Centre for Homelessness Impact
Better evidence for a world without homelessness

Cardiff University Prifysgol Caerdydd
Centre for Trials Research
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Ministry of Housing, Communities & Local Government

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

V3.0
15.09.2025

Table 1: Impact Evaluation Summary

Project title	Test & Learn: Outreach services with a health specialism for people rough sleeping - optimisation and pilot cluster randomised controlled trial
Delivery Partner	Change Grow Live (CGL)
Evaluator	Cardiff University
Principal Investigator, and affiliation	Peter Mackie, Cardiff University
Co-Investigators, and affiliations	James White, Cardiff University Rebecca Cannings-John, Cardiff University Yvonne Moriarty, Cardiff University Rhiannon Evans, Cardiff University Rachel Brown, Cardiff University
Protocol authors	Peter Mackie, Rebecca Cannings-John, Yvonne Moriarty, Rhiannon Evans, Rachel Brown, Linda Adara, Muhammad Riaz, Mia Sydenham, Andrea Longman, James White
Impact evaluation design	**Phase 1:** Optimisation **Phase 2:** Pilot cluster Randomised Controlled Trial (cRCT)
Population	**Phase 1:** Stakeholders with experience of design and delivery of health outreach services for people rough sleeping **Phase 2:** People rough sleeping living on the streets in intervention and control sites, staff delivering the intervention, staff delivering usual practice in control sites, and Local Authority representatives (if site withdrawal from cRCT received)
Setting	**Phase 1:** Organisations delivering health-related outreach services and Local Authorities in England **Phase 2:** Local Authorities in England
Number of clusters	**Phase 1:** N/A **Phase 2:** 16
Target number of service users eligible for routine data capture	**Phase 1:** N/A **Phase 2:** 640 (estimated 40 per cluster)
Target number of interview participants	**Phase 1:** 10 stakeholders **Phase 2:** 18 service users, 12 staff
Primary outcome measure	**Phase 1:** N/A **Phase 2:** Housing situation

Secondary outcome measure	**Phase 1:** N/A **Phase 2:** Health status

Table 2: Protocol Version History

Version	Date	Reason for revision
2.0	28.05.2025	Change of CHI key personnel (Table 3 pg. 4 and 5). Study timeline updated 3-month extension (Table 4 pg. 15 and 16). Data flow diagram updated with 3-month extension (Figure 2 pg. 34). Inclusion of engagement and retention strategies (Section 8.2 pg. 39). Updated IPE plan (Section 11 pg. 45). Updated economic evaluation time horizons (Section 12.2.3 pg. 54).
3.0	15.09.2025	Change of Cardiff University Senior Trial Manager (maternity cover) and Key CHI Personnel Table 3 (pg. 4 and 5). Inclusion of routinely collected contextual data for IPE Table 4 (pg. 15). Correction to wording of EQ VAS self-rated health scale (pg. 36). Collection of interim contact data to include treatment, care or advice (anonymised) (pg. 38 and 39). Defining, coding, and analysis of institutional setting data (Section 10.4 pg. 42 and 43). Updated IPE plan (Section 11 pg. 45).

Table 3: Key Personnel and Team Contributions

Staff	Affiliation	Contribution
Peter Mackie	Cardiff University, School of Geography and Planning	Principal Investigator
Rhiannon Evans	Cardiff University, Centre for Development, Evaluation, Complexity and Implementation in Public Health Improvement (DECIPHer)	Optimisation Phase Lead
Rachel Brown	DECIPHer	Process Evaluation Lead

James White	Cardiff University, Centre for Trials Research (CTR) & DECIPHer	Trials Lead
Ken Gibb	University of Glasgow	Economic Evaluation Advisor
Yvonne Moriarty	CTR	Senior Trial Manager
Elinor Coulman (maternity cover from July 2025)	CTR	Senior Trial Manager
Linda Adara	CTR	Trial Manager
Rebecca Cannings-John	CTR	Senior Statistician
Muhammad Riaz	CTR	Trial Statistician
Mia Sydenham	CTR	Senior Data Manager
Andrea Longman	CTR	Data Manager
Christopher Usborne	CTR	Senior Administrator
Guillermo Rodriguez-Guzman (until August 2025)	Centre for Homelessness Impact (CHI)	CHI responsible, quality assurance, contribution to overall evaluation
Beth Isaac (from September 2024)	CHI	CHI Evidence Lead, quality assurance, contribution to overall evaluation design and delivery
Rebecca Jackson (until October 2024) Emily Ashmore (from September 2024 to December 2024) Paul Sargent (from December 2024 to May 2025) Moya Grassick (from June 2025)	CHI	CHI Programmes Lead, contribution to study design and delivery, recruitment of areas

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ISRCTN Registry: ISRCTN11572394

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*formerly known as the Department for Levelling Up, Housing and Communities (DLUHC)

Abbreviations:

CGL: Change Grow Live

CHI: Centre for Homelessness Impact

CRi: Crime Reduction Initiative

CRiiS: CRi Information System

cRCT: [Pilot] cluster Randomised Controlled Trial

CTR: Centre for Trials Research, Cardiff University

DECIPHer: Centre for Development, Evaluation, Complexity and Implementation in Public Health Improvement, Cardiff University

IPE: Implementation and Process Evaluation

ITT: Invitation to Tender

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

QC: Quality Control

RTLFB: Residential Time-Line Follow Back Inventory

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1. BACKGROUND

People experiencing homelessness, particularly those rough sleeping, experience poorer health outcomes than housed populations (Aldridge et al., 2018; Fazel et al., 2014; Lewer et al., 2019; Waugh et al., 2018). The challenge of accessing appropriate healthcare is perceived to be a major barrier to better health outcomes amongst this population; inflexible services in inaccessible locations are deemed to be particularly problematic (Elwell-Sutton et al., 2017; Omerov et al., 2019).

National Institute for Health and Social Care Excellence (NICE) guidelines on integrated health and social care for people experiencing homelessness set out recommendations that seek to address this challenge. For people rough sleeping, a key recommendation is the provision of outreach services with a health specialism (NICE, 2022). This intervention is increasingly widespread across the UK, though far from ubiquitous. The service aims to bring healthcare directly to people rough sleeping. Guidelines produced by Ungpakorn and Torry (2020) suggest outreach with a health specialism can range from nurses and pharmacists to GPs and health visitors but can include an even wider variety of professional backgrounds. All must demonstrate expert engagement skills, specialist knowledge of homelessness and its impacts, and advanced clinical practice to offer complete episodes of care.

In their systematic scoping review of outreach with a heath specialism[1], Kopanitsa et al. (2023) concluded it is likely that the intervention improves healthcare access for people experiencing homelessness. Qualitative research suggests these improvements are achieved by overcoming physical barriers to healthcare access and building caring relationships (Omerov et al., 2019; Ungpakorn and Rae, 2019). 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, Kopanitsa et al. (2023) conclude that randomised study designs are required to more robustly evaluate the effectiveness of this approach.

The current study responds to this research gap through an evaluation of outreach services with a health specialism for people rough sleeping 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. It is particularly important to note that given the intended focus on housing outcomes, the intervention will be oriented around an assertive outreach approach that seeks to support people to exit rough sleeping (Mackie et al., 2017). Many outreach services with a health specialism do not explicitly incorporate this orientation towards improved housing outcomes.

Outreach services will be newly commissioned for the purposes of this study. Change Grow Live (CGL) are the nurse outreach provider. The intervention provided by Change Grow Live

[1] In this study outreach was defined more broadly to include places other than the street where people rough sleeping usually congregate, for example in shelters, hostels or foodbanks, or in community centres where they may go for services other than health care.

lacks a set of clearly defined common delivery principles and programme theory, therefore to maximise intervention functioning, and to ensure likely effectiveness, the study includes a Phase 1 'optimisation stage'. This will be followed by Phase 2 - a 'pilot cluster randomised controlled trial (cRCT)' of outreach services with a health specialism across 16 Local Authority (LA) areas in England.

2. PROJECT SUMMARY

2.1. Project Description

This is a pilot cluster Randomised Control Trial (cRCT) with nested intervention optimisation of health outreach services for people rough sleeping living on the streets in Local Authorities (LAs) in England. The study has been split into two phases - Phase 1: Optimisation to gain an in-depth understanding of the intervention and theorised mechanisms of change, and Phase 2: pilot cRCT with a nested Implementation and Process Evaluation and Economic Evaluation.

2.1.1. Phase 1 - Optimisation

The overarching aim of the optimisation phase is to maximise intervention functioning and effectiveness. There are three specific objectives it will address:

1. Understand and refine the programme theory of outreach services with a health specialism for people rough sleeping ("the intervention"), which includes causal mechanisms, activities, implementation processes, delivery context and targeted outcomes.
2. Identify if and how intervention activities, implementation processes and the delivery context need to be modified to maximise intervention functioning.
3. Recommend, support, and monitor the modification of intervention activities, implementation processes and the delivery context.

Optimisation activities will include:

- Desktop review of the intervention manual and training materials to develop candidate programme theory.
- Initial key stakeholder workshop to develop candidate programme theory, involving stakeholders from delivery teams, primary care and policy settings.
- Qualitative interviews with wider stakeholders.
- Lived experience workshop inputting into intervention optimisation.
- Final key stakeholder workshop to confirm programme theory.

2.1.2. Phase 2 - Pilot cluster randomised controlled trial with an integrated implementation and process evaluation, and economic evaluation

After the programme theory has been confirmed and any intervention modifications have been made, a pilot cRCT with an integrated implementation and process evaluation, and economic evaluation, will be carried out in Phase 2 in 16 Local Authorities (LAs) in England,

randomising 8 areas to receive the nurse outreach intervention and 8 to remain with their usual practice (control).

The objectives of Phase 2 are to:

1. Assess the viability of the intervention, and barriers and facilitators to implementation, including contextual factors, acceptability to LAs, nurses and service users, engagement of service users, and fidelity of intervention delivery.
2. Identify and explore the mechanisms of change through which the intervention works.
3. Determine the feasibility of the trial methods, including LA recruitment and randomisation, LA and service user retention, data collection processes – including the proportion of service users present in routine data collection, as well as any adaptations.
4. Offer suggestive evidence of the impacts of the intervention on the housing situation and health of individuals, as well as intervention costs and benefits.

Pilot cRCT activities will include:

- Recruitment and randomisation of LAs.
- Analysis of routine data in intervention and control sites relating to demographics, health and housing outcomes of people living on the streets.
- Qualitative interviews with key staff and people living on the streets in intervention and control areas, and LA representatives (if any site withdraws from the cRCT).
- Observation of practice.
- Analysis of staff time and resource logbooks.

2.2. Study Triangulation

This study will incorporate four key strands of research: 1. Optimisation, 2. cRCT, 3. IPE, and 4. Economic Evaluation. The first strand (optimisation) will improve understanding of the intervention and maximise its functioning – this provides a crucial starting point for the study, ensuring there is clarity over the intervention being evaluated in the remaining three strands. The subsequent three strands are complimentary, each with a different focus. The pilot cRCT provides an opportunity to determine suggestive evidence of the intervention impacts and the viability of the trial methods, while the economic evaluation will consider costs and benefits. The IPE will focus on how the intervention works and its viability.

3. STUDY TIMELINE

Table 4: Study Timeline

Strand	Staff responsible/ leading	Activity	Dates
cRCT	Centre for Homelessness Impact (CHI)	Identification and recruitment of study sites. Expressions of interest mapped against funder inclusion and exclusion criteria.	April - June 2024
Optimisation	Cardiff University	Develop a programme theory description and model. Consultation workshops and interviews with stakeholders and intervention delivery teams.	May - November 2024
cRCT	Cardiff University Statistician	Randomisation protocol prepared and randomisation of sites.	May - July 2024
Intervention	Change Grow Live (CGL)	Recruitment and training of outreach workers and nurse practitioners.	July - November 2024
Process evaluation	Cardiff University	Data collection commences, observation of practice, interviews in intervention and control LAs (including any site withdrawals), time and resource logbooks, and routinely collected contextual data.	January 2025 - February 2026

Economic evaluation	Cardiff University with input from Glasgow University	Data collection commences, including time and resource logbooks.	January 2025 - February 2026
Intervention	CGL	Intervention delivery	January 2025 - May 2026
cRCT	Cardiff University with routine data collection by CGL and Local Authorities (LAs)	Pilot randomised controlled trial in 16 LAs in England. 8 intervention and 8 control LAs.	January 2025 - June 2026
		Baseline routine data collection	*January 2025 - October 2025*
		3 month follow-up routine data collection	*April 2025 - January 2026*
		6 month follow-up routine data collection	*July 2025 - April 2026*
Study reporting	Cardiff University	Reporting and dissemination activities.	June 2026

4. INTERVENTION OPTIMISATION AND COMPARATOR

4.1. Intervention Optimisation

4.1.1. Optimisation aims

The intervention aims to improve both the housing situation and health status of people rough sleeping. Key elements of the intervention include:

- A nurse integrated into an outreach team.
- Working full-time, nurses completing regular shifts with the outreach team.
- Nurses delivering healthcare and treatment, health advice and support to access health services.
- An assertive outreach approach[2], intended to support people to exit rough sleeping.

The overarching aim of the optimisation phase is to maximise intervention functioning and effectiveness. There are three specific objectives it will address:

[2] Assertive outreach differs from traditional street outreach programmes because it is a deliberate and strategic attempt to end homelessness.

1. Understand and refine the programme theory of outreach services with a health specialism for people rough sleeping ("the intervention"), which includes causal mechanisms, activities, implementation processes, delivery context and targeted outcomes.
2. Identify if and how intervention activities, implementation processes and the delivery context need to be modified to maximise intervention functioning.
3. Recommend, support, and monitor the modification of intervention activities, implementation processes and the delivery context.

4.1.2. Optimisation overview

Four stages of activity will be conducted as part of the optimisation phase.

Stage 1. Desktop review to develop candidate programme theory (May/June 2024)

The evaluation team will work with CHI and CGL to consult existing intervention materials to generate an initial understanding of the intervention. This will be termed the 'candidate programme theory'. It will report the following aspects of the intervention: the causal mechanisms through which the intervention is intended to work; intervention activities; the intended process for delivery including delivery agents (e.g. lead nurses and nurses) and resources; contextual factors that might shape if and how the intervention functions in real world practice; and the intended and unintended outcomes. This candidate programme theory will be presented as a narrative summary and logic model. Key gaps in knowledge will be summarised as part of the narrative.

