Centre for Healthcare Randomised Trials

Effectiveness and cost-effectiveness of a peer-delivered, relational, harm reduction intervention to improve mental health, quality of life, and related outcomes, for people experiencing homelessness and substance use problems:
The 'SHARPS' cluster randomised controlled trial.

Statistical Analysis Plan

A UK Collaborative Trial funded by the NIHR Health Technology Programme

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Signatures

By signing this document, I am confirming that I have read, understood and approve the statistical analysis plan (SAP) for the SHARPS trial.

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Date: **24th July 2024**

Version History

SAP version	Protocol version*	Section number changed	Description of and reason for change	Date of change
Version 1	Version 1		New document, based on SAP template Version 2	24/07/2024

* Please refer to 'Statistical Analysis Plan (SAP) review after Protocol updates' document that will be updated throughout the trial, documenting any amendments to the protocol and its relevance to the SAP.

Glossary of Abbreviations

Table containing all abbreviations used in the statistical analysis plan, e.g.

AE	Adverse Event
AUC	Area Under the Curve
CACE	Complier average causal effect
CARE	Consultation and Relational Empathy Measure
CEST	Client Evaluation and Self Treatment
CHaRT	Centre for Healthcare Randomised Trials
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
cRCT	Cluster Randomised Controlled Trial
CRF	Case Report Form
DMC	Data Monitoring Committee
DMEC	Data Management and Ethics Committee
EbyE	Experts by Experience
EQ-5D-5L	EuroQol Quality of Life 5 Dimensions
ETHOS	European Typology of Homelessness and Housing Exclusion
GAD	Generalised Anxiety Disorder
GDPR	General Data Protection Regulation
HSRU	Health Services Research Unit
ICC	Intraclass correlation coefficient
ICECAP-A	ICEpop CAPability Measure for Adults
ISE	Interpersonal Support Evaluation
ITT	Intention-to-Treat
JSS	Job Satisfaction Survey
LDQ	Leeds Dependence Questionnaire
MAP	Maudsley Addiction Profile
MAR	Missing at Random
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research

NoMAD	Normalisation Measure Development Questionnaire
NPT	Normalisation Process Theory
PHQ-ADS	Patient Health Questionnaire Anxiety and Depression
PIEs	Psychologically Informed Environments
ProQoL	Professional Quality of Life Scale
QALY	Quality Adjusted Life Year
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SD	Standard Deviation
SHARPS	Supporting Harm Reduction through Peer Support
SSQ	Social Satisfaction Questionnaire
TSA	The Salvation Army
TSC	Trial Steering Committee
YFC	Years of Full Capability

Table of Contents

SHARPS

1. Introduction

Those who are experiencing homelessness have an increased risk of chronic health problems, problem substance use, and mental health challenges which arise from the social and economic challenges they face. The SHARPS trial aims to evaluate how peer support compares to standard homelessness care.

This statistical analysis plan (SAP) documents the analysis for the SHARPS trial.

The SAP is based on the protocol Version 1, and any deviations from the plan will be described.

2. Study Aims and Objectives

The **primary aim** of the study is evaluate the effectiveness and cost-effectiveness of a 12-month Peer Navigator-led, co-produced, relational, harm reduction and psychologically informed environments (PIEs) intervention for adults who are experiencing homelessness and problem substance use, for improving mental health, quality of life, and related outcomes, within social care settings compared with standard homelessness care.

The **primary objective** is to conduct a 2-arm pragmatic cluster RCT (cRCT) across social care homelessness settings in 20 cities/towns in England and Scotland to determine whether the 12-month SHARPS intervention improves mental health and quality of life (co-primary outcomes), compared to standard homelessness care, in adults who are experiencing homelessness and problem substance use.

The **secondary and process evaluation objectives** are:
1. Compare secondary outcomes, including substance use/harms, risk-taking behaviour, social functioning/support, physical health, homelessness, therapeutic alliance, and relational empathy;
2. Undertake a cost-utility and cost-consequence analysis of the SHARPS intervention.
3. Conduct a process evaluation guided by MRC guidance and Normalisation Process Theory (NPT) to examine transferability, context, and intervention 'fit';
4. Assess intervention adherence/fidelity via mixed methods;
5. Examine Peer Navigator (and Support Workers in control sites) outcomes/experiences via mixed methods.

