STATISTICAL ANALYSIS PLAN (SAP)

Test & Learn: Outreach services with a health specialism for people sleeping rough - optimisation and pilot cluster randomised controlled trial

Study ISRCTN number:	ISRCTN11572394	SAP version number:	2.0 (27 April 2026) Final APVD
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SAP REVISION HISTORY

Protocol version	Updated SAP version number	Section number changed	Description and reason for change	Date changed
2.0	Draft 1.1	Various	CHI feedback.	19/08/2025
2.0	Draft 1.2	Roles and Responsibilities Sample size	Change of CI and Statisticians. Adding on Professor Jim Lewsey's (TSC statistician's) comments on sample size.	03/11/2025
3.2	V2.0	Statistical analysis: sensitivity analysis,	Change suggested by CI after discussion with CHI. Change based on discussion in TSC meeting.	22/04/2025

		missing data analysis, additional analysis Feasibility criteria	Updated following minor modification of protocol V3.2.	

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ABBREVIATIONS

AE	Adverse Event
CGL	Change, Grow, Live
CHI	Centre for Homelessness Impact
CI	Confidence Interval
cRCT	Cluster Randomised Controlled Trial
CRi	Crime Reduction Initiative
CRiiS	Crime Reduction Initiative Information System
CTR	Centre for Trials Research
DECIPHer	Centre for Development, Evaluation, Complexity and Implementation in Public Health Improvement
EQ-5D-5L	EuroQol Five Dimensions Five Levels Quality of Life Questionnaire
ICC	Intraclass Correlation Coefficient
IQR	Interquartile Range
ITT	Invitation to Tender (like Intention to treat)
LA	Local Authority
LNNM	London Network of Nurses and Midwives
MHCLG	Ministry of Housing, Communities and Local Government
NICE	National Institute for Health and Social Care Excellence
PPI	Public and Patient Involvement
QC	Quality Control
RTLFB	Residential Timeline Follow Back Inventory
SAE	Serious Adverse Event

SAP	Statistical Analysis Plan
SD	Standard Deviation
SOP	Standard Operating Procedure

CONTENTS

1. INTRODUCTION

In this Statistical Analysis Plan (SAP), we describe a detailed methodology for the final statistical analysis of the Test & Learn pilot cluster randomised controlled trial (cRCT). This SAP will be kept in the electronic trial master file (eTMF) along with all other documents in this trial. This SAP will be used to provide input to the statistical sections of the funder report. In the final analysis and reporting, any deviations from this SAP will be logged and justified. The final analysis for reporting the study will be conducted by the authors of this SAP or any other experienced statistician available to the trial at the time of the final analysis, who will ensure the data integrity during analysis following the strict guidelines of the Centre for Trials Research (CTR) at Cardiff University as laid out in relevant standard operating procedures (SOPs) and funder guidelines. This analysis plan has been reviewed by the Chief Investigator and former senior trial statistician (RCJ) and agreed by the Trial Management Group before sign-off by the author (senior trial statistician, MR), and the chief investigator (RCJ/PM). A copy of this SAP will be sent to the Trial Steering Committee for review, and their comments will be accommodated as appropriate.

This SAP is only for the quantitative elements of the study. To ensure consistency, some of the sections of this analysis plan have been directly replicated from the Test & Learn study protocol (version 2.0) [1].

2. BACKGROUND

2.1 RATIONAL AND RESEARCH QUESTION

People experiencing homelessness (rough sleeping), experience poorer health outcomes than those who are housed [3-5]. The challenge of accessing appropriate healthcare is perceived to be a major hurdle to better health outcomes amongst people rough sleeping; inflexible services in inaccessible locations are deemed to be particularly problematic [6-7].

The National Institute for Health and Social Care Excellence (NICE) [8] guidelines on integrated health and social care for people experiencing homelessness set out recommendations that seek to address this challenge. For people rough sleeping, the NICE key recommendation is outreach services provision with a health specialism [8]. This intervention is increasingly widespread across the UK, though far from ubiquitous.

As part of the process of supporting people to access and receive immediate healthcare, service users can also be supported beyond the initial on-street contact to support them in accessing appropriate accommodation. The effects of the intervention on housing outcomes remain

underexplored and despite signs of positive health outcomes, [9] concluded that randomised study designs are required to more robustly evaluate the effectiveness of this approach.

To respond to this research gap, we are conducting a pilot cRCT of Health Outreach services for people rough sleeping on the streets in Local Authorities (LAs) in England. With a particular focus on housing outcomes, this study will focus on nurses working with outreach teams to support people rough sleeping who are living on the streets. The intervention will be oriented around an assertive outreach approach that seeks to support people to exit rough sleeping [10].

2.2 OBJECTIVES

The aim is to conduct a pilot cRCT to determine suggestive evidence of the intervention impacts and the viability of the trial methods. The research questions are:

1 **Intervention viability**
- 1.1 Is the intervention acceptable to service users, LAs, and nurses?
- 1.2 Are the intervention delivery staff able to engage service users?
- 1.3 Is the intervention delivered with fidelity?

2 **Defining treatment as usual**
- 2.1 Is it possible to accurately describe treatment as usual in control sites?

3 **Trial methods: randomisation and recruitment of LAs**
- 3.1 Is randomisation acceptable to LAs and why/why not?
- 3.2 What proportion of recruited LAs are retained throughout the trial?
- 3.3 Are there any potential ethical, practical, statutory, or other legal barriers that impact recruitment and randomisation processes?

4 **Trial methods: data collection procedures**
- 4.1 Are methods of data collection feasible and what refinements (if any) are needed?
- 4.2 To what extent can service users be followed up for data collection purposes?
- 4.3 What proportion of data is collected and completed for service users at baseline and follow-up?
- 4.4 Are outcome measures suitable and what refinements (if any) are needed?