Consultation with key stakeholders: Initial workshop on candidate programme theory (July 2024)

The evaluation team will host the first of two stakeholder workshops.

The aims of the first workshop are to:

- Reach a shared understanding between stakeholders on the candidate programme theory (based on desktop review to date).
- Address the gaps in the programme theory identified by the desktop review.
- Identify what modifications are required, if any, to intervention activities, implementation processes and the delivery context.
- Identify data sources and additional stakeholders to help support in addressing gaps and modifying the intervention.

This workshop will include 8-10 key stakeholders including CGL and individuals who have previously delivered these services. Other stakeholders will be identified through CGL and CHI as needed. It will run online over 90 minutes to two hours. It will include a presentation of the narrative summary and logic model from the desktop research and a facilitated discussion.

Following this workshop, the team will review the programme theory and make updates based on new knowledge and gaps. If modifications are required, they will provide recommendations to CHI for intervention modifications who will develop additional training with the intervention provider.

Stage 3. Qualitative interviews with stakeholders and consultation workshop with people with lived experience of homelessness (September/November 2024)

The evaluation team will conduct interviews with national stakeholders who have prior experience of delivering or designing outreach services with a health specialism for people rough sleeping.

The aims of the interviews are to:

- Understand how the intervention functions in 'real world' contexts.
- Identify characteristics of the delivery system that may facilitate or inhibit the successful functioning of the intervention.
- Identify what modifications are required to intervention activities, implementation processes and the delivery context.

Approximately 10 interviews will be conducted via an online platform. Data will be thematically analysed. The team will review the programme theory and make updates based on new knowledge. They will provide recommendations to CHI and CGL for intervention modifications and support this process as appropriate.

We will additionally hold a workshop with people with lived experience of homelessness, facilitated through CHI Lived Experience Network. The aim of this workshop will be to input into intervention optimisation developed through the previous stakeholder workshop and interviews. We will sense check the findings with their experiences, with the aim of making any required adjustments to the refined intervention. People will be invited to attend via the Lived Experience Network Lead. We will aim to have no more than 8 members attending to ensure the group is not too large and everyone has the opportunity to input. Two members of the research team will attend to facilitate the session. The session will last 60-90 minutes and only written notes will be taken.

Stage 4. Consultation with key stakeholders: Final workshop to confirm programme theory (November 2024)

The evaluation team will host the second of two stakeholder workshops.

The aims of the second workshop are to:

- Review and confirm the programme theory.
- Discuss the process for delivering the modified intervention and address perceived challenges.

This workshop will include 8-10 stakeholders. It will include stakeholders from the first workshop, and additional stakeholders identified through the optimisation phase. It will run over 90 minutes to two hours online. It will include a presentation of the results of the optimisation process to date and a facilitated discussion.

Following this session the team will finalise the programme theory. They will share it with CHI and other relevant stakeholders (e.g. CGL) in a narrative form with logic model, along with a summary of discussion of strategies to ensure the delivery of the modified intervention.

4.1.3. Optimisation eligibility and recruitment

Optimisation phase participants will include a range of national stakeholders who have prior experience of designing or delivering health outreach services to people rough sleeping and outreach team workers and nurse practitioners that have or will receive the intervention training.

The evaluation team will use publicly available information to contact key stakeholders and work with the CHI Project Manager to identify its stakeholders. The evaluation team and CHI Project Manager will identify and contact potential participants and distribute details of the research. Potential participants will register their expression of interest to take part in an interview by completing an online form.

The evaluation team will send potential interviewees an invite and information sheet and consent form to decide if they would like to take part in an interview. The evaluation team will send a follow-up email to establish interest and arrange a meeting. Informed consent procedures are detailed in Section 15.2.

Table 5: Optimisation Inclusion and Exclusion Criteria

	Inclusion criteria	Exclusion criteria
Optimisation workshops	● Key stakeholder with expert knowledge of outreach with a health specialism for people rough sleeping.	● Based outside the UK.
Optimisation lived experience workshop	● Members of the CHI Lived Experience Network with lived experience of homelessness.	● Based outside the UK.
Optimisation interviews	● Local Authority/Organisation with experience of designing or delivering outreach services with a health specialism to people rough sleeping. ● Stakeholder, clinician, or professional staff.	● Based outside the UK.

	• Outreach team workers and nurse practitioners that have or will receive the Test and Learn with health specialism bespoke training package.	

4.2. Intervention and Comparator

4.2.1. Intervention

An intervention programme theory will be a key output of the optimisation phase, developed through consultation of the extant literature on outreach services with a health specialism for people rough sleeping, stakeholder workshops, and individual stakeholder interviews.

The intervention aims to ensure that people who are on the street have access to healthcare and are adequately safeguarded (Dorney-Smith, 2022). 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. Equally, improved health may move service users onto a longer-term path to entering appropriate accommodation.

Outreach with a health specialism is mainly focused on primary care health outreach and can be differentiated from specialist mental health and addiction outreach. However, outreach nurses should be able to assess mental health and addiction issues and provide appropriate signposting to services.

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 outlined in a first draft of the TIDierR Framework (Table 6). This is a developing piece of work which is being refined through the optimisation phase. A final TIDieR framework and logic model will be available as a future study output.

4.2.2. Comparator

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.

4.3. Intervention Dates

The intervention will be delivered for a duration of 17 months, commencing January 2025 until May 2026 (note the trial data collection ends earlier than the intervention delivery).

Table 6: TIDier Framework*

(Hoffmann, et al. 2014)

*Note that the Tidier TIDieR Framework and intervention description will be updated as an output of the optimisation phase.

Brief Name: Provide the name or a phrase that describes the intervention	Outreach services with a nurse health specialism for people rough sleeping.
Why: Describe any rationale, theory, or goal of the elements essential to the intervention	The overarching rationale of the intervention is that nurses meet service users where they are rough sleeping, which increases contact with service users. Nurses have a respected identity as a health professional that service users may trust to support them. This trust can be enhanced by nurses having professional knowledge to identify and deliver the correct service provision and having the expertise and professional standing to secure service access. Nurses' identification of a health care need for service users can also ensure access to appropriate housing, as health care needs can result in an accommodation entitlement.
What (Materials): Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)	Standard and bespoke training is a key component of the intervention. **Standard Training:** Standard nurse training modules (treating substance use etc.) will be made available to outreach nurses through CGL. This training is sourced from the Queens's Nursing Institute, LNNM, Fairhealth and Aneemo training and resource platforms. **Bespoke Training:** Outreach nurses will receive a bespoke training package with a focus on supporting people rough sleeping. Four half day training sessions will be delivered by an expert

	professional. Two will be delivered online and two will be delivered in person. These will be complemented by a range of other electronic resources. Training will include didactic learning and scenario-based interaction.
What (Procedures): Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	There are four key intervention components: 1) **Outreach nurse training:** Includes standard and bespoke training. 2) **Outreach with specialism shifts:** Outreach nurses accompany outreach teams to deliver healthcare on the street and arrange access to healthcare and housing. 3) **Outreach nurse supervision and quality assurance:** Clinical supervision of nurses by a Lead Nurse. 4) **Service follow-up and Multi-disciplinary Team (MDT) meetings:** Arrangement of follow-up healthcare and housing services after outreach sessions. Attendance at MDT meetings to advocate for the service user.
Who provided: For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given	1) **Outreach nurse training** **Standard training:** Training will be facilitated by CGL and primarily provided through the Queens's Nursing Institute, LNNM, Fairhealth and Aneemo. **Bespoke training:** Training will be developed by Samantha Dorney-Smith (expert advisor on health outreach intervention) and hosted by CGL. 2) **Lead Nurse** The Lead Nurse based in CGL (equivalent to top NHS band 7) will oversee and line manage the 8 trained outreach nurses (equivalent to top NHS band 6).

	3) Outreach nurses Outreach with a health specialism will be provided by eight appointed outreach nurses. Desirable competencies for the outreach nurses include: ● An advanced assessment course and/or significant experience of clinical triage in an A&E department ● History of working with people who have experienced homelessness ● A proven ability to assess and manage clinical risk independently ● Level 3 safeguarding training (including an understanding of self-neglect) ● Ability to directly prescribe (i.e. the ability to provide an immediate prescription) or to provide drugs by Patient Group Direction. Training could be provided to outreach nurses on Patient Group Direction if someone has an advanced assessment course but no prior Patient Group Direction experience (Dorney-Smith, 2021). Based on previous case examples of outreach nurses, it has been suggested that they should be a band 7 equivalent to ensure they have the requisite experience and expertise (Dorney-Smith, N.D.). **4) Outreach teams** Typically, 1-2 members of the designated outreach team will accompany the nurses during the outreach shifts. The number of accompanying outreach workers can be negotiated, but the key is that outreach nurses should not go alone.

	5) Other professionals (for MDT meetings) A range of partnering teams and professionals will be required to ensure that service users' complex needs can be met, and appropriate care can be planned. These can include (Dorney-Smith, 2022): ● Local Authority rough sleeping pathway lead ● Outreach team (beyond team immediately supporting intervention) ● Mental health teams ● Social worker ● Police ● Primary care physician
How: Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	1) **Outreach nurse training:** Will be delivered in person and online. 2) **Outreach with health specialism shifts:** Will be delivered in person on the street as direct service user contact. 3) **Outreach nurse supervision and quality assurance:** Will be delivered in a group or individual format online or via telephone. May entail occasional in-person meetings. 4) **Service follow-up and MDT meetings:** May be delivered online, via telephone or in person depending on the services that outreach nurses follow-up with or the meetings they attend.
Where: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	1) **Outreach nurse training:** Online activities will be remotely accessed through the relevant platform. The venue for in-person training is to be agreed. 2) **Outreach with specialism shifts:** Will be delivered mainly on the

	street. Outreach teams will identify the location of the service users as they will have more experience and knowledge of their location. 3) **Outreach nurse supervision and quality assurance:** Online meetings will be remotely accessed through the relevant platform. The venue of in-person meetings will likely be at CGL offices. 4) **Service follow-up and MDT meetings:** Online meetings will be remotely accessed through the relevant platform. In-person meetings will be accessed at the location of the services that outreach nurses follow-up with.
When and how much: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose	**Outreach nurse training:** A. **Standard training:** Training will be made available to outreach nurses on an ongoing basis. CGL will arrange a hosting platform and Samantha Dorney-Smith will share resources to be hosted alongside training modules provided by the Queens's Nursing Institute, LNNM, Fairhealth and Aneemo training and resource platforms. B. **Bespoke training:** Training will be delivered as four half day sessions. Two will be delivered online and two will be delivered in person. Their working week will be split as follows: 1) **Outreach with health specialism shifts** It is recommended that outreach nurses will spend 60% of their week on shifts.

	This should include a minimum of two shifts on the streets with service users, which should each take approximately eight hours (Dorney-Smith, N.D.). **2) Outreach nurse supervision, quality assurance, and training** The Lead Nurse will meet with the outreach nurses collectively on a weekly basis. This meeting will be conducted online. Each nurse will also have monthly (where possible) clinical supervision meetings with the Lead Nurse. This will take roughly 20% of their time. **3) Service follow-up and MDT meetings** Nurses will spend approximately 20% of their time ensuring data and information are complete and to secure follow-up services. This includes completing data used for the trial. They may also be required to spend time attending MDT meetings.
Tailoring: If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	The intervention should always comprise delivery of the four central components. The outreach activities delivered to service users and the resulting follow-up activities will be personalised to the individual. Activities will also be dependent on services and resources available to outreach nurses. Based on previous outreach with a health specialism interventions, it has been recognised that the delivery model is flexible and fit for purpose and can be adapted well to ongoing changes (Dorney-Smith & Sivasathiaseelan, 2020).
Modifications: If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)	To be completed at reporting stage.

How well (Planned): If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them	Key fidelity measures will include: **Outreach nurse training** ● Completion of standard and bespoke training. **Nurse outreach with health specialism shifts** ● Delivering in outreach settings for approximately 15-16 hours per week ● Uptake of treatment/support offer ● Providing immediate treatment where relevant ● Manageable caseloads **Outreach nurse supervision and quality assurance** ● Number of supervision sessions between Lead Nurse and nurses **Follow-up services and MDT meetings** ● Follow-up services secured for service users where appropriate ● Uptake of follow-up service offer ● Number of MDT meetings attended by outreach nurses
How well (actual): If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	To be completed at reporting stage.

5. PILOT CLUSTER RANDOMISED CONTROLLED TRIAL

5.1. Aim, Objectives and Research Questions

5.1.1. Aim and objectives

The aim is to conduct a pilot cRCT to determine suggestive evidence of the intervention impacts and the viability of the trial methods. A set of evaluation feasibility criteria will be used to assess this (outlined in Table 8).

5.1.2. Research questions

The research questions are:

1 **Intervention viability**
- 1.1 Is the intervention acceptable to service users, Local Authorities, 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 Local Authorities (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?

Many of these research questions will be addressed through the Implementation and Process Evaluation. This section of the protocol focuses primarily on the impact component of the trial.

5.2. Study Design

5.2.1. Two-arm pilot cluster randomised controlled trial

The study design is a two-arm pilot cluster randomised controlled trial (cRCT). Local Authorities (LAs) are the unit of randomisation. 16 eligible LAs will be randomly assigned by an independent statistician in a 1:1 ratio (8 LAs per arm) to receive funding to embed a health professional as part of the outreach team (a qualified nurse) or remain with their usual practice.

5.2.2. Randomisation technique

Block randomisation of varying sizes will be used, stratified by the Rough Sleeping Initiative (RSI) funding allocation 2022-2025, per individual rough sleeping (£) of the 16 eligible LAs. Strata are created based on the median RSI funding allocation of the 16 LAs. The rationale for selecting the LA RSI funding allocation per individual rough sleeping 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 outcomes of housing situation in a future RCT. A random allocation sequence will be generated in blocks using the *ralloc* program in Stata 17. More details on this are available in the randomisation protocol in Appendix A.