3. General Study Design

SHARPS is a 2-arm superiority pragmatic cRCT with 14 clusters in England and 6 clusters in Scotland. The trial is powered on detecting an effect size of 0.4SD on the

quality-of-life primary outcome (ICECAP-A). This is equivalent to a difference of 0.076 between the intervention groups.

4. Interventions to be evaluated

The SHARPS intervention is practical and emotional support from a Peer Navigator. Each of the 10 clusters in the intervention group will have a Peer Navigator who will work with their clients for a 12-month period. All Peer Navigators will have lived experience of problem substance use and/or homelessness and varied experience of recovery / harm reduction. There is a small support budget available to the Peer Navigators to use in their work with clients for things like travel to appointments, essential food and clothing etc.

The control group will not have Peer Navigators. Control participants will receive standard care within The Salvation Army (TSA) services. Area differences might exist, but standard care will usually provide support workers to help with housing applications, contacting relatives, and wider support services.

5. Randomisation, Allocation and Blinding

Randomisation will be done at the cluster level to minimise imbalance on the cluster level covariates. As Scotland and England have differences in covariates, the randomisation will be stratified by country. In both Scotland and England, the Carter-Hood(2008) algorithm is used to for covariate constrained randomisation.
The Scotland covariates to balance are:
- Demographic characteristics:
    - population size
    - % population identify as white
    - % population income deprived
    - % working age population employment deprived.
- Mental health:
    - suicide rate per 100,000.
- Risk behaviours:
    - adults in drug treatment per 1000
    - adults in alcohol treatment per 1000
    - adults in co-dependency treatment per 1000
    - drug-related deaths per 100,000
    - alcohol-specific deaths per 100,000
    - alcohol-related hospitalisations per 100,000
- Homelessness:
    - households assess as homeless per 1000 households
    - households in temporary accommodation per 1000 households.
- Number of TSA services.

The England covariates to balance are:
- Demographic characteristics:
    - population size
    - % population identify as white

- o deprivation score (IMD 2019).
- Mental health:
  - o suicide rate per 100,000.
- Risk behaviours:
  - o adults in drug treatment per 1000
  - o adults in alcohol treatment per 1000
  - o drug-related deaths per 100,000
  - o rate of alcohol dependency per 1000
  - o proportion of opioid and/or crack-cocaine users not in treatment.
- Homelessness:
  - o relief duty owed per 1000.
- Number of TSA services.

This data comes from Public Health Scotland and Office for Health Improvement and Disparities published area profiles.

The randomisation process is done in two stages. For each country, the clusters are allocated into two groups (A and B) using the Carter-Hood algorithm. This produces a set of the most optimal allocations based on the sum of the equally weighted z-scores of each covariate. Additional conditions are that Edinburgh and Glasgow cannot be in the same allocation for the Scottish clusters and Birmingham and London must be in separate allocations for the English clusters. The 2 most optimal allocations for Scotland and 5 most optimal allocations for England are selected for the second stage.

In the second stage, groups A and B are randomly allocated to intervention and control. A random number (either 1 or 2) is generated for Scotland and a second random number (between 1 and 5) is generated for England. These numbers indicate which allocations are selected for Scotland and England.
The two stages of the randomisation process are performed by different statisticians to blind the trial statistician to intervention allocation.
A full description of the randomisation specification is included in the appendix of this plan.

6. Outcome Measures

6.1. Primary Outcome
SHARPS has co-primary outcomes to be measured at 12 months:
- • mental health (compositive measure PHQ-ADS)
- • quality of life (ICECAP-A)

6.2. Secondary Outcomes
The secondary outcomes are:
- • Patient Health Questionnaire Anxiety and Depression (PHQ-ADS), and ICEpop CAPability Measure for Adults (ICECAP-A) [6- and 15- month outcomes]
  EuroQol Quality of Life (EQ-5D-5L)