5 **Impacts**
- 5.1 What are the potential impacts of the intervention on the housing situation of service users?
- 5.2 What are the potential impacts of the intervention on the health of service users?

3. STUDY MATERIALS

3.1 TRIAL DESIGN

This is a two-arm, parallel-group, open-label, multicentre pilot cRCT examining the feasibility of LAs receiving funding to embed a health professional (a qualified nurse) as part of the outreach team for people rough sleeping living on the streets in LAs in England. The trial statisticians are kept blind to the allocation of LAs/service users to study arms.

3.1.1 Intervention

The intervention comprises four key components:

1. Standard and bespoke nurse training;
2. Balanced outreach and desk-based shifts;
3. Nurse supervision and quality assurance;
4. Service follow-up. Details of the intervention are described according to the TIDieR Framework in the protocol [1].

3.1.2 Control

Treatment as usual is street outreach without a health specialism. There can be significant heterogeneity across street outreach services. Details of outreach delivery in comparator sites will be assessed through the process evaluation (not covered in this SAP).

3.2 RANDOMISATION

The randomisation plan as described in the study protocol [1] is reproduced here in this SAP. Each LA (a cluster) was the unit of randomisation. 16 eligible LAs were randomly assigned by an independent statistician in a 1:1 ratio (8 LAs per arm) to receive funding to embed a health professional (a qualified nurse) as part of the outreach team or remain with their usual practice (control). Block randomisation of varying sizes was used, stratified by the Rough Sleeping Initiative (RSI) funding allocation 2022-2025 per rough sleeper (£) of the 16 eligible LAs. LA RSI Strata (low risk, high risk) were created based on the median RSI funding allocation of the 16 LAs. The rationale for selecting the LA RSI funding allocation per rough sleepers population as a balancing variable is because it is likely to be correlated with availability of rough sleeping services it is ringfenced for. The availability of services is likely to influence the outcomes of the housing situation in a future RCT. A random allocation sequence was generated in blocks using the *ralloc* program in Stata 18. Further details on the randomisation process can be found in the randomisation protocol [2].

3.3 SAMPLE SIZE

This sample size statement is reproduced from the study protocol [1]. The study is aimed at evaluating the feasibility of a full-scale cRCT and determining recruitment and response rates, estimates of effect sizes and intra-cluster correlation coefficients for the primary outcome in a future full-scale cRCT with other sources of evidence, as well as providing in depth knowledge on the views and experiences of health outreach workers and people who received care.

A sample size calculation was provided by Centre for Homelessness Impact (CHI) based on the number of LAs and service users that could viably be recruited within the time and budget available. The sample size was based on 80% power, 5% alpha, a minimum detectable effect size (MDES) of 0.53, an average cluster size (LA) of 40 service users, ICC of 0.1, allocation ratio 1:1, and 10% attrition [1]. We therefore aim to randomise 16 clusters (LAs) with 8 to receive funding to embed a health professional as part of the outreach team (a qualified nurse) and 8 to remain with their usual practice, with a total of 711 LA service users required in total.

However, this is a pilot cRCT, and for pilot and feasibility trials, while a sample size justification is important, a formal sample size calculation may not be appropriate [37]. Therefore, the above mentioned sample size is suggestive only, and analysis will be conducted on the sample size we achieve at the end of the trial.

3.4 FRAMEWORK

This trial investigates the feasibility of a future full-scale trial.

3.5 INTERIM ANALYSES

There are no interim analyses.

3.6 PLANNED SAMPLE SIZE ADJUSTMENT

As this is a feasibility study, there are no plans to adjust the sample size.

3.7 STOPPING RULES

Not applicable: this is a pilot cRCT.

3.8 TIMING OF FINAL ANALYSIS

In this study, end of trial is defined as the date on which data for all service users are frozen after the last service user has had their 6-month follow-up routine data collected.

3.9 TIMING OF ALL DATA COLLECTION AND OUTCOMES ASSESSMENT

All primary and secondary outcomes will be assessed at baseline and at 3- and 6-month post randomisation follow-up (Table 1).

Table 1: Data collection schedule

Data (variables)	**Data collection time points**		
	Baseline	**3-month follow-up**	**6-month follow-up**
Randomisation of LAs	X		
LA RSI Strata	X		
Name of randomised LAs:	X		
Service users' enrolment	X		
Service users' demographics (Appendix D)	X		
LAs Retention	X	X	X
Service users' retention		X	X
Intervention Fidelity	X	X	
Primary outcome: Housing status (Appendix A)	X	X	X
Health Related Quality of Life: EQ-5D-5L and EQ-VAS) (Appendix B)	X	X	X
Resource Use: Health services (Appendix C)	X	X	X

4. STATISTICAL PRINCIPLES

4.1 LEVELS OF CONFIDENCE AND P-VALUES

A two-sided type I error level of 5%, corresponding to a two-sided 95% confidence level, will be used for the statistical analysis. When reporting the results, we will present point estimates and 95% confidence intervals (CIs), but p-values will not be reported.

4.2 ADJUSTMENT FOR MULTIPLICITY

As a pilot, our analyses are exploratory rather than confirmatory; no statistical hypothesis testing will be performed, and no p-values will be reported. Therefore, no adjustment for multiplicity will be undertaken.

4.3 ADHERENCE AND PROTOCOL DEVIATIONS

Non-adherence and protocol deviations will be handled according to CTR SOP/009/5 (Protocol/GCP non-compliance and serious breaches).