5.3. Research Setting

The pilot RCT will be conducted in England. All LAs that return an expression of interest to CHI will be eligible for the sampling frame. Essential criteria for inclusion of the LAs are outlined in Table 7. CHI will select 16 Local Authority areas in England for the study, based on assessment and scoring via a rubric (see Appendix B). Each LA will individually meet with CHI in an introductory meeting, meet CGL, and sign a contract. More details on this are available in the randomisation protocol in Appendix A.

5.4. Masking

This is an unblinded study where LA staff, research teams, and data collectors will know the intervention allocation. The randomisation schedule will be stratified and will be prepared and held by an independent statistician within the CTR. Allocations of LAs will be blinded from the trial statisticians conducting the final analysis. All data collectors and participants will not be blinded at baseline or follow-up data collection.

6. POPULATION

6.1. Eligibility

The following criteria will be used to determine eligibility for study inclusion:

Table 7: 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).	• Local Authority areas which already have an embedded health specialist who does shifts with the local outreach team.

	● 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.	
People living on the streets and included within Local Authority and CGL routine data collections	● 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 included within CGL or Local Authority routine rough sleeping data collections.	● People rough sleeping who are not living on the streets and not included in LA or CGL routine data collections.

The study inclusion criteria focus on people living on the streets for two main reasons. First, it is likely that people living on the streets will be better known to outreach services, therefore significantly increasing the likelihood of successful baseline and follow up data collection. Second, this subgroup of people rough sleeping are further away from being accommodated than peers who spend less time sleeping on the streets, and therefore the intervention has potential for greatest impact.

Crucially, nurses will be permitted to support other people rough sleeping, but trial eligibility criteria will focus only on those living on the streets. The IPE and economic evaluation will capture data from nurses on the time spent with the eligible vs ineligible trial population.

6.2. Recruitment and Enrolment

Recruitment and enrolment relate primarily to the initial enrolment of Local Authorities into the study. Data collection on outcomes for people rough sleeping will be captured through amended routine data collections by Local Authorities and CGL nurses/staff.

6.2.1. Local Authorities

In February 2024, CHI will open the Test and Learn Outreach with Health Specialism project to Local Authorities to register expressions of interest to take part in a cluster Randomised Control Trial (cRCT) to evaluate an Outreach with Health specialist service. Eligible LAs will be invited to apply. 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 will be sought.

An online webinar will be held to introduce the Test and Learn Programme and provide more detail on the outreach with a health specialist intervention. Interested LAs will complete an online application for consideration and screening against inclusion and exclusion criteria as documented in Appendix B. Successful applicants will be notified in July 2024 and 16 Local Authority areas randomised.

The implementation partner (CGL) will work across all trial sites to 1) deliver the outreach with a health specialist intervention in sites randomised to intervention and 2) to support sites with collating and extracting routine data from their standard outreach services. CGL will appoint a team member to this routine data collection role.

6.2.2. 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. 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 this routine data will be shared with Cardiff University for analysis.

Trial flow and data flow diagrams are included on the next pages (Section 6.3).

6.3. Flow Diagrams

Figure 1: Trial Flow Diagram

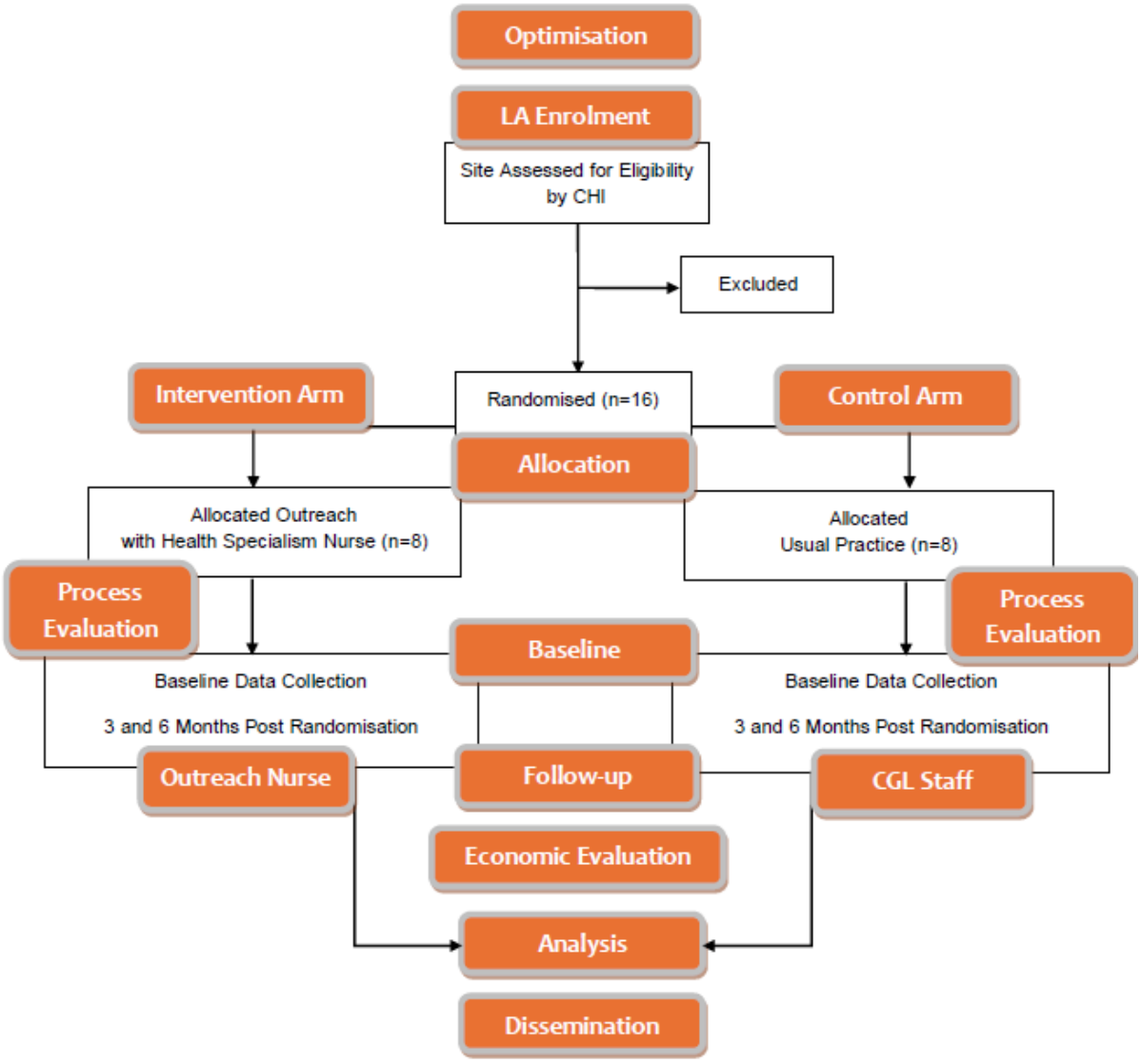


Figure 2: Quantitative Data Flow Diagram

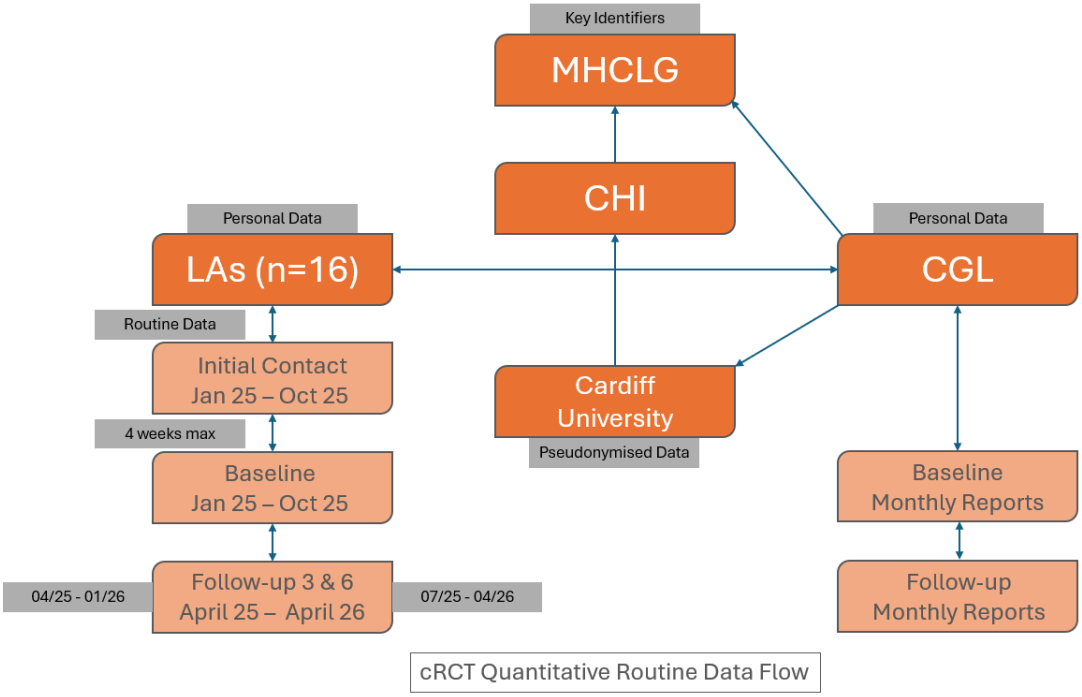
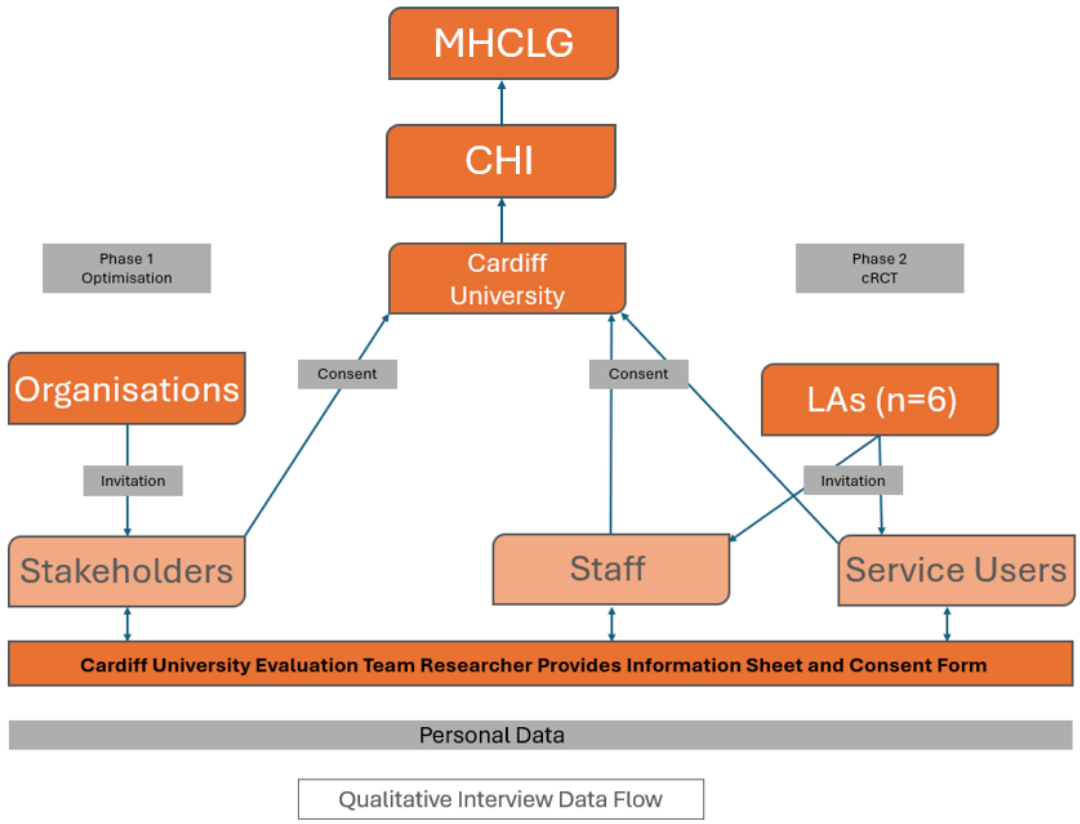


Figure 3: Qualitative Data Flow Diagram



7. OUTCOME MEASURES

7.1. Evaluation Feasibility Criteria

As a pilot cRCT, the main outcome is evaluation feasibility criteria that will determine the viability of the trial methods, and the fidelity and acceptability of intervention delivery. The criteria were devised by the trial team, with input from expert advisors with relevant trial and subject knowledge. These were also approved by an independent Trial Steering Committee (TSC). Evaluation feasibility criteria are presented in Table 8 and will be monitored by the independent TSC.

Feasibility against 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 met). These criteria should be applied with discretion as during the study solutions to substantively improve each may be identified.

Table 8: Feasibility Criterion

Feasibility Criterion	Red	Amber	Green
Trial methods			
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. Data is collected for more than 60% of service users at baseline and the final follow-up on primary outcome	<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

7.2. Primary Outcome

7.2.1. Definition

The primary outcome is housing situation defined using the housing outcomes listed in the CHI adapted version of the Residential Time-Line Follow-Back (RTLFB) inventory (Tsemberis et al, 2007) (Appendix C).

At the broadest level, the inventory distinguishes between three main types of housing situation: homeless, not homeless, and living in an institution. The trial will explore changes in these housing situations. Analysis will also allow exploration of potential movement from

roofless forms of homelessness (e.g. rough sleeping) to houseless forms of homelessness (e.g. temporary accommodation).

Arguably, overall health status could also be considered a primary outcome for this intervention given the health-related support offered by the nurse. However, the ultimate objective of assertive outreach activities is to support people to stop rough sleeping and move into accommodation where their needs, including health-related needs, can be met more effectively. For this reason, the authors and MHCLG as the funder of the programme make the judgement that service users' housing status should be the primary outcome.

7.2.2. Instrument

The housing outcomes listed in the RTLFB provide a point-in-time assessment on a service user's housing situation at each data collection point (baseline, midline, and endline). These housing outcomes will be added to LA routine data collection.

7.2.3. When is it measured?

Housing situation will be collected at baseline, 3-month and 6-months follow-up timepoints. 6 months is the primary follow-up point, but 3 months follow-up is incorporated in case 6-month is missing.

