A self-efficacy enhancement alcohol reduction intervention for men on-remand in prison: the APPRAISE feasibility pilot RCT

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Scientific summary

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Scientific summary

The prevalence of at-risk drinking, which includes drinking at levels that harm a person's health, is far higher amongst those in contact with the criminal justice system (73%). For those on remand in prison, the prevalence is between 62% and 68%. This compares to 35% in the general population.

Alcohol brief interventions (ABIs) are a secondary prevention activity, aimed at those individuals who are drinking in a pattern that is likely to be harmful to health and/or well-being. Similarly, the theoretical validity of a self-efficacy-enhancing alcohol intervention in other settings has shown evidence of potential effect.

Study aims and objectives

Objective 1: to pilot the study measures and evaluation methods to assess the feasibility of conducting a future definitive multicentre, pragmatic, parallel-group randomised controlled trial.

1a. Is it feasible to conduct a future multicentre 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 multicentre RCT? This includes standard deviations of potential continuous primary outcomes and estimates of recruitment met across trial arms and study, 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 National Health Service (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 randomised controlled trial 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.)

4a. Do the two 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 receive the intervention?
4d. Are at least 60% of those who received the intervention followed up at 12 months across trial arms and study sites?

Objective 5: to ascertain what alcohol services are available in male remand prisons and how coronavirus disease discovered in 2019 has affected services.

5a. To ascertain what alcohol services are currently provided within male remand prisons.
5b. To explore the prison governors' understanding of brief interventions.
5c. To understand how the coronavirus disease discovered in 2019 pandemic has impacted the services available in male remand prisons.
5d. To identify whether the impact of the COVID-19 pandemic upon services could be avoided in the future.

Methods

Phase 1 pilot trial

Phase I was a two-arm, parallel-group, individually randomised pilot study of a self-efficacy-enhancing psychosocial alcohol intervention for men on remand in prison to provide data, including economic, recidivism and health data, on feasibility and an assessment of the likely impact of the APPRAISE intervention to inform the feasibility of a future definitive multicentre RCT.

The Phase I pilot trial was undertaken in two prison settings, one in Scotland and one in England. Those eligible to participate were adult men detained on remand in either the Scottish study site or the England study site who had been in prison for 3 months or less and had an Alcohol Use Disorders Identification Test (AUDIT) screening score of 8 or more. The original recruitment target was 180 participants, 90 at each study site.

The target was reached at the England study site; however, restricted access to the prison estates due to COVID-19 meant we were unable to recruit any further participants at the Scottish study site. As a result, we recruited 132 participants (90 in England and 42 in Scotland), who were randomised. In England, 46 participants were randomised to the intervention and 44 to care as usual. For participants in Scotland, 22 were randomised to the intervention and 20 to care as usual. Allocation was conducted at the level of the participants, randomised to the active or control intervention using stratified block randomisation by site, via sealed envelopes, based on a predetermined random number allocation carried out by the study Trials Unit.

The APPRAISE intervention focused on enhancing self-efficacy and comprised four steps: Step 1 comprised a 1 × 40-minute face-to-face session in which the nine elements were delivered by an interventionist in the prison setting. Steps 2, 3 and 4 were 20-minute booster sessions to be delivered by phone, on or as close as possible to days 3, 7 and 21 post liberation. Interventions were delivered by Change Grow Live practitioners who had received prior training in intervention delivery. Care as usual across both sites comprised an alcohol assessment and referral onto further alcohol support options if requested. Due to COVID-19 restrictions, access to both study sites for the research assistants (RAs) and research team was halted, resulting in liberation data not being accessible. There was limited capacity of the interventionists to follow up on liberation data of those in the intervention group or deliver post-liberation intervention.

Data were collected at TP0 before randomisation (baseline), TP1 (6 months) and TP2 (12 months). Follow-up assessments were attempted where participants had been (a) not liberated, (b) liberated and in the community or (c) liberated and then re-incarcerated, and were conducted by phone; hard copies of the follow-up questionnaire were sent by post with an accompanying letter to be completed and returned to the study team via a pre-paid envelope, or via hard copy in prison. As a result, modifications were made to the follow-up method to also include contact via text message, WhatsApp, Facebook and an electronic Qualtrics link to the survey sent by phone or e-mail. The case report forms (CRFs) were adapted to facilitate self-completion.

The primary outcome was alcohol consumed in the 28 days prior to TP2 (12-month follow-up), assessed using the extended AUDIT-C. The following secondary outcome measures were used across the three time points: Warwick-Edinburgh Mental Well-being Scale (WEMWBS); Drinking Refusal Self-efficacy Questionnaire – revised (DRSEQ-R); Negative Alcohol Expectancy Questionnaire (NAEQ); EuroQol-5 Dimensions, five-level version; Readiness to Change Ruler; Economic Form 90.

Results

Of 182 men on remand approached across two study sites, 132 were randomised (90 in England; 42 in Scotland) with 46 randomised to intervention and 44 to care as usual in England, and 22 randomised to intervention and 20 to care as usual in Scotland.

A total of 53 in-prison interventions were delivered. One day-3 post-liberation intervention was delivered, no day-7 post-liberation intervention was delivered and one day-21 post-liberation intervention was delivered. At 12 months out of all 132 randomised, 18 were followed up, 53 (40%) were not liberated, 47 (36%) were uncontactable and 14 (11%) had been released but could not be located. Data completeness was 96% at baseline and 8% at 12 months.

Mindful of the very small sample sizes and that as such caution should be applied, provisional indications suggest that self-efficacy may be a determinant of alcohol consumption and further exploration of interventions targeting self-efficacy should be considered. We were able to develop a micro-costing methodology protocol and collect provisional scoping of routine data sources to support future cost-effectiveness analyses. We were unable to access both PNC and NHS data for participants in either study prison.

