Development of a trial application to assess the effectiveness and cost- effectiveness of adult d**R**ug scr**E**ening and brief intervention**S** in key h**E**alth, social care and justice set**T**ings:

The RESET project protocol

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Background/Rationale

Between 2010 and 2019 the number of people using drugs increased by 22% globally (1). In England and Wales around 9% of adults have used an illicit drug with 2% being frequent users (2). In the UK general population around 26% of adults are risky drinkers (38% of men, 16% of women) (3) with substance use amongst those involved in the criminal justice system being higher. A recent review found 63% of people in the UK criminal justice system scored positive for risky drinking (4)and the prevalence of drug use was 81% (5) with an interlink between both alcohol and drug use. Therefore, it is sensible to include both drugs and alcohol into a single substance use intervention.

In England and Wales, alcohol-related crime is estimated to cost society £11.4 billion (6) and drugs £20 billion annually (7). Effective interventions therefore have the potential to significantly reduce the costs relating to substance use as well as increase individual social welfare (8).

Brief substance use interventions are a secondary prevention activity, which are aimed at those individuals who are using substances in a pattern that is likely to be harmful to health and/or well-being. They have been frequently shown to be effective in primary healthcare (9, 10) and there is some evidence in hospital settings (11) (12), but they are typically delivered by practitioners who are not addiction specialists, to non-treatment, opportunistic populations (13). Furthermore, there is some evidence of efficacy in regards to reducing recidivism in the criminal justice system (14). Although there is limited evidence regarding the effects of drug-targeted brief interventions on drug use (15-17), most of the work has been carried out outside the UK.

This project will utilise co-production methods. Co-producing research is now becoming more and more prevalent around the world. It is often called different things (18). These include participatory action research (19), knowledge translation (20)and collaborative research (21). Methodology can vary greatly depending on where the research is carried out and by whom. In order for true co-production to take place it is important for academics to ‘climb down from the ivory tower’ and spend time with agencies to fully understand where the work will take place (22). This was shown in the Home Office funded Restorative Justice Trials. The study journal article discusses the intricacies of conducting research with practitioners and mentions: “Magistrates’ court clerks were not so cooperative. While two small RCTs in Northumbrian Magistrates’ Courts were eventually completed, their samples were only achieved by dogged persistence of the Northumbria Manager, Dorothy Newbury-Birch” which sums up the difficulties in one sentence (23). In projects worked on previously by the research team, recruiting participants was not the difficult part, however, following them up for research projects (especially randomised controlled trials) is difficult (14, 23) (24). Often the individuals are happy to be followed up and are keen to be involved however, often because of their chaotic lifestyles this is difficult to do (14, 23) but is expensive to do properly.

The key strength of co-production research, and aspirations of co-production researchers, is that their research has real-world application, and is picked up and used by those who would most benefit from it (22). Making a positive change for the lives of individuals, groups, and communities is fundamental, particularly from a public health co-production perspective (25).

It is important that strategies be put into place to utilise a co-production method of working with practitioners and of course service users where possible so that the findings can be implemented (4, 23). Whilst it has been argued academics and criminal justice practitioners may be seen by many as coming from two very different places, the boundaries between them may not be as large as many believe (26), and a co-production approach where researchers, practitioners and community members working together could lead to real translational research (27). This is summed up perfectly by Shepherd, 2014, as evidence needing to flow through the ecosystem from generation to end-user, where both push and pull are needed (28).

Aims and objectives

The overarching aim of the RESET study is to develop a trial application to assess the effectiveness and cost-effectiveness of drug and alcohol brief interventions and screening in key health, social care, and criminal justice settings. The work is iterative to ensure that all information is gathered and updated to inform the future research protocol.

In order to appropriately assess effectiveness, a series of specific study objectives will be carried out as follows:

- Objective 1: to establish a research team with appropriate skills and expertise
- Objective 2: review and analysis of how similar types of SBI tools/interventions might be of use/implemented in the UK context and are already used in other international settings
- Objective 3: scoping current use of existing drug SBI tools/interventions in UK settings to identify learning/best practice examples throughout the course of the award and feed learning into research design
- Objective 4: identification and engagement of relevant stakeholders. For example, discussions with specific communities and population groups, policy makers, local drug and alcohol services, practitioners and service users
- Objective 5: investigations with key stakeholders (for example, specific age groups or settings) to inform where and how drug SBIs might be targeted within any given setting
- Objective 6: development of new academic and/or practitioner partnerships to support anticipated drug SBI research. For example, research expertise with particular interventions or drugs, within particular settings
- Objective 7: to develop an application to complete a 2-phase evaluation (pilot and feasibility, followed by trial/s) on the effectiveness and cost-effectiveness of targeted drug screening and brief interventions including extended brief interventions in

reducing drug use and associated harm in health, social care and justice settings in the UK, including a comparison of effectiveness between settings.