7.2.4. For whom is it measured?

The outcome measure will be collected for all service users that meet the inclusion criteria in both intervention and control sites.

7.2.5. Measure and validation

The RTLFB was adapted by CHI in consultation with the UK homelessness sector to include housing outcomes that are best suited to the UK housing context.

7.3. Secondary Outcomes

We will include the following secondary outcomes: health status and health service interactions. All instruments can be found in Appendices D and E.

7.3.1. Health status

7.3.1.1. Instrument

LAs will adapt their routine data collection to include the 5-level EQ-5D version (EQ-5D-5L) (Appendix D). The EQ-5D-5L is a widely used generic measure of health status consisting of two parts: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ 5D-5L was introduced by the EuroQol Group in 2009 to improve the instrument's sensitivity and to reduce ceiling effects, as compared to the EQ-5D-3L.

The EQ-5D-5L was chosen as it is an encompassing short questionnaire, commonly used in this population, covering the domains (physical health [pain/mobility], self-care, mental health [anxiety/depression]) relevant to the study population. Consultation with LAs suggests it is of a manageable length. Furthermore, it can be converted to quality-adjusted life year (QALYS) for the economic evaluation.

7.3.1.2. When is it measured?

The secondary outcome measure of health status (EQ-5D-5L) will be measured at three time points: baseline, 3-month and 6-months post baseline.

7.3.1.3. For whom is it measured?

EQ-5D-5L will be collected for all service users across intervention and control sites.

7.3.1.4. Measure and validation

The EQ-5D-5L is a health-related quality of life (HRQL) instrument that has been validated in various contexts. The descriptive system of EQ-5D-5L comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems (Appendix D). The patient is asked to indicate their health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. Health state index scores generally range from less than 0 (value of a health state equivalent to dead; negative values representing values as worse than dead) to 1 (the value of full health), with higher scores indicating higher health utility.

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 D). The VAS can be used as a quantitative measure of health outcome that reflects the patient's own judgement.

7.3.2. Interactions with health services

7.3.2.1. Instrument

Basic data on health service interactions/health service resource use will be captured using questions adapted from the MHCLG Rough Sleeping Questionnaire (RSQ) (Appendix E).

7.3.2.2. When is it measured?

The health service resource use questions will be asked at the baseline, 3-month and 6-months follow-up time points.

7.3.2.3. For whom is it measured?

Health service resource use will be collected for all service users across intervention and control sites.

7.3.2.4. Measure and validation

This is not a validated measure. The service interaction types are routinely captured by MHCLG in the RSQ.

8. DATA COLLECTION

8.1. Data Collection Methods

In intervention sites, housing situation data (primary outcome), health status data (secondary outcome), and health service interaction data (secondary outcome) will primarily be collected by nurses as part of their normal routine service delivery at baseline, 3 and 6 months. They will also be supported by a dedicated CGL team member and outreach workers. At follow-up, service users will either be recontacted on the streets, contacted using known telephone numbers, or nurses/CGL team member will seek to locate individuals through other service providers (e.g. hostels and day centres). CGL will amend their routine data collection platform to capture outcome data.

In control sites, housing situation data (primary outcome), health status data (secondary outcome), and health service interaction data (secondary outcome) will be collected by outreach workers as part of their normal routine service delivery at baseline. At follow-up, a dedicated CGL team member will support the collection of follow-up data at 3 and 6 months in control sites. Service users will either be recontacted on the streets, using known telephone numbers, or the CGL team member will seek to locate individuals through other service providers (e.g. hostels and day centres). The CGL team member will work across all control sites, potentially travelling between them to aid sites in collating data. They will also assist the local teams in their data uploading and in tracking service users who have previously been included as part of the study and following-up with these service users.

Data will be manually input into the CGL managed CRi Information System (CRiiS). For intervention sites, baseline data will be entered by the outreach nurse, and follow-up data with assistance from a CGL team member. For control sites, the relevant data extracts will be provided to CGL, then all data will be manually entered into CRiiS by the CGL team member.

As data will be collected by nurses and/or outreach workers ('users') as part of their everyday service delivery, there will be an element of user preference determining how it is collected. Staff can either enter data directly into the database using a CGL provided mobile device whilst they are with the service user or make paper notes and transfer them at the office via the online portal.

To aid in managing the burden on staff in collecting additional routine data, sites will be informed that they can stop collecting data once they have reached a caseload of 120. A larger sample size would have very limited benefit to the study, whereas the withdrawal of a Local Authority due to data collection challenges would have a significant impact.

Table 9: Data Collection Procedures and Assessment Timeline

Assessment point	Type of data	Data collection approach
First contact (four-week window to collect baseline)	Contact recording and eligibility assessment.	Nurses and outreach workers. On the street/in the community.
Baseline	Baseline characteristics (age, sex, gender, nationality, care experienced, left an institution in the last 85 days – see Appendix F), primary and secondary outcomes (pre-intervention).	Nurses and outreach workers. On the street/in the community.
Interim contact data*	Contact date for each contact occurrence with service user to record data and/or to receive treatment, care or advice.	Nurses and outreach workers and CGL team member. On the street/in the community (intervention sites only).
Midline (3 months after baseline – 4-week window to complete)	Primary and secondary outcomes including reason for non-contact if applicable.	Nurses, outreach workers, and CGL team member. On the street/in the community, telephone (if contact details provided), through other organisations (e.g. NHS).
Interim contact data*	Contact date for each contact occurrence with service user to record data and/or to receive treatment, care or advice.	Nurses and outreach workers and CGL team member. On the street/in the community (intervention sites only).
Endline (6 months after baseline – 4-week window to complete)	Primary and secondary outcomes including reason for non-contact if applicable	Nurses, outreach workers, and CGL team member. On the street/in the community, telephone (if contact details provided), through other organisations (e.g. NHS).

*Interim contact data collected in intervention sites only to assess level of contact per service user, treatment, care or advice given (anonymised), and to facilitate follow-up data tracking

8.2. Retention Strategies

Individual service user routine data collection engagement and retention will be managed by nurses and outreach workers and a CGL team member. Service user interview engagement and participation will be managed by nurses and outreach workers and an evaluation team member.

When appropriate, and as a token of gratitude for their time, service users may be provided with 'thank you' vouchers. This is perceived to be fair compensation for an individual's time.

For routine data collection, this will be in the form of a food and drink voucher up to the value of £10, so the individual can purchase something to eat or light refreshment (e.g. a coffee). In the intervention areas, the nurses also have payment cards with which they could buy food or coffee for individuals to increase engagement. This is a common tool for many front-line homelessness services and would not be out of usual practice for the outreach team or service users in control areas, enabling equality across the two groups and encouraging engagement for the important follow-up at 3 and 6 months.

As a thank you for participating in an individual interview, service users in intervention and control sites will be offered a £20 high street shopping voucher. CHI Lived Experience Network members input into developing this strategy.

8.3. Data Management Procedures

Pseudo-anonymised datasets from the CRisS database will be extracted as csv files and securely transferred electronically from CGL to Cardiff University using an access-managed Microsoft Teams space. Data downloads will be monthly, to allow checking for data completeness. At Cardiff University, the data will be stored on a secure server, only accessible to staff who have been given access. Access is controlled by the Trial Manager and is a delegated duty outlined on the trial delegation log.

Trial data provided by CGL will be de-identified before transfer. Any potentially identifiable data such as date of birth or open text fields will be checked and recoded by CGL (i.e. DOB calculated as age at time of data collection, treatment care or advice given – names and locations redacted and study ID number removed).

Due to the nature of the data collection, Cardiff University Data Managers will be unable to validate source data. All data will be collected and handled by CGL acting on behalf of the data controller, MHCLG as per their data protection policy, which can be found here: https://www.gov.uk/government/organisations/ministry-of-housing-communities-local-government/about/personal-information-charter.

Qualitative data (service user and staff interviews/observational data) will be transferred directly to Cardiff University servers following data collection. Interview audio recordings will be labelled with participant identification numbers. All transcripts will be checked for accuracy

and identifiable information will be removed or anonymised (e.g. removing names/location/gender).

The full Cardiff University data management procedures for Test & Learn: Outreach services with a health specialism for people rough sleeping may be seen in the project data management plan which will cover Cardiff University data management processes. This is available on request.

9. SAMPLE SIZE AND POWER CALCULATION

9.1. Sample Size / Power Calculation

The aim of this pilot cRCT is to evaluate feasibility and acceptability of outreach services with a health specialism for people rough sleeping and provide indicative evidence of its effectiveness. The study will determine numbers of service users eligible for routine data collection and response rates, estimates of effect sizes and intra-cluster correlation coefficients 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 CHI based on the number of LAs and service users that could viably be engaged 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 (Table 10). 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.

Table 10: Sample Size Calculations

		Overall
Minimum Detectable Effect Size (MDES)		0.53
Pre-test/ post-test correlations	level 1 (service user)	-
	level 2 (cluster)	-
Intracluster correlations (ICCs)	level 2 (cluster)	0.10
Alpha[7]		0.05
Power		0.8
Alternative hypothesis: One-sided or two-sided		Two-sided
Average cluster size		40
Number of clusters[8]	Intervention	8
	Control	8
	Total	16

Number of service users	Intervention	320
	Control	320
	Total	640
Expected attrition at cluster level	%	0
Expected attrition at individual level	%	10
Effective sample (Clusters)	**Total**	16
Effective sample (Service users)	**Total**	711

9.2. Attrition Assumptions

As this is a pilot cRCT, estimating a realistic rate of attrition in service users is an objective of this study.

10. ANALYTICAL STRATEGY

A detailed statistical analysis plan will be written and finalised before any analysis is undertaken. A brief overview of the intended approach is detailed below. The reporting of findings will be in accordance with the CONSORT guidelines for randomised pilot and cluster RCTs. All analyses will be performed in Stata v17.0 or R.

10.1. Analytic Sample

All analyses will be on an intention to treat (ITT) approach and will include service users that are included in the study, irrespective of how much intervention is received.

10.2. Descriptive Statistics

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 included, and completion of baseline interview and follow-up points. The feasibility criteria relating to data collection on the primary outcome at baseline and 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-month follow-up period intervention sites.

We will tabulate baseline characteristics of both the LAs (e.g. region, RSI funding allocation 2022-2025 strata) and the service user characteristics measured at baseline (e.g. age (years), sex assigned at birth, gender identity, nationality, care experienced, left an institution in the last 85 days – see Appendix F); these will be shown by trial arm and summarised using means and standard deviations (SDs) (or medians and interquartile (IQR) ranges, as appropriate) for continuous outcomes, frequencies and percentages for categorical outcomes.

10.3. Analyses

As this is a pilot RCT, point estimates and 95% CIs will be presented but p-values for hypothesis testing will not. It is important that these tests are interpreted in the context that they are not fully powered such that a smaller effect would not suggest the intervention was ineffective. However, if the 95% CIs indicates significant benefit, then another trial would not be necessary.

10.4. Primary Analysis

The rate of completion of the primary outcome - housing situation via the RTLFB inventory will be reported at each follow-up time point (baseline, 3 and 6 months). In service users providing valid data, we will summarise their housing situation using frequencies and proportions in three ways:

- Level 1: Categorical outcome – homeless, not homeless, institution
- Level 2: Categorical outcome – rough sleeping, temporary and/or unstable, hidden, institution, stable but insecure, stable and secure
- Level 3: Categorical outcome - all twelve categories (A1 to E12)

See Appendix C for the coding of the outcomes.

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 RTLFB Inventory of 'functional homelessness'. The RTLFB 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.

The primary analysis will use a multilevel (two levels) mixed-effects generalised linear modelling technique to examine the intervention effect on Level 2 categorisation of housing situation at 6 months.

The model will contain the trial arm 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, resulting in 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 as all service users will be rough sleeping. A general equation of

the multilevel mixed-effects generalised linear model for our analysis can be described as follows:

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

The fitted model can be formulated as bellow:

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

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 1, it takes values as (1=stable but secure), (2=stable but insecure), (3=hidden, temporary and/or unstable), (4=rough sleeping).

- $X\beta + Zu = \eta$ 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 gender.
- 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). The effect estimates will be used for the sample size calculation of a future definitive study.

For analysis of the Level 1 outcome, 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.

For the categorical (ordinal) outcome of Level 3 all twelve categories (A1 to E12) will be included. The mixed-effects generalised linear model will be fitted with the assumption of ordinal distribution, a logistic link function and a suitable linear predictor η including a random effect of the Local Authority. In all analyses, model assumption will be evaluated to insure a best fit of the model.

10.5. Secondary Analyses

We will describe the rates of completion of the health status outcome reporting the five items from the EQ5D using frequencies and proportions. The total EQ5D score will be reported at each time point (baseline, 3 and 6 months) using means (SD), or median (IQR) as appropriate. The modelling approach for EQ5D total score will follow the same approach using a mixed-effects generalised linear model. The outcome measure, total EQ5D score 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)η 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 taken with the EQ VAS score (between 0='The worst health you can imagine' and 100='The best health you can imagine').

10.6. Sub-group Analysis

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 determining treatment effects or differences in effects between subgroups.

10.7. Sensitivity Analysis

We will examine the balance of covariates (baseline demographics or factors associated with intervention and outcome) by arm and decide whether adjustment is required, and if so, perform as a separate sensitivity analysis to check for movements in the estimated effects.

10.8. Missing Data

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 (years), 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 (Templ, 2008). No imputation will be performed in this current pilot study.

10.9. Interim Analyses

There are no interim analyses to be performed.

10.10. Adjustment of Confidence Intervals and p-values for Multiple Statistical Tests

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

11. IMPLEMENTATION AND PROCESS EVALUATION (IPE)

11.1. Aim, Objectives and Research Questions

11.1.1. Aim and objectives

The implementation and process evaluation (IPE) aims to collect data to understand how the outreach with a health specialism intervention is implemented, whether the hypothesised mechanisms of action are activated, and how contextual aspects impact on outcomes. Data will be collected to address specific research questions developed for the IPE as well as to provide interpretation and depth of understanding of trial data on primary and secondary outcomes.

