Use of the Mental Capacity Act 2005 with people experiencing multiple exclusion homelessness in England

1 Protocol details

1.1 Full Title

Use of the Mental Capacity Act 2005 with people experiencing multiple exclusion homelessness in England

1.2 Protocol Version Control

Version number: **1.0**
Final: **Final**
Date: **13.8.24**

1.3 Names and contact details

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2 Chief Investigator (CI) Signature

The Chief Investigator and the KCL RGO (Sponsor office) have discussed this protocol. The investigators agree to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the study in compliance with the approved protocol, EU GCP, the UK General Data Protection Regulation, UK Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the Research Governance Framework (2005 2nd Edition; as amended), the Sponsor's SOPs, and other regulatory requirements as amended.

Kritika Samsi
Chief investigator

1 February 2024

3 Abbreviations and Definitions

CI	Chief Investigator
KCL	King's College London
Main REC	Main Research Ethics Committee
Participant	An individual who takes part in a study
PPI	Patient and Public Involvement
RGO	Research Governance Office
SAE	Serious Adverse Event
SSC	Study Steering Committee

CONTENTS

4 Summary

Protocol Full Title	**Use of the Mental Capacity Act 2005 with people experiencing multiple exclusion homelessness in England**
Protocol Short Title	Mental Capacity Act 2005 and multiple exclusion homelessness
Protocol Version number	1.0
Protocol Date	13.8.24
IRAS Number	327441
REC Reference	24/LO/0509
Study registration details	Research Registry: researchregistry9952
Chief Investigators	Kritika Samsi
Study co-ordinator	Jess Harris
Sponsor name	King's College London
Funder	NIHR Health & Social Care Delivery Research (HSDR) Programme
Topic under investigation	Understanding and carrying out mental capacity assessments when people are experiencing homelessness and complex needs
Purpose of research	To improve mental capacity understanding and practice, and in doing so improve support for a highly marginalised population
Primary objective	To improve service responses to adults who are homeless
Secondary objective(s)	To increase national understanding of mental capacity
Number of Participants	10 national expert interviews; 45 practitioners and 30 people with lived experience interviews in sites; 30 practitioners testing Tool re-interviewed.
Study Type/ Design	Qualitative interviews; national survey.
Study Duration	Overall study: 2.5 years; 1.10.23 – 31.3.2026 Fieldwork in study sites: Sept 2024 – Nov 2025
Study Endpoints	Completion of fieldwork, analysis and write up, production of Tool and Guidance and Study Report, dissemination
Main Inclusion Criteria	Adults experiencing homelessness and multiple exclusion; practitioners working with them across services.
Data collected & storage arrangements	Data will be stored on secure King's College London drives in password protected files accessible only to the KCL members of the research team.

5 Roles & Responsibilities

5.1 Role of Sponsor and Funder

KCL sole-sponsored studies: The sponsor, King's College London (KCL), will take primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. KCL takes responsibility for arranging the initiation and management of this research, and for ensuring that appropriate standards, conduct and reporting are adhered to regarding its facilities and staff involved with the project.

Roles & responsibilities of the funder: The study funder, the National Institute for Health and Care Research (NIHR) Health & Social Care Delivery Research (HSDR) Programme will monitor the progress of the study, via regular reporting by the study team, and is responsible for publishing the final study Report.

5.2 Protocol Contributors

Jess Harris, Research Fellow, KCL. Reviewed by both Co-Chief Investigators and co-Research Fellow.

5.3 Roles & Responsibilities of Study Management Committees, Groups & Individuals

A Study Steering Committee (SSC) has been formed which comprises 17 members of experienced policy makers, senior practitioners and service leads, and researchers in this field; 15 members are independent from sponsor and investigators. It includes one independent member who has taken on the leadership role for data monitoring and ethics and another independent member who has taken on the role of SSC Chair. A separate Patient and Public Involvement (PPI) Advisory Group has been formed of six members, led by the PPI lead within the study team; all members have lived experience of multiple exclusion homelessness. Both groups will meet six-monthly throughout the study to inform and oversee the study.

6 Introduction

WHY THIS RESEARCH IS NEEDED NOW

The mean age at death for people experiencing homelessness in 2020 was 45.9 years for men and 41.6 for women in England and Wales (Office for National Statistics (ONS), 2021). By comparison, the mean age of death in the general population was 76 years for men and 81 years for women (in 2017: ONS, 2018). Since 2010, the number of people sleeping rough in England is estimated to have risen by 38% (Department for Levelling Up, Housing & Communities (DLUHC), 2022b), and in 2020 the estimated number of deaths of people experiencing homelessness (in England and Wales) was 42.7% higher than 2013 (ONS, 2021).

This study focuses on the use of the Mental Capacity Act 2005 (MCA) with a significant sub-group of the homeless population, namely those with experience of multiple exclusion homelessness (MEH). This term is used to capture the overlapping of a range of experiences associated with profound social exclusion, including not just homelessness but also institutional care, substance misuse, and 'street culture' activities (such as begging and street drinking) (Cornes et al., 2011; Manthorpe et al., 2015). A survey of 1,286 users of UK homeless support services found 47% of people had experienced all three of these facets of MEH (Fitzpatrick et al., 2011). During COVID-19, of the 37,000 people temporarily housed under the 'Everyone In' scheme, an estimated 25% had a combination of support needs – relating to mental and physical health, drug and/or alcohol use, and arising from exiting the criminal justice and care systems (Crisis, 2021).

