drink.

Element 5 Situation-appraisal and appropriate coping strategies: High risk situations and antecedents of over-drinking identified and alternative coping strategies considered. Situations are identified in order that appropriate coping and response strategies are practiced prior to the situation next occurring. Coping strategies verbalised by participant, praise provided and strategies developed further and modelled by interventionist. Participants talk through the strategy and visualise themselves carrying it out (covert modelling). The better ingrained and more automated the response is, the higher one's self-efficacy and the lower the probability of relapse (Kok et al 1992). Avoidance of high risk situations may be necessary in the first instance (although can be unrealistic) until mastery with low risk situations is achieved (progressive mastery). Core set of general control strategies also discussed: reduction in rate of drinking, sipping drinks, low-alcohol content drinks and alternating between soft or low-alcohol drinks.

Element 6 Goal setting: realistic sub-goals set, short-term so that unachievable goals initially avoided. Setting proximate goals in relation to self-efficacy development can facilitate success promptly with increase in motivation towards accession to distal goals. This approach likened to a Stepladder approach of focusing on the few rungs in front of you. For example, goal may be to reduce quantity of alcohol consumption on certain days of the week.

Element 7 Relapse: Likelihood of relapse was discussed and importance of identifying the events that resulted in the relapse, not attributing relapse to stable causes, such as ability or uncontrollable causes as this can result in lowering of self-efficacy and expectation of future success. Attribution to relapse discussed and focus on appraisal due to unstable causes and not to a personal failure/ability. Majority of relapse occur as a result of emotional distress, social pressure and interpersonal conflicts, therefore appropriate relapse strategies discussed and practiced.

Element 8 Self-evaluation and self-reinforcement: reward for success through affective self-reaction e.g. self-congratulations. The alcohol diary is a means of self-evaluation and self-reinforcement, success is attributed to their ability and skill resulting in feelings of pride.

Element 9 Culmination: reflection of preceding discussion, conclusions drawn, praise given on progress and decisions made. Plans and goals reiterated and confirmed. Agreement regarding mobile phone follow-up on liberation.

Table 2: APPRAISE Elements

Element : Preliminary discussion	Opening strategies
	Introduction to APPRAISE study
	Introduction to APPRAISE
	Consent, confidentiality, engagement rules, trust
Element : Acquiring and providing information	Feedback on AUDIT score
	Establish perception of impact of alcohol on health and life
	Standard units of alcohol
	Recommended drinking levels
	Alcohol-related health problems
	Legal drink/drive limit
	Tips on reducing consumption
	Where to obtain information/support (prison and liberation)
Element 3: Self-monitoring	Diary card – when, where, whom, type of drink, why
Element 4: Increasing awareness	Balance sheet – pros and cons of drinking
	Physiological sensations identified
	Alternative appraisal of somatic sensations identified
	Strategies to reduce
Element 5: Situation-appraisal and appropriate coping strategies	High risk situations and antecedents of over-drinking identified
	Alternative coping strategies identified
	Coping strategies verbalised by participant
	Praise provided
	Strategies developed further through co-production
	Strategies modelled by interventionist
	Participant verbalises strategies and visualises them
	Plan for exposure/avoidance to low risk situations and high risk situations
	General control strategies: reduction in rate of drinking, sipping, low-alcohol content and alternating between soft or low-alcohol drinks
Element 6: Goal setting	Setting realistic sub-goals (short-term)
	Facilitating success and increasing motivation
Element 7: Relapse	What happens if you relapse
	What caused the relapse?
	How do I understand relapse?
Element 8: Self-evaluation and self-reinforcement	Using my alcohol diary as a means of self-evaluation and self-reinforcement
	Self-congratulations and rewarding my success
	What do I attribute my success to?
Element 9: Culmination	Reflections and conclusions
	Plans and goals reiterated and confirmed

8.5 Intervention delivery and staff training

The intervention condition will be delivered by CGL staff. These are existing staff who are currently engaged in the delivery of alcohol services and through care in the prison setting and on liberation. At each of the two research sites, we will have a 'Care as Usual' interventionists for the control arm and separate interventionists trained to deliver the APPRAISE intervention. In preparation for the application. Two members of the CGL team at each site will be trained to deliver APPRAISE to those participants randomised to the intervention arm and the remaining members of the team will have no training (control team). This method to minimize contamination has been used in other similar intervention studies (55, 56). However, as this is a pilot study, we will explore the possibility of residual contamination and the practicality of being able to allocate staff according to randomization within the process evaluation in order to inform a future definitive trial. The weekly de-brief/reflective sessions with intervention workers will also enable us to explore possible contamination.