- harmful substance use (Maudsley Addiction Profile (MAP), Leeds Dependence Questionnaire, (LDQ))
- risk taking behaviours (MAP)
- social functioning including occupation/education roles (MAP)
- physical health (MAP, EQ-5D-5L)
- housing status (self-report housing status)
- social outcomes, therapeutic alliance with the Peer Navigator (intervention group) and support workers (control group), and service accessibility (items from the Social Satisfaction Questionnaire (SSQ) Interpersonal Support Evaluation List 12 item version (ISE))
- service utilisation (MAP, self-report service utilisation (health, social care, and criminal justice), items from Client Evaluation of Self and Treatment (CEST))
- relational empathy (Consultation and Relational Empathy measure (CARE))

All above outcomes are assessed at baseline, 6-, 12-, and 15-months post baseline except the CARE measure which will not be completed at baseline. In addition, the following data will be collected from:
Peer Navigators and intervention service staff (at baseline and 6- and 12- months post baseline)
- Normalisation Measure Development Questionnaire (NoMad)

Peer Navigators and control site support workers (at baseline and 12-months post baseline)
- Professional Quality of Life Scale (ProQoL)
- Job Satisfaction Survery (JSS)

7. Timing of Outcome Measurements

		Post-randomisation (months)		
Outcome Measure	Baseline	6	12	15
PHQ-ADS	✓	✓	✓	✓
ICECAP-A	✓	✓	✓	✓
EQ-5D-5L	✓	✓	✓	✓
MAP	✓	✓	✓	✓
LDQ	✓	✓	✓	✓
SSQ	✓	✓	✓	✓
ISE	✓	✓	✓	✓
CEST	✓	✓	✓	✓
CARE		✓	✓	✓
Self-reported housing status	✓	✓	✓	✓
Self reported service utilisation				
Health	✓	✓	✓	✓
Social care	✓	✓	✓	✓
Criminal justice	✓	✓	✓	✓

8. Adverse Events
Serious adverse events are not expected to occur in SHARPS but any disclosures of harm to themselves or others will be recorded on an adverse events form. Any adverse

events experienced by research staff and Peer Navigators will also be recorded on adverse event forms.

9. Sample Size and Power Calculation

Randomisation is done at the cluster level and intervention clusters will each recruit 25 participants while control clusters will each recruit 30 participants, to reach a total of 250 + 300 = 550 participants. The anticipated loss-to-follow-up rates of 40% and 50% in the intervention and control arms respectively will result in a trial of 300 participants. Assuming an intraclass correlation coefficient (ICC) of 0.01, this will have 90% power to detect an effect size of 0.4SD at 5% level of significance.

10. Statistical Methods

10.1. General Methods

There will be a single final analysis of the outcome data which will be done after recruitment has closed and all follow-up data has been received and the database closed. Analyses will be on the intention-to-treat (ITT) principle.

Baseline and outcome data will be summarised by arm with categorical data described with count and percentage and continuous data described with mean and standard deviation or median and interquartile range depending on the distribution.

10.2. Interim Analysis

There are no planned interim analyses for efficacy or futility, but an independent Data Monitoring and Ethics Committee (DMEC) will monitor trial progress and specifically any safety issues.

10.3. Primary Outcome

The primary outcomes will be analysed with a repeated-measures mixed-effects linear model. In SHARPS, clusters are randomised, and the outcome is measured at the participant level with three follow-up points. This gives two types of non-independence of observation and the chosen approach is to include random effect coefficients for participant and cluster intercepts. Fixed effects will be included for treatment, timepoint, country, and the baseline score of the outcome. Fixed effects will also be included for treatment-time interactions and a combination of these, and the treatment variable will be used to obtain the treatment effect at each follow-up point.

As suggested by Leyrat et al (2017) the Satterthwaite method to adjust for a small number of clusters by reducing the number of degrees of freedom will be used.

10.4. Secondary Outcomes

The secondary outcomes will be analysed with the same fixed and random effects as the primary outcome using a repeated-measures mixed-effects linear model. Adjustment for small cluster numbers will again use the Satterthwaite method.

10.5. Missing Data

10.5.1.   Missing Outcome Data

The sensitivities of treatment effect estimate to missing outcome data will be explored; these models will explore the robustness of the treatment estimate to whatever small amount of missing data there is. We will follow the strategy outlined in Fiero et al (2016). This approach uses a combination of multiple imputation and pattern-mixture models to explore the effect of missing not at random data. Multiple imputation with chained equations will be used to impute missing data and these imputed values are then multiplied by different scalars to create cases where missing data has lower and higher outcome scores than the observed data. The situation where data is missing at random corresponds to when the scalar equals one.