The research is timely and relevant in light of both the recognition by policymakers of the picture outlined, and the evidence that the assessing of mental capacity is a problematic area of practice with people experiencing MEH. The present policy context is underpinned by an express target of ending rough sleeping by the end of this Parliament (Prime Minister's Office, 2019). In the September 2022 cross-government rough sleeping policy paper, *Ending Rough Sleeping For Good*, MEH was expressly discussed (DLUHC, 2022a), with a strong focus on mental health and adult safeguarding. However, neither mental capacity nor its assessment were addressed. Safeguarding Adults Boards have engaged with homelessness by commissioning SARs (Preston-Shoot, 2020b) since their description as 'powerful tools' in an earlier government rough sleeping strategy document (Ministry of Housing, Communities & Local Government, 2018: 31). However, we see a discrepancy between the evidence of problems around capacity assessments arising from these SARs in homelessness cases and the lack of focus on capacity assessment in the 2022 policy paper. There is a similar absence (or only passing mention) of capacity assessment in a number of other recent interventions in the homelessness policy and practice arena (All-Party Parliamentary Group for Ending Homelessness, 2022; McCulloch et al., 2022; The Queen's Nursing Institute, 2022; NICE, 2022a).

One significant exception to this picture is NICE's (2022b) guideline on social work with adults experiencing complex needs. Though not focused on homelessness, the guideline recognizes homelessness as one of an array of 'circumstances and experiences' (including cognitive impairment) 'that could lead to discrimination or inequalities' (NICE, 2022b: 12). It incorporates reference to the MCA throughout and touches on several phenomena that feature in the MEH literature, for example, addictions, substance misuse, acquired brain injury and executive function. That said, this guideline does not give operational guidance of the kind this study is developing. In a similar vein, the Draft MCA Code of Practice (HM Government, 2022), while importing some recent thinking about nuances in capacity (for example, executive function) does not give detailed operational guidance. We will revise a specialist assessment tool in order to improve practice and inform policymakers. We believe that promoting competent capacity assessments when they are called for has the potential to lead to more timely care, support and treatment for this population. It may identify current discrimination and service neglect, and we expect it to generate greater understanding for all practitioners working with this population.

We envisage that the kinds of decision which prompt concerns about mental capacity are around: seeking or refusing treatment (and whether to remain to receive treatment), saying 'no' to unwanted associates on the street, accepting care and support or adult safeguarding under the Care Act 2014, and managing money (for example, prioritising substance use over adequate nutrition). Are ostensibly risky decisions about these things being made with capacity within the terms of the MCA? With such decisions being of obvious importance for health and well-being, it is troubling that current indications are that non-specialist practitioners often lack confidence and skills in the use of the MCA with this population. An adherence to the 'presumption' of capacity, where unwise decisions might indicate otherwise, also means that assessments are reportedly not taking place.

Finally, we would hope that stronger engagement with this population on the part of professionals when it comes to capacity assessment would not abruptly end with a finding that the person falls outside the parameters of the MCA. Ultimately, a finding of capacity in relation to a specific decision should not sanction neglect. The research aims to increase the chances that people in this population benefit from the empowerment and protection ethos of the MCA but also the care, support and safeguarding that they may need, and be eligible for, under the Care Act 2014.

LITERATURE REVIEW

In preparation for the study bid, we conducted a rapid literature review late October 2022, using the search terms: "mental capacity" AND (homeless* OR rough sleep*) Date range: 2005 to-date. Limited to England and/or Wales.

We searched the following databases (with platforms):

APA PsycInfo (Ovid); Applied Social Sciences Index & Abstracts (ProQuest); CINAHL (EBSCOhost); EMBASE (Ovid); Health and Care Evidence, from Health Education England (NHS Knowledge and Library Hub); Health Management Information Consortium (Ovid); MEDLINE (Ovid); Social Services Abstracts (ProQuest); Sociological Abstracts (ProQuest); PubMed; Social Care Online; Social Policy and Practice (Ovid).

Following deduplication, 188 results from these searches were reviewed on title and abstract; 59 of these went forward for full-text perusal; 19 of these were then included.

We did not find any research focused specifically on mental capacity and people experiencing homelessness, but we did identify three recent publications on homelessness, not included at Stage 1, where the topic of mental capacity was a significant element. These are summarised first. We then move, in turn, to research on Safeguarding Adults Reviews, publications from an associated sector initiative, and expert commentary.

Nguyen et al. (2022) undertook a 'snapshot audit' of the health, care, support and accommodation needs of people identified as being homeless who were inpatients in one week in February 2022 in 15 acute, three Mental Health and one Community Healthcare hospital in London. In the acute hospitals, 86 people were counted: 34.9% of them exhibited tri-morbidity (physical illness, 100%; mental ill health, 47.7%; substance misuse, 59.3%). There were 'concerns around cognitive impairment or fluctuating mental capacity' in 30.2% of the 86 patients (p.23).

Armstrong et al. (2021a) conducted an interview study in homeless hostels, with 18 staff and 15 people experiencing homelessness from across six hostels in London and Kent. This was exploratory work to inform a palliative care in-reach intervention in hostels (Armstrong et al., 2021b). One finding was that staff were concerned that external services often assumed that residents had capacity to refuse treatment, frequently without assessing them, meaning that hostel staff were left to support residents alone. Staff described the assessment of capacity as complex when people were self-neglecting or had significant health problems, against a background of substance misuse. The capacity assumptions being made were described by the researchers as examples of an external service barrier to accessing health and social care for the hostel residents (Armstrong et al., 2021a).