Table 3: Staff Training Summary

Activity	**Time**
Preparation meetings with Senior Managers and their team for participation in the study consisting of 3 meetings between April 2018 and September 2018 at each study site	Approx. 0.5 days staff time in total
4 staff undertaking 1.5 days study training	Approx. 6 days staff time in total
Staff time for weekly reflective/de-brief research sessions where we will support staff and record data as part of the process evaluation 1hr at each study site	Approx. 1.5 days staff time in total over 4 month recruitment period
4 staff undertaking a 0.5 day re-visit of study procedures and de-brief mid-way through the recruitment period	Approx. 2 days staff time in total

Training for those who will deliver the intervention will be provided by the RAs with AH, RS and DN-B. Training will last approx. 1.5 days although it may be delivered in blocks to fit the working environment. Training will cover all aspects of the study: theoretical and key elements, principles of the interventions as well as trial procedures and protocol, research processes, study rationale, patient eligibility, randomization process, study paperwork completion and handling of participant withdrawal. A training and practice manual will also be provided. During the recruitment phase of the trial, the intervention workers at each site will have external intervention-specific supervision delivered by the research team (RS) as well as providing an opportunity for reflective practice and professional supervision. We will also provide the opportunity to revisit all aspects of the study as covered in the original training sessions. Supervision and de-briefing will be provided weekly to the interventionists by the study team and through face to face visits and telephone contact. This will be overseen by RS. Ongoing access to the RAs and AH and DN-B will be available at all times of the data collection.

9.0 Phase II Process evaluation (Objective 3) Months 6-22

We have drawn on the new MRC framework for process evaluation to guide the planning, design and proposed conduct of the process evaluation (35). The aim of the process evaluation is threefold: first, to assess how the intervention was implemented, second, to undertake some preliminary exploration of causal mechanisms underpinning the intervention and third, to assess the context within which the intervention is delivered.