Study Design

This study is mixed methods and will comprise two systematic reviews (objectives 2 and 3) and 18 focus groups/interviews with key stakeholders and community members spanning each location and setting (objective 5). By utilising all the data collected from these objectives, the team will be able to outline an evidenced plan for the trial. The focus groups/interviews will obtain qualitative evidence which will be analysed as described below. The project timeline is detailed in the Gantt chart below, highlighting the milestones for this research.

As this study uses a variety of methods to achieve the seven objectives detailed above, each one from 1-6 will be detailed below, explaining how objective 7 will be achieved. Individual protocols will be drawn up for certain elements of the research such as the systematic reviews and will go into further depth than this main study protocol.

TABLE 1: Gantt Chart

Month of project	1	2	3	4	5	6	7	8	9	10	11	12	13
Year	2023									2024			
Month	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Project Management Group meetings													
Develop protocols													
OBJ 1 - establish a research team													
OBJ 2 - two systematic reviews (one quantitative and one qualitative)													
OBJ 3 - scope existing drug SBI tools													
Prepare paper work for ethical approval													
Ethical approval submission													
OBJ 4 - qualitative work with stakeholders													
OBJ 5 - qualitative work with community													
Data analysis													
OBJ 6 - development of partnerships													
OBJ 7 - development of application for phase2													

OBJECTIVES 1 AND 6

Establish a research team and development of new academic and/or practitioner partnerships to support anticipated drug SBI research. For example, research expertise with particular interventions or drugs, within particular settings.

The team currently bring together disciplines such as social sciences, statistics, health research, economics, health psychology, public health and criminology. The team are also experts in carrying out co-production research (29). As part of objective 1, the team intend to identify relevant other members of academia and the community to develop the work. The team will meet monthly to develop the study and examine the findings of the other objectives.

The team will be developed further over the next year to include the necessary academics and stakeholders to carry out the trials. This will include representatives from each of the three areas (health, social care and criminal justice) as well as academics relating to

economics/health economics, health psychology and intervention development. Further, the best clinical trial units will be identified to potentially work with the team on the future study. As part of RESET, the research team intend to work with three newly established HDRCs to develop this work, South Tees, Kent (Medway) and Blackpool to ensure that a representative sample of the population can be obtained going forward.

OBJECTIVES 2 AND 3

Objective 2: Review and analysis of how similar types of SBI tools/interventions might be of use/implemented in the UK context and are already used in other international settings

Objective 3: scoping current use of existing drug SBI tools/interventions in UK settings to identify learning/best practice examples throughout the course of the award and feed learning into research design

To meet objective 2, the research team will carry out a rapid review of the literature over the last 20 years to ascertain types of tools/interventions used in these settings. The TIDieR guidelines will be utilised to ascertain what the ingredients of the interventions are (30). This will involve looking at published literature but will also involve a detailed exploration of grey literature, particularly looking at government websites from across the world. The review has been registered on Prospero reference: CRD42023429726. The review will include both male and female participants and the inclusion/exclusion criteria for this review is as follows:

Systematic Review 1: Inclusion criteria

- Studies that include quantitative studies, specifically randomised controlled trials with any comparison (control) group.
- Brief intervention will be defined as in the definition as any interventions that are either short brief (up to three hours) or extended (up to 15 hours).
- Studies that include accounts from people aged 18 and above.
- Studies published in any language, from any country will be included.

Systematic Review 1: Exclusion criteria

- Studies that focus on other types of brief intervention not defined above.
- Studies published prior to 2003.

Further to this, a separate review of studies that have been published will be carried out to understand the barriers and facilitators across the different studies to understand how to embed these into the future study. In addition to interventions, the data will be used to explore and synthesise the diagnostic properties of opportunistic screening tools, to identify those tools that could be further assessed within a pilot study. The review has been registered on Prospero reference: CRD42023429734. The inclusion/exclusion criteria for this second review will also include male and female participants and is as follows:

Systematic Review 2: Inclusion criteria

- Studies that include qualitative findings (including from survey results) the barriers and facilitators for screening and/brief interventions.
- Brief interventions that are categorised as low intensity and short in duration, typically consisting of 1-3 short sessions of counselling and or education.
- Studies that include accounts from people aged 18 and above.
- Studies that include qualitative findings from both the participant and the person delivering the SBI.
- Studies published in any language, from any country, will be included.

Systematic Review 2: Exclusion criteria

- Studies that focus on other types of brief intervention not defined above.
- Studies published prior to 2003.
- Studies that are only quantitative.