Andrews and Botting (2020) analysed speech, language and communication needs (SLCN) data from 322 people in London who were rough sleeping (living on the streets) and found that 55 (17.1%) were recorded as having SLCN. This compares with an estimated prevalence of 9.92% in the general UK adult population. The authors suggested: 'homelessness staff may not adequately appreciate the role of language in [mental capacity] assessments, potentially leading to inappropriate decisions about capacity' (p.932). We would emphasize that a failure to realise the significance of SLCN may lead to less than optimal support for the person to make the decision/s in question (s.1(3) MCA).

Safeguarding Adults Review work

Our review identified nine analyses of Safeguarding Adults Reviews (SARs) where homelessness was a significant factor and the quality of professional practice relating to mental capacity assessment was highlighted. Under the Care Act 2014 a SAR must be commissioned by Safeguarding Adults Boards (SABs) where there is concern about the way local agencies have worked together to safeguard an adult who has died because of suspected or confirmed abuse or neglect or where the person is still alive but is thought to have suffered serious abuse or neglect. Neglect includes 'self-neglect' (Department of Health and Social Care (DHSC), 2022: para 14.17). MEH often results in self-neglect (Preston-Shoot, 2020b) and, importantly for this study, because self-neglect at its most serious often involves reluctance on the part of the person to accept help, mental capacity can come into question because of the risks the person may be running (Braye et al., 2017; Martineau et al., 2021: 23-27).

The first analysis to focus exclusively on SARs where homelessness was a factor, conducted by members of the study team, with most of the 14 reviews concerned involving MEH, identified four aspects of poor MCA practice: a failure to conduct capacity assessments; a lack of confidence in applying the MCA when the person was manifesting fluctuating capacity due to drug and alcohol misuse; a failure to consider the person's executive function; and a failure to identify the presence of coercion or undue influence and its effect on capacity (Martineau et al., 2019).

These findings were echoed by a national analysis of 231 SARs completed between April 2017 and March 2019, including 25 where homelessness was a factor, which in addition reported poor understanding of MCA principles, misunderstanding of the so-called 'diagnostic threshold', and poor recording (Preston-Shoot et al., 2020). Focusing on a sub-set of 11 SARs where MEH was in play, Preston-Shoot (2020b), identified the following issues, either directly to do with assessing capacity, or adjacent: the need to assess the likelihood and significance of risks; executive function and the impact of trauma; the potential need for advocacy; the need to challenge assumptions about lifestyle choice; and, the need to demonstrate creativity and persistence in attempting to engage with the person.

In another analysis, refusal of help by the person concerned was reported in 15 of the 21 cases of people who had experience of homelessness (Martineau and Manthorpe, 2020). Legal context is provided here by the fact that the local authority’s duty to conduct a needs assessment where there is an appearance of need (s.9 Care Act 2014) remains in place in the face of refusal where the person lacks capacity to refuse the assessment or where the person is experiencing, or is at risk of, abuse or neglect, which includes self-neglect (s.11(2) Care Act 2014).

Two papers analysing SARs which highlight failures to conduct mental capacity assessments involve cases of homelessness and brain injury (Norman, 2016; Holloway and Norman, 2022). In the first, ‘Tom’ was described as having a moderate traumatic brain injury (TBI) and undiagnosed mental health problems, and as being a substance user. The author is critical of professionals whom, she suggests ‘simply saw an addict’ (Norman, 2016: 346) and who at no stage assessed his mental capacity despite the view that he was ‘endlessly making “unwise” decisions both in terms of lifestyle choices and with regards to care’ (p.348).

In the case of ‘Jonathan’, serious physical illness was combined with ‘a series of historic strokes and TBIs’, and mental capacity assessments were ‘not undertaken because of assumptions that Jonathan was able to make informed decisions for himself, despite considerable evidence to the contrary.’ (Holloway and Norman, 2022: 73). Cited by both of these brain injury papers, Oddy et al. (2012) provide important context here: this was a Glasgow study which reported that 48% of its homeless participants reported a history of TBI, compared to 21% of a matched control group.

Sector initiative

Between 2019-21 the Local Government Association (LGA) and the Association of Directors of Adult Social Services (ADASS) organised 12 events on homelessness, which drew together researchers (including members of the study team), stakeholders and experts by experience. Drawing on evidence (not limited to capacity questions) from participants at the events and between times, this initiative led to the publication of two reports (Preston-Shoot, 2020a; Preston-Shoot, 2021a) and was followed by a book on homelessness and adult safeguarding (Cooper and Preston-Shoot, 2022). These publications include a particular emphasis on the importance of addressing executive function and the impact of adverse childhood experiences, trauma, and brain injury, together with the importance of capacity assessment training. In addition, touching on the legislative framework, Preston-Shoot (2020a: 30) refers to the existence in some jurisdictions of options for the ‘civil containment and protective detention of people with severe and enduring substance misuse problems’. Elsewhere, the author has questioned whether the MCA and its Code of Practice were ‘framed sufficiently clearly to enable practitioners to apply the legal rules confidently in cases of considerable complexity.’ (Preston-Shoot, 2021b: 213).