4.4 DEFINITION AND ASSESSMENT OF ADHERENCE

In this study, service users' adherence to the intervention is not recorded as such because the intervention is delivered by a nurse who visits the service user. However, a record of how many times a service user was seen by the visiting nurse over the study period is kept.

4.5 PRESENTATION OF ADHERENCE

We will present the above-mentioned adherence descriptively.

4.6 DEFINITION OF PROTOCOL DEVIATION

Non-compliances of GCP and/or protocol will be categorised as either a deviation, violation or serious breach according to CTR SOP/009/5. A planned or unplanned departure from the study protocol that does not increase risk or decrease benefit or does not have a significant impact on the service user's rights, safety or welfare; and/or on the integrity of the data is called a protocol deviation. An unplanned departure from the protocol or GCP that increases the risk or decreases the benefit; or may have an impact on the service user's rights, safety or welfare; and/or on the integrity of data, is called a protocol violation. A breach of the protocol or GCP which is likely to significantly affect the safety or physical or mental integrity of the trial service users or the scientific value of the trial is known as a serious breach. This is not a trial of an investigational medicinal product, and we do not expect any serious breaches and violations.

4.7 PRESENTATION OF PROTOCOL DEVIATIONS

Any deviations will be summarised descriptively by the study arms.

4.8 ANALYSIS POPULATION

This pilot cRCT is conducted in England. All LAs that returned an expression of interest to CHI were eligible for the sampling frame. CHI selected 16 LAs areas in England for the study, based on assessment and scoring, with CTR randomising LAs to the two study arms [2]. People from these LAs (service users), living on the streets (defined as seen sleeping on the streets on at least six separate occasions over a period of up to 6 months) and included within CGL or LAs routine rough sleeping data collections (routine data), comprise the analysis population. If a LA

withdraws before data collection, then the LA will be replaced with another randomly selected recruited LA and service users from this LA will be included in the analysis.

The primary analysis will be conducted as intention-to-treat (ITT), meaning that all service users with available outcome data will be analysed based on their allocation as determined by the randomisation, regardless of how much intervention the service user is exposed to. We will explore the data if any of the service users in the intervention have not seen the visiting nurse at least once during the study period. Then, we will conduct a separate sensitivity analysis including only those service users who have seen the visiting nurse at least once in the intervention arm, and everyone in the control arm. We will also explore not re-classifying service users with a housing status of Institution, and we will exclude them from the time point.

4.9 STUDY POPULATION

4.9.1 SCREENING DATA

No screening data will be collected by CGL as everyone entered onto their database is eligible. We will not be collecting data/reporting numbers on ineligible service users.

4.9.2 ELIGIBILITY

The following criteria for inclusion in this study are described in the study protocol [1]:

Table 2: Pilot cRCT Inclusion and Exclusion Criteria

	Inclusion criteria	**Exclusion criteria**
Local Authority recruitment	• Have sufficient numbers of people rough sleeping to potentially receive health outreach support (expect around 40 people rough sleeping to come through the service during the baseline period). • Have an outreach team. • Be in reasonable distance (defined by CHI) to a CGL clinical service (to act as a clinical base to host the nurse). • Willingness to be involved and support data collection procedure.	• Local Authority areas which already have an embedded health specialist who does shifts with the local outreach team.
People living on the streets and included within Local Authority	• People living on the streets (defined as seen sleeping on the streets on at least 6 separate occasions over a period of up to 6 months) and	• People rough sleeping who are not living on the streets and not included in

and CGL routine data collections	included within CGL or Local Authority routine rough sleeping data collections.	LA or CGL routine data collections.

4.9.3 RECRUITMENT AND ENROLMENT OF LAs

A detailed recruitment plan is available in section 6.2 of protocol version 1.0 [1]. Recruitment and enrolment relate primarily to the initial enrolment of LAs into the study. Data collection on outcomes for service users will be captured through amended routine data collections by LAs and CGL nurses/staff.

4.9.3.1 Local Authorities

Expressions of interest from single LA areas or adjacent LAs who share both an outreach provider and are in the same integrated care system sub-region were sought. Interested LAs completed an online application for consideration and screening against inclusion and exclusion criteria as documented in table 2 above and in Appendix A in the study protocol. CGL is working across all trial sites to support sites by collating and extracting routine data from their standard outreach services. CGL has appointed a team member to this routine data collection role.

4.9.3.2 Routine data relating to people rough sleeping

Local Authorities and CGL will be guided by the evaluation team to adapt their routine data collection for the duration of the study so that data across sites is uniform and can be pooled for sharing, and to include the primary and secondary outcome measures. Routine data will be collected via outreach workers/CGL nurses/CGL team members during service delivery and will be utilised to capture demographic characteristics and to measure baseline and follow-up housing and health outcomes, and health service usage of people living on the streets in intervention and control sites. MHCLG will be the data controllers for this trial and all other Test and Learn trials as part of the wider consortium. They will publish a privacy notice explaining what data is being collected, for what purpose, and on what legal basis. This privacy notice will explain that routine data will be shared with Cardiff University for analysis.

4.9.4 WITHDRAWAL/LOSS TO FOLLOW UP

4.9.4.1 WITHDRAWAL

4.9.4.1.1 Withdrawal of Local Authorities

If a LA wishes to withdraw from the study, it will be confirmed in writing and the CTR team will be notified by CHI. If a LA withdraws:

- **before recruitment has started** (data collection on service users has not commenced), then we will replace with another randomly selected recruited LA, and it will retain the allocation of the LA that withdrew.
- **after recruitment has started** (data collection on service users has commenced), and the LA will have started and should not be replaced. Individuals already recruited to the trial, should be retained for analysis and followed up as normal unless the LA withdraws fully from the trial and follow-up.