The objectives are:

- To explore whether the intervention is delivered as intended and is reflective of the training content
- To examine whether the mechanisms of change identified in the programme theory operate as theorised and whether other mechanisms exist
- To explore acceptability and viability of the intervention and examine perceived impacts of the intervention from the perspectives of staff and service users
- To provide data for interpretation of trial outcomes
- To explore the feasibility and acceptability of main trial processes

11.1.2. Research questions

The research questions for the IPE reflect MRC Process Evaluation guidance on key domains (Moore, 2015) and have been developed to explore: fidelity; reach; acceptability; context; mechanisms of change; differentiation from usual care; perceived outcomes and trial processes.

RQ1 Is the intervention delivered with fidelity?

1.1 Does the intervention content reflect the training received by outreach nurses?

1.2 What adaptations to intervention content are made and how do these impact delivery as intended?

1.3 Are outreach nurses able to spend the intended time on intervention activities?

RQ2 Does the intervention reach the intended target population of people rough sleeping?

RQ3 Is the intervention acceptable to service users, other professionals, and nurses?

3.1 What do the nurses think about the intervention components, and what gaps in the provision have been identified?

3.2 How do service users perceive the intervention components received and what gaps in provision are identified?

3.3 Do other professionals interact with the service and work effectively with outreach nurses, including integration with existing teams?

3.4 Does the lead nurse supervision operate as intended and it is acceptable to outreach nurses?

RQ4 How do context factors impact intervention delivery?

4.1 How do variations in time of day, length of shift and local geographical factors influence intervention delivery?

4.2 How does the availability of local services (housing and health) impact intervention outcomes?

4.3 How do variations in local data sharing processes, professional structures and collaborative relationships impact intervention delivery and outcomes?

RQ5 What evidence is there for the mechanisms of change as identified in the intervention logic model and does the evidence suggest revisions to this model?

5.1 Does the outreach nurse role represent 'fresh' engagement for outreach teams, creating opportunities to have new and reframed conversations around housing and other social care needs and what are the outcomes of this?

5.2 Does outreach nurses' professional credibility increase engagement with both service users and outreach services related to housing? If so, how?

5.3 Does the clinical expertise of outreach nurses increase clients' confidence in, and uptake of, health, social care, and housing services? If so, how?

5.4 Are outreach nurses able to provide clinical and legal advocacy for service users and is this effective?

5.5 Does inter-professional recognition between outreach nurses and other health professionals improve quality of related care assessments? If so, how?

5.6 Does the outreach nurse role increase the number of people identified as having a valid pathway to accommodation entitlement based on a significant health need and what are the outcomes of this?

5.7 How do outreach nurses pre-existing experiences and inter-personal skills act as barriers/facilitators to intervention delivery?

5.8 What other mechanisms of change are evident?

RQ6 To what extent can the intervention be differentiated from existing outreach provision?
6.1 Is it possible to accurately describe treatment as usual in control sites and the differences from intervention content?

RQ7 What are the perceived outcomes of the outreach with a health specialism intervention on those receiving the service?
7.1 What housing and health needs are met/unmet by the intervention?

RQ8 Are trial methods feasible and acceptable?
8.1 Is randomisation acceptable to LAs and why/why not?
8.2 Are there any potential ethical, practical, statutory, or other legal barriers that impact recruitment and retention of LAs and randomisation processes?
8.3 Are methods of data collection feasible and what refinements (if any) are needed?
8.4 Are the target population (people rough sleeping) recruited and retained effectively?

11.2. Research Design and Methods

11.2.1. Overview

The embedded IPE will adopt a mixed methodology, drawing on routinely collected contextual data, and qualitative interviews aimed at understanding lived experience of those delivering and receiving the service. We will purposively sample six sites (four intervention and two usual care control sites). We will also interview LA representatives should any site withdrawals be received.

Within each sampled intervention and control site we will conduct semi-structured interviews with two staff members. These will be conducted by telephone (or online, depending on staff interviewee preference). We will also conduct in-person, semi-structured interviews with three service users (n=18) in these sites. Site staff will support us in identifying key characteristics to include in sampling service users for interviews with the aim of recruiting a varied sample in terms of sex, age, ethnicity, and other key factors identified across the whole sample.

At each sampled site, the researcher will also conduct two observations of intervention delivery and will complete a checklist and field notes. Observations will reflect the main study aims and will 1) Explore how the organisational and geographic context influences the delivery of the outreach service within the Local Authority; 2) Explore the fidelity of the intervention within the Local Authority and differences with usual care.

A time and resource logbook proforma will be completed by staff delivering the service.

Finally, we will interview a key member of staff in each LA that opts to withdraw from the study (potential maximum of 8 interviews). Again, these will be conducted by telephone (or online, depending on staff interviewee preference).

Table 11: Overview of IPE Activities and Objectives

Activity	Objective
Interviews with staff (LAs/nurses)	Intervention: 1. To assess i] acceptability and ii] fidelity of the intervention. 2. To identify any evidence of mechanisms of change as outlined in developed programme theory. 3. To explore barriers and facilitators of service delivery (including contextual factors). Trial methods: 1. To assess acceptability of randomisation. 2. To assess i] feasibility of data collection methods and ii] refinement needed. 3. To assess potential ethical/practical/ statutory/legal barriers that impact recruitment and randomisation. Indicative outcomes: 1. To assess perceived outcomes on service users receiving the intervention. 2. To examine any housing and health needs unmet by the intervention.
Interviews with service users	Intervention: 1. To assess acceptability of the intervention. 2. What evidence is there for the mechanisms of change as identified in the programme theory? 3. To understand service user experiences of receiving the intervention. Indicative outcomes: 1. To assess perceived outcomes for service users receiving the intervention. 2. To examine any housing and health needs unmet by the intervention.
Observation on intervention delivery	Intervention: 1. To assess fidelity of the intervention delivery. Trial methods: 1. To assess i] feasibility of data collection methods and ii] refinement needed.
Time and resource logbooks	Intervention: 1. To assess fidelity of the intervention delivery.

Routinely collected contextual data (interim contact data including level of contact per service user, treatment, care or advice given)	Indicative outcomes: 1. To assess perceived outcomes on service users receiving the intervention. Intervention: 1. To assess acceptability of the intervention 2. To assess fidelity of the intervention delivery
Interviews with staff in LAs that opt to withdraw	Trial methods 1. To assess any potential ethical, practical, statutory, or other legal barriers that impact retention of LAs.

11.2.2. Population

The population will be CGL/LA staff (outreach workers and nurses) and service users in four intervention and two control sites, and LA representatives from any site that opts to withdraw from the cRCT.

Table 12: IPE Interview Inclusion and Exclusion Criteria

Individual	Inclusion criteria	Exclusion criteria
Service Users	• 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). • Sufficient level of conversational English.	• People rough sleeping, not eligible to be included in routine data capture for the cRCT. • Incapable of giving informed consent.
Intervention Staff	• Outreach team workers and nurse practitioners delivering the outreach with a health specialism service in selected LAs. • Lead nurse supervising nurse practitioners. • Outreach team workers supporting nurses to complete outreach shifts.	• Intervention staff that have not received the Test and Learn with health specialism bespoke training package (e.g. agency cover).
Usual Practice Staff	• Outreach team workers delivering usual practice in selected LAs.	• Agency cover staff.
LA Representative	• LA site withdrawal confirmed in writing/notified via CHI.	• LA staff/representative with no understanding or

	• LA site project lead or nominated staff representative involved in homelessness provision.	sufficient knowledge of reasons for withdrawal.

11.2.3. Sampling strategy

A purposive sampling strategy will be used to identify a range of sites to ensure they are representative of a broad range of geographical areas (e.g. urban and rural) and population sizes and size of homeless population.

Service users accessing support from the local outreach service will be informed of the opportunity to take part in interviews and asked for expressions of interest. We will aim to interview a diverse range of service users by gender, age, and ethnicity across the whole sample of six areas.

Sampling levels are guided by information power (Malterud et al., 2015) whereby a relatively small number of participants is justified by the specialist knowledge and information power that they hold, which would not be improved upon by continued recruitment.

All intervention sites will be asked to complete the time and resource logbooks.

Table 13: IPE Sampling Size

Activity	Sampling size n=
Observations	2 on-street shifts per site (3 intervention & 3 control sites) (N=12)
Intervention and control site interviews	2 staff per site (N=12) 3 service users per site (N=18)
Time and resource logbooks	8 intervention sites
Interviews with LAs that opt to withdraw	Up to a maximum of 8 interviews

11.2.4. Recruitment

- Service user interviews:

Individual interview participants will be recruited as follows in both intervention and control sites:

Wider Local Authority staff will be key gatekeepers. Staff will be briefed early in the study on the intention to interview service users and asked for their advice on approaching people. Staff will then be asked to gain informal expressions of interest from people they are supporting, which will then be followed up where possible during site visits by the research staff.

Outreach staff will introduce the researcher to interested participants who meet the inclusion criteria and are available at the time of on-site visit by the research staff member. The researcher will explain the purpose of the study and provide an information sheet, which can be read by the service user or read out by the researcher if preferred. The service user will be invited to ask any questions and, once these are addressed, the researcher will gain written consent for interview participation. This will then be confirmed verbally at the start of interview recording. Interviews will be conducted in a quiet space where possible in the context of on-street delivery, but in sight of LA staff at all times.

- Staff Interviews:

The evaluation team, CHI Project Manager, and LA Project Lead will identify and contact potential participants and distribute details of the research. Site staff will be approached by the evaluation team and asked if they are interested in taking part in an interview. Should any site withdrawals be received, LA Project Lead staff will be invited to take part in an interview or nominate a site representative with sufficient knowledge of reasons for withdrawal.

The evaluation team will provide potential participants with an information sheet and consent form to decide if they would like to take part in an interview. The evaluation team will follow-up to establish interest and arrange an online/telephone interview.

11.2.5. Data collection

Routine data will be collected as per Section 8 of this protocol.

Semi-structured interview guides will be developed for staff and service user interviews. Different staff interview guides will be developed for intervention and control site staff. Topics will include:

Intervention:

- Descriptions of routine/intervention service delivery (including any associated costs to deliver these, e.g. material costs)
- Barriers and facilitators to delivery as intended
- Perceptions of mechanisms of change relating to the intervention
- Attitudes to service content and views on any additional service needs not being addressed

Trial methods:

- Attitudes towards randomisation methods
- Barriers and facilitators to randomisation and data collection methods
- Refinements to amended routine data collection tools
- Factors influencing withdrawal (where relevant)

Indicative outcomes:

- Perceptions of impacts of the intervention

For service users, interviews will include:

- Experience of receiving support, including barriers and facilitators to accessing services
- Perceptions of service content and any unmet needs
- Perceived mechanisms and impacts of the intervention

Observation data collection will be conducted in the format of field notes during site visits to capture any relevant contextual information as well as through a structured observation checklist based on developed programme theory of the intervention. Checklists will include reflections on numbers and types of interactions with service users, factors within the geographical and local context that impact on intervention delivery, fidelity of delivery based on the types of support offered to service users, quality and consistency of the intervention delivered by staff.

Intervention staff will be asked to complete a time and resource logbook proforma which will outline resource spent on various intervention components.

11.3. Data Analysis

Routine contextual data will be thematically coded to understand nurse and service user interactions, e.g. treatment, care, and advice given and service user responses, as well as perceived acceptability of the intervention and fidelity of delivery.

Interview data will be transcribed verbatim and field notes will be transferred electronically and expanded where relevant. Qualitative data will be analysed using deductive and inductive coding. Initial coding will be aligned with the research questions as a means of organising the data for subsequent interpretation. Using a mixed methods approach we will undertake a thematic content analysis, in which themes will be identified and organised into an analytical framework.

Observational checklist and resource logbook data will be analysed using content analysis and will feed into the overall analytical framework. We expect this to include themes from the optimisation (Phase 1), which may be further developed and refined, and additional 'new' themes that arise from Phase 2 of the trial. NVivo 12 software will be used to process this data. Each portion of analysis will be reviewed by a second researcher and discussed within the team to ensure rigour.

12. ECONOMIC EVALUATION

12.1. Aim, Objectives and Research Questions

Aim: The economic evaluation seeks to understand the extent to which the economic and societal benefits of the intervention offset the associated costs of undertaking it.

Objective: The overall objective is to better understand to what extent the outreach with a health specialism service achieved good value for money.

Research Question: To what extent did the benefits of the outreach with a health specialism service exceed its costs?

12.2. Research Design and Methods

12.2.1. Overall approach

The economic evaluation will utilise a cost-benefit analysis (CBA) to understand whether the outreach programme offered value for money – that is whether the monetised benefits of the programme exceeded the associated costs. The CBA framework set out below aligns with the principles set out in the HM Treasury Green Book (The Green Book, 2022).

To undertake a CBA, both the benefits and costs must be expressed in monetary terms. Sections 12.2.4 and 12.2.5 set out the expected costs and the benefits, and critically, the means of monetising the benefits.

We note that for this CBA to be of maximum relevance for MHCLG, we will strive to align its parameters and assumptions as much as possible with existing cost-benefit analyses conducted by MHCLG. Information on these assumptions is not available at the time of writing, so this protocol outlines the evaluation team's current assessment. However, if more appropriate assumptions on consensus-based values are identified by MHCLG, these will be utilised for the evaluation. These could be described in a future protocol amendment. We also acknowledge that one wider goal of the pilot is to help bring more consensus to accepted parameters and definitions of such avoided costs/benefits in the homelessness sphere.

12.2.2. Relevant alternatives/counterfactuals

There are alternative methods of undertaking value-for-money assessments:

- Cost effectiveness analysis – This is used when the benefits of a programme can be aggregated into common units, but the benefits cannot be monetised. Many health programmes utilise a CEA analysis where the intervention can be aggregated to a single non-monetisable outcome, e.g. cost per avoided cardiac event.

- Cost consequence analysis – This is used when the benefits of a programme cannot be aggregated into common units and instead are presented separately alongside their associated costs to provide a comprehensive summary of costs and effects.

- Cost benefit analysis – This is used when the benefits of a programme can be monetised and presented alongside their associated costs. This allows researchers to provide an assessment of costs and benefits summarised in monetary terms. Note, however, that some benefits or costs might not be monetisable and will be described as such.

Following guidance in the HM Treasury Green Book, we will attempt to conduct a social cost-benefit analysis as the recommended approach to undertake value-for-money assessments.