Expert commentary

Our review identified four expert commentaries on homelessness which included reference to mental capacity assessment, three in relation to access to healthcare, one focused on mental health services. In outlining various nurse-led interventions Dorney-Smith et al. (2018) emphasized the importance of mental capacity assessments, highlighting potentially relevant, and often unrecognized, factors within this sub-population: mental health problems, personality disorder, complex trauma, brain injury, learning disability, autism, and poor language skills. Dorney-Smith et al. (2020) focused on homeless people attending the emergency department, noting that capacity is often assessed when the person decides not to seek treatment. The person may be unwilling to engage in a mental capacity assessment: the multi-disciplinary team (MDT) should discuss a plan to obtain external evidence about the person and gain their trust. It may be appropriate to bring in a healthcare professional with expertise in capacity assessments. Lamb and Joels (2014) recounted a case involving StreetMed outreach nurses working with a person with long-term alcohol use and an inability to retain relevant information. An Independent Mental Capacity Advocate (IMCA) was employed to assist in his move to a housing project with 24-hour care.

Finally, in a paper about mental health services for single homeless people, Timms and Drife (2021: 111) suggested that where signs and symptoms of mental disorder are difficult to identify for a Mental Health Act Assessment, ‘[o]ne way ahead may be to change the focus from symptoms to whether the individual has the capacity […] to make an informed choice – such as a decision to refuse services or to stay on the street […] It does not replace an assessment of symptoms but complements it. If capacity is compromised regarding a vital decision concerning health and well-being, this should be considered as significant evidence in the assessment for involuntary hospital admission.'

Ongoing research

The only ongoing research on this topic of which we are aware is a small project by one study team member (SM: www.kcl.ac.uk/research/mca-meh). This involves expert interviews and analysis of qualitative data from a previous KCL study on homelessness, self-neglect and safeguarding by members of the study team, where the topic of capacity assessment emerged as a theme (Harris, 2022).

RATIONALE

Any discussion of what constitutes a 'good' mental capacity assessment starts with the relevant sections of the MCA, including the principles (s.1), together with the Code of Practice (chapters 3, on supporting decision making, and 4, on the meaning of capacity and how it should be assessed: Department for Constitutional Affairs (2007)). As a baseline, a good assessment is one that clearly defines the decision, when it needs to be taken and what information the person needs to understand. It should comprise a thorough exploration of the four abilities (s.3(1)) in relation to that information, all practicable steps taken to help the person to make the decision, real-world observations as required, with a statement of finding, and, where the finding is of an inability to make the decision, a statement that this is because of an impairment of, or a disturbance in the functioning of, the mind or brain (s.2(1)). The capacity assessment should be prior to, and separate from, any best interests analysis that follows.

However, this study is not only concerned with the 'technicalities' of good, but also the broader values underpinning assessment. In thinking about this particular population, the study will examine if and how assessments are carried out, where, by whom, with what specialist support, in relation to what decisions, and with what resource implications, and importantly, whether assessors have the knowledge and skills to understand the potential impacts of MEH on a person's cognitive state.

The project will pay particular mind to the distinction between the recording of the assessment and the process of assessment. Though there will always be emergency scenarios, phenomena such as fluctuating capacity, impaired executive function and a reluctance to engage may call for professionals (often multi-disciplinary) to remain in the assessment 'space' over a protracted period. This has been described as a matter of taking up 'a position of ongoing and benign curiosity' or enquiry (Marshall et al., 2022: 69).

The project will enhance understanding of this challenging work. For example, it will explore how professionals work with people who are reluctant to take part in an assessment, mindful of case law that illustrates that while a refusal to engage might itself be an indication of a lack of decision-making capacity in one case (W NHS Trust v P [2014] EWHC 119 (COP)), it might not be so in another (Re QJ [2020] EWCOP 3). It will add to the growing body of knowledge about capacity assessments and executive function (National Institute for Health and Care Excellence (NICE), 2018; George and Gilbert, 2018; Allen, 2022; Cameron et al., 2022), particularly important in light of its inclusion in the new MCA Draft Code of Practice (HM Government, 2022). The study will also contribute to understanding of assessment approaches where alcohol dependence is a component, recent case law demonstrating some of the difficulties here (eg London Borough of Tower Hamlets v PB [2020] EWCOP 34).

Interviews which involve people experiencing MEH will potentially contribute to an understanding of what a good assessment is from the point of view of the person assessed, both by enquiring of their views and, where possible, exploring their experience of being assessed. We believe this would be a novel and vitally important contribution to national understanding of capacity assessment under the MCA.

The study will explore the context of capacity assessments with this population. This will involve examining practitioners' understanding of the relevance of mental capacity to the discharge of their obligations under other legislation, for example the Care Act 2014 and the Human Rights Act 1998. Part of that context may also involve structural, resource, and attitudinal barriers to good practice. What has been called the capacity 'cop out' – an adherence to the s.1(2) MCA presumption by professionals in the face of strong evidence to the contrary – has been used to 'dismiss people' and to allow agencies to withdraw (Aspinwall-Roberts et al., 2022). It is a practice that potentially has implications where the positive obligations on the state under Articles 2 and 3 European Convention on Human Rights are concerned. Analogous approaches among psychiatrists in relation to some kinds of patient have recently become the subject of debate and described as constitutive of an ‘exclusion culture’ (Beale, 2022: 16).