Imputation will be performed separately for each trial arm and cluster. The Stata code for imputation is included in the appendix.

10.5.2.   Missing Baseline Data

Data missing at baseline will be reported as such. If required primary and/or secondary outcome data will be imputed with cluster specific mean for continuous data and missing binary/categorical data will include a missing indicator.

10.6. Non-compliance
It is possible but unlikely that there will be non-compliance in the Peer Navigation arm of the trial, both at the individual and cluster level.

10.6.1.   Individual level
Participants in clusters randomised to Peer Navigation who do not engage or receive the full Peer Navigator experience would be classed as non-complying at the individual level. A complier average causal effect (CACE) will be estimated for these participants using the principal scores method suggested in Agbla (2018).

10.6.2.   Cluster level
This corresponds to the very unlikely situation of a Peer Navigator stopping and not being replaced and so all participants in the cluster do not receive Peer Navigation. CACE will be estimated for these participants using the instrumental variables method suggested in Agbla (2018).

10.7. Statistical software
All analysis will be carried out in Stata 18.

11. Dummy Tables

Baseline
(summary statistics are count(percentage) unless indicated

	Peer Navigation	Standard Care
Age	Mean,(SD)	Mean,(SD)
Gender		
Male		
Female		
Non-binary		
Prefer not to say		
Prefer to self-describe		
Is Gender identity same as birth sex?		
Yes		
No		
Prefer not to say		
Marital status		
Single		
In a relationship		
Married / civil partnership		
Divorced / separated		
Widowed		
Ethnic group		
White Scottish		
Other White British		
White Irish		
Gypsy/Traveller		
White Polish		
Other White European		
Other White		
Mixed or multiple ethnic group		
Asian, Asian Scottish, Asian British		
Other ethnic group		
African, African Scottish, African British		
Caribbean, Caribbean Scottish, Caribbean British		
Black, Black Scottish, Black British		
Arab, Arab Scottish, Arab British		
Prefer not to say		
Highest level of education		
Primary school		
College/Diploma		
Secondary school		
University/Degree		
Postgraduate		
Other		
Description of where currently staying		

Social housing where you are the tenant/joint tenant		
Private rented sector housing where you are the tenant/joint tenant		
Owner-occupied housing i.e. your own flat/house where you are the owner/co-owner		
Living with friends i.e. in the friend's flat or house etc		
Living with a partner in their flat/house		
Living with parents, in their house, flat etc		
Living in with other family i.e. in their flat or house etc.		
Emergency accommodation (such as a B&B or a night shelter)		
Rough sleeping, on transport or in transport hub (bus stop or train station), in a tent or car		
Temporarily at friend's/family's home–on an informal basis (sofa surfing)		
Hostel		
A caravan, or squat		
Asylum accommodation		
Supported accommodation		
Other		
Do you consider yourself to have a disability?		
Disability description		
Mobility		
Learning disability		
Mental health		
Sensory impairment		
Developmental disability		
Long term condition		
Other		
Served in the Armed Forces		
Been in foster/residential care		
Religion		
No religion		
Hindu		
Sikh		
Christian (including Church of England, Catholic, Protestant and all other Christian denominations		
Jewish		
Buddhist		
Muslim		
Any other religion		
Main language		
English		
Other		