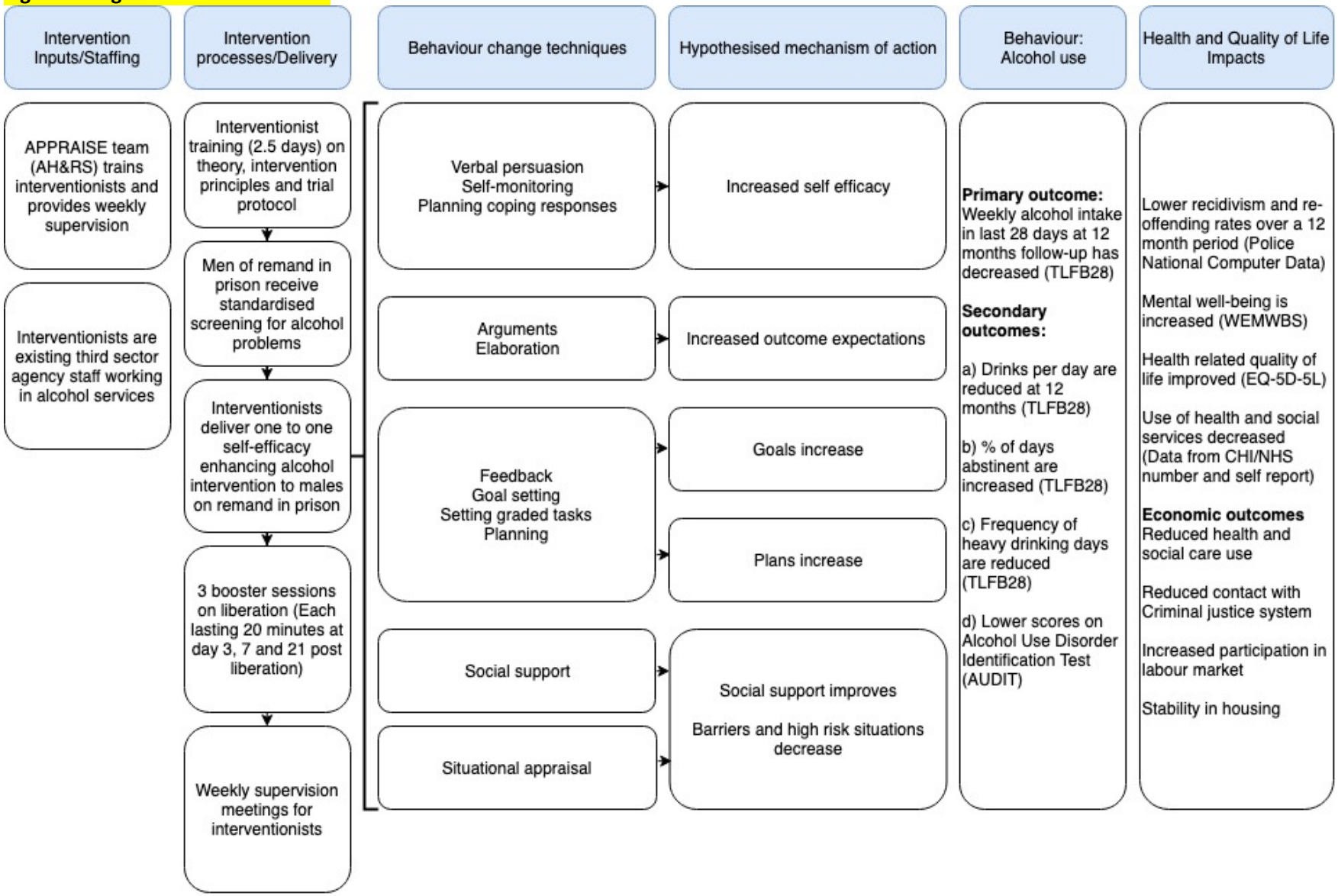
9.1 Implementation

The total APPRAISE intervention comprises four sessions that will be offered to participants and understanding what was delivered and how it was delivered is a key component of understanding the **implementation delivery** of APPRAISE (57, 58). Through quantitative measures in relation to fidelity (quality) and dose (quantity), alongside the extent to which APPRAISE reached the study participants, we will record the number of sessions offered, delivered, duration and content, to assess whether the intervention sessions were delivered as per protocol. We will obtain the quantitative data from participant study records, logs and documents to capture dose. To capture the quality of what was delivered, we will audio record and undertake audio recordings of intervention delivery in the 1st APPRAISE session and the 2nd, 3rd and 4th APPRAISE phone sessions. We will also audio record 20% of those allocated to the control condition. In-depth qualitative interviews with all implementers and purposively selected participants will also be conducted at each study site. We will interview intervention workers after they have delivered the intervention

9.2 Mechanism of impact

We will also explore the causal **mechanisms** to provide increased understanding of how the delivered intervention influences change through the quantitative assessment of key behavioural markers (mediators) of change i.e. self-reported self-efficacy, using the Drinking Refusal Self-efficacy Questionnaire – revised (DRSEQ-R)(45) outcome, and alcohol expectancy, using the Negative Alcohol Expectancy Questionnaire (NAEQ) (46). These will be assessed at TP0, TP1 and TP2 and an exploratory prognostic analysis will be undertaken to explore the nature of change within these domains and their relationship to observed outcome. In addition, we will undertake qualitative exploration of participant responses to, and interactions with, the intervention, providing the opportunity to identify unanticipated pathways and consequences at 12 months follow up. An intervention logic model informed by social cognitive theory has been developed (Figure 2).

Figure 2: Logic Model for APPRAISE



9.3 Context

Understanding the **context** within which APPRAISE is delivered, we wish to understand and record factors that will enable the delivery and or impact of the intervention at scale. We will record any differences in delivery in and across study sites where local organisational and devolved country contexts may have implications for future intervention design and delivery.

We have identified in Section 8.5 how we will explore the possibility of residual contamination. Qualitative interviews will also be conducted as part of the process evaluation (Table 4) where we will interview both men in the intervention and control arm as well as intervention workers and non-intervention workers (control arm) during the study. This will be with the purpose of identifying any evidence of contamination between those in the intervention and control arm and/or the intervention and non-intervention workers. We will also collect data about the wing/area in the prison the participant is located and which other participants in the study they are likely to have most contact with.