The study is informed by recent work from the *Mental Health and Justice* project, in particular the ‘contested assessment’ workstream, on which one of the study team (ARK) was a senior researcher (https://mhj.org.uk/6-contested-assessment/). We highlight three aspects relevant to improving capacity assessments:

(1.) The importance of self-awareness and reflection on the part of the assessor, not least in relation to their own values; multidisciplinary review mechanisms likely have a role here (Kane et al., 2022).

(2.) Where ethnic and cultural factors may be in play, we note the observation by Kane et al. (2022) that liaison ‘psychiatrists were resourceful (and humble) in involving the patient’s family and cultural experts to clarify the situation’. The MCA Code of Practice (Department for Constitutional Affairs, 2007: para 310) recommends awareness of ‘cultural, ethnic or religious factors that shape a person’s way of thinking, behaviour or communication’.

(3.) The focus in Kane et al. (2021) on closing the ‘translation gap’ between the criteria in s.3(1) MCA (the four ‘abilities’) and the real-world rationales for assessment findings made by professionals.

This study’s aim is to develop understanding in these areas of assessment practice as well as producing a revised tool, developed in consensus, with specific assessment strategies (building on the work of Ariyo et al., 2021), to aid in the capacity assessment of people experiencing MEH. We plan for learning from this study to be transferable to other challenging, resource-intensive domains not necessarily involving homelessness, for example, cases of self-neglect, alcohol/substance dependence or treatment refusal.

THEORETICAL FRAMEWORK

Programme Theory has been co-developed for the study to help understand and describe the current concerns and unknowns about the use of MCA assessment with people experiencing MEH, and how the use of a specialist MCA Tool may support improvements. The Theory will be reviewed and refined as findings emerge, to maintain a focus on the identification of uncertainties and on answering the research question. It will support the Tool development and testing, which in turn will inform the final refinement of the Theory.

The process of Theory development has focused on identifying core components: practitioner attitudes, skills and expertise in relation to both the MCA and in MEH; the application and adaptation of the MCA assessment process to the context(s) of MEH (eg taking a trauma-informed approach, longitudinal/multi-phase outreach approaches; multi-disciplinary and observational approaches in cases of non-participation), and the likely contextual complications (high levels of mental ill health, chronic physical ill health, acquired brain injury, substance use, distrust of services, speech and language difficulties and neurodiversity among the target population).

The early stage Theory underpins the focus on a specialist MCA assessment Tool as a central component of this study: it hypothesises that the complex health and social care interventions required to effectively support an individual experiencing MEH may currently not proceed, or may be inappropriately formulated, as the mental capacity of an individual who appears to take a decision to reject an offer of support, or fails to respond to support, may not have been considered or adequately assessed.

6.1 Key Words

Homeless, Mental Capacity Act, Capacity Assessment, Multiple Exclusion Homelessness, Toolkit, Severe and Multiple Disadvantage.

7 Study Purpose and Objectives

The study will explore how Mental Capacity Act 2005 assessments are being carried out with people experiencing multiple exclusion homelessness in England, and whether the use of a specialist tool can assist and improve assessments.

OBJECTIVES

1. To analyse approaches to MCA assessments with people experiencing MEH in order to improve practice for this population.
2. To update a specialist MCA assessment tool for MEH through co-production with expert practitioners and public advisors with experience of homelessness (PPI) and other stakeholders, informed by the emerging study findings.
3. To pilot an evaluation of the MCA assessment tool for MEH to understand usability, refine the Tool update, and to evidence the impact, if any, on MCA assessments for this population.

8 Study Design and Flow Diagram

The study will employ a mixed-methods approach to carry out six interrelated work packages (WPs), followed by a programme of dissemination and impact activities. A flow diagram of the study activities is included below. The study team have worked iteratively with a range of stakeholders, including the study Collaborators, Study Steering Committee (SSC) and PPI Advisory Group members, with support from colleagues in the NIHR Research Design Service (RDS), to develop the research question, objectives and methods. Informed by the Medical Research Council framework on evaluating complex interventions (Skivington et al., 2021), this process has included a focus on a wide range of contextual factors, has aimed to maximise the diversity of perspectives shaping the study, and has prioritised consideration of the practical application of the research findings, in order to maximise the study impact.

STUDY PREPARATORY PHASE, INCLUDING WP1 & WP2:

This stage will involve bringing the research team together, as well as the initial meetings of both the SSC and the PPI Advisory Group, and auditing support and training for PPI advisors. Preparation of applications for sponsorship (from KCL) and for ethical permissions (from the Health Research Authority Social Care Research Ethics Committee (SCREC)) will include the drafting of study instruments and documents, in consultation with all study advisors. Formal recruitment of three geographically, socio-economically and ethnically diverse study sites will include a process of seeking local governance permissions and meetings with stakeholders in each site and circulating introductory information to raise awareness of the study.

SCOPING REVIEWS (WP1):

Following the PRISMA-ScR protocol (Tricco et al., 2018), we will conduct scoping reviews of the following categories of evidence:

1. Specialist MCA tools, including international examples from jurisdictions with similar approaches to mental capacity, (2005 to-date). We expect these to range from simple itemised proformas listing principles and criteria of the MCA (or its international analogues) to tools for specific populations containing tailored assessment strategies and guidance (Ariyo et al., 2021). This review will involve developing a framework for tool analysis. It will involve searching an eclectic range of sources and draw on the expertise and contacts of members of the research team and Collaborators, several whom have been involved in tool development.
2. Academic literature, from 2005 to-date, in an update of the review contained in this Research Plan.
3. Court of Protection and High Court inherent jurisdiction case law. We will search Westlaw, Lexis+ UK, the British and Irish Legal Information Institute (Bailii), and The National Archives (which started a case law service for judgments from April 2022), from 1 October 2007 (when the MCA came fully into force), for cases involving MEH.
4. Safeguarding Adults Reviews (SARs) where homelessness was a factor, published since 2020. This will build on work conducted by SM (Martineau et al., 2019) and SAR expert Michael Preston-Shoot (SSC member) but focus on capacity assessments.