For objective 3, The research team will carry out an ongoing review of literature to identify best practice examples. Furthermore, a structured search across different local authorities and different agencies will be carried out. Key individuals will be emailed and social media will be utilised to find as much published and unpublished literature as possible. The information will be scrutinised by the team and members of the community will be involved to take the work forward.

OBJECTIVES 4 AND 5

For objectives 4 and 5, 18 focus groups will be carried out across the geographical areas (Table 1). Participants will be identified via a series of events held in each of the geographical areas (objective 4). Furthermore, the newly developed HDRC's will act as gatekeepers to key individuals within each area and setting. The purpose of these focus groups is to ascertain exactly what specific context area to work in (i.e for criminal justice this could be police, court, probation and prison). Once this has been ascertained, the research team will work with specific stakeholders relating to the area identified as the most effective to carry out a walk-through of how the work can be undertaken in that setting. The inclusion criteria is those that work in the relevant context areas. This information about who exactly will be involved in this qualitative work will be identified in the reviews discussed in objectives 2 and 3. It is anticipated that these stakeholders will be (but not limited to):

- Health care settings: GP's, Nurses, Paramedics, carers, mental health service workers
- Social care settings: Social workers, social care staff (including support staff)
- Criminal justice settings: prison officers, prison governors, police officers, custody suite staff, probation officers, drug and alcohol workers
- Individuals who have lived experience in any of the three settings.

The research team will meet with people who may be targeted across the key areas to ascertain their thoughts about how the interventions could be developed – these will be stratified by age/gender and geographical area. All focus groups will be arranged at a time to suit participants. Interviews will take up to one hour and will be digitally audio-recorded with permission (written consent), then transcribed, anonymised and checked.

Table 1: Interviews/focus groups with stakeholders

	Geographical Site		
	South Tees	Blackpool	Kent (Medway)
Context area	Heath *2	Heath *2	Health *2
	Social Care *2	Social Care *2	Social Care *2
	Criminal Justice *2	Criminal Justice *2	Criminal Justice *2

Data Analysis

Data analysis is relevant to objectives 2, 3, and 5. As mentioned, a separate protocol will be drafted for the systematic reviews.

All of the interviews/focus groups will be audio recorded, transcribed verbatim and anonymised before being analysed thematically (31, 32). Applied thematic analysis is a phenomenological approach to qualitative analysis that focuses on the individual experiences of participants (31, 32). Analysis begins with line-by-line coding of transcripts with similar codes being grouped together into themes and sub-themes. An inductive approach was used when coding the transcripts as no existing theory was used to facilitate the coding, (31). These themes will be discussed further and agreed by all members of the group.

Data Management

All data for this study will be stored in accordance with The General Data Protection Regulations 2016/679. All consent forms for the interviews will be stored within a locked room within Teesside University. Transcripts from interviews will be stored in a shared folder on a secure network drive which is only accessible by the research team. All identifiable information shall be removed from the transcripts, and pseudonyms will be used in all documentation in order to protect the identity of participants. A database will be stored in a secure network folder at Teesside University containing participant names and pseudonyms in case anyone wishes to remove themselves from the research project, this will allow the researcher to remove this data. This file will be deleted once the research has concluded. Teesside University act as data processor and data owner.

Ethical approval

Ethical approval will be sought for the qualitative components (objectives 4 and 5) from Teesside University prior to the work starting.

OBJECTIVE 7:

To develop an application to complete a 2-phase evaluation (pilot and feasibility, followed by a trial/s) on the effectiveness and cost-effectiveness of targeted drug screening and brief interventions (SBIs) including extended brief interventions in reducing drug use and associated harm in health, social care and justice settings in the UK, including a comparison of effectiveness between settings.

The team will meet regularly over the duration of this work (at least monthly either in person or online) to develop and plan the design of the pilot and definitive trial. This will involve decision making of which settings this should be in based on the findings of this development work.

In terms of the pilot trial, we will be looking at the following:

1. To pilot study outcomes and evaluation methods, assess the parameters associated with the conduct of an effectiveness trial and to assess whether operational criteria have been met and if so develop and implement a full trial protocol for an appropriately powered effectiveness study which will include progression criteria based on stop/go criteria
2. To pilot potential screening tools.
3. To qualitatively explore the feasibility and acceptability of referral pathways, intervention delivery and study assessments from the perspectives of the participants and staff.
4. To co-produce with staff and participants with lived experience of substance use an online/paper training manual to be used for the trial which includes trial information and intervention training.