A *counterfactual* identifies what would have happened in the absence of the programme. Anything observed over and above the counterfactual we consider 'additional'. It is these additional benefits which represent economic and societal gains and are what we seek to understand the monetary value of. In the context of this trial, we consider the control arm to provide the counterfactual. The random assignment of areas to each arm somewhat improves the credibility that observed differences in outcomes (i.e. housing stability and security as well as health benefits) can be attributed to the outreach with health specialism programme. Furthermore, the inclusion of other characteristics and controlling for baseline differences in outcomes will help to further strengthen the robustness of the counterfactual. Therefore, the economic evaluation will use parameters that account for baseline imbalances in line with the analytical approach described in Section 10.4.

12.2.3. Time horizons

The HM Treasury Green Book stipulates that the costs and benefits should be calculated over the lifetime over which the benefits are expected to last.

In the case of the outreach programme, the timings are as follows: the service runs for a period of 17 months from January 2025 to May 2026, baseline data collection takes place between January 2025 and October 2025 (ten months), with outcome data collection phased over most of the period of service delivery, ending in April 2026. For each individual, in treatment or control, there is baseline data collection followed by a data collection three months later (mid-period) and then a final six-month data collection. From a CBA perspective this means that the live period in question is only six months since first contact, reducing issues of discounting and net present value.

There is limited evidence which suggests how long the benefits (e.g. housing situation, health benefits or reduced service use) are expected to last for once the support is removed from those in the intervention arm. Given the uncertainties around the long-term outcomes of those in the trial, this economic evaluation will assess the value for money over the six months between baseline data collection and six-month follow up data collection. However, we note that this is likely to be an underestimate of the potential benefits of the intervention.

We anticipate that the costs of the outreach services with a health specialism programme may exceed the benefits over this short time horizon (a description of costs and benefits is below). Hence, we expect to carry out a breakeven analysis to produce an estimate of how many years service users in the intervention arm would need to remain housed for, until the benefits justified the costs[3]. This will entail applying discount rates and taking account of inflation to determine the breakeven rate.

12.2.4. Costs

We anticipate that the **costs** will include primarily:

- **Intervention costs**: This includes all costs incurred to set up and deliver the outreach services with a health specialism, including bespoke outreach nursing training to work with people rough sleeping.

- **Materials and equipment:** This includes other costs such as equipment and materials to offer treatment.

A note on apportioning the cost of the nursing outreach service: The full cost of the nursing component needs to be calculated, recognising that nurses will spend time taking part in evaluation activities, serving people included in the study, and also serving people not included in the study that they encounter. We will consistently exclude evaluation costs throughout the CBA.

We will apportion costs according to the proportion of time spent working with people eligible to be included in the trial, drawn from logbook data provided by the nurses. Time spent in supporting the evaluation (including data collection) above what would be considered necessary for standard practice will be excluded from the calculations.

A note on how staff are employed: The nursing staff in this trial will be employed by CGL. Potential future intervention delivery and scale-up is likely to involve NHS-funded nurses where costs are higher (e.g. due to higher pension costs). We will undertake sensitivity analysis around costs assumptions regarding the nursing staff.

12.2.5. Benefits

We anticipate that the **benefits** of the intervention, scaled by the size and duration of the impact outcome can be grouped across the following categories: avoided costs associated with improved housing situations (primary outcome measure) and the (monetised) impact of the intervention on the health of the service users (secondary measure). We discuss these in turn.

[3] Breakeven analysis aligns with Cost Effectiveness Analysis in Green Book terms, enabling arguments to be made for the programme without the need for the stronger evidence requirements that relate to CBA, though it is more dependent on modelling assumptions which can be further tested in sensitivity analysis terms.

Avoided costs. It is anticipated that there would be a number of costs that would be avoided if someone was able to cease rough sleeping, over and above the counterfactual.

We do not think the short life cycle of the pilot permits distinguishing two types of direct benefits – ending rough sleeping and therefore going into temporary accommodation (TA); but then over time moving from TA to settled accommodation. However, for this trial we do note that moving into TA itself increases TA usage and costs and these would need to be factored into the CBA.

We also understand the lack of consensus around critical values for avoided costs more generally and note that narrowing this divergence is a priority outcome anticipated form the Test & Learn exercise as a whole – we thus expect to use the more consensual and agreed measures where it is appropriate to do so.

Pleace and Culhane (2016) undertook research to understand the use of public services by those that are homeless. Pleace and Culhane (2016) utilised qualitative interviews with 86 people experiencing homelessness for at least 90 days from across England to understand their levels of service use, which informed an estimation of associated costs. The authors then sought to understand the potential cost saving associated with moving someone from homeless to homed. This is a challenging exercise for two main reasons: firstly, there is no clear counterfactual, i.e. what the service use would be for the same person were they not homeless; and secondly, service use may partly be determined by previous experiences during homelessness. The estimated cost saving from Pleace and Culhane (2016) of going from homeless to homed is presented in the table below (Table 14).

The authors caution that their sample is not representative, however this remains the most comprehensive assessment of the associated costs of homelessness known to the evaluation team.

As mentioned above, we will consult with MHCLG analysts to ensure the most appropriate and up-to-date cost savings estimates are used, aligned with assumptions used by their own CBAs.

Given the inherent uncertainty in using values that may not be representative of the population, optimism bias adjustments will be applied to ensure that the benefits are not overstated (or costs understated).

Due to data and research limitations, we have not included any potential disbenefits that may arise from being housed.

Table 14: Estimated Annual Cost Saving from Reduced Public Service Use when Going from Homeless to Homed (2023/24 prices)

Units Cost	Annual Cost Saving (2023 prices)
Reduction in use of drugs and alcohol services	£398 per person
Reduction in the use of mental health services	£632 per person
Reduced NHS service costs	£1,294 per person
Reduced Criminal Justice System costs	£3,008 per person
Reduction in use of hostels and night shelters[4]	£14,173 per person
Reduction in services specific to those who are rough sleeping[5]	£1,412 per person

Source: Pleace and Culhane (2016)
All prices converted from 2016 prices to 2023 prices using the GDP deflator

A second though not independent approach concerns the Crisis PWC research (2018) which also produced a similar table (Table 15) with a range of outcomes.

Table 15: Selected CBA Homelessness Proxies (PWC, 2018)

Outcome proxy	Programmes providing the service	Proxy benefit type	Proxy benefit value per homeless individual p.a. (2023 prices)	Option to apply to CBA
Employment	HPG, RSI, RSAP	Increased economic output	£10,650 for people rough sleeping	Yes
Access to drug and alcohol services	RSAP	Avoided cost to the exchequer	£396 for people rough sleeping and the broader group of core and wider homeless individuals	Yes, the estimate for individuals in long term housing is used as a proxy for

[4] This estimate includes new burdens that may be placed on public finances such as housing benefits or continued support services.
[5] This includes specific services for those not accommodated by homelessness services, i.e. rough sleeping or squatting. This cost saving is therefore only applicable to this demographic.

				prevention services
Access to mental health services	RSI, RSAP	Avoided cost to the exchequer	£630 for people rough sleeping and the broader group of core and wider homeless individuals	Yes, the estimate for individuals in long term housing is used as a proxy for prevention services
Access to NHS	RSI, RSAP	Avoided cost to the exchequer	£5,811 for people rough sleeping	Yes, the estimate for individuals in long term housing is used as a proxy for prevention services
Access to criminal justice services	RSI	Avoided cost to the exchequer	£3,003 for people rough sleeping and the broader group of core and wider homeless individuals	Yes, the estimate for individuals in long term housing is used as a proxy for prevention services
Wellbeing from moving form temporary onto permanent housing	RSAP	Benefit to the service user	£26,349 for people rough sleeping	Yes

Source: RSM (2024) Economic Assessment of Options Appraisal Table 10. Selected rows.

Finally, in a separate review by CHI (September 2024), we can sense heterogeneity of different measures identified in recent research over the last ten years. Key examples in annual 2023 prices include:

- Homelessness related services (£1,819 [MHCLG formerly DLUHC] to£18,558 [Pleace and Culhane])
- Police and criminal justice (£5,927 [MHCLG formerly DLUHC] to £15,028 [Pleace and Culhane])
- Health-related services (£9,498 [MHCLG formerly DLUHC] to £10,345 [Bramley, et al.])

Table 16: Estimated costs by service type and services included (in 2023 prices)

	MHCLG (formerly DLUHC) 2020	Pleace and Culhane 2016	Bramley, et al. 2015	Johnsen, et al. 2022
Homeless-ness related services	High needs: 1,819 Low needs: 1,695 Only 'rough sleeping services' valued using Bramley, et al. 2015	18,558 Hostel Night shelter Daycentre Outreach *Note: Costed based on detailed pattern of service use*	4,061 Hostels (rate above Housing Benefit) 'Rough sleeping services' *Note: Costed services used, proxied by whether they have seen different types of workers. Unclear which rough sleeping services are included in the calculation*	9,051 Hostel B&B Other TA / supported accommodation *Note: Costed based on last accommodation only. Does not assign costs to people who were sleeping rough (e.g. outreach)*
Police and Criminal Justice	High needs: 5,927 Low needs: 3,110 Arrest Conviction Prison	15,028 Arrest Court appearance Injunctions for nuisance / anti-social behaviour	6,871 Imprisonment Offending	7,259 Caution Arrest Attended court Required to wear a tag Police custody Prison Warning for nuisance / anti-social behaviour Given a ticket
Health-related services	High needs: 9,498 Low needs: 3,054 A&E GP Ambulance Mental health	9,672 A&E GP Ambulance Mental health appointment and stay, including community	10,345 A&E Ambulance Mental health stays Hospital stay Drugs treatment	9,508 A&E GP Ambulance Mental health appointments and stay Hospital appointments

	appointments and stay Hospital appointments and stay Alcohol treatment Drugs treatment	mental health team Hospital appointments and stay Alcohol treatment Drugs treatment		and stay Alcohol treatment Drugs treatment

Overall, we see a range of estimates, different sampling strategies and analytical approaches as well as examples where there is less variation (e.g. health-related services) and others where the limits double in size. These need to be assessed and evaluated and then scaled to the lifetime of the project for the primary CBA but also annualised and discounted for any required breakeven analysis.

Our approach will be to review, assess and test the different options open to us, building on developments in our expertise on estimates of avoided costs arising from the programme as a whole.

Health improvements. It would be anticipated that transitioning from sleeping on the streets to stable housing would see improvements in one's physical and mental health. Note that these are personal benefits accrued by the individual rather than savings to the public purse (described in the section above). Incorporation of physical and mental health benefits into a cost-benefit analysis is typically achieved by estimating the number of Quality Adjusted Life Years (QALYs) associated with the intervention[6]. However, common measures of estimating the increase in QALYs are typically better suited to understand changes over the long-term, rather than the short-term. The trial follow-up period is 6 months and as such is not expected to provide a robust measure of impact. But we will test this expectation in our modelling by incorporating QALYs into the secondary benefits alongside EQ5D-5L. The trial uses QALYs rather than WELLBYs (WELLBYs is recommended in Green Book Guidance) because it is most relevant to the intervention (health-related quality of life) and is more aligned with the theory of change.

Turning to EQ5D-5L – (See Outcome Section 7 and Appendix D). This is in brief, a health status measure that covers five dimensions of health (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) with five levels of severity in each dimension. This measure can be easily translated to QALYs, and monetised. There are some disadvantages (i.e. what it actually measures, ceiling effects – particularly in relation to this population etc.) but on balance it is the best indicator to use.

[6] Where a QALY is a measurement of quality of life. Each additional QALY carries a monetary value of £60,000 (n 2010 prices), as set out in the HM Treasury Green Book.

12.2.6. Sensitivity analysis

It is good practice to test the sensitivity of the overall result by following clues in the literature to test our low, central and high estimates of particular inputs into the CBA model. We will also assess, where appropriate, confidence intervals and statistical significance of the model under different assumptions. This can also test different levels of optimism bias, see below.

We will also undertake sensitivity analyses to account for higher staffing cost (i.e. higher pension costs) if this intervention were to be delivered by NHS staff.

12.2.7. Optimism bias

Optimism bias (OB) both on the costs side and the benefits side has long been recognised as a possible question mark over the veracity of net benefit results. While much of the Green Book evidence relates to infrastructure projects, we need to consider a range of possible OB estimates suggesting that good practice sets this between 10-20%, with a preference for the higher end of that range. We will continue to discuss the approach and narrowing our chosen OB measure value with MHCLG who vary their OB factors according to intervention type and sale and quality of data. To account for the uncertainty of the avoided costs and benefits, optimism bias adjustments of 20% will be applied[7].

12.2.8. Other considerations

The monetary value of all costs and benefits will be uprated to the current price year (2024 prices).

Whilst the CBA is only expected to explore costs and benefits over the six months the trial runs for, costs of benefits that run beyond this (i.e., for the breakeven analysis and over several years) will be subject to discounting to ensure that all costs and benefits are expressed in their 'present value'. The Green Book prescribed discount rate is 3.5%, or 1.5% for health benefits[8].

12.3. Data Collection

Table 17 below outlines at a high level the data collection and analysis methods for indicators relevant to the economic evaluation.

[7] This optimism bias adjustment is subject to change to ensure that we align our value for money assessment with CBAs undertaken within the homelessness and rough sleeping team at MHCLG.
[8] Note, discount rates begin to fall after 30 years.

Table 17: VfM Indicators and Methods

Indicator	Data Collection Method	Analytical Method
Reduction in people who are rough sleeping – either through avoided rough sleeping or transitioning from rough sleeping to housed	Included in routine data collection. Housing outcomes drawn from the CHI adapted version of the Residential Time-Line Follow-Back (RTLFB) inventory (see Outcome Measures - Section 7).	Using regression analysis to compare intervention and control groups.
Health status	EQ5d-5L included in routine data collection (see Outcome Measures – Section 7).	Using regression analysis to compare intervention and control groups.
Interactions with health services	Questions adapted from MHCLG rough sleeping Questionnaire and included in routine data collection.	Using regression analysis to compare intervention and control groups.