5. Prevention of Future Deaths Reports (from when they were introduced under the Coroners and Justice Act 2009). These are made by coroners to those who may have power to take preventative action when an inquest reveals circumstances that create a risk of future deaths. Recipients are under a duty to respond. Most reports and responses are published on the Chief Coroner's website, which is searchable.

6. Local Government & Social Care Ombudsman decisions (for the last five years). We will search the Ombudsman's database for decisions relating to capacity and MEH.

The priorities in these reviews will be to retrieve evidence that:

1. Informs our proposed development of the MCA assessment tool for MEH;
2. Examines health and social care practice in relation to capacity and MEH;
3. Explores legal, ethical and other debates in this sphere.

EXPERT INTERVIEWS (WP2):

Following Minimal Risk Ethical Registration (from King's College London), scoping interviews will take place with national policy, legal and practice leads (n=10) to complement the early meetings with the SSC and PPI Advisory Group, and scoping reviews, in informing the development of the quantitative and qualitative work packages. Interviews will be carried out by a researcher online at a time of convenience to the participant. All interviews will be audio-recorded, transcribed and checked by the interviewer prior to thematic analysis. Initial familiarisation with the data and coding by the two research fellows will be informed by discussions with the study Co-Leads throughout the process to reflect on emerging themes. This will be followed by workshop discussions with the wider research team, in order to shape the outline findings and the questions for the subsequent phases of the study. These in turn will be discussed with the SSC and the PPI Advisory Group, and refined as required following input from these two key study stakeholder groups.

QUANTITATIVE: NATIONAL SURVEY OF PRACTITIONERS (WP3):

Following Minimal Risk Ethical Registration (from King's College London), an online survey (using the online surveys platform) of practitioners working with people who are homeless across sectors and professions will develop a broad contextual picture including attitudes, any barriers and concerns, resource implications, and perceived good practice relating to MCA assessments and homelessness; will include identification of any use of tools, guidance or training; and will generate early evidence to address knowledge gaps surrounding the prevalence of specialist approaches to the MCA with homeless populations to inform later phases of the study. It will be informed by the findings from the scoping reviews and expert interviews. The survey will target practitioner groups via stakeholder organisations including: NHS Safeguarding Leads; Homelessness provider organisations; Homeless health providers via national networks (acute and primary care); and social workers. A prize draw for a shopping voucher will be offered to encourage participation. The survey will be brief, to maximise participation, but will include free text fields to encourage expansive responses from those that wish. We anticipate around 300 responses nationally, which will enable us to conduct descriptive and bivariate analysis. We will monitor responses to ensure targeting of particular practitioner groups, geographic regions, and any other area of potential lower response rates.

QUALITATIVE: STUDY SITE FIELDWORK

In-depth fieldwork across three contrasting study sites in England will include interviews with two stakeholder groups:

PRACTITIONER INTERVIEWS (WP4):

Semi-structured interviews (n=45; 15 per site) will be carried out with a range of professionals involved in decision-making about care with and for people experiencing MEH including: social workers, homelessness mental health and generic outreach workers, ambulance and emergency department (A&E) staff and GPs, to develop a rich body of data to build on the survey findings. Interviews will explore if and how the MCA is being implemented in everyday practice with people who are homeless, including where there are concerns about individuals who appear to make 'unwise decisions' in a context of high levels of risk, service-refusal, and/or self-neglect. Interviews will explore practitioners' attitudes, confidence, assumptions, approaches and any tools that different individuals and wider professional groups bring to their practice. We will seek to identify good practice, while exploring with participants what 'good' looks like for different decisions in different contexts, including factors such as time pressures and service gaps or limitations. We will develop an understanding of where good practice may mean deferring to another professional or approaches involving working collaboratively to carry out interdisciplinary assessments and any contextual inhibitors, such as access to skills and resources (including time) to realise these models.

The research will also address practitioner experience of what happens after assessment, whether this a decision under the MCA as to what is in the person's best interests, or where the person is found to have decision-making capacity. This is important because it may be that concerns about the implications of a finding of incapacity in relation to a decision is inhibiting practitioners from conducting assessments. It will involve examining practitioners' understanding of the relevance of mental capacity to the discharge of their duties under other legislation.

Interview participants will be recruited via emailed calls for participants via service networks within the study sites. Selection will prioritise a diverse range of roles across different settings where decision making about care may take place. We will initially target a balance of participants within more focused roles within inclusion health and social care, working with homelessness, and those with less exposure to, and experience of, working with people experiencing MEH. However, the target interview participants will be constantly under review as particular areas of interest emerge from early findings. The number of interviews may exceed the target number if new perspectives are identified which could inform the study findings.