We will conduct a descriptive analysis of outcomes including measures of central tendency and estimates of precision for continuous outcomes and proportions for categorical outcomes. Inferential analysis at the pilot stage will focus on the primary outcome, percent days abstinent from substance use. After conducting diagnostic plots and selecting an appropriate regression approach, adjusting for baseline values and stratification variables as covariates, we will present the marginal effect, mean difference between the groups and 80% confidence intervals as an estimate of potential effect. This analysis will allow us to confirm or revise our sample size calculation. At this stage we will also explore the pattern of missing data for each outcome, if missing data exceeds 40% for an outcome, we will make judgements about whether to incorporate the outcome in the definitive study.

Research design: Mixed method, prospective, pragmatic RCT combining both quantitative and qualitative evidence. The study will be conducted across England covering a diverse socio-economic and ethnic population. We will develop the inclusion/exclusion criteria.

Control arm: In the development year we will identify whether the control arm should be a pure control (no active ingredients) or have an active ingredient such as feedback and a leaflet as happened in the SIPS trials (14, 33, 34).

Intervention: We will be looking at the evidence to ascertain what the intervention will be but understand that as a brief intervention this will need to be short. We will also look at each context to decide who the best people to deliver the intervention will be. It is expected that

the intervention will encompass the elements of the FRAMES approach for eliciting behaviour change (35).

Randomisation: Randomisation will be conducted by a statistician independent of the research team (at University of Kent). Individuals will be randomised to one of the agreed conditions stratified by geographical area. Individuals will not know which arm they are randomised to when they agree to take part in the study. We intend to explore the use of online tools to carry out the randomisation and data collection to make it easier for the practitioners.

Proposed sample size: One of the fundamental things we will investigate during the development year is what the proposed sample size will be. We will look at clinically important differences to determine the numbers needed to come into the pilot/definitive trial.

Screening: We will look at all validated tools for screening but will use a short version of any tool to make it easier for the practitioners.

The primary outcome measure will be reduction in substance use. We do intend to explore secondary outcome measures including mental health, wellbeing, service use and criminal justice behaviour.

Follow ups: One of the main issues with trials is following people up (22). We intend to carry out a review of strategies and ways of doing this, but we also intend to add an extra follow-up time frame at around eight weeks post intervention to check contact data. It is expected that there will be a follow-up at six months and 12 months (with 12 months being the time frame for the primary outcome measure) Trial participants' baseline and follow up questionnaires will be linked with a unique ID.

Training: All staff in all included sectors will receive training in the study procedures and intervention by members of the team. We intend to do these using manuals, online and face to face based on the results of the reviews. Research staff and trainers will maintain regular contact with schools throughout the study period, including site visits and telephone and email and WhatsApp support.

Data analysis - trial: We will use the commonly used ways of carrying out data analysis using descriptive statistics to report baseline data and extent of interventions delivered. The primary effectiveness analysis will be by treatment allocated and will employ a fractional regression adjusted for key covariates. Differences between the groups will be presented as odds ratios and marginal means and associated 95% confidence intervals. Dichotomous secondary outcomes will be analysed in a similar manner, for continuous variables linear regression, with or without transformation here necessary, will be undertaken and differences between the groups presented as mean differences and 95% confidence intervals. Exploratory analyses will also be undertaken, for example, to examine differences in outcome by gender, deprivation and extent of intervention received, though there may be limited power to investigate these comparisons. We will consider any difference in attrition rates, and any non-randomness of the attrition, when comparing outcomes between the two groups. There are no planned interim analyses. The pattern and extent of missing observations because of loss

to follow-up will be examined to investigate both the extent of missingness, and whether it is missing at random or is informative. The use of appropriate multiple imputation techniques will be considered. Analysis will be governed by a data analysis plan generated and agreed prior to analysis being undertaken.

Data analysis – health economics: We will look at the world-wide evidence in relation to the economic and health economic component of the study and have asked Professor Jeremy Bray from the University of North Carolina at Greensboro in the USA, who is an honorary Professor at Teesside University to work with us on this. He is a world-leading expert in carrying out economics and health economics work with trials of drug and alcohol interventions in a variety of settings (36-38). It is expected that the economic component will include both a within trial cost-utility and cost-consequence analysis and a model-based analysis taking the perspective of the public sector. The cost-utility analysis will use measures of effectiveness limited to health-related quality of life. Tools to be used will be agreed by the team based on the findings in the development year and tested in the pilot year. A detailed analysis plan will be developed.

Community involvement: This development year gives us the opportunity to do true co-production work with members of the community. We will work with the newly established HDRCs to identify relevant groups and individuals to talk to and to involve in the research, ensuring we have diversity in relation to age, gender and ethnicity. A key part of this work will be the research team going to communities to discuss the project rather than expecting them to come to the University. We will work with members of the community over the development year to ensure that they are integrally involved in the research.

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