Table 4. Process evaluation summary

Process evaluation component	**Objective**	**Main research questions**	**Data source**
Dose: delivered	2a	What proportion of the interventions were offered and subsequently successfully delivered?	Quantitative data from participant study records, logs and documents of successful (includes duration) and unsuccessful delivery (includes reasons for latter)
Dose: quality (fidelity)	2b	To what extent was the intervention delivered as intended?	20% of cases will be audio recorded (with participant consent) of intervention delivery in the 1st APPRAISE session the 2nd, 3rd and 4th APPRAISE phone sessions. Data will be coded to assess delivery of essential theoretical elements and the use of the Behaviour Change Counselling Index (BECCI) (59) to assess intervention fidelity. Audio recordings of 20% of control cases will be recorded to ascertain any drift from protocol.
Contamination	2b	Is there any evidence of contamination between: those that receive the intervention(s) and those that are in the control condition and/or between those workers delivering the intervention?	Qualitative interviews with men* on remand from intervention (n=8 at each site) [n=16] and control arm (n=8 at each site) [n=16]. N=32. Qualitative interviews with intervention workers (n=4) and non-interventionists (n=4) at each study site, N=8.
Mechanism of change	2c	To what extent was the intervention delivery consistent with the underpinning theory? Are the key behavioural markers appropriate for the mechanism of behavior change?	Quantitative data from self-reported alcohol self-efficacy and alcohol expectancies Qualitative interview data with men* on remand from intervention (n=8 at each site) [n=16] and control arm (n=8 at each site) [n=16]. N=32..

	3a	How acceptable is the trial intervention and procedures to men on remand and on liberation? What are the barriers and facilitators?	Qualitative interviews with men* on remand in both conditions (n=8 at each site) [n=16] and control arm (n=8 at each site) [n=16]. N=32.
	3a	How acceptable is the trial intervention and procedures to key stakeholders? What are the barriers and facilitators?	Qualitative interviews with prison staff (including healthcare staff); commissioners; policy makers and third sector partners (N=8).
Context	3a	What factors enable the delivery and/or impact of the intervention at scale?	Qualitative interviews with stakeholders including prison staff (including healthcare staff); commissioners; policy makers and third sector partners (N=8).

***The interviews will be conducted with the same N=32 men**

10.0 Quantitative statistical analysis

Progress of participants through the study will be presented in accordance with CONSORT guidelines and allow us to describe key parameters required for a full trial design; rates of eligibility, consent, adherence, retention at follow-up and data completeness of key outcome measures.

The statistical analyses will be primarily descriptive, providing a realistic estimate of eligibility, recruitment, intervention delivery and retention rates in the study population. These key trial parameters will inform the power calculations for a future definitive trial and confirm other aspects of trial design (in particular the acceptability of study processes and outcome measure to participants and staff). Data pertaining to the flow of participants through the study will be ascertained and include numbers screened, prevalence of the target condition, numbers providing contact details, numbers eligible and willing to consent and numbers followed up successfully at TP1 and TP2 months. In addition, we will ascertain data completeness of the instruments and any potential bias in the completion of follow-up data.

We will incorporate a sensitivity analysis to explore the effects of missing data, and we will implement this as requested. This will involve using multiple imputation to impute missing data on the primary outcome (weekly alcohol intake in standard units) in a supplementary analysis, in addition to performing a complete cases analysis for the analysis of the primary outcome as originally proposed. We will use the resulting 95% confidence intervals of the between trial-arm differences to provide a guide to indicate the likely effect sizes that will be observed in a definitive trial under a missing-at-random assumption. In addition, we will add and subtract one unit differences (in alcohol standard units) to the missing data as part of a sensitivity analysis to explore how the 95% confidence intervals change depending on our assumptions about the missing data, bearing in mind that the imputed data cannot be less than zero. This is similar to the sensitivity analysis method suggested in White et al. [White, I. R., Horton, N. J., Carpenter, J., & Pocock, S. J. (2011). Strategy for intention to treat analysis in randomised trials with missing outcome data. *BMJ, 342*, d40.], which involves determining how large an amount can "be added to or subtracted from the imputed data without changing the clinical interpretation of the trial". We will adopt a similar approach to determine how sensitive the conclusions of the pilot study (and indeed the decision of whether or not to proceed to a definitive trial) are to our assumptions about the missing data. This will all be included in our analysis plan for the study.