English proficiency		
Very well		
Well		
Not well		
Not at all		
Sexual orientation		
Straight/heterosexual		
Gay or Lesbian		
Bisexual		
Other		
Physical or mental health conditions or illnesses lasing or expected to last 12 months or more		
Conditions or illnesses reduce your ability to carry out day-to-day activities		
Yes, a lot		
Yes, a little		
Not at all		
Currently pregnant		
Number of patient visits to A&E in past 6 months	Mean,(SD)	Mean,(SD)
Number of inpatient stays in past 6-months	Mean,(SD)	Mean,(SD)
Number of outpatient visits in the last 6-months	Mean,(SD)	Mean,(SD)
Number of hospital day admissions in the last 6-months	Mean,(SD)	Mean,(SD)
Number of emergency ambulance hospital visits in the last 6-months	Mean,(SD)	Mean,(SD)
Number of emergency ambulance treatments in the last 6-months	Mean,(SD)	Mean,(SD)
Number of hospital patient transport uses in the last 6-months	Mean,(SD)	Mean,(SD)
Number of doctor appointments in the last 6-months	Mean,(SD)	Mean,(SD)
Number of visits from the doctor in the last 6-months	Mean,(SD)	Mean,(SD)
Number of visits to the nurse in the last 6-months	Mean,(SD)	Mean,(SD)
Number of visits from the nurse in the last 6-months	Mean,(SD)	Mean,(SD)
Currently on prescription medication		
Number of prescriptions in the last 6-months	Mean,(SD)	Mean,(SD)
Professional visits in the last 6-months		
NHS Physiotherapist	Mean,(SD)	Mean,(SD)
NHS Dietician	Mean,(SD)	Mean,(SD)
NHS Dentist	Mean,(SD)	Mean,(SD)
Occupational therapist	Mean,(SD)	Mean,(SD)

Community Psychiatric Nurse	Mean,(SD)	Mean,(SD)
Number of community-day centres used (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)
Number of social worker visits (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)
Number of visits to social worker in the last 6-months	Mean,(SD)	Mean,(SD)
Visits from care worker or adviser (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)
Arrested, cautioned, or fined in the last 6-months		
Number of times arrested, cautioned, or fined in the last 6-months	Mean,(SD)	Mean,(SD)
Appeared in court in the last 6-months		
Number of court appearances in the last 6-months	Mean,(SD)	Mean,(SD)
Been in prison in the last 6-months		
Total prison days in the last 6-months	Mean,(SD)	Mean,(SD)
Patient reported outcome measures at baseline		
PHQ-ADS	Mean,(SD)	Mean,(SD)
ICECAP-A	Mean,(SD)	Mean,(SD)
EQ-5D-5L	Mean,(SD)	Mean,(SD)
MAP	Mean,(SD)	Mean,(SD)
LDQ	Mean,(SD)	Mean,(SD)
SSQ	Mean,(SD)	Mean,(SD)
ISE	Mean,(SD)	Mean,(SD)
CEST	Mean,(SD)	Mean,(SD)

Monthly follow-up data

	6 months		12 months		15 months	
	Peer Navigation	Standard Care	Peer Navigation	Standard Care	Peer Navigation	Standard Care
Description of where currently staying						
Social housing where you are the tenant/joint tenant	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Private rented sector housing where you are the tenant/joint tenant	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Owner-occupied housing i.e. your own flat/house where you are the owner/co-owner	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Living with friends i.e. in the friend's flat or house etc	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Living with a partner in their flat/house	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Living with parents, in their house, flat etc	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Living in with other family i.e. in their flat or house etc.	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Emergency accommodation (such as a B&B or a night shelter)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Rough sleeping, on transport or in transport hub (bus stop or train station), in a tent or car	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Temporarily at friend's/family's home–on an informal basis (sofa surfing)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Hostel	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
A caravan, or squat	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Asylum accommodation	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Supported accommodation	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Other	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of patient visits to A&E in past 6 months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of inpatient stays in past 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of outpatient visits in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of hospital day admissions in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)

Number of emergency ambulance hospital visits in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of emergency ambulance treatments in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of hospital patient transport uses in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of doctor appointments in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of visits from the doctor in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of visits to the nurse in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of visits from the nurse in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Currently on prescription medication	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of prescriptions in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Professional visits in the last 6-months						
NHS Physiotherapist	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
NHS Dietician	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
NHS Dentist	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Occupational therapist	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Community Psychiatric Nurse	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of community-day centres used (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of social worker visits (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Number of visits to social worker in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Visits from care worker or adviser (excluding Salvation Army) in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Arrested, cautioned, or fined in the last 6-months	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of times arrested, cautioned, or fined in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)

Appeared in court in the last 6-months	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of court appearances in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Been in prison in the last 6-months	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Total prison days in the last 6-months	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)

MAP follow-up data

	6-months		12-months		15-months	
	Peer Navigation	Standard Care	Peer Navigation	Standard Care	Peer Navigation	Standard Care
Alcohol						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Heroin						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Problem opioids						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Problem benzos						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Cocaine – hydrochloride						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Cocaine – crack/base						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amphetamines						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)

Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Novel psychoactive substances						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Other drugs						
Used in past month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days used in past month	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Amount consumed on a typical day	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Drugs overdose in the past month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Other overdoses						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Ever had a drugs overdose						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Last overdose						
Ambulance called	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Peer administered naloxone	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Treated in A&E	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Nothing	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Other	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of times been in drug treatment						
1	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
2	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
3	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
4	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
5	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
5-10	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
>10	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How long in treatment (weeks / months / years)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Services used in the past 6-months (3-months in the 15M follow-up)						

Needle exchange service	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Specialist substitution/ opiate replacement drug treatment	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
GP based substitution/ opiate replacement drug treatment	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
In-patient detoxification	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Residential rehabilitation	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Counselling	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Support for employment	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Housing support	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Support group	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Other	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
In a drug substitution programme at present	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Injected drugs in the past month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Used a needle or syringe which had been used by someone else						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of times	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
How often used a new, unused needle						
Never	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Rarely	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Sometimes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Often	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Always	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Penetrative sex in the past month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Without using a condom	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of people without using a condom	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Nights spent in the following places						
Own or rented home	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Relatives'/Partner's/Friend's/others' home	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Hostel/other temporary accommodation	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
On the street (homeless)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Prison/other detention/police station	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)

Hospital/residential treatment	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Other	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Length of time in most recent place of residence	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Paid work in the last month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Absent due to sickness or unauthorised absence in the past month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Voluntary job in the last month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
In training or education in the last month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days attended	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Looking after dependents in the last month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Unemployed in the last month						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
How many days unemployed	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
In a relationship in the last month	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Days in the last month in contact with						
Partner	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Children	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Your friends	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Days in the last month in serious conflict with						
Partner	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Children	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Your friends	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)	Mean,(SD)
Illegal activities in the last month						
Selling drugs						

Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Fraud/forgery						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Theft from a property						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Theft from a person						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Shoplifting						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Theft from a vehicle						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Theft of a vehicle						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Other theft						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Criminal damage (e.g. deliberate damage to property)						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)

Public order offence (e.g. threatening/abusive behaviour or harassment)						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Soliciting (i.e. to offer or accept money or other compensation for sex)						
Yes	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)	Count(Percentage)
Number of days	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)
Number of times per day	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)	Mean(SD)

Outcomes

	Peer Navigation	Standard Care	Adjusted mean difference*
PHQ-ADS			
6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
ICECAP-A			
6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
EQ-5D-5L			
6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
MAP			
6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
LDQ			
6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value

	12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
SSQ				
	6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
ISE				
	6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
CEST				
	6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
CARE				
	6-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	12-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value
	15-month	Mean,(SD)	Mean,(SD)	Difference, 95% CI, p-value

[*]The analysis model includes fixed effects for country and the baseline score of the respective outcome. Fixed effects are also included for treatment and timepoint and the interaction of these. Random effects are included for participant and cluster.

12. References

Carter, B.R., Hood, K. Balance algorithm for cluster randomized trials. *BMC Med Res Methodol* **8**, 65 (2008). https://doi.org/10.1186/1471-2288-8-65

Agbla SC, DiazOrdaz K. Reporting non-adherence in cluster randomised trials: A systematic review. Clin Trials. 2018 Jun;15(3):294-304. doi: 10.1177/1740774518761666. Epub 2018 Apr 2. PMID: 29608096; PMCID: PMC6485377.

13. Appendices

13.1. Derived Patient reported Outcome Measures (PROMs)

The PROMs are shown in the table below. Codes developed in-house will be checked and validated by an independent statistician using dummy data. Table 13.1 describes how each score will be calculated.