Note, this data is collected by the research team for the purposes of the study; CGL manage their own withdrawal data collected for health/treatment service delivery.

4.9.4.1.2 Withdrawal of service users

The Ministry of Housing, Communities and Local Government (MHCLG) is the "data controller". MHCLG are responsible for determining what personal information is collected and how it is used. Service users can find more information about their rights at Homelessness and rough sleeping: Outreach with a health specialism: privacy notice - GOV.UK.

Service users may ask to withdraw from the study by getting in touch with MHCLG using the contact details in section 11 of this privacy notice. The statistical element of the trial concerns the collection and use of routine data supplied by LA sites, managed in a central CGL database. If a service user requests to withdraw from the study and the CTR team is directed by CGL or MHCLG to not include their data in the trial, we will exclude them from the analysis.

4.9.4.2 LOSS TO FOLLOW-UP

Individual service user routine data collection and retention is managed by nurses and outreach workers and a CGL team member. Service user interview engagement and participation is managed by nurses and outreach workers and an evaluation team member. CGL will make every effort to reduce the rate of loss to follow-up using the methods listed below:

i. The importance of getting follow-up data is emphasised to all service users at baseline and at the follow-up assessment.

ii. The embedded researcher at CGL will work with outreach teams to improve retention, and can collect the housing status data from the outreach teams where agreed.

iii. Data collection team have a four-weeks window for the follow-up assessment (questionnaires) to be completed. CGL are responsible for tracking the data collection for follow-up.

4.9.4.3 PRESENTATION OF WITHDRAWAL/LOSS TO FOLLOW-UP

We will describe the baseline characteristics of participants either lost to follow-up or withdrawn from the study, participants remaining in the study and all participants, as recommended by CHI guidance [11]. Attrition data will also be presented into the CONSORT flow diagram.

4.10 BASELINE CHARACTERISTICS

Local Authorities:

- Region
- RSI funding allocation 2022-2025 strata
- Randomisation arm (intervention, control)

Service users' demographics and baseline characteristics (Appendix D):

- Age at first contact
- Sex
- Gender
- Nationality (UK, EEA, Non-EEA)
- Care experienced
- Left an institution/armed forces in the last 85 days

Outcomes:

- Housing situation (Appendix A)
- Health-related quality of life: EQ-5D-5L and EQ-Vas (Appendix B)
- Resource use: Health service questionnaire (Appendix C)

4.11 DESCRIPTIVE STATISTICS

Normality of continuous variables will be examined using histograms or boxplots. As appropriate, continuous variables will then be summarised using mean and standard deviation (SD) or median and interquartile range (IQR) while categorical variables will be summarised using frequency and percentage (%). Frequency (%) of missing values will also be reported for each variable. All baseline characteristics will be presented by the study arms (intervention vs treatment as usual) so that any differences of the baseline variables can be examined descriptively. The baseline data may also be plotted using appropriate methods such as bar graphs, histograms, and boxplots.

5. STATISTICAL ANALYSIS

5.1 PRIMARY OUTCOMES DEFINITIONS

5.1.1 Evaluation feasibility criteria of the pilot cRCT

The primary outcome for this pilot cRCT is the evaluation feasibility criteria that will determine the viability of the trial methods, the fidelity, and acceptability of intervention delivery, and it will determine whether a full-scale RCT of the intervention is warranted. The criteria are presented in the following table (Table 3) and will be examined by the independent Trial Steering Committee (TSC).

These criteria will be assessed using a traffic light system (green: all criteria are met; amber: the majority of criteria are met and with adaptations to methods all criteria could be met; red: the minority of criteria are not met. These criteria should be applied with discretion as during the study solutions to substantively improve each may be identified.

Table 3: Feasibility Criteria

Trial methods	**Red**	**Amber**	**Green**
1. Successful recruitment and randomisation of 16 Local Authorities	<10	10-15	16
2. 12 Local Authorities remain in the pilot study	<10	10-11	≥12
3. Primary outcome data is collected for more than 60% of service users at the final follow-up (6-months)	<50%	50-60%	>60%
Intervention			
4. The intervention being delivered with fidelity	Low	Medium	High
5. The intervention is acceptable to service users, Local Authority staff, and nurses	Low	Medium	High

5.1.2 Primary housing outcome (categorial)

The Residential Timeline Follow-Back (RTLFB) inventory distinguishes between three main types of housing situation: homeless, not homeless, and living in an institution (i.e., a prison, probation facility, hospital or asylum support accommodation) and will be determined at each follow-up time point (baseline, 3 and 6 months).

The primary housing outcome is the Level 2 service users' housing situation as defined using the housing outcomes listed in the CHI adapted version of the (Appendix A - Level 2) [1]. For service users where valid data is provided, we will determine their housing situation in the following way:

Housing outcome Level 2 – ordinal:

- Rough sleeping,
- Hidden, temporary and/or unstable,
- Stable but insecure,
- Stable but secure,
- Institution.

5.2 TIMING, UNITS AND DERIVATION OF PRIMARY OUTCOME

The primary outcome listed in the RTLFB provide a point-in-time assessment on a service user's housing situation at each follow-up These housing outcomes are added to LA routine data collection. Housing situations of the service user are collected at baseline, 3-month and 6-months follow-up timepoints.

5.3 LIST OF SECONDARY OUTCOMES

- Housing outcome Level 1 – Categorical (Binary): Homeless, not homeless, institution
- Housing outcome Level 3 – Categorical: All twelve individual categories (A1 to E12)

The categories in level 1 & 3 are described in Appendix A.