13. QUALITY CONTROL AND ASSURANCE

13.1. Data Quality and Assurance

The CRiiS database is owned and maintained by CGL, who will manage the data. CGL will be responsible for anonymising the data before it is sent to the CTR. Quality control (QC) will be performed by the Trial Data Manager before the data is sent to the Trial Statistician.

User acceptance testing will be conducted by the Trial Data Manager and CGL data business partner prior to live data being entered into the database to test that calculated fields work correctly and data is fully anonymised when transferred.

Due to the nature of the data collection, it will not be possible to perform QC on the source data.

13.2. Protocol Deviations and Non-Compliance

The Principal Investigator will report any non-compliance of the trial protocol or the conditions and principles of Good Clinical Practice to the Centre for Trials Research (CTR) in writing as soon as they become aware of it. CTR Quality Assurance Team will follow standard operating procedures and review if a deviation, violation, or serious breach has occurred. If required, they will identify and allocate a lead to conduct further investigations.

14. REGISTRATION

14.1. Register

The trial is registered with the ISRCTN Registry (International Standard Randomised Controlled Trial Number) Ref: ISRCTN11572394.

15. ETHICS

15.1. Ethical Approval

Ethical approval for Phase I of the study (Optimisation) was obtained from Cardiff University School of Medicine Research Ethics Committee (18/07/2024 Ref:24/38).

Ethical approval for Phase 2 of the study (cRCT) was obtained from Cardiff University School of Medicine Research Ethics Committee (17/10/2024).

All work complies with the General Data Protection Regulation 2016 and the Data Protection Act 2018, the Common Law Duty of Confidentiality.

15.2. Informed Consent

15.2.1. Phase 1 and Phase 2 staff interviews

The evaluation team will contact participants via email and send them an information sheet and consent form allowing enough time to consider their decision to participate. If participants would like to attend an interview, they will complete the consent form by agreeing to the statements and return the form to the evaluation team via email, keeping a copy for their records. A follow up email will confirm if they would like to attend an interview, and a suitable date and time agreed.

Participating in the research is entirely voluntary and will not be a requirement of the role in the delivery of the project. Stakeholders, outreach team workers, nurse practitioners, and LA staff can choose not to take part if they wish.

15.2.2. Phase 2 service user interviews

LA outreach workers and nurses will be asked to introduce the research during routine practice and gain informal expressions of interest to take part in an interview. They will then introduce the researcher to interested participants. The researcher will explain the purpose of the study and provide an information sheet, which can be read by the service user or read out verbally by the researcher if preferred. The information sheet will be concise and written using plain language that is familiar and appropriate. There is no provision for language interpreting

and translation, participating in an interview requires a sufficient level of conversational English and capacity to consent.

The service user will be invited to ask any questions and, once these are addressed, the researcher will gain written consent for interview participation. This will then be confirmed verbally at the start of interview recording. Interviews will be conducted in a private space where possible in the context of on-street delivery, but in sight of LA staff at all times.

Participating in the research is entirely voluntary and will not affect receiving outreach with health service support. Service users can choose not to take part in any aspect of the research if they wish and will be advised of their right to withdraw in the information sheet and reminded at the time of interview.

15.2.3. Phase 2 routine data

CGL and Local Authority sites collect routine data as part of normal service delivery. For the cRCT, CGL and Local Authority sites will collate routine data in a central database. Local Authority sites as independent data controllers and MHCLG as data controllers will have data privacy notices explaining the personal data they collect, how they use, store and delete it, the legal basis for using personal data, and service user's legal rights in relation to this study. Further details can be found in Section 16.2.

15.3. Withdrawal

Interview participants have the right to withdraw consent for participation in the study at any time. Interview participants will be advised of their right to withdraw in the information sheet and consent form and reminded at the time of interview. The participant's care or employment/role will not be affected by declining to participate or withdrawing from the study. If a participant initially consents but subsequently withdraws from the study, clear distinction will be made as to what aspect of the study the participant is withdrawing from.

These aspects could be:

- Withdrawal from participating in an interview.
- Withdrawal from previously collected data (If data analysis has been conducted, participants will be unable to withdraw from previously collected data, this will be specified in the information sheet and consent form).

Participants who consent and subsequently wish to withdraw should notify the evaluation team via email or telephone. In addition, service users can request withdrawal through their outreach worker/nurse practitioner who will notify the evaluation team. Withdrawal notifications should be sent to the Trial Manager who will complete the study withdrawal form on the participant's behalf and log it in the study withdrawal file. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager.

15.4. Ethical Challenges

In Phase 1 there are no risks of participants experiencing physical, emotional or psychological harm or distress.

In Phase 2 service users will be advised that they do not have to answer any questions that may cause distress and that they can stop the interview at any time. As interviews will be conducted during outreach visits, this means that CGL/LA staff, who are professionals with experience of supporting this population, will be available should any issues arise during interviews that may require immediate support. The researchers will raise any such issues with CGL/LA staff, with the consent of the participant.

Interviews will not be conducted with any service user who is unable to consent. Research staff will follow University Lone Worker Guidance at all times and conduct data collection activities in sight of LA/CGL staff. The PE Lead and Trial Manager will be aware of the times and dates of data collection and the researcher on site will be required to make contact at the end of each session to confirm their safety. Should research staff experience any distress or incidents of concern during data collection, they will report this to the PE Lead, who will then liaise with the Trial Manager for appropriate support and follow-up actions.

15.5. Risks

A trial risk assessment will be completed by the Trial Manager to identify any potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. A copy of the trial risk assessment may be requested from the Trial Manager.

15.6. Safeguarding

Cardiff University has a Lead Safeguarding Officer, two Principal Safeguarding Officers and a network of Designated Safeguarding Officers where required. These Officers will work with other agencies where appropriate to ensure legal and regulatory compliance and to achieve the aims of the University's safeguarding policy. Current post holders' details can be found on the Safeguarding Public Information pages of the website located here.

We will ensure that all interview participants are provided with an information sheet prior to data collection, which details examples of where confidentiality would have to be breached (i.e., when children are in danger).

If researchers suspect that a participant is at risk of immediate harm, they will take immediate action by informing the appropriate emergency service (e.g., Police).

In the event of discovering a situation which may present a risk to participants or others, the researcher will inform the lead member of staff at the site. CGL/LA staff/site teams will then follow their Local Safeguarding Policies.

Disclosures/safety concerns raised by fieldworkers/the evaluation team must be captured on an adverse event report form and sent to the study mailbox at the Centre for Trials Research (CTR) Test&Learn@cardiff.ac.uk within 24 hours of knowledge of the event, and the Principal Investigator should be notified as soon as possible.

16. DATA PROTECTION AND INDEMNITY

16.1. Data Protection Statement

All information about individuals will be handled in confidence and will only be seen by the evaluation team and the Ministry of Housing, Communities and Local Government (MHCLG) as data controller. Study data (for example interview data) will be stored at Cardiff University and will be kept separate from personal information (name and email address) until requested by the data controller. To protect interview participant identity, we will replace names with a study ID number and will never share personal information with anyone except when requested by the data controller. Only members of the evaluation team and the data controller will have access to view identifiable data. The only time we will break confidentiality is if a participant tells us that they or someone else is at risk of harm. We would then need to tell someone who can help. In some instances, officials from regulatory authorities may need to access data for checking the quality of the research. All members of the evaluation team and regulatory bodies are trained in data protection issues and bound by the terms of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

16.2. Legal Basis

Cardiff University, as sub-processor acting on behalf of the Ministry of Housing, Communities and Local Government (MHCLG) - the data controller, may use personal data for the following purposes and on the following lawful bases.

The processing of personal data will be conducted under the legal basis of the UK General Data Protection Regulation (UK GDPR), specifically Article 6(1)(e). Article 6(1)(e) pertains to the processing of personal data necessary for performing a task in the public interest or exercising official authority vested in the controller.

The selected legal basis for processing personal data aligns with the public task basis under the UK GDPR – 6(1)(e) and 9(2)(j). The evaluation team is committed to conducting the evaluation in the public interest and exercising official authority vested in the controller. The collection and processing of personal data are essential for this trial's research and statistical purposes. The overarching goal is to contribute to the wellbeing of those at risk of homelessness.

Where special category data is processed, the legal basis for processing it is Article 9(2)(g) of the UK GDPR, that processing is necessary for reasons of substantial public interest.

16.3. GDPR Compliance

Cardiff University, on behalf of MHCLG (data controller) is committed to respecting and protecting participant's personal data in accordance with their expectations and Data Protection legislation.

Further information about Data Protection, including:

- participant rights
- the legal basis under which personal data is processed for research
- MHCLG's Data Protection Policy
- how to contact MHCLG's Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at Homelessness and rough sleeping: Outreach with a health specialism: privacy notice - GOV.UK (www.gov.uk)

16.4. Data Processing Roles

Data controller: MHCLG assumes the role of the data controller and holds the responsibility for determining the purpose and means of processing personal data within the scope of the RCT.

Processors and sub-processors: CHI will act as a processor with Cardiff University Research (evaluation team) and CGL (delivery and data collection) acting as sub-processors under the instructions and on behalf of the data controller.

Local Authorities and MHCLG will act as independent data controllers, as set out by a relevant Memorandums of Understanding. With MHCLG acting as data controller, this enables the sharing of data with processors and sub-processors of this project.

Further information can be found:
Homelessness and rough sleeping: Outreach with a health specialism: privacy notice - GOV.UK (www.gov.uk)

16.5. Data Archiving

At the end of the evaluation, Cardiff University will securely transfer all data to the data controller. CGL will securely transfer the master dataset with key identifiers to the data controller. Identifiable data will be shared by CGL with MHCLG in an agreed format via a secure platform specified by MHCLG. Once MHCLG download that file, the encryption key and password for the file will be shared verbally via a phone call. Once transferred, the data controller may keep data securely stored for up to five years after the completion of the study, after which this will be further reviewed. Data will be stored, processed and archived as per

the MHCLG charter (Personal information charter - Ministry of Housing, Communities and Local Government - GOV.UK (www.gov.uk).

All data collected and processed by Cardiff University, CHI, and CGL will be destroyed 3 months after the end of the evaluation in accordance with their data sharing agreements.

Cardiff University evaluation team will have access to a secure data portal via the data controller to enable re-analysis for publication reasons or audit if required.

Retained data provides an audit trail were the evaluation to be selected for an inspection or in the case of research fraud. It also supports Open Science and promotes reproducibility which is important for transparency.

There may be scenarios where Cardiff University and MHCLG are subject to a legal obligation to disclose or share personal data, such as with law enforcement agencies, regulatory bodies or public authorities in order to prevent or detect crime. Cardiff University and MHCLG will only ever disclose personal data to these third parties to the extent required to do so by law.

Service user records will be retained by CGL for 8 years after they finish treatment with the service and their files will be deleted after this.

16.6. Indemnity Statement

Cardiff University will take on responsibility for the delivery of the evaluation. Cardiff University will be covered by Cardiff University's public liability cover and will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/evaluation team. Cardiff University does not provide compensation for non-negligent harm.

Non-negligent harm: This trial is an academic, investigator-led and designed trial, coordinated by the Centre for Trials Research (CTR). The Principal Investigator, local Investigators and coordinating centre do not hold insurance against claims for compensation for injury caused by participation in a trial and they cannot offer any indemnity.

Negligent harm: Cardiff University does not accept liability for any breach in the other sites' duty of care, or any negligence on the part of employees of sites.

17. STUDY MANAGEMENT

17.1. Trial Management Group (TMG)

The TMG consists of the Principal Investigator (Chair), Co-applicants, the Senior Trial Manager, Trial Manager, Senior Data Manager, Data Manager, Senior Trial Statistician, Trial Statistician, Optimisation Lead, Process Evaluation Lead and Trial Administrator.

The role of the TMG is to assist in the trial set up by providing specialist advice, input to and comments on the trial procedures and documents (information sheets, protocol etc). They also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet either face-to-face or using audio-conferencing facilities. Meetings will take place monthly during the evaluation. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

17.2. Trial Steering Committee (TSC)

The TSC consists of Chair (Sharon Cox), Principal Investigator, Trial Manager, Statistician, Trial Administrator, Homelessness Expert (policy/practice Sarah Waters), two Members with Lived Experience, External Statistician (Jim Lewsey), and Health Outreach Expert (Janet Keauffling).

The role of the TSC is to act as the oversight body for this evaluation on behalf of Cardiff University, providing advice through its independent Chair to the Trial Management Group, Funder and the CTR on all aspects of the evaluation. One academic member will Chair the group. The TSC will meet four times during the lifetime of the evaluation. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter.

17.3. Project Team

This group consists of the Principal Investigator, Senior Trial Manager, Trial Manager, Senior Data Manager, Data Manager, and Trial Administrator who meet weekly to discuss the day-to-day issues that arise from managing the evaluation.

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Appendix A: Randomisation Protocol V1.1

1. Study design
Intervention optimisation followed by a multicentre pilot cluster randomised controlled trial (cRCT) with an integrated process evaluation, and economic evaluation. Eligible local authorities (LAs) will be randomly assigned by an independent statistician in a 1:1 ratio to receive funding to embed a health professional as part of the outreach team (a qualified nurse) or remain with their usual practice. Follow up surveys will be collected 3 and 6-months after baseline assessment.

2. Unit of randomisation
The unit of randomisation will be LAs in England. In cases where two or more LAs share an outreach team, they will be treated as a single site.

3. Number of groups
Two arm study to either receive funding to embed a health professional as part of the outreach team or remain with their usual practice.

4. Number to recruit
16 LAs (8 to embed the health professional and 8 to continue as usual).

5. Randomisation ratio
LAs will be randomly assigned to embed the health professional and usual practice in a 1:1 ratio.

6. Type of randomisation
Block randomisation of varying block sizes will be used to allocate LAs.

6.1 Block randomisation
Blocking is a way to maintain balance of numbers in group allocation and is defined as randomisation sequences that are generated in blocks. Each block will have an equal number of intervention group allocations with the order of treatments within the block randomly permuted e.g. Block size of 4 with allocation order 1001, 1010, 1100 etc. A *computer-generated sequence* will select a particular block arrangement within the block size, which sets the allocation order for the LAs.

6.2 Minimising imbalance
6.2.1 Stratification
Balance is required within the following strata: low and high Rough Sleeping Initiative (RSI) funding allocation for 2022-25 per average monthly number of people rough sleeping (Jan-Dec 23). The cut off for the low/high funding strata will be based on the median RSI funding allocation per individual rough sleeping population of the 16 recruited LAs.

6.3 Stratification/balancing variables:
Stratification will be low and high Rough Sleeping Initiative (RSI) funding allocation per individual rough sleeping (£) based on the eligible recruited LAs and so allocation of intervention and usual practice will be balanced within strata.

The rationale for selecting the LAs RSI funding allocation per individual rough sleeping 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 are likely to have an effect on outcomes of housing stability in a future RCT.

6.4 Number of randomisations to prepare:
Only one randomisation list will be prepared.

7. Allocation concealment
The Stata ralloc program will be written and run by the trial statistician and an independent statistician will randomise the LAs after all are recruited. This will ensure that there can be no bias or cherry-picking of LAs for intervention. Since individual participant data will be collected by nurses delivering the intervention (outreach support or remain with their usual practice), then blinding before baseline or follow-up data collection is not possible. Allocations of LAs will be blinded from the trial statisticians.
If required, randomising LAs in blocks will also be considered if recruitment of LAs is slower than expected, and delaying allocation would delay delivery. We will do so in blocks of a minimum of four LAs, to reduce the risk of subversion, and potential for imbalance.

8. Blinding
This is an unblinded study where LA staff, research teams, and data collectors will know the intervention allocation. The randomisation schedule will be stratified and will be prepared and held by an independent statistician within the CTR.

- The trial statisticians will be blinded to allocation.
- All trial team, data collectors, and participants will not be blinded at baseline or follow-up data collection. Data will be collected by nurses delivering the intervention (outreach support or remain with their usual practice).

9. Fallback procedures in case of primary system failure
All LAs will be randomised at the same time and ahead of recruitment and baseline collection. No fallback procedure is required.

10. Implementation of design
Study population /unit of randomisation

1. The pilot trial will be conducted in England. All LAs that return an expression of interest to CHI will be eligible for the sampling frame.
2. Eligible LAs will:
    - have sufficient numbers to recruit (expect around 40 people rough sleeping to come through the service);
    - where they have an outreach team but they don't have a health specialist based within that outreach team;
    - in reasonable distance (defined by CHI) to a CGL clinical service (to act as a clinical base to host the nurse).
3. CHI will select LAs for the study based on assessment and scoring (via rubric) (see appendix A).

Recruitment of each LA

1. Each LA will individually meet with CHI in an introductory meeting, meet CGL, and sign a contract.
2. The name, region, RSI allocation funding data for each of the 16 recruited LAs will be recorded on an Excel spreadsheet and sent by CHI (Michelle Binfield michelle@homelessnessimpact.org or Rebecca Jackson

rebecca@homelessnessimpact.org) to independent CTR statistician Mandy Lau (ML) (LauTM@cardiff.ac.uk) for allocation.

1. Ideally, allocation of the LAs will occur after **ALL 16 LAs have been recruited and signed a memorandum of understanding**.
    a. If more than 16 LAs are sent (N), we will randomly select N-16 LAs not to be initially allocated. These LA will act as a replacement in case of withdrawal (see Withdrawal procedure section below).
    b. If less than 16 LAs are recruited by CHI:
        i. with no further recruitment intended, we will allocate these LAs using stratified block randomisation as planned.
        ii. with further recruitment intended, we will allocate LAs in blocks (e.g. 6, 6, 4 or 12, 4) to minimise risk of delay, but stratification will not be used since the median cannot be calculated to create the strata. A minimum of four LAs should be included in any one block; however allocations will not be sent out until the block has been filled/recruited to avoid unblinding.

Allocation of recruited LAs

1. Before the LA data is received, the senior statistician (Rebecca Cannings-John (RCJ)) will generate the random number block allocations in Stata (using the *ralloc* command) (see appendix B) and will save, and email this in an Excel data file to ML. This list will contain a generated Site ID, strata code (0/1) and an allocation (A/B).
2. On receipt of the LA data, the independent CTR statistician (ML) will:

Select the replacement LA:

i. Number the LAs from 1 to N and name the field *LA_ID*;
ii. Randomly select one LA not to be included in the allocation using =RANDBETWEEN(1,16). This LA will act as a replacement in case of withdrawal.
iii. Remove the LA from this list by cutting and pasting on to a new sheet and call the sheet 'additional LA'.

b. **Allocate the LAs:**

i. Identify the balancing variable 'RSI funding 22-25 per RS'. If not included, please calculate it = 'RSI funding 22-25' divided by 'Average RS per month Jan-Dec 23'.
ii. Generate a random number for each LA using the formula = RANDBETWEEN(1,100) and copy and paste the values of the array so that they do not change. Name the field *rand_ID*;
iii. Calculate the median RSI funding allocation per individual rough sleeping based on the recruited LAs and place each LA into a new field called *Strata* where:
    1. 0=low RSI funding allocation (< median RSI funding allocation per RS (£));
    2. 1=high RSI funding allocation (> median RSI funding allocation per RS (£)).

Sort the data on Strata and *rand_ID*.

iv. Open the allocation file (T and L allocation codes from ralloc.xls) and allocate the LAs to arms A and B by copying and pasting from the IorC column according to Strata;
v. Allocate the A and B codes to either Intervention and Usual Practice.
vi. Save the file as "*T and L Final allocations <date>.xls*".

Run checks on the data for balance within strata and overall (4 As and 4Bs within each strata);

c. Email the spreadsheet to CHI (Guillermo Rodriguez (GR) (guillermo@homelessnessimpact.org, Michelle Binfield (MR) (michelle@homelessnessimpact.org), and Rebecca Jackson (RJ) (rebecca@homelessnessimpact.org), copying in Linda Adara (AdaraL@cardiff.ac.uk) (CTR Trial Manager). The allocations along with Site IDs will be kept in a restricted folder with access only provided to Yvonne Moriarty (Senior Trial Manager), Linda Adara, and Andrea Longman (LongmanA1@cardiff.ac.uk) (Data Manager)). The same Site IDs will be used for data collection.
d. CHI will then inform each LA of their allocation (outreach support or usual practice).

Withdrawal procedure

If a LA withdraws:

- **before recruitment has started (no consent from participants taken)**, 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 (consent from at least one participant has been taken)**, and the LA will have started the intervention and should not be replaced. Individuals already recruited to the trial, should be followed-up as normal *unless* the LA withdraws fully from the trial and follow-up.

11. Risk of subversion

- Randomising LAs in blocks after recruitment by the independent CTR statistician will ensure that the possibility of guessing the intervention allocation is minimised.
- Intervention will be allocated by an independent CTR statistician to retain blinding of the trial statisticians to intervention allocation. Thus, there is a complete separation of recruitment and randomisation allocation.

12. System testing

We will test the block allocations in Stata to ensure balance (see appendix C). Stata code and all testing documents are held here: https://cf.sharepoint.com/:f:/r/teams/TestandLearnDLUHCproject2/Shared%20Documents/E-TMF/e-TMF%20Shell%20Folders/08.%20Data%20Management/8.5%20Statistics/Randomisation?csf=1&web=1&e=QnuSyJ

And back up here: S:\Centre for Trials Research\Research\Mixed Studies\KiVa\19.0 Randomisation\19.1 Randomisation procedure\ralloc prgram

Appendix B: CHI Outreach and Health – Scoring Rubric (extracted from original document, correct as at June 2024)

Outreach & Health Eligibility Criteria

1. Each Test & Learn project should be unique to the area and there should not be a similar project delivered, commissioned or available. This is to improve the evaluation, more information is available in the FAQ.

Is there delivery of Outreach with a health specialism or a similar service in your area? YES/NO (*if you are not sure please contact us at programmes@homelessnessimpact.org to discuss)

If yes, add the details including why this would be considered different to the Test & Learn service specification (500 words)

2. Please share how many referrals you would expect to make [over XX months, determined per project] as part of this new service and how you have arrived at this estimate. This is so we can estimate the total number of referrals across the project. We won't score your applications on this but we will take it into consideration once all applications have been scored to ensure the overall project will meet the required number of participants. - 30%

3. Can you confirm that in the case that your area is selected (selection is randomised) to be one of the areas that does not have the service delivered in the area (control group) that you will commit to continuing to take part and meeting the requirements of the evaluation. Areas in the control group will receive a £10,000 incentive to support their involvement.

4. Please state which existing Change, Grow, Live service is nearest to your area (this will provide a clinical base for the nurse to work from when not out with the outreach team). How close to your area is this service, and if not close, how will you mitigate the impact of that?

CHI scoring rubric:

EOI Questions

1. Please demonstrate why you want to support the delivery of this project in your area, including outlining the level of need in your area and your experience of working on innovative projects. (750 words) - 25%

2. Please detail how you, and/or your partners, would support Change, Grow, Live in the delivery of this service, including a description of the pattern/ timetable of your Outreach Team and how the Nurse would fit in with this. Please include any experience you have of setting up a new service. (1000 words) - 30%

3. Please demonstrate your commitment to the Evaluation process outlined in the specification and guidance for applicants, including your experience of data sharing and evaluation with external partners. (500 words) - 20%

4. How will you support the Nurse to embed into the Outreach Team and carry out their work safely? Include examples of projects you have delivered with similar challenges. (750 words)- 25%

Scoring Rubric

	Score Guide	Please demonstrate why you want to deliver this particular service, including outlining the level of need, or predicted need, in your area and your experience of working on innovative projects. (750 words) 25%	Please detail how you, and/or your partners, would deliver this service including a description of the pattern/ timetable of your Outreach Team and how the Nurse would fit in with this. Please include any experience you have of setting up a new service. (1000 words)- 30%	Please demonstrate your commitment to the Evaluation process outlined in the specification and guidance for applicants, including your experience of data sharing and evaluation with external partners. (500 words) 20%	How will you support the Nurse to embed into the Outreach Team and carry out their work safely? Include examples of projects you have delivered with similar challenges. (750 words)- 25%
0	Nil or inadequate response. Fails to demonstrate an ability to meet the requirement	Failure to demonstrate why the service is needed in the area or any previous work on innovative projects.	No detail provided on how service will be delivered, timetable or of setting up new services in the area.	Demonstrates no understanding of the evaluation process and the requirements of it. No previous examples of data sharing provided.	Totally fails to meet the requirement - information not available
1	Response is partially relevant and poor. The response addresses some elements of the requirement but contains insufficient/limited detail or explanation to demonstrate how the requirement will be fulfilled.	Little or no description of the requirement for this type of service in the area. Poor example of working on innovative projects, and no evidence that the area will be able to deliver this service.	Does not provide a detailed implementation plan and scant description of timetable. No track record of deliverables provided.	Does not describe any previous collaboration with other services/service provision/evaluators particularly around evaluation of projects and information governance.	Response is brief with limited or inadequate strategies to support the work of the Nurse and address safety.
2	Response is relevant and acceptable. The response addresses a broad understanding of the requirement but may lack details on how the requirement will be fulfilled in certain areas	Demonstrate that the area requires the service and has a plausible need and desire to have the service in the area. Previous examples provided of working on projects, however limited in their innovation or effectiveness.	Describes a basic implementation plan including a timetable. An understanding of setting up a new service, which is functionary, some concerns remain over deliverability and timeframes.	Demonstrates understanding of basic information sharing and partnership working but does not explore how this fits within the wider service or Test & Learn project	Demonstrates some understanding and plan to support the nurse to embed and carry out the work safely. Some evidence of where this happened in other contexts.
3	Response is relevant and good. The response is sufficiently detailed to demonstrate a good understanding and provides details on how the requirements will be fulfilled.	Describes a clear rationale for needing to deliver this project in their area. A track record of implementing new services that were robustly evaluated and project management experience related to this.	Provides a clear description of the delivery of new services, from inception meetings, through to project closure. Provides a timetable of outreach activity. Provides evidence of previously, rapidly setting up services, including the recruitment of staff and engaging with senior leaders across the local homelessness system to do so.	Describes a clear organisational commitment to the improvement of services using data and robust evaluations. Has a track record of working positively on information governance/data protection issues and a positive mindset to address these.	Response is good with a clear plan and strategy to address safety, safeguarding and to embed the nurse within the team. Evidence and examples of where this has been achieved previously.
4	Response is completely relevant and excellent overall. The response is comprehensive, unambiguous and demonstrates a thorough understanding of the requirement and provides details of how the requirement will be met in full.	Clear need and desire to have the service in this area. Enthusiasm and commitment to work on an innovative project	Fully demonstrates the service delivery plan, with a timetable and plan for Nurse to fit in with this. Demonstrate previous experience or skills to set up new services fully.	Full and comprehensive understanding of the evaluation and data sharing process. Demonstrate previous experience or skills and commitment to the process.	Full response with robust evidence, policies and practice to achieve the aim of supporting the Nurse to embed within the team and to conduct the work safely. Demonstrates previous experience and examples of similar work.

Appendix C: 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) Rough sleeping

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.

DK/NA

The data will be coded in three ways:

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 D: Secondary outcome measure: 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

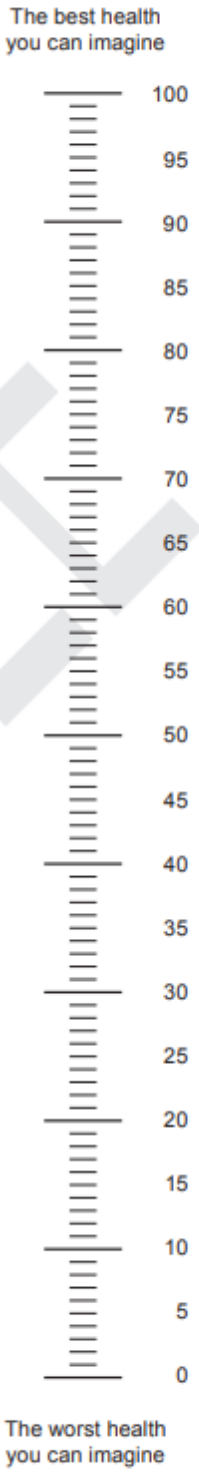
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

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 E: 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 F: Demographics (baseline only)

Age (Database to calculate age and this should be reported, not DoB):

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: Male

Female

Trans Male

Trans Female

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