Table 13.1 Calculation of PROMs score

PROMs	Calculation
PHQ-ADS	Reference: Kroenke K, Wu J, Yu Z, Bair MJ, Kean J, Stump T, Monahan PO. Patient Health Questionnaire Anxiety and Depression Scale: Initial Validation in Three Clinical Trials. Psychosom Med. 2016 Jul-Aug;78(6):
ICECAP-A	Reference: https://www.bristol.ac.uk/population-health-sciences/projects/icecap/icecap-a/
EQ-5D-5L	Reference: EuroQol Research Foundation. EQ-5D-5L User Guide, 2019. Available from: https://euroqol.org/publications/user-guides.
MAP	Reference: Marsden, J. Gossop, G. Stewart, D. Best, D. Farrell, M. Lehmann, P. Edwards, C. & Strang, J. (1998) The Maudsley Addiction Profile (MAP): A brief

	instrument for assessing treatment outcome, Addiction 93(12): 1857-1867.
LDQ	Reference: Raistrick, D., Bradshaw, J., Tober, G., et al. (1994) Development of the Leeds Dependence Questionnaire (LDQ): a questionnaire to measure alcohol and opiate dependence in the context of a treatment evaluation package. Addiction, 89, 563–72.
SSQ	Reference: Raistrick D, Tober G, Heather N, Clark JA. Validation of the Social Satisfaction Questionnaire for outcome evaluation in substance use disorders. Psychiatric Bulletin. 2007;31(9):333-336. doi:10.1192/pb.bp.106.014258
ISE	Reference: Cohen S., Mermelstein R., Kamarck T., & Hoberman, H.M. (1985). Measuring the functional components of social support. In Sarason, I.G. & Sarason, B.R. (Eds), Social support: theory, research, and applications. The Hague, Netherlands: Martinus Niijhoff.

13.2. Stata code

Table 13.2 provides sample Stata code for the analysis of each outcome.

Outcome	Stata code

Primary Outcome:	```mixed phq_ads i.TreatmentNo##i.timepoint country phq_ads_B || ClusterID: || StudyNo:, satterthwaite```
	