Phase II process evaluation and survey

In Phase II, the aim of the process evaluation was threefold: first, to assess how the intervention was implemented, second, to undertake some preliminary exploration of change mechanisms underpinning the intervention, and third, to assess the acceptability and context within which the intervention was delivered through interviews with study participants and key stakeholders involved in supporting the trial. A survey of prisons in Scotland and England was conducted to ascertain what alcohol services were available for men on remand in prisons and how COVID-19 had affected these services.

Study records and semistructured interviews provided the data for the process evaluation. Purposive sampling was used for interviews. Due to COVID-19, the target of 40 interviews was not attainable. Thematic analyses using a NPT lens to support thematic identification. All interviews were digitally recorded and transcribed verbatim ahead of analysis.

High levels of practitioner behaviour change skills were identified from the Behaviour Change Counselling Index (BECCI) scores of the four intervention delivery sessions recorded at the Scotland site. Differences in median dose delivered between study sites were noted. CGL intervention training evaluation was positive. From the data available evidence of contamination was limited.

Fifteen semistructured interviews were conducted with three participant groups [remand participants, Change Grow Live (CGL) team and wider stakeholders] from across the two study sites. The themes generated suggested a strong acceptability of the intervention with investment in time, capacity and space identified to support implementation, as well as the buy-in from all stakeholders, development of trust and relationships as key facilitators to supporting behaviour change.

From 59 prisons in Scotland and England, successful e-mails were sent to 55 prison governors. Seventeen (31%) were completed. The findings confirmed that the COVID-19 pandemic had undoubtedly impacted upon alcohol and wider prison services available to men on remand.

Strengths of the study

- The APPRAISE study is, to the best of our knowledge, the first pilot trial of an alcohol-focused self-efficacy-enhancing intervention for men on remand.
- The study provides significant insight into the feasibility and acceptability of pilot trials for this particular population.
- The ethical approval process for the prison setting across devolved countries provided useful insights into how to navigate the submission and approvals process across a range of ethics committees.
- The study provided good evidence of the feasibility of recruitment, training interventionists and subsequent in-prison delivery of the APPRAISE intervention to 73% of men on remand, randomised to the intervention, within a highly complex prison setting.
- The economic findings provide valuable insights, as we believe this to be the first of its kind for this type of intervention in this setting.
- Useful insight was gained regarding the access to PNC and NHS Service Use Data.
- The process evaluation provided insights into the perspectives of the remand participants, the intervention delivery team and wider stakeholders on the acceptability and feasibility of intervention implementation.
- Our patient and public involvement (PPI) colleague, a co-applicant on the study, provided unique insights and guidance throughout the study.

Limitations of the study

- Protracted multiple ethical approvals across devolved countries and processes meant a significant delay in recruitment commencing, particularly for the Scotland site.
- We were unable to deliver the post-liberation elements of the intervention.
- The onset of the COVID-19 pandemic resulted in prison restrictions and no access to the prison site, meaning we were unable to identify if participants had been released or not at 6 months, with no access at the England site at 12 months and very limited access at the Scotland site at 12 months.
- Although the COVID-19 pandemic was undoubtedly a factor in the low percentage followed up, only 13% (18/132) of those who received the intervention were followed up at 12 months.
- Changes to the study protocol to include self-completion of follow-up data may have made it difficult for participants to complete the survey, resulting in larger proportions of missing data as compared to RA survey completion at baseline, where missing data were minimal.
- We did not include probation services in the trial, which on reflection would have strengthened our post-liberation follow-up process.

Recommendations regarding a definitive randomised trial

From the study progression criteria for a full RCT, we have identified the following recommendations:

1. Buy-in for a research trial of this nature in prison requires significant pre-study trust and relationship development, buy-in from the prison estate, governor, prison officers, peer mentors and embedded third-sector services.
2. Recruitment and randomisation of men on remand to a future APPRAISE RCT are possible, with trust in the research team an important factor.
3. Training team members of existing alcohol services to deliver APPRAISE as per protocol is possible.
4. Delivery of the in-prison APPRAISE intervention is possible and would require appropriate space, time and team member capacity.
5. Economic evaluation is possible.
6. Post-liberation intervention delivery and follow-up would only be possible if there was a robust follow-up process identified and in place.
7. Further exploration of the inclusion of and collaboration with the probation service in the service delivery and implementation of the APPRAISE intervention, and that of voluntary groups and agencies at local community levels engaged specifically in post-discharge support services, may

offer higher success rates of post-liberation intervention delivery and a more robust follow-up process.
8. PPI membership should be strengthened to reflect the complexity of the prison setting and the range of stakeholders within the criminal justice system.

Conclusion

Addressing alcohol harm in prisons, at what can be considered a 'teachable moment', can provide men with an opportunity for reflection on their risky drinking and their current position.

Many men on remand do not have the opportunity to access mainstream prison health or public health services. An intervention such as APPRAISE offers an opportunity to provide an extended behavioural-based alcohol intervention to men on remand. The APPRAISE study has identified that despite the complexities of ethical approval and the time taken to build relationships and trust, it is possible to undertake key elements of a future RCT, but not all, namely follow-up. Further focused research needs to be undertaken to explore, identify and develop a robust process and system to optimise follow-up post liberation.

The evidence base to meet the needs of men on remand in relation to risky drinking remains weak. However, there are opportunities to build on the work of APPRAISE to ensure equal access to interventions that have the potential to positively impact their relationship with and use of alcohol.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN36066.

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