Analysis of the primary outcome, total consumption in the past 28-days at TP3 using the TLFB-28 within intervention groups will be analysed in order to provide estimates of the variance within and between groups for exploration of sample size calculations for a definitive RCT. Further the use of a comprehensive cohort design will allow analysis of the variance of the battery of outcome measures within groups to explore their utility in a more definitive study.

The health economic analyses will describe the costs of introducing and running the study intervention and will focus on examining prison resource data we should collect (and how) in terms of ongoing staff and capital

costs. Following on from this analysis we will produce the protocol for a definitive trial, including a sample size calculation.

11.0 Qualitative analysis

All interview data will be transcribed and thematic analysis undertaken in order to answer the research questions relating to objectives 1d, 2c, 3a and context identified in Table 1 above. Braun and Clarke's (2006) framework for qualitative thematic analysis will guide this, as it is congruent with the theoretical perspective of the study (60). To facilitate an understanding of each stakeholder group's perspective the data will initially be analysed within group. The rationale for undertaking the analysis within each stakeholder group is to enable targeting of remedial actions within the design of a future definitive RCT. Themes running across the data in relation to each question will then be collated providing a multi-perspective understanding of the stakeholder experience in relation to each element of the intervention/study under scrutiny.

In particular the qualitative analysis will provide evidence to verify the feasibility and acceptability of the APPRAISE study intervention to participants specifically elements 5-8 and inform the process evaluation in Phase 2 to better understand and explain the social processes associated with the intervention through the lens of Normalisation Process Theory (NPT) (61-64).

12.0 Risks and benefits

12. 1 Potential risks

Talking about experiences related to harmful, hazardous or dependent alcohol consumption (risky drinking) may be emotionally distressing for the study participant. We will ensure that, if at any time during the study a participant becomes distressed or upset, we will offer to discontinue the discussions and inform an appropriately trained person for onward referral to appropriate services. We already have strong relationships with both proposed study sites following our previous work with them during the PRISM-A study and have established contact with identified gatekeepers at each site who are keen to engage with the study. The gatekeepers' role will be to identify and minimise any undue burden or potential risk to participants. We will implement a study communication strategy through a series of information sessions about the APPRAISE study across both study sites to ensure all staff who engage with study participants are aware of and understand the protocol for responding to any distress as a result of study participation (how to respond and who to contact). They will therefore be well prepared to answer any initial queries from potential participants in the first instance and from actual participants during the course of the study. This will minimise risk and maximise protection for any participants who may become distressed or require further advice about their alcohol consumption.

Understanding the criminal justice system and the prison regime is fundamental in minimising burden to participants and staff. Our knowledge and understanding gained from research in the criminal justice system, including prisons, include the UK restorative justice trials (36), the Tobacco in Prisons Study (PHR 15/55/44); RISKIT-CJS with young offenders (PHR 14/183) (65) and with staff and men on remand through the PRISM-A study. This work has ensured that we built on an excellent understanding of the research context in forming our study design and data collection methods, therefore minimising burden to participants and staff.

Where participants disclose any specific information relating to potential offences, or if the researcher understands there to be a threat to the participant or others, we will inform a member of prison staff in accordance with established safeguarding procedures. Participants will be made aware of this before taking part in the study, using appropriate guidance from the prison service on wording of this limitation to confidentiality. We will provide all study participants with a leaflet providing health information relating to alcohol consumption. Where participants request information related to alcohol consumption risky drinking, we will where consent is given, refer them to the prison health centre, where they will be able to access trained guidance, support and advice from staff.

12.2 Researcher risks

The RA's will undergo a number of training sessions from the prison services: prison induction, Personal Protection Training (PPT), Fire Safety and Professional boundaries. The RAs will be provided with a personal alarm and will be accompanied by a member of prison staff where necessary. We will be advised by the prison staff on risk and safety at all times and will adhere to this and their policies. The RAs will not be lone working, however the NHS lone working policy is relevant to the work that they will be doing within the prison setting and this policy will be adhered to. We will appoint RAs who have experience of conducting research in a prison/criminal justice setting. RAs will also have weekly de-briefing sessions with the research team during periods of fieldwork and will be given the opportunity to discuss any issues more often if necessary.