LIVED EXPERIENCE INTERVIEWS (WP5):

Interviews (n=30; 10 per site) with a diverse sample of individuals with experience of MEH will be carried out face-to-face. Interviews will be co-led by a PPI Peer-Researcher and another member of the research team (JH or SM) to enhance rapport with lived experience interview participants, and for general safety and emotional support. This is a recommendation of the study's PPI Advisors, who emphasise that people experiencing MEH are likely to feel much more comfortable talking to someone with direct experience of their situation. Participants may include both individuals who have and those who do not have experience of MCA assessments for decisions around their care and support. Where possible we will seek to explore participants' direct experience of assessment. Our recent experience of carrying out research interviews with people experiencing MEH who had been referred to Adult Safeguarding was that the experience and service name were often not recalled, so discussions focused more broadly on attitudes to and ideas about safeguarding, about assessment processes, and about help to manage risk.

We have identified a seven-month period for the lived experience interviews, but if not completed within this period the process will continue until a sufficient number and quality of interviews have been completed. When planning fieldwork, we will factor in preparatory visits to organisations for information sharing and trust building, as a first stage of participant recruitment. Interviews will normally take place at venues familiar to the participant, such as day centres, and the research team expect to spend a day or half day at the venue, to be flexibly available to carry out interviews when it suits participants. It may take more than one meeting to carry out the interview, and the approach needs to be flexible, as many people will only feel relaxed talking outside, where they can smoke, or at particular times of the day. We are confident that the relaxed process of explaining and chatting before, throughout, and after interviews will be sufficient for most participants to overcome any concerns about participation and to value the process. We will offer a printed 'certificate of participation', a shopping voucher as a thank you for participating, and the opportunity to receive updates (or not) about the progress of the study. We will emphasise the value of someone sharing their time, experiences and opinions and we will try to leave an individual feeling confident about the importance of their contribution.

Analysis of all interview data will be scrutinised for consistencies or themes using Framework analysis (Ritchie & Spencer, 1994) which involves six phases: 1) Familiarising with the data (reading transcripts or replaying the audio-recording); 2) generating initial codes; 3) searching for themes, collating codes into potential themes; 4) reviewing themes (in data workshops involving the research team); 5) defining and naming themes; and 6) authoring of the report, response to ideas from the consultations, and subsequent outputs. This method of analysis is well suited to applied qualitative research (Goldsmith, 2021).

TOOL DEVELOPMENT AND PILOT EVALUATION (WP6)

CO-PRODUCED UPDATE OF SPECIALIST TOOL:

The research team will work with national stakeholder representatives, expert practitioners and PPI advisors via a Policy Lab approach (Hinrichs-Krapels et al., 2020), which draws together varied perspectives on a complex topic, under-pinned by co-production principles (Davies et al., 2021). Policy Labs were developed within KCL as a transparent engagement method for synthesising evidence and facilitating research evidence uptake into policy and practice. This multi-stage approach of discussions, mainly synchronous (face-to-face and online workshops) but additionally asynchronous methods (individual meetings and email submissions), will be the platform to oversee the update and development of the MCA Tool (Clowes et al., 2017), using a consensus-based methodology. Workshops will consider expert submissions and suggestions in light of the emerging study evidence (initially the scoping reviews, national survey and practitioner and lived experience interview findings; subsequently, messages from piloting the draft updated Tool in study sites). This stepped process of co-production will also generate case scenarios for inclusion, led by expert practitioner study collaborators, and will scope and commission an introductory training module as part of the Tool update, to be available free, online, alongside the Tool to introduce and facilitate its use.

PILOT TESTING AND EVALUATION OF SPECIALIST TOOL:

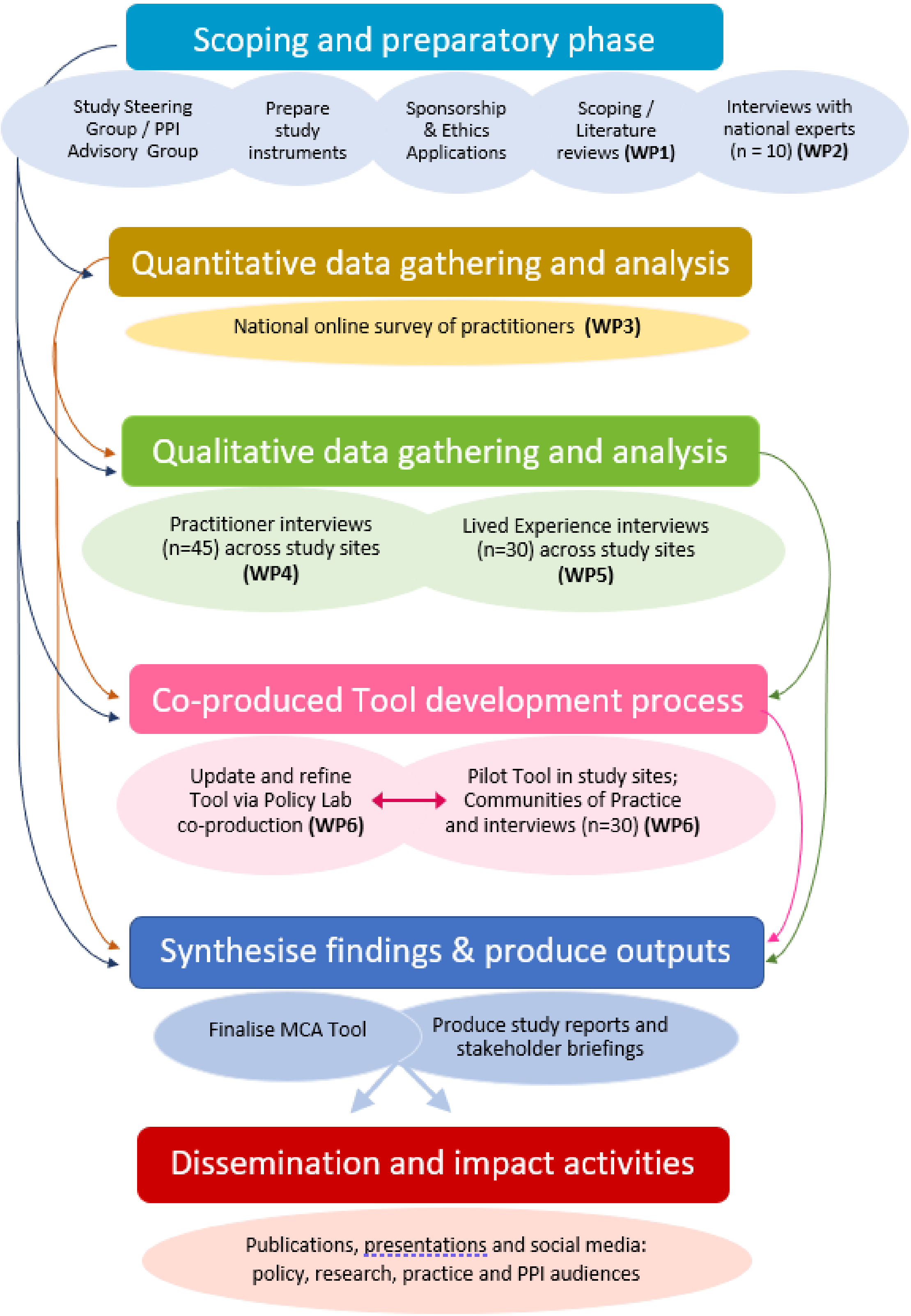
Tools developed to support assessment processes and decision making are primarily tested via piloting and evaluation processes to assess usability, as part of their refinement (O'Cathain et al., 2019) unlike the validation processes for an outcome measure Tool. The study will work with a range of practitioners (total n=30) in different service settings in each study site (n=10 in each site), identified through the WP4 interviews, to capture experiences of using the initial update of the specialist Tool in varied health and social care decision-making situations. This piloting will explore the Tool's accessibility and acceptability to practitioners (informed by implementation science criteria) and effectiveness, including any barriers to its use and suggested improvements. Factors to be considered include: any impact on practitioner confidence (there may be a dip in confidence when practitioners review their prior attitudes and approaches), assessment prevalence (we hypothesise that more will take place), any changes to assessment processes (duration, location, different models of professional participation) and recording.

While changes in the long-term outcomes for the individuals being assessed are beyond the focus of this study, the pilot evaluation will capture the conclusions of MCA assessments using the Tool, including any best interests determinations and service interventions as a result, and ask practitioners to reflect on whether these assessment outcomes appear to be changing as a result of use of the Tool. In each study site we will establish and facilitate a Community of Practice, which will meet three times over the piloting phase to introduce the Tool to those piloting it (in the absence of the online training model), to facilitate reflective interprofessional discussion about its use and possible improvement, and to support and encourage continued commitment to the piloting process. Semi-structured interviews with participating practitioners (and possibly some senior/strategic staff if changes to assessment outcomes are impacting service demands) (n=30; 10 per site) at the end of the piloting phase will enable an exploration of individual experiences of using the Tool, confidentially and in depth, including attitudes, processes, outcomes and contextual factors. Findings from these interviews will inform the final phase of the Tool update.

Study Setting

The initial scoping expert interviews and survey both have a national scope (England-wide). However, the qualitative study site fieldwork, including the Tool testing phase, will take place in three geographically, socio-economically and ethnically diverse study sites which have been selected for their contrasting populations, service infrastructure, and degree of prior investment in thinking and working in this area. The same fieldwork and Tool testing will be carried out in each of the three sites, although different service settings, sectors and individual practitioner roles may be involved, depending on local service configurations.

FLOW DIAGRAM OF STUDY ACTIVITIES



9 Participant selection

- 45 practitioners working with homelessness in roles across social care, health and housing support will be recruited for interview (15 in each local authority site).
- 30 service users will be recruited for interview (10 in each local authority site). Participants will be purposively sampled to capture a range of diverse characteristics (gender; age; ethnicity; sexual orientation; substance use; health and social care needs; service use).

9.1 Participant inclusion criteria

Service user inclusion criteria

- Service users are able to give informed consent to take part in an interview.
- Service users are over 18 years of age.
- Service users are experiencing, or have experienced, homelessness and other facets of multiple exclusion homelessness.

Practitioner inclusion criteria

- Practitioners are able to give informed consent to take part in an interview.
- Practitioners are over 18 years of age.
- Practitioners are working with people experiencing, or who have experienced, homelessness and other facets of multiple exclusion homelessness.

9.2 Participant exclusion criteria

Service user exclusion criteria

- Service users are unable to give informed consent to take part in an interview.
- Service users are under 18 years of age.
- Service users have not been homeless.
- Service users have not had experience of one or more of: substance use, mental ill health, street culture activities, or other facets of multiple exclusion homelessness.

Practitioner exclusion criteria

- Practitioners are not able to give informