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

Health Economics Analysis Plan

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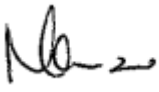

Version History

HEAP version	Protocol version*		Section number changed	Description of and reason for change	Date of change
Version 1	Version 6			New document, based on HEAP template Version 2	<<date>>

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Glossary of Abbreviations

AE	Adverse Event
AUC	Area Under the Curve
CEA	Cost-Effectiveness Analysis
CEAC	Cost Effectiveness Acceptability Curve
CEM	Cost-Effectiveness Model
CHaRT	Centre for Healthcare Randomised Trials
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CUA	Cost-Utility Analysis
DCE	Discrete Choice Experiment
DMEC	Data Monitoring and Ethics Committee
EQ-5D-5L	EuroQol Group's 5-dimension health status questionnaire
GLM	Generalised Linear Model
HCRU	Healthcare Resource Use
HEAP	Health Economics Analysis Plan
HERU	Health Economics Research Unit
HRQoL	Health-Related Quality of Life
HSUV	Health State Utility Value
ICECAP-A	ICEpop CAPability Measure for adults
ICER	Incremental Cost Effectiveness Ratio
iNMB	Incremental Net Monetary Benefit
ITT	Intention-to-Treat
MAR	Missing at random
NMB	Net Monetary Benefit
OLS	Ordinary Least Squares
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALYs	Quality Adjusted Life Years

SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
TSA	The Salvation Army
YFC	Year of Full Capability

1. Introduction

People experiencing homelessness are some of the most marginalised and disadvantaged individuals in UK society. Those experiencing homelessness and problem substance use can find it challenging to access the healthcare and treatment they need. Due to unstable housing, they experience significant social and economic challenges (e.g., poverty, social exclusion) which place them at greater risk of a range of acute and chronic health problems, as well as problem substance use and severe mental health challenges (Lui M. and Hwang S.W. 2021, Fornaro M. et al. 2022). Harm reduction approaches that are peer-delivered, and trauma/psychologically informed have shown considerable promise for improving outcomes and delivery of care to these individuals.

The Supporting Harm Reduction through Peer Support (SHARPS) feasibility study demonstrated that Peer Navigators can help to improve service engagement and increase access to medication assisted treatment. This type of support can lead to reductions in drug use and risky injection practices. Specifically, study participants indicated that the lived experience of Peer Navigators helped enable the development of trusting relationships. A cluster randomised controlled trial (cRCT) will now assess the effectiveness and cost-effectiveness of a Peer Navigator intervention with this population. This Health Economics analysis plan (HEAP) documents the methods and analysis plans for evaluating the cost-effectiveness of the SHARPS intervention versus standard care. The HEAP is based on the SHARPS protocol version 6. Any deviations from the protocol will be described and justified here.

2. Study aims and objectives

The **primary aim** of the SHARPS study is to assess the effectiveness and cost-effectiveness of a Peer Navigator intervention on those experiencing homelessness and problem substance use who are finding it challenging to access the healthcare and treatment they need.

The **primary objective** of the economic evaluation is to conduct a cost utility analysis to determine the cost effectiveness of the 12-month SHARPS intervention compared to

usual care provided by The Salvation Army (TSA), in adults who are experiencing homelessness and problem substance use.

The **secondary objective** is to undertake a cost-consequence analysis which will identify, and where possible measure, all costs, and consequences (effects) of the intervention, compared to standard homelessness care.

3. Study design and participants

A two-arm, pragmatic, cluster randomised controlled trial (cRCT) will be conducted with embedded economic evaluation and mixed methods process evaluation. Individuals will be recruited who are: over the age of 18 years; experiencing/at risk of homelessness and self-report problem substance use; and attending TSA homelessness services across 20 included clusters (towns/cities). Each cluster will be randomised (1:1) to either the intervention or control arm using covariate-constrained allocation based on area-level characteristics. The target sample size is 550 participants in total. Outcomes will be collected at six- and 12-months post baseline data collection. Outcomes from the Peer Navigators will be collected at 12 months post baseline data collection. A full economic evaluation will be conducted from a public sector perspective (including costs falling on the third sector). Given that all costs and benefits occur within a single year, discounting will not be required for the main within trial analysis.

4. Interventions to be evaluated

SHARPS intervention

The health technology being assessed is the SHARPS intervention. This is a relational, co-produced, peer-delivered intervention, informed by harm reduction and psychologically informed environments (PIEs) principles (Schneider et al. 2022). The intervention itself is laid out in the SHARPS intervention guide and training manual that were produced as part of the feasibility study (Parkes et al. 2022) and updated for the full trial (available from the research team on request). The guide provides the Peer Navigators with most of the necessary information to carry out their role, including practical tools, anticipated challenges, and information about the needs of specific sub-populations. This also includes a specific training programme undertaken by each Peer Navigator. The Peer Navigators will work intensively with up to 25 clients for a 12-month

period to facilitate changes to their lives, including attending NHS/housing/welfare appointments with them. Each Peer Navigator will provide practical and emotional support to clients on their 'caseload'.

Control group

In the control group, participants will receive the local standard care pathway from TSA services. While standard care within these settings may vary between areas, it usually involves having Support Workers help those attending services with a range of issues, for example, with housing applications, contacting relatives, or accessing wider support services.

5. Economic overview

5.1. Economic analysis

The within-trial economic analysis will be performed using individual participant level data from those enrolled. The analytical approaches will take the form of a cost-utility and cost-consequences analysis. Based on the trial data, incremental cost-effectiveness (and cost-utility) ratios (ICERs) will be calculated as the ratio of the difference in the mean costs to the difference in mean effects (or utility measure) between the intervention and control group. If 12 month data are supportive of a significant beneficial effect of the intervention, and uncertainty related to cost-effectiveness, further analyses will explore potential for longer-term cost-effectiveness based on extrapolation of estimated differences in health related quality of life/wellbeing and service costs over extended periods up to five years. In this analysis, costs and outcomes incurred beyond one year will be discounted at the rates recommended in the NICE reference case (NICE, 2013).

5.2. Jurisdiction

The trial will be conducted in 20 clusters (cities/towns) in England and Scotland in the UK, which has a National Health Service (NHS) that provides publicly funded healthcare, primarily free of charge at the point of use.

5.3. Perspective

The economic analysis will be primarily from the public sector perspective (including costs falling on the health care provider, social care providers, housing services, and criminal justice services). Whilst the third sector is bearing the cost of delivering the intervention in the study, the intervention has the potential to be funded through public funds (health and/or social care, public health) as part of future rollout. Therefore, the costs incurred by the third sector organisations will also be included in the primary economic analysis. The intervention shows promise in delivering both cost savings and broader societal benefits. By enhancing the mental health and overall quality of life of the target population, it may contribute to a reduction in substance use. This, in turn, could lead to decreased reliance on high-cost health and social care services, such as ambulance callouts and accident and emergency departments. Evaluations of substance use interventions also commonly estimate costs and consequences for the criminal justice system and so these will also be included in the analysis.

5.4. Time horizon

The economic analyses will compare costs and consequences between the treatment allocation arms over the trial follow-up period of 12-months. If the intervention demonstrates efficacy at 12 months, and uncertainty around cost-effectiveness, secondary analyses will explore potential for longer-term cost-effectiveness based on extrapolation of estimated differences in costs and effects out to five years.

6. Economic data collection and management

6.1. Statistical software

Trial data analyses will be conducted using STATA Statistical Software (StataCorp 2025). Extrapolation of longer-term cost effectiveness will be based on simple model developed in Microsoft Excel or other appropriate decision modelling software (e.g. TreeAge Pro, TreeAge Software LLC).

6.2. Resource utilisation

Details of the measurement and valuation of the identified resources are included in Table 1.

Identification of resources

For the NHS and Personal Social Services (PSS) perspective, data will be collected on the use of health services, including general practice, other community-based services, prescribed medication use, and hospital-based services (inpatient and day case admissions, outpatient attendances, accident and emergency visits, and ambulance use). Social care data will be collected on the resources required to deliver the intervention versus usual care (including those of the third sector), use of community day centres, and visits with social workers and care workers. Information will also be collected on criminal justice and housing status.

Measurement of resource use data

Delivery of intervention: the resources required to deliver the Peer Navigator intervention versus usual care will be obtained from various sources, guided by a bespoke data collection proforma (Appendix 1). This has been developed to capture the capital, staff, consumable, and overhead costs associated with recruiting, training, employing and supervising the Peer Navigators and Support Workers in their respective roles within the third sector organisation (TSA) delivering the intervention. This includes costs falling on the employing organisation (TSA), and those falling on any other organisations involved in the training and/or supervision of these staff (in this case the Scottish Drugs Forum, partner organisations within the trial and University of Stirling research staff running the trial). These costs may be adjusted to inform likely costs of future role out by different agencies. Costs will be estimated on an annual basis and apportioned on a per client basis based on estimated client caseloads and duration of client engagement with the service. Costs of employing and training Support Workers (those who deliver usual care at control group sites) will be estimated in a similar way. The extent to which Peer Navigators act as a substitute for and reduce the client workload falling on Support Workers at intervention sites will be assessed in exit interviews with TSA managers and Peer Navigators. Based on findings of these respective data collection exercises, the expected additional cost of providing the Peer Navigator care versus usual Support Worker care will be determined. Scenario analysis will cover the range of possibilities, from assuming the cost of providing Peer Navigator support per client is fully incremental (in addition to

Support Worker time), to assuming it fully substitutes Support Worker time required for the care of clients.

Health care resource utilisation: data on the use of NHS services (including primary care, community care, medication, and secondary care-based services) will be captured using participant-reported questionnaires administered by the research team at baseline, six, and 12 months (see Appendix 1).

Other social care resource utilisation: use of other social care services run by local authorities or third sector organisations other than TSA will be collected as part of the participant-reported questionnaires administered by the research team in both arms at all time points. This includes use of community day centres, social worker office and home visits, and visits with other social care workers or advisors (other than those employed by TSA).

Criminal justice services: data collection has been limited to, arrests, cautions, or fines, court appearances, and imprisonment as part of the participant-reported questionnaires.

Housing: Data on housing is restricted to housing status (see Table 1 for categories) collected at baseline, and at 6 months and 12 months follow-up.

Valuation of resource use data

All resource use will be valued in monetary terms using appropriate UK unit costs or participant valuations estimated at the time of analysis (2025-2026). Unit costs for NHS primary and secondary care resource use will be based on nationally representative published sources. The cost of medications will be obtained from the British National Formulary (Joint National Formulary 2025). Community and primary care costs will be based on national estimates published in the Unit Costs of Health and Social Care 2024 Manual (Jones et al. 2025). Hospital resource use will be costed using NHS reference costs by specialty or, where sufficient details are available on reasons for admissions, Healthcare Resource Groups (groups of events that have been judged to consume similar levels of resource). These costs will be obtained from the most recently published national reference costs (NHS England 2025) at the time of analysis. All

costs will be reported in pounds (£) sterling, expressed in the latest cost year for which unit costs are available at the time of the final analysis. The cost of each resource item will be calculated by multiplying the number of resource units used by the relevant unit cost. The total cost incurred for each individual participant will then be calculated as the sum of the cost of all resource elements over the duration of follow-up.

Criminal justice resource use will be valued using unit costs from published sources such as The Crown Prosecution Service and Ministry of Justice reports (See Table 1). Limited data have been identified on average costs of crimes to the police and other criminal justice services, particularly for Scotland. Furthermore, details on the types of crime and court cases are not being collected. Therefore, indicative costs of policing and CJS resources, based on unit cost estimates from England, will be applied, making clear assumptions about the probable nature of crimes and their expected impact on public resources. These will be built up from several sources as detailed in Table 1. Prison costs are available for the devolved nations and will be applied based on country of site.

Housing status will be costed based on the application of annual housing and support costs, attributable to different types of accommodation, that fall on the public sector. These will come from several sources, including previous cost-effectiveness studies (Pleace and Bretherton. 2019), the Scottish Homelessness Report (2021), and Local Housing Allowance rates (by Site). Since the data being collected for those in rented private or social housing does not enable determination of whether housing support is being claimed, an assumption will be made that this is the case. The impact of this will be tested in sensitivity analysis.

Table 1 Unit costs and sources to be used for the costing of participant level resource use data

Resource use item	How measured	Source of measurement	Unit costs*	Source of valuation
Accident and Emergency services	Number of visits	Resource use questionnaire	£271	Weighted average cost of consultant led emergency care service with full resuscitation facilities and designated accommodation for reception of patients and other type of A&E/ minor injury activity. NHS Reference Costs: VB01Z VB11Z
Inpatient admissions[+]	Number of admissions and number of nights	Resource use questionnaire	£2,255	Weighted average of all Admitted Patient Care services excluding day cases (NHS Reference Costs)
Outpatient department	Number of attendances	Resource use questionnaire	£170	Weighted average cost of consultant led and Non consultant let outpatient care services (NHS Reference Costs)
Day cases	Number of admissions	Resource use questionnaire	£894	Weighted average cost of all day cases (NHS Reference Costs)
Ambulance transport	Number of incidents	Resource use questionnaire	£462	Weighted average cost of See and convey incidents NHS Reference costs
Ambulance treatment	Number of incidents	Resource use questionnaire	£308	Weighted average cost of See and Treat incidents NHS Reference Costs

Patient transport use	Number of visits to NHS facilities	Resource use questionnaire	£43.64	NHS. Improving non-emergency patient transport services (2021)
Primary care				
Seen Doctor	Number of visits	Resource use questionnaire	£45	Per surgery consultation lasting 10 minutes PSSRU Unit costs
Seen Nurse	Number of visits	Resource use questionnaire	£53	Per hour with qualification PSSRU Unit costs
Medicine	Number of medicines	Resource use questionnaire Maudsley Addiction Profile (Amended)	TBA	Various Joint Formulary Committee
Physiotherapist	Number of visits	Resource use questionnaire	£41	Cost of One-to-One appointment, PSSRU Unit costs
Dietician	Number of visits	Resource use questionnaire	£62	PSSRU Unit costs
Dentist	Number of visits	Resource use questionnaire	£121	Per hour of patient contact time PSSRU unit costs
Occupational Therapist	Number of visits	Resource use questionnaire	£54	Cost of per hour of a (local authority worker), PSSRU Unit costs
Community Psychiatric Nurse	Number of visits	Resource use questionnaire	£94	Cost per hour (face to face contact) PSSRU unit costs
Social and care services				

Community /day centre use	Number of visits	Resource use questionnaire	£84	Weekly cost of use of service use, PSSRU Unit Costs
Social Worker home visit	Number of visits	Resource use questionnaire	£58	Per hour with qualifications cost PSSRU
Social Worker office visit	Number of visits	Resource use questionnaire	£58	Per hour with qualifications cost PSSRU
Care Worker or adviser	Number of visits	Resource use questionnaire	£30	Cost per hour of a community support worker, PSSRU Unit Costs
Justice services				
Arrest/caution/fined/ Out of court disposals	Times	Resource use questionnaire	£450	Home Office. The economic and social costs of crime (2018)
Court appearance (trial)	Times	Resource use questionnaire	CPS costs Various, based on type of hearing and type of court (to be informed by assumptions about nature of crimes) Operating costs Cot per sitting day (TBC)	Cost of a trial in a magistrate's or Crown court Costs - Annex 1 | The Crown Prosecution Service HM Courts & Tribunals Service annual report and accounts 2024 to 2025 HM Courts & Tribunals Service annual report and accounts 2024 to 2025 - GOV.UK

			Legal aid (defence) Indicative costs of solicitor and barrister fees (TBC)	Crown Court Fee Guidance: Crown Court fee guidance - GOV.UK The Criminal Legal Aid (Remuneration) (Amendment) Regulations 2022: The Criminal Legal Aid (Remuneration) (Amendment) Regulations 2022
Imprisoned	Days/Months	Resource use questionnaire	£51,108 £47,140	Ministry of Justice. Cost per place per prisoner by individual prison. https://assets.publishing.service.gov.uk/media/65f4229810cd8e001136c655/costs-per-place-per-prisoner-2022-2023-summary.pdf Scottish Prison Service, Annual report and accounts https://www.sps.gov.uk/sites/default/files/2024-09/SPS%20Annual%20Report%20and%20Accounts%202023-24.pdf
Intervention				

Peer Navigator Intervention	Days of engagement	Trial office	TBC (Average Cost per day)	See Peer Navigator recruitment and employment proforma: In Appendix section 11.2
Usual Care Support Worker	Days of engagement	Trial office	TBC (Average Cost per day)	See Peer Navigator recruitment and employment proforma: In Appendix section 11.2
Housing provision	Participant reported status	Demographics questionnaire	Average annual cost to public sector	
Social housing where you are the tenant/joint tenant	Approximated duration of stay	Demographics questionnaire	£6,619 (£12,230)	Pleace and Bretherton. (2019) adjusted to 2023/24 prices. Figure in brackets includes housing first support.
Private rented sector housing where you are the tenant/joint tenant	Approximated duration of stay	Demographics questionnaire	£6,279 (£11,891)	Pleace and Bretherton. (2019) adjusted to 2023/24 prices. Figure in brackets includes housing first support
Owner-occupied housing i.e. your own flat/house where you are the owner/co-owner	Approximated duration of stay	Demographics questionnaire	(£6,840)	Local authority LHA – assuming ownership with mortgage of a 2 bedroom flat/house
Living with friends i.e. in the friend's flat or house etc	Approximated duration of stay	Demographics questionnaire	(£6,000)	Local authority LHA – assuming formal tenancy agreement and eligible for one room
Living with a partner in their flat/house	Approximated duration of stay	Demographics questionnaire	(£6,000)	Local authority LHA – assuming formal tenancy agreement and eligible for one room (only one partner can claim)

Living with parents, in their house, flat etc	Approximated duration of stay	Demographics questionnaire	NA	Not eligible to claim housing benefits
Living in with other family i.e. in their flat or house etc.	Approximated duration of stay	Demographics questionnaire	NA	Not eligible to claim housing benefits
Emergency accommodation (such as a B&B or a night shelter)	Approximated duration of stay	Demographics questionnaire	£13,758	Pleace and Bretherton. (2019) adjusted to 2023/24 prices. Includes rents and support
Rough sleeping, on transport or in transport hub (bus stop or train station), in a tent or car	Approximated duration of stay	Demographics questionnaire	NA	
Temporarily at friend's/family's home–on an informal basis (sofa surfing)	Approximated duration of stay	Demographics questionnaire	NA	
Hostel	Approximated duration of stay	Demographics questionnaire	£23,443	Pleace and Bretherton. (2019) adjusted to 2023/24 prices. Includes rents and support
High Intensity supported housing (e.g. SA Life house)	Approximated duration of stay	Demographics questionnaire	£31,290	Pleace and Bretherton. (2019) adjusted to 2023/24 prices. Includes rents and support

A caravan, or squat	Approximated duration of stay	Demographics questionnaire	NA	
Asylum accommodation	Approximated duration of stay	Demographics questionnaire	£35,654	Estimated from Home Office Annual Accounts Home Office annual reports and accounts - GOV.UK

Key: *, Unit costs are liable to change in the main report based on data availability at time of analysis; +, value indicative – inpatient admissions will be costed using specialty or health care resource group specific unit costs where sufficient details are provided.

6.3. Outcomes

Identification of outcome(s)

The co-primary outcomes of the SHARPS trial are participant mental health (from PHQ-ADS scores) and quality of life (from ICECAP-A scores) at 12 months.

In accordance with guidance for economic evaluation in health and social care to be conducted, where possible, using generic, multi-attribute, preference-weighted measures that are consistent with economic theory (NICE, 2013; NICE, 2022), cost-effectiveness will be assessed using Quality Adjusted Life Years (QALYs). These are derived from utility scores obtained using the EQ-5D-5L quality of life instrument (Herdman, M. et al. 2011), and Years of Full Capability (YFC), calculated using utility values obtained from responses to the ICECAP-A instrument (Al-Janabi et al. 2012). A cost-consequence analysis will also consider all other outcomes being collected in the SHARPS trial (including the PHQ-ADS scores).

Measurement of outcome(s)

EQ-5D-5L data will be collected at baseline, six, and 12 months. Study researchers who are independent of the intervention delivery will collect outcomes from participants in face-to-face meetings or by phone where data will be entered on study tablets by the researchers. As the intended effects of the intervention are wider than health effects, we will also estimate the incremental cost per YFC gained. Capability will be measured at the same time points as EQ-5D-5L using the ICECAP-A (Al-Janabi et al. 2012) measure which measures broader wellbeing.

Valuation of outcome(s)

Individual utility scores will be generated from responses to the EQ-5D-5L. This will be done using the NICE recommended valuation tariff at the time the analysis is conducted (NICE 2022). Currently, the NICE reference case stipulates that EQ-5D-5L profiles should be cross walked to the preferred EQ-5D-3L valuation set using the mapping algorithm developed by Hernadez-Alava et al. (2023). It should be noted that work has been ongoing to generate a new UK direct valuation tariff for the EQ-5D-5L, which will be used in place of the above if published and recommended by NICE at the time of the analysis.

The valuation set enables a health state utility value (HSUV) to be calculated for each participant response based on the preferences of a representative sample of the UK general population. The health state utility values represent the desirability of the health states described by the EQ-5D-5L on a scale anchored by full health (1) and death (0). Thus, health state utility values for individual participants are tracked over time based on their responses to the EQ-5D-5L at baseline, six, and 12 months, and an area-under-the-curve approach will be used to calculate QALYs for the 12-month follow-up period of the trial. Participants who have died will be treated as if their last measured utility score was relevant up to the time of death and then set to 0 from that time onwards. YFC will be calculated in the same way but using capability/wellbeing utility scores derived using the ICECAP-A scoring algorithm (Flynn et a. 2015). The ICECAP-A scores reflect the desirability of the wellbeing states described by the instrument, based on the preferences of a representative sample of the UK general population. Unlike QALYs, however, the scale is anchored on the lowest possible wellbeing state (0) and the best possible wellbeing state (1) described by the instrument. In this context, death is assigned a score of zero (no capability/wellbeing) from the time of death.

7. Economic data analysis

All analyses will be performed using intention-to-treat principles, comparing the two groups as randomised. The costs of each category of resource will also be estimated separately from each perspective. The final and only analysis will be conducted at the end of the trial, which will be after all participants have reached the 12 months post randomisation follow-up.

7.1 Discount rates for costs and benefits

As costs and benefits will not be assessed beyond 12 months post baseline, discounting will not be required.

7.2 Within trial analysis

Analysis of resource use and costs

The results will be presented as means for each treatment allocation arm and the mean difference in total resource use between the two arms (details in Tables 2 and Table 3).

Standard deviations (SD) and the number of participants included for each resource item will also be presented. Appropriate regression techniques will be used to estimate adjusted mean costs and the difference in adjusted mean costs (and their associated 95% confidence intervals) between the intervention and control group, considering the cluster randomised design (Gomes et al. 2012, Gomes et al. 2012, Canaway et al. 2019). The analysis will include random effect coefficients for the participant and cluster intercepts. Fixed effects will be included for treatment and country.

Analysis of outcomes

The results will be presented as means and the incremental mean difference in QALYs between intervention and control, and the incremental mean difference in YFC (details presented in Table 4). QALYs for each patient over the 12-month period will be calculated from the health state utility values (HSUV) derived from EQ-5D-5L responses and baseline, 6, and 12 months; an area under the curve approach will be used to calculate QALYs on for each individual participant. Appropriate regression techniques will be used to estimate adjusted mean QALYs and the difference in adjusted mean QALYs (and their associated 95% confidence intervals) between the trial arms, considering the cluster design of the study (Gomes et al. 2012, Gomes et al. 2012, Canaway et al. 2019). The analysis will include random effect coefficients for the participant and cluster intercepts. Fixed effects will be included for treatment, timepoint, country and the baseline score of the outcome.

Analysis of cost effectiveness

The results will be presented as means and the mean difference in total costs and effects between the two treatment allocation arms (Table 5). Cost and outcome data will be combined to calculate an incremental cost-effectiveness ratio (ICER), expressed as the mean difference in costs over the mean difference in effects (QALYs and YFC) from the public sector perspective (see section 5.3). The net monetary benefit (NMB) statistic (Paulden, M. 2020) will be calculated to determine the preferred option at increasing thresholds of willingness to pay per QALY and per YFC.

The incremental net monetary benefit (iNMB) of the intervention in question is equal to:

$$iNMB = \lambda \times \Delta E - \Delta C$$

where λ represents a decision-maker's willingness to pay for a one-unit gain in the outcomes of interest. If the above expression is greater than zero for the peer support intervention, then it may be considered cost-effective at the threshold value (λ) applied. Given that society's willingness to pay per unit of outcome is unknown, the iNMB will be calculated for increasing values of λ, including those typically used to guide value-based health care decision making in the UK NHS (£20,000–£30,000 per QALY gained).

Uncertainty in the point estimate of incremental cost per QALY and YFC gained, will be quantified using a parametric approach that appropriately considers the cluster randomised design of the trial. This will likely require a bivariate multilevel model, where costs and outcomes are analysed together in a single regression model, accounting for clustering and correlation in the estimated joint difference in costs and effects (Gomes, M. et al. 2012). The probability that the intervention is cost-effective at various thresholds (λ) of willingness to pay per QALY and per YFC gained will be depicted using a cost-effectiveness acceptability curve.

Subgroup analysis/analysis of heterogeneity

There are no plans to conduct any subgroup analysis in the trial.

Sensitivity analysis

Uncertainty in the methodological choices made in the economic evaluation will be assessed through several sensitivity analyses. These will involve making plausible changes to key methodological assumptions and uncertain input values to understand how changes in those assumptions or values impact the cost-effectiveness results and conclusions. Examples include impact of missing data (see section 7.4), unit costs used to value resource use, assumptions about the extent to which the Peer Navigators provide a substitute for Support Worker involvement in the care of clients.

Scenarios exploring longer-term cost-effectiveness

If the intervention demonstrated efficacy at 12 months, we will build a simple model to extrapolate estimated differences in costs and effects beyond the 12 month follow-up period of the trial. The model will use projections of survival, informed by the application of standardised mortality ratios to age specific estimates of annual all-cause mortality rates obtained from UK life tables (e.g. Aldridge et al. 2018; ONS, 2025). Mean costs and utility estimates (in the standard care arm), and the estimated incremental effects associated with exposure to the SHAPRS intervention will be applied over an extrapolated time horizon, under alternative assumptions about their trajectory over time. Model scenarios will include maintenance of estimated differences in costs and effects over time and varying rates at which estimated differences diminish to zero over time. The model will be run probabilistically, based on second order sampling form distributions assigned to mean cost and utility estimates in the control group, and the estimated increments attributable to the intervention. Results will be summarised in the form of cost-effectiveness scatter plots and cost-effectiveness acceptability curves. To mitigate the uncertainties associated with long-term extrapolation of costs and outcomes, the modelled projections will be limited to a maximum of five years.

7.3 Data cleaning for analysis

Data inconsistencies will be assessed and amended by CHaRT on an ongoing basis. Prior to database lock, any further inconsistencies identified by the trial statisticians or health economists will be resolved at source through consultation with CHaRT and if necessary, the trial management group, prior to commencing the analysis. The analysis will proceed once all follow-up data have been cleaned and the database locked.

7.4 Missing data

Descriptive analyses will be conducted to establish the nature of the missing data (Faria, R. et al. 2014). This analysis will inform the base case assumptions, recording the likely missing mechanism for missing data and the appropriate methods for handling them. The descriptive analysis will identify the amount missing by trial group at each follow-up period. The analysis will include the use of graphical tools such as missing data patterns to inform whether the missing data needs to be modelled in individual components or at the aggregate level.

Logistic regressions will be used to investigate which factors, such as baseline covariates and post-randomisation variables, are associated with the probability of missingness and they will also be used to explore whether missingness is associated with previously observed outcomes. The results of the descriptive analysis will be discussed with the trial team (researchers, clinicians, trial management group, trial Experts by Experience group etc.) to infer possible reasons for missing data and inform the assumption about the missing data mechanism. If data can be reasonably assumed to be missing at random (MAR), multiple imputation using chained equations will be used to impute plausible values for missing cost and utility components. The imputation models will include any covariates included in the analysis model and other auxiliary variables that are predictive of missingness.

8 Reporting

8.2 Reporting standards

The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines (Husereau, D. et al. 2022) will be followed when reporting the health economic evaluation in a format appropriate to stakeholders and policy makers.

8.3 Reporting deviations from the HEAP

Any deviation from HEAP will be described and justified in the final published report

9 Dummy Tables

9.1 TABLE 2: AVERAGE RESOURCE USE

RESOURCE	**Peer Navigator**	**Usual Care**	**DIFFERENCE**
Secondary Care	Mean (SD)	Mean (SD)	Mean (95% CI)
Accident and Emergency			
Inpatient admissions			
Outpatient department			
Day Cases			
Ambulance transport			
Ambulance treatment			
Patient transport use			

Primary care			
Seen Doctor			
Seen Nurse			
Taking Medicine			
Over the counter medication			
Physiotherapist			
Dietician			
Dentist			
Occupational therapist			
Community Psychiatric Nurse			
Social and Care services			
Community /day centre use			
Social worker home visit			
Social worker office visit			
Care worker or adviser			
Justice services			
Arrest/Caution/Fined	Count (%)	Count (%)	
Court appearance			
Imprisoned	Count (%)	Count (%)	

9.2 TABLE 3: AVERAGE COSTS

RESOURCE	**Peer Navigator**	**Usual Care**	**DIFFERENCE**
Secondary Care	**Mean (SD)**	**Mean (SD)**	**Mean (95% CI)**
Accident and Emergency			
Inpatient admissions			
Outpatient department			
Day Cases			
Ambulance transport			
Ambulance treatment			
Patient transport use			
Primary care			
Seen Doctor			
Seen Nurse			
Taking Medicine			

Over the counter medication			
Physiotherapist			
Dietician			
Dentist			
Occupational therapist			
Community Psychiatric Nurse			
Social and Care services			
Community /day centre use			
Social worker home visit			
Social worker office visit			
Care worker or adviser			
Justice services			
Arrest/Caution/Fined			
Court appearance			
Imprisoned			

9.3 TABLE 4 QUALITY OF LIFE

RESOURCE	**Peer Navigator**	**Usual Care**	**DIFFERENCE**
EQ-5D-5L	**Mean (SD)**	**Mean (SD)**	**Mean (95% CI)**
Baseline			
6-month			
12-month			
QALY			
ICECAP-A			
Baseline			
6-month			
12-month			
QALY			

9.4 TABLE 5 INCREMENTAL COST EFFECTIVENESS

Intervention	**Costs (C) £**	**Effects (E) (QALYs/YFC)**	**Δ Cost (C) £**	**Δ Effects (QALYs/YFC)**	**ICER (ΔC/ΔE)**	**Probability of Cost effectiveness at £10k, 20k, 30k, etc**

Peer Navigator						
Usual Care						
Sensitivity Analysis						

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11 Appendices

11.1 Resource use questionnaire (6-month follow up)

Which of these best describes where you are currently staying (please select one option)?

Social housing where you are the tenant/joint tenant	☐	Emergency accommodation (such as a B&B or a night shelter)	☐
Private rented sector housing where you are the tenant/joint tenant	☐	Rough sleeping, on transport or in transport hub (bus stop or train station), in a tent or car	☐
Owner-occupied housing i.e. your own flat/house where you are the owner/co-owner	☐	Temporarily at friend's/family's home–on an informal basis (sofa surfing)	☐
Living with friends i.e. in the friend's flat or house etc	☐	Hostel	☐
Living with a partner in their flat/house	☐	A caravan, or squat	☐
Living with parents, in their house, flat etc	☐	Asylum accommodation	☐
Living in with other family i.e. in their flat or house etc.	☐	Supported accommodation	☐
Other	☐		

This section asks about your use of health and social resources <u>since you joined the study.</u>

Healthcare use

1. Since you joined the study, have you visited an accident and emergency department as a patient?

Yes ☐ No ☐

If yes, how many times?

2. Since you joined the study, have you been in hospital as an inpatient (i.e., stayed overnight)?

Yes ☐ No ☐

If yes, how many times?

For each inpatient stay, how many nights did you spent in hospital and what was the main reason for your stay?

Number of nights for inpatient stay	**Main Reason for inpatient stay**

3. Since you joined the study, have you attended hospital as an outpatient (i.e., an appointment at hospital or clinic but you did not stay overnight)?

Yes ☐ No ☐

If yes, how many times?

4. Since you joined the study, have you attended a day hospital? (i.e., you have been admitted to hospital but not kept in overnight)

Yes ☐ No ☐

If yes, how many times?

5. Since you joined the study, have you been taken to hospital in an emergency ambulance?

Yes ☐ No ☐

If yes, how many times?

6. Since you joined the study, has an emergency ambulance been called for you and you were treated at the scene but did not attend hospital?

Yes ☐ No ☐

If yes, how many times?

7. Since you joined the study, have you been taken to or from hospital using a patient transport service?

Yes ☐ No ☐

If yes, how many times?

8. Since you joined the study, have you had any appointments (face-to-face or by telephone) with a doctor at a GP practice?

Yes ☐ No ☐

If yes, how many appointments?

9. Since you joined the study, has a doctor visited you where you live?

Yes ☐ No ☐

If yes, how many times?

10. Since you joined the study, have you visited a nurse at a GP practice?

Yes ☐ No ☐

If yes, how many times?

11. Since you joined the study, has a nurse visited you where you live?

Yes ☐ No ☐

If yes, how many times?

12. Are you currently taking any prescription medication?

Yes ☐ No ☐

If yes, what prescription medication?

13. How many times have you received a prescription for any medication since you joined the study?

14. Since you joined the study, have you visited any of the following?

Professional visited	**Number of visits**
NHS Physiotherapist	
NHS Dietician	
NHS Dentist	
Occupational therapist	
Community Psychiatric Nurse	

Social and care services

1. Since you joined the study, have you used community/day centres (not including The Salvation Army services)?

Yes ☐ No ☐

If yes, how many times?

2. Since you joined the study, have you been visited by a social worker (not including The Salvation Army staff) where you live?

Yes ☐ No ☐

If yes, how many times?

3. Since you joined the study, have you visited a social worker at their office?

Yes ☐ No ☐

If yes, how many times?

4. Since you joined the study, have you visited a care worker or adviser at their office (not a Salvation Army support worker)?

Yes ☐ No ☐

If yes, how many times?

5. Since you joined the study, have you been visited by a care worker or adviser (not a Salvation Army support worker) where you live?

Yes ☐ No ☐

If yes, how many times?

Police and criminal justice contacts

1. Since you joined the study, have you been arrested, cautioned, or fined?

Yes ☐ No ☐

If yes, how many times?

2. Since you joined the study, have you appeared in court?

Yes ☐ No ☐

If yes, how many times?

3. Have you been in prison since you joined the study?

Yes ☐ No ☐

If yes, how many days in total?

11.2 Data collection proforma for capturing the cost of the peer support intervention versus usual care

Peer Navigator recruitment and employment proforma

1. **What resources/costs did The Salvation Army incur to recruit to the Peer Navigator post?**

   Staff time/grades involved in preparing job adverts, shortlisting, interviewing, contracting:

Staff role	Time input	Hourly rate	Oncosts (pension contributions, NI, tax)

   Advertising costs (fees): £_____

2. **Once recruited, how many hours of training did the Peer Navigator attend?**

   (Please specify the number of hours) _____hrs

3. **To train the Peer Navigators, provide the time inputs and hourly rate of all staff involved.**

   (Include preparation and delivery time for this training)

4. **What are the contracted hours of the Peer Navigator?**

   a. Working weeks per year (after annual leave entitlement): _____ weeks

   b. Working hours per working week: _____ hours

5. **What are the salary and oncosts of employing the Peer Navigator?**

   (Please specify the amount)

Hourly rate (£)	Employer oncosts (including of employer national

	insurance and superannuation contributions) (£)

6. **What is the weekly allowance for Peer Navigators to enable them to support clients?**
   (Please specify the amount)
   £_____

7. **What additional expenses does The Salvation Army incur to employ the Peer Navigator annually?**
   (Please estimate the total amounts but do not include anything already covered in question 6)

Expense	**Total amount per year**
Travel	
Subsistence	
Others (please specify) ….	

8. **What proportion of contracted working time do Peer Navigators spend:**
   - a. In direct contact with clients: _____ %
   - b. Performing administrative roles: _____ %

9. **How many clients could a Peer Navigator support at any given time, working at 100% capacity?**

10. **What are the costs of supervising and line managing the Peer Navigator?** Please specify the roles, time commitment and gross annual salaries of staff involved in the supervision and management of Peer Navigators.

Staff role	Time input	Hourly rate	Oncosts?

11. What office space does The Salvation Army provide for use by the Peer Navigators?

(Select one)

A. A dedicated desk in an individual office
B. A shared desk in an individual office
C. A dedicated desk in shared office space
D. A shared desk in shared office space

12. What specific IT equipment do The Salvation Army provide for the Peer Navigator

(Select all that apply)

A. Shared use of a desk top computer with monitor
B. Sole use of a dedicated desk top computer
C. Shared use of a laptop
D. Sole use of a laptop
E. Tablet
F. Smartphone
G. Other (please specify) …….

13. Do you know what The Salvation Army's overhead costs are as a percentage of total client oriented staffing costs? By overheads we mean to include annualised costs of capital (buildings and equipment), maintenance, utilities, cleaning, administrative services such as HR or IT support).

A. Yes
B. No

If yes, what is the percentage: _____

Support Worker recruitment and employment proforma

1. **What resources/costs does The Salvation Army incur to recruit a support worker?**
   Staff time/grades involved in preparing job adverts, shortlisting, interviewing, contracting:

Staff role	Time input	Hourly rate	Oncosts (pension contributions, NI, tax)

   - Advertising costs (fees): £_____

2. **Once recruited, how many hours of training does a support worker attend?**
   (Please specify the number of hours) _____hrs

3. **To train a support worker, provide the time inputs and hourly rate of all staff involved.**
   (Include preparation and delivery time for this training)

4. **What are the contracted hours of a support worker?**
   a. Working weeks per year (after annual leave entitlement): _____ weeks.
   b. Working hours per working week: _____ hours

5. **What are the salary and oncosts of employing a support worker?**
   (Please specify the amount)

Hourly date (£)	Employer oncosts (including of employer national insurance and superannuation contributions) (£)

6. **What is the weekly allowance for support workers to enable them to support clients?**

   (Please specify the amount)

   £_____

7. **What additional expenses does The Salvation Army incur to employ a support worker annually?**

   (Please estimate the total amounts but do not include anything already covered in question 6)

Expense	**Total amount per year**
Travel	
Subsistence	
Others (please specify) ….	

8. **What proportion of contracted working time do support worker spend:**

   a. In direct contact with clients: _____ %

   b. Performing administrative roles: _____ %

9. **How many clients could a support worker support (have on their case load) at any given time, working at 100% capacity?**

10. **What are the costs of supervising and line managing a support worker?** Please specify the roles, time commitment and gross annual salaries of staff involved in the supervision and management of Peer Navigators.

Staff role	Time input	Hourly rate	Oncosts?

11. **What office space does The Salvation Army provide for use by Support Workers**?

    (Select one)

E. A dedicated desk in an individual office
F. A shared desk in an individual office
G. A dedicated desk in shared office space
H. A shared desk in shared office space

12. **What specific IT equipment do The Salvation Army provide for the Support Workers?**

(Select all that apply)

H. Shared use of a desk top computer with monitor
I. Sole use of a dedicated desk top computer
J. Shared use of a laptop
K. Sole use of a laptop
L. Tablet
M. Smartphone
N. Other (please specify) …….

13. Do you know what The Salvation Army's overhead costs are as a percentage of total client oriented staffing costs? By overheads we mean to include annualised costs of capital (buildings and equipment), maintenance, utilities, cleaning, administrative services such as HR or IT support).

A. Yes
B. No

If yes, what is the percentage: _____