12.3 Potential benefits

At this point in time we are unable to say that there are definitive benefits for men on remand and society due to the weak evidence base. However, alcohol brief interventions have been widely used in a range of health care settings with no reports of risk being noted (8). Potential benefits to the individual and society from more moderate drinking habits would be those linked to health and social benefits, public sector costs, productivity and criminal and social disruption. We will explain to study participants through the Participation Information Sheets that they will be providing important information that will be used to inform how we can best provide alcohol advice, information and healthcare for males on remand in future.

12.4 Ethical arrangements

We have experience of the ethics processes and procedures for undertaking research within the prison setting. The study RAs will provide potential participants with information of possible benefits and known risks during information giving discussions and before consent is obtained.

12.5 Research Governance

The Research Governance and Quality Assurance office (The University of Edinburgh) will review the study and determine if an independent risk assessment will be performed by an Academic and Clinical Central Office for Research and Development (ACCORD) Clinical trials monitor to decide if a) monitoring is required and b) if so, at what level. An independent risk assessment may also be carried out by ACCORD Quality Assurance Group to determine if an audit should be performed before, during and/or after the study and if so, at what locations and with what frequency.

Edinburgh University will be the nominated sponsor of the research. The study will have a Project Management Group (PMG) which will consist of PIs, RAs, named collaborators and 2 lay members. Further to this we will set up a TSC with embedded DMEC. The project will be subject to the requirements of the *Data Protection Act* and the *Freedom of Information Act* and other relevant UK and European legislation relevant to the conduct of clinical research. The project will be managed and conducted in accordance with the Medical Research Council's *Guidelines on Good Clinical Practice in Clinical Trials* (www.mrc.ac.uk) which will include compliance with national and international regulations on the ethical involvement of patients in clinical research (including the *Declaration of Helsinki*).

All data will be held in a secure environment identified by a unique participant identification number. Master registers containing participant identifiable information and participant identification numbers will be stored in a secure area separate from the majority of data. Data management will be conducted by Edinburgh University Clinical Trials Unit. All staff employed on the project will be employed by academic organisations and subject to the Terms and Conditions of Service and contracts of employment of the employing organisations. The project will use standardised research and clinical protocols and adherence to the protocols will be monitored by the Project Management Group and the DMEC.

12.6 Quality control measures

Professional Standards: All members of the research team are expected to adhere to the highest professional standards of scientific integrity. The research team will adhere to the principles of Good Research Practice as follows:

Honesty: The research team will be honest across the whole range of scientific work, including experimental design, generating and analysing data, publishing results, and acknowledging the direct and indirect contributions of colleagues, collaborators, students and others.

Accountability: The research team will ensure that the research that they are undertaking is consistent with the terms and conditions as defined by the sponsoring body and/or covered by agreements between the research team and the sponsor/funder. This includes, but is not restricted to, ensuring that the research programme carried out is as defined in the original proposal to the sponsor/funder, unless amendments have been agreed in writing; that finance is used solely for the purpose that it was intended; that reports are both accurate and produced on time and that conditions relating to publication and ownership of Intellectual Property are adhered to.

Confidentiality: The research team will ensure personal information is not passed on, except following prescribed procedures, and must keep it secure. The research team are required to respect the intellectual property of others and to observe commercial and official secrecy. We do however recognise that in certain circumstances there may be limits to the normal ethical practice of ensuring confidentiality. If in the opinion of the research team/sponsor, there is a risk that as a direct result of the research, researchers have a duty to ensure that a named person responsible will be informed immediately that disclosure of information takes place. This commitment to disclose will be made clear to participants at the outset of the research. Professor Holloway (PI) will act as named key contact persons and reach a decision on whether to trigger this action.

Openness: While it is recognised that research interests need to be protected at times, the research team are encouraged to be as open as possible in discussing their work with other scientists and with the public.

Conflict of Interest: The research team must be honest and make full disclosure about conflict of interest issues, whether real, potential or perceived, when reporting results. Disclosure of a personal conflict of interest in research must be made to the Principal Investigator as soon as reasonably possible.