- Health status: Health-Related Quality of Life (HRQL: Appendix B)
- Resource use: interactions with health services (Appendix C)

5.4 ORDER OF TESTING

Not applicable.

5.5 TIMING, UNITS AND DERIVATION OF SECONDARY OUTCOMES

For the secondary outcomes of housing status Level 1 & 3, see the description of primary outcome of housing Level 2 in section 5.1.2 above. The description of the other two secondary outcomes is as follows:

Health-related quality of life (HRQL) - EQ-5D-5L

The EQ-5D is a health-related quality of life (HRQL) instrument that has been validated in various contexts [12-16]. It is a 5-item questionnaire (EQ-5D-5L) with an additional EQ visual analogue scale (EQ-VAS). The visual analogue scale gives a quantitative measure of the service user's self-reported state of their overall health.

The EQ-5D-5L is a descriptive system of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) rated with five levels: 1. no problems, 2. slight problems, 3. moderate problems, 4. severe problems, 5. unable to/extreme problems. Service users rate their health status on the scale by selecting an appropriate response out of the above-mentioned five levels [12]. Service users' responses for each item are collected at baseline and follow-ups (3 and 6 months) and are combined to compute a score (index) determining service user's health state at each time point. We will use a readily available Stata program implemented in Stata via command "eq5dmap" which can map EQ-5D-5L (current version with 5 levels scale) to EQ-5D-3L (older version with 3 levels scale) to compute the EQ-5D-5L index (score).

The EQ VAS records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled 0 = 'The worst health you can imagine' and 100 = 'The best health you can imagine' (Appendix B). The VAS gives a quantitative measure of the service user's self-reported state of their overall health.

Resource use: interactions with health

Basic data on health service interactions/health service resource use are captured using questions adapted from the MHCLG Rough Sleeping Questionnaire (RSQ) (Appendix C). Service users will be asked to complete this at the baseline, 3-month and 6-months follow-up time points. This is not a validated measure. The service interaction types are routinely captured by MHCLG in the RSQ. In this, frequencies of GP visits, Accident & Emergency visits, Receiving an Ambulance call out, attending a Mental Health appointment, attended an outpatient hospital appointment, a mental health hospital stay, been admitted into hospital, receiving drug use treatment, receiving alcohol use treatment are collected.

5.6 ANALYSIS METHODS

A detailed approach to the statistical analysis is provided below. The findings will be reported in accordance with the CONSORT guidelines for pilot RCT and cluster RCTs. All analyses will be on an ITT approach.

5.6.1 LIST OF METHODS AND PRESENTATION

5.6.1.1 Unit of analysis

For all statistical analysis, individuals (service user) will be the unit of analysis. LA (cluster) will be the unit of analysis if any analysis is aimed at LAs such as description of LAs.

5.6.1.2 Description of the trial sample by the arms

Baseline characteristics of both the service users (e.g. age, sex, gender, nationality, care experienced, left an institution in the last 85 days, EQ5D, EQ VAS, housing situation) and LAs (e.g. region, RSI funding allocation 2022-2025 strata); these will be described for the overall sample by the trial arms and summarised using descriptive statistics as stated above in section 5.11. If there is a substantial missingness in the primary outcome of interest due to withdrawal or loss to follow-up, summary statistics of the baseline variables will be presented separately for those with and without missing data, respectively, as well as by the study arms.

5.6.1.3 Analysis of the feasibility criteria

The primary analysis of the pilot cRCT will determine whether the prespecified evaluation feasibility criteria (i.e., the viability of the trial methods, the fidelity, and acceptability of intervention delivery) are met. A CONSORT flow diagram will show the number of LAs recruited and randomised, and withdrawals after randomisation of LAs as well as the number of service users, completion of baseline and follow-up data. The feasibility criteria, relating to data collection on the primary outcome at follow-up will be reported as point estimates with 95% confidence intervals (CIs) (Campbell et al, 2012; Eldridge et al, 2016). We will also describe the number of interim contacts over the 6 months follow-up period by the study arms.

5.6.1.4 Analysis of the primary outcome (housing situation)

The aim of the potential primary outcome analysis will be to pilot the analyses and descriptively examine effectiveness of the intervention in terms of housing situation of the service users at follow-ups as well as determine an effect estimate for a future full scale trial if warranted and feasible to be conducted. As this is a pilot cRCT, not powered for effectiveness, point estimates and 95% CIs will be presented but p-values for hypothesis testing will not be reported [17]. It is important that these tests are interpreted in the context that they are not fully powered such that a small effect would not suggest the intervention was ineffective. However, if the 95% CI indicates significant benefit, then another full-scale trial may not be necessary.

For each service user, housing situation via the RTLFB inventory will be determined at each follow-up time point (3- and 6-months). We will describe the rates of completion of housing status using frequencies and proportions. In service users providing valid data, we will summarise their housing situation using frequencies and proportions of the following housing outcome:

Housing outcome-level 2:

- 1= rough sleeping
- 2= hidden, temporary and/or unstable
- 3= stable but insecure
- 4= stable but secure
- 5=institution

If a service-user reports to be in an institution (e.g. prison, probation facility, hospital or asylum support accommodation) at the time of follow-up, they are neither defined as homeless or not homeless. For this reason we will use the additional definition of homelessness developed by Residential TLFB Inventory of 'functional homelessness' [18]. The Residential TLFB Inventory developed rules that detailed when an institutional setting would be considered functional homelessness e.g., a psychiatric hospitalisation (institutional setting) would not be considered functionally homeless if a service-user was living in a stable setting (i.e. not homeless) prior to the hospitalisation and returned there once discharged. However, if the service-user was rough sleeping prior to hospitalisation and returned to the street upon discharge, then they would be considered functionally homeless for that entire duration. For this reason, if a service-user reports to be in an institution at the time of follow-up we will take their previous housing situation for the purpose of the analysis; this will be used for of all levels of categorisation.

For the primary housing outcome level 2, the analysis will use a mixed-effects generalised linear modelling techniques [19-25] to examine the intervention effect on Level 2 categorisation of housing situation at 6 months follow-up.

The model will contain the trial arms as a main fixed effect, will adjust for LAs RSI funding allocation 2022-2025, and will account for the nesting (random effect) of service users within LA, considering observations within the same cluster likely to be correlated (ignoring this can lead to underestimated standard errors and overstated statistical significance). We will not adjust for baseline measure of the outcome as all service users will be rough sleeping. A general equation of the mixed-effects generalised linear model [19-25] for our analysis can be described as follows:

$$g(X,u) = X\beta + Zu + \varepsilon$$

The fitted model can be formulated as below:

$$g\{E(X,u)\} = X\beta + Zu$$

where:

- $y \sim F$ (i.e., the outcome y follows a distribution F (e.g., normal, binomial, ordinal etc.))
- y is the (n×1) vector of responses from the distribution F such as for the outcome level 2, it takes values as (1=rough sleeping, 2= hidden, temporary and/or unstable, 3=stable but insecure, 4= stable but secure)
- Service users with institution housing will be excluded from the analysis.
- $X\beta + Zu = \eta$ is called a linear predictor and its terms are described as below:
- X is an (n×p) design/covariate matrix for the fixed effects β including the study arms (intervention=1 versus control=0) and LAs RSI funding allocation 2022-2025 strata (e.g., 0=low RSI funding allocation, 1=high RSI funding allocation) and other baseline covariates such as service users' age and sex.
- Z is the (n × q) design/covariate matrix for the random effects u assumed to be normally distributed with mean 0 and (q × q) variance matrix (Σ). In this study, it may be kept limited to the random effect of local authority (clusters) only matrix Σ.

The effect size will be reported as an absolute risk differences (intervention minus control) alongside 95% CIs, at each time point. Adjusted relative risk ratios for intervention versus control will be computed from the model presented alongside 95% CI. We will also estimate the clustering of outcomes by trial arm via intra-cluster correlation coefficients (with 95% CIs).

5.6.1.5 Analysis of the secondary outcomes

1. Housing outcome Level 1: binary outcome - 0=Homeless, 1=not homeless

For the secondary housing outcome-level 1, a similar analysis approach as mentioned above for the housing outcome-level 2 (primary outcome) will be adopted using mixed-effects generalised linear model. The outcome will be a binary outcome (homeless=0 vs not homeless=1) and a mixed effect logistic regression model with the assumption of binomial distribution, will be used to compute the point estimate as relative risk ratios alongside 95% CI.

2. Housing outcome Level 3: Categorical outcome - all twelve categories (A1 to E12)

For the secondary housing outcome-level 3 (ordinal: all twelve categories; 1=E12 to 12=A1, appendix A) will be included as a dependent variable. The mixed-effects generalised linear model will be fitted with the assumption of ordinal distribution, a logistic link function, and a suitable linear predictor including a random effect of the Local Authority, and a suitable linear predictor including a random effect of the Local Authority.

3. HRQL (EQ-5D-5L)

We will describe the rates of completion of the health status outcome reporting the five items from the EQ5D using frequencies and proportions. The EQ5D score (index) will be computed and reported at each time point (baseline, 3 and 6 months) by the trial arms using means (SD), or median (IQR) as appropriate. To examine effectiveness of the intervention on EQ5D total score, similar modelling approach using a mixed-effects generalised linear model techniques [17-23], will be used. The outcome measure, EQ5D score (index) at 3 and 6 months follow-up, will be assumed to be normally distributed, and a mixed-effects generalised linear model will be fitted with the assumption of normality (F) including fixed-effects for the baseline EQ5D score, interactions of intervention arms and time points (3 or 6 months follow-up) and LAs RSI funding allocation 2022-2025 strata, and a random effect for the Local Authority. The model fit will be assessed using appropriate statistics including residuals, in case of any departure from the model assumptions, an alternative method of modelling such as Generalised Estimating Equation (GEE) will be explored. A similar approach of analysis will be used with the EQ visual analogue scale (VAS) score (between 0='The worst health you can imagine' and 100='The best health you can imagine'). The effect estimates from this analysis will be presented as adjusted mean differences at 3- and 6-months follow-ups with 95% CIs.

4. *Resource use- interactions with health*

Data are collected on frequencies of GP visits, Accident & Emergency visits, receiving an ambulance call out, attending a mental health appointment, attended an outpatient hospital appointment, a mental health hospital stay, being admitted into hospital, receiving drug use treatment, and receiving alcohol use treatment. The data of these secondary outcomes will be mostly used for the purpose of health economic analysis. However, we will describe each item listed above at each time point (baseline, 3 and 6 months) by the trial arms using means (SD), or median (IQR) as appropriate. However, we may create a total score (total frequencies) of all resources used by summing up the frequencies of all items and consider it as a continuous outcome. To examine effectiveness of the intervention on the total score, we will use mixed-effects generalised linear modelling techniques with a suitable distributional assumption such as Poisson or Negative Binomial distribution [19-25], will be used. The effect estimates from this analysis will be presented as adjusted mean differences at 3- and 6-months follow-up with 95% CIs.

In all analyses, model assumption will be evaluated to ensure a good fit of the model.

5.7 COVARIATE ADJUSTMENT

We have a priori decided a set of covariates including age, gender, care experienced, nationality, and LAs RSI funding allocation 2022-2025 strata as stated above in the primary outcome analysis section, we will adjust the effect of intervention on primary and secondary outcomes for these priori selected covariates in the regression models. For EQ-5D-5L and Resource use-interactions with health, the baseline measures are essential covariates as part of the model fitting.

5.8 ASSUMPTION CHECKING

See sections 5.6 and 5.9.

5.9 ALTERNATIVE METHODS IF DISTRIBUTIONAL ASSUMPTIONS NOT MET

The housing outcomes (levels 1–3) consist of ordered categories and they will be modelled using an ordinal distribution. In cases where the outcome is binary, a binomial distribution will be used instead. The distribution of other secondary outcome measure such as EQ-5D-5L (Index score and EQ VAS) will be examined using histograms or boxplots; if there are any substantial departures from normality, transformations (e.g. logarithmic) will be attempted. If transformations do not improve the distributions of the outcome scores, assumptions of other suitable distributions (e.g. log-normal, Poisson, or negative binomial) will be considered. If the assumption of a suitable distribution is not appropriate for the continuous outcomes, non- or semi-parametric statistical methods such as GEE [26-30] and quantile regression [30-33] will be considered. As we mentioned above in the primary outcome analysis, for our categorical or dichotomous outcome, we will use mixed-effect multinomial/ordinal logistic [19-25, 31-34] or mixed-effect logistic regressions [26, 32] within the framework of mixed-effects generalised linear models [19-34].

5.10 SENSITIVITY ANALYSES

Although not required as this being a pilot trial, exploratory sensitivity analysis may be conducted based on a per-protocol population as defined in section 4.8. Any variation in follow-up across LAs will be described – this will include a summary of intervention exposure (e.g. nurse availability and duration across sites) by LAs. To examine the effect of nurses who left (stopped providing services in the intervention arm) in some of the LAs, we will conduct a sensitivity analysis by excluding those sites where nurses stopped services.

5.11 SUBGROUP ANALYSES

In a full scale RCT, analyses of a difference in treatment effect for subgroups might provide useful information. However, such analyses in a pilot trial are not applicable because the primary focus is not on making a definitive conclusion on the intervention effect or differences in effects between subgroups.

5.12 MISSING DATA

Missingness is likely to occur in the primary and secondary outcomes as well as in independent variables of interest other than the randomisation arms. The quantity and distribution of missing data will be determined. We will estimate the proportion of missing data for all covariates and outcomes. The patterning and percentage of missing data will inform the likely analytical strategy in a full-scale effectiveness trial. Using CHI guidance, if more than 5% of any variable (covariates and outcomes) is missing then we will examine whether those missing are conditional on covariates (e.g. age, sex, nationality, care experienced, left an institution in the last 85 days) or outcome data using logistic regression (to predict missingness). We will also use visualisation of missing data by using the R-package VIM. No imputation will be performed in this current pilot study. To examine patterns of attrition, we will describe missing in the outcomes data at follow-up by the study arms (intervention vs. control) by the follow-up time-points (3 months vs. 6 months).

In addition, we will describe whether follow-up differs systematically by key baseline characteristics by those missing vs not missing at the 3- and 6-months follow-ups and will use logistic regression models to examine whether any baseline characteristics predicts the missing follow-ups. These analyses will be conducted by the study arms.

5.13 ADDITIONAL ANALYSES

Service users' exposure time analysis

The definition of service user exposure time will depend on the patterns of data availability. A service users could be observed to have:

- completed last follow-up, OR
- lost to follow-up, OR
- withdrawal/death, OR

- the follow-up window ends.

Hence service users' exposure time is calculated as bellow: $SET\ (days) = [(Date\ of\ last\ fu\ or\ death\ or\ withdrwal, lost\ to\ fu\ or\ censoring\ (end\ of\ fu)) - (Date\ of\ baseline)] + 1$

Service users' exposure time (SET) will be graphically compared between the Intervention and Control using boxplots, histograms and Kaplan-Meier curve. SET will be described by the study arms and overall using Median (IQR) and Minimum-Maximum. SET will be categorised as (SET< 90 days, SET ≥90 and <180 days, and SET ≥180 days) and will be presented as frequency (percentage-%) by the study arms and overall. The above stated presentation SET will be explored by the LAs by the study arms. Based on information available in the data, we will determine and report how SET is calculated for participants with incomplete follow-up, censored cases, deaths or moves out of area. The presentation of SET and the nurse exposures at 3 and 6 months follow will be presented by the sites.

5.14 HARMS

We are not recording serious adverse events (SAEs) for this study. The only adverse events (AEs) we will collect will be if the qualitative fieldworker experiences any AEs when out on site. These will be escalated to the appropriate outreach or safeguarding team and an adverse event form completed as an internal CU record (see Section 15.6 of the protocol [1]).

5.15 STATISTICAL SOFTWARE

The main software packages used for the statical analysis will be Stata version 18 [35] or R version 4.1.2 or higher [36] via RStudio (RStudio, Boston, MA, USA).

6. REFERENCES

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6.3 Data Management Plan

38. X:\339068351-TstLrn-p\eTMF\08. Data Management\8.1 Data Management\Data management/Test and Learn Data Management Plan v1.0 20250122

6.4 Trial Electronic Master File (folder)and Statistical Master File (folder)

39. X:\339068351-TstLrn-p\eTMFX:\339068351-TstLrn-p\eTMF\08. Data Management\8.5 Statistics

APPENDICES

APPENDIX A: PRIMARY OUTCOME MEASURE: HOUSING SITUATION

Which of these experiences best describes where you are staying now (please select only ONE option)?

A) A place you own or rent (including with others)

1. You own (as the sole or joint owner).

2. Rent from a private landlord (where you are the sole or joint tenant).

3. Rent from your local council or housing association (where you are the sole or joint tenant).

B) Staying with others

4. Owned or rented by friends or family where you live on a long-term basis, but do not have a tenancy agreement.

5. Owned or rented by friends or family where you live on a short-term basis. This includes sofa surfing.

C) In some form of temporary or supported accommodation

6. Emergency accommodation provided by a local council or charity, such as space in a night shelter or B&B.

7. Temporary accommodation provided by or on behalf of your local council, such as a hostel.

8. Supported accommodation, for example where there is a staff member on site or on call, and you are expected to stay long-term.

D) Sleeping rough

9. Rough sleeping, on transport or in a transport hub (bus stop or train station), in a tent or car, or stairwells, barns, sheds, derelict boats or buildings.

E) Other options

10. A prison, probation facility, hospital, asylum support accommodation or similar.

11. Squatting, including with others.

12. Accommodation linked to your work or studies, for example student accommodation, military accommodation or accommodation linked to a business.

<u>The data will be coded in three ways:</u>

Level 1	**Level 2**	**Level 3**
Homeless	Rough sleeping	• Rough sleeping, on transport or in transport hub (bus stop or train station), in a tent or car, or in stairwells, barns, sheds, derelict boats or buildings (D9)
	Temporary and/or unstable	• Temporary accommodation provided by or on behalf of your local council, such as a hostel. (C7) • Emergency accommodation provided by a local council or charity, such as space in a night shelter or B&B. (C6)
	Hidden	• A place owned or rented by friends or family where you live on a short-term basis. This includes sofa surfing (B5). • Squatting, including with others. (E11)
Not homeless	Stable but insecure	• A place owned or rented by friends or family where you live on a long-term basis, but do not have a tenancy or legal right. (B4) • Accommodation linked to your work or studies (E12) • Long-term accommodation classed as supported accommodation. (C8)
	Stable and secure	• A place you own (where you are the sole or joint owner) (A1) • A place you rent from a private landlord (where you are the sole or joint tenant) (A2)

		• A place you rent from your local council or a housing association (where you are the sole or joint tenant) (A3)
Institution	Institution	• A prison, probation facility, hospital or asylum support accommodation. (E10)

APPENDIX B: Health Related Quality of Life (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ❑
- I have slight problems in walking about ❑
- I have moderate problems in walking about ❑
- I have severe problems in walking about ❑
- I am unable to walk about ❑

SELF-CARE

- I have no problems washing or dressing myself ❑
- I have slight problems washing or dressing myself ❑
- I have moderate problems washing or dressing myself ❑
- I have severe problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

- I have no problems doing my usual activities ❑
- I have slight problems doing my usual activities ❑
- I have moderate problems doing my usual activities ❑
- I have severe problems doing my usual activities ❑
- I am unable to do my usual activities ❑

PAIN / DISCOMFORT

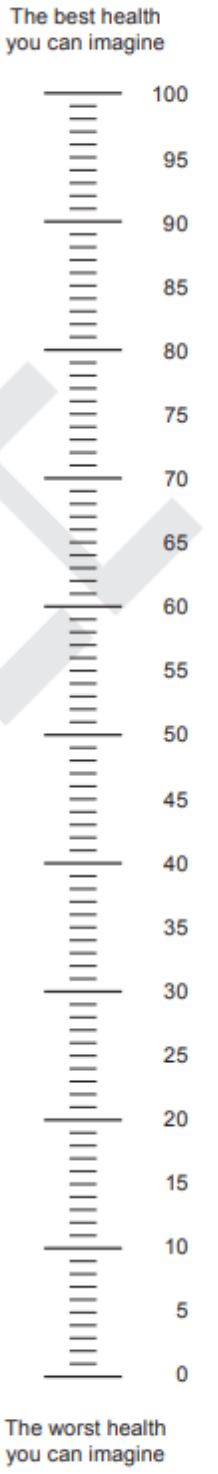
- I have no pain or discomfort ❑
- I have slight pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have severe pain or discomfort ❑
- I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

- I am not anxious or depressed ❑
- I am slightly anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am severely anxious or depressed ❑
- I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



APPENDIX C: RESOURCE USE: HEALTH SERVICES

In the last 3 months how many times have you experienced the following…?

	Frequency
Visited a **GP** (appointment or walk ins)	
Attended **Accident & Emergency**	
Received an **Ambulance** call out	
Attended a **Mental Health** appointment	
Attended an outpatient **hospital appointment**	
A **mental health hospital stay**	
Been **admitted into hospital**	
Received **drug use** treatment	
Received **alcohol use** treatment	

APPENDIX D: DEMOGRAPHICS (BASELINE ONLY)

Age (Database to calculate age and this should be reported, not date of birth):

Nationality:

UK national

EEA national

Non-EEA national

Unknown nationality

Prefer not to answer

Sex assigned at birth: Male

Female

Prefer not to answer

Gender identified as: Man

Woman

Trans Man

Trans Woman

Non-Binary

Other

Prefer not to answer

Are you care experienced? (i.e. previously looked after, accommodated or fostered by a Local Authority): Yes/No/prefer not to answer

In the last 85 days (12 weeks + 1 day) have you left an institution:

Prison (adult or youth): Yes/No/prefer not to answer
Other justice accommodation (e.g. accommodation provided by the National Probation Service (i.e. Approved Premises)): Yes/No/prefer not to answer
General and psychiatric hospitals: Yes/No/prefer not to answer
UK armed forces: Yes/No/prefer not to answer
Asylum support (previously 'National Asylum Support Services'): Yes/No/prefer not to answer