	 ```mixed ICECAP_A i.TreatmentNo##i.timepoint country ICECAP_A_B || ClusterID: || StudyNo:, satterthwaite```

Secondary Outcomes:	```mixed outcome i.TreatmentNo##i.timepoint country outcome_B || ClusterID: || StudyNo:, satterthwaite```

Missing outcome imputation	```sort TreatmentNo```
	```forvalues i=1/2 {```
	``` keep if TreatmentNo==`i'```
	``` tempfile imputation`i'```
	``` mi impute chained outcomes, ///```
	``` age gender country timepoint```
	``` add(30) by(clusterID) ///```
	``` rseed(61278)```
	``` save `imputation`i'', replace```
	``` use followup_data.dta, clear```
	``` }```
	```use `imputation1', clear```
	```append using `imputation2'```

13.3. Randomisation Specification

Randomisation Specification for the SHARPS cluster randomised trial version 1.0
Trial Title: Effectiveness and cost-effectiveness of a peer-delivered, relational, harm reduction intervention to improve mental health, quality of life, and related outcomes, for people experiencing homelessness and substance use problems: The 'SHARPS' cluster randomised controlled trial.
Chief Investigators: Professors Tessa Parks, University of Stirling & Graeme MacLennan, University of Aberdeen.
1. Introduction
This document outlines the randomisation plan for the SHARPS cluster randomised trial. The trial aims to evaluate the effectiveness and cost-effectiveness (compared with standard homelessness care) of a 12-month Peer Navigator-led, co-produced, relational, harm reduction and PIEs intervention for adults who are experiencing homelessness and problem substance use, in improving mental health, quality of life, and related outcomes, within social care settings. The design 2-arm pragmatic cluster RCT across social care homelessness settings in 20 cities/towns in England and Scotland.
Briefly here, the allocation will take part in two sperate allocation procedures because we do not have a common set of covariates with comparable data for both Scotland and England. Therefore, we will stratify allocation by country.
Table 1 – version history

Version number	Updates and reasons	Date
1.0	First draft	10/04/2023

2. Randomisation Method
We will allocate clusters to intervention and control group using covariate constrained randomisation. This approach minimises imbalance on cluster level covariates, which is a potential risk in cRCTs with fewer clusters, stratified by country (Scotland versus England).
3. Randomisation Procedure and minimisation covariates
We will use Carter and Hood's (2008) algorithm to optimise balance on the following for clusters located in Scotland:
- Demographic characteristics: population size, % population identify as white, % population income deprived, % working age population employment deprived.
- Mental health: suicide rate per 100,000.
- Risk behaviours: adults in drug treatment per 1000, adults in alcohol treatment per 1000, adults in co-dependency treatment per 1000, drug-related deaths per 100,000, alcohol-specific deaths per 100,000, alcohol-related hospitalisations per 100,000.
- Homelessness: households assess as homeless per 1000 households, households in temporary accommodation per 1000 households.

- Number of TSA services.

And for clusters located in England we will use the following:
- Demographic characteristics: population size, % population identify as white, deprivation score (IMD 2019).
- Mental health: suicide rate per 100,000.
- Risk behaviours: adults in drug treatment per 1000, adults in alcohol treatment per 1000, drug-related deaths per 100,000, rate of alcohol dependency per 1000, proportion of opioid and/or crack-cocaine users not in treatment.
- Homelessness: relief duty owed per 1000.
- Number of TSA services.

These data will be obtained from area profiles published by the Office for Health Improvement and Disparities/Public Health Scotland.

5. Implementation

The Carter and Hood algorithm is implemented in R. The scripts to run the algorithm will be saved in the SHARPS drive. The tables of covariates are in Section 9 below. The allocation will take place in two batches in the following manner.

1. An independent statistician will run the Stata code outlined in section 10 below to
   a. Randomly allocate groups A and B to intervention and control. The independent statistician will send this information directly to the trial manager in Stirling, this will be treated as confidential information until both English and Scottish sites are allocated.
   b. Generate a random number to select one of the optimally balanced designs, one number for Scottish sites (either 1 or 2) and one number for English sites (between 1 and 5).

   These random numbers will be concealed from the statistician implementing the Carter and Hood algorithm in R.

2. The 6 Scottish sites will be allocated into two groups labelled A and B using the Carter and Hood algorithm. A constraint is that Glasgow and Edinburgh cannot be in the same allocation. Any optimally balanced design that includes Glasgow and Edinburgh in the same allocation will be discarded. The remaining optimally balanced designs will be ranked from lowest (rank 1) imbalance score to highest. The random number will be revealed by the independent statistician, design with this rank will be selected as the allocation for Scotland. The trial statistician will then send the allocation of Scottish sites labelled group A and group B to the trial manager in Stirling via a password protect file. The trial manager will confirm receipt via email, this confirmation of receipt will be saved in the allocation folder.

3. The 14 English sites will be allocated into two groups labelled A and B using the Carter and Hood algorithm. A constraint is that London and Birmingham cannot be in the same allocation. Any optimally balanced design that includes London and Birmingham in the same allocation will be discarded. The remaining optimally balanced designs will be ranked from lowest (rank 1) imbalance score to highest. The random number between 1 and 5 will be revealed by the independent statistician, design with this rank will be selected as the

allocation for England. The trial statistician will then send the allocation of English sites labelled group A and group B to the trial manager in Stirling via a password protect file. The trial manager will confirm receipt via email, this confirmation of receipt will be saved in the allocation folder.

6. Monitoring and Quality Assurance

Extensive testing on dummy data has been carried out, the script code has been verified by two statisticians.

7. Blinding

In an attempt to blind researchers collecting outcome data, all participants will be recruited and consented into the study by members of the research team who are not involved in the quantitative data collection. We will also provide guidance to TSA staff to ensure they are aware that they must not discuss the study with Researchers. Researchers will be required to record and report any breaches that occur where the condition of the cluster is revealed to them. We will review all breaches if any occur following the 6-month data collection point. However, even if we are unable to maintain blinding of Researchers, data collection will go ahead as planned.

Intervention participants, Peer Navigators, TSA staff and core research staff including statisticians and health economists will not be blinded to intervention allocation. Given the nature of the intervention, it is not possible to blind participants and TSA staff as the presence of Peer Navigators in these services will be known to these groups. It is also useful for statisticians to know which participants are intervention vs. control as this can help with safety in terms of monitoring mental health and other outcomes given the vulnerability of the population. To address potential bias concerns, full plans for statistical analysis of outcome data will be pre-registered (the practice of registering hypotheses, methods, and planned analyses online prior to any data analyses).

8. References

Carter, B.R., Hood, K. Balance algorithm for cluster randomized trials. *BMC Med Res Methodol* **8**, 65 (2008). https://doi.org/10.1186/1471-2288-8-65