Codes of Practice: The research team is expected to observe the standards of scientific practice set out in guidelines published by appropriate scientific societies and other relevant professional bodies such as the Nursing and Midwifery Council and Research Councils. The team will also work within the remit of The University of Edinburgh's Code of Practice for Research which has been adopted from the UK Research Integrity Offices Code of Practice for Research (UKRIO).

DATA MANAGEMENT

Personal Data

The following personal data will be collected as part of the research:

- Name, CHI/NHS number, PNC number, and location data (e.g. prison site & postcode).

Personal data will be stored by the research team in a lockable filing cabinet in the PIs office, 2m6, School of Health in Social Science, University of Edinburgh, Old Medical Quad, Teviot Place, Edinburgh. Access to keys will be restricted to only those who require access. Consent forms will be stored separately from all other data.

Data from the second study site in Durham, England will be anonymized and will identify participants only with their screening number. All data will be sent to the coordinating site (Edinburgh University) by secure courier where it will be kept in a locked filing cabinet, in a locked room, with restricted access. Personal and sensitive/wider data will be transported separately to each other in a secure manner.

Personal data will be stored for 24 months after the study has ended.

Transfer of Data

Data from the second study site in Durham, England will be anonymised and will identify participants only with their screening number. All data will be sent to the coordinating site (Edinburgh University) by secure courier where it will be kept in a locked filing cabinet, in a locked room, with restricted access. Personal and sensitive/wider data will be transported separately to each other in a secure manner.

No personal data will be transferred outside the borders of the UK, or stored or collected on computer servers outside of UK borders.

Audio files of interviews will be transcribed by 1st Class Secretarial Services who are a university approved supplier. Audio files will be uploaded securely to a password protected site by the researchers where the transcription company will be able to access the file. Transcribed files will be returned to the researchers using the same secured online platform and will be downloaded then stored securely in restricted access folders on the university's shared drive.

As Joint Data Controllers with clients, 1st Class Secretarial are registered with the Information Commissioners Office as part of GDPR compliance, registered number Z2116676. They offer secure upload and download facility. Audio recordings will be destroyed after transcription. 1st class secretarial Client Charter and privacy statement are available in the supporting documents.

Data Controller

A data controller is an organisation that determines the purposes for which, and the manner in which, any personal data are processed.

The University of Edinburgh and NHS Lothian are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site)

Data Breaches

Any data breaches will be reported to the University of Edinburgh and NHS Lothian Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

ADVERSE EVENTS

We do not envisage adverse events or abnormal distress to occur to participants as a result of participation in this trial. However, regular discussions with members from our trial steering group and embedded DMEC will enable us to identify and act quickly should any concerns arise.

GOOD CLINICAL PRACTICE

ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. Participants willbe The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasized that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy will be filed in the Investigator Site File (ISF).

Study Site Staff

The Investigator will be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

Confidentiality

All evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place.

STUDY CONDUCT RESPONSIBILITIES

PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, will be reviewed and approved by the Chief Investigator.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 10 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot

A summary report of the study will be provided to the REC within 1 year of the end of the study.

CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

No intervention will be provided by the research team after the study ends. Participants will be provided with contact information should they wish to get further support in relation to their alcohol use.

INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

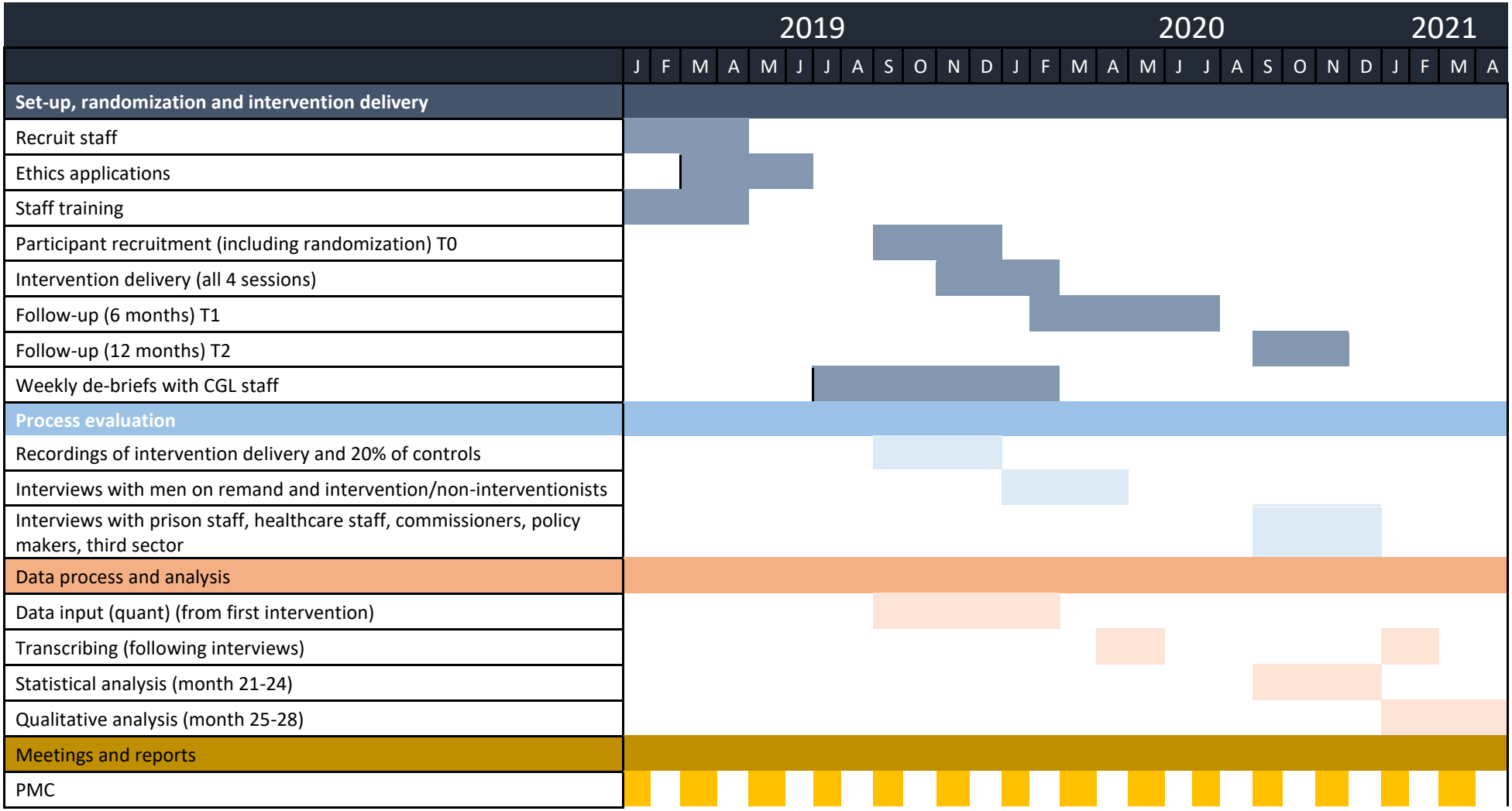
REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

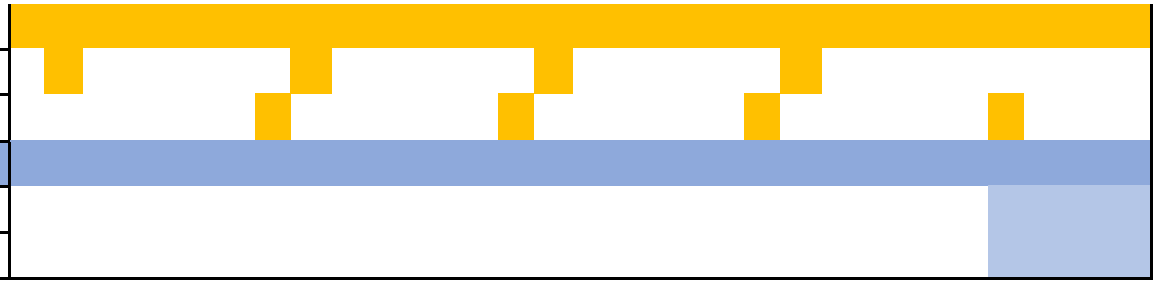
AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

13.0 Gantt chart and Milestones

Table 5:Gantt chart and Milestones



MWG	
TSC	
6-montly reports	
Writing up	
Draft/final report	
Publications (continuing beyond end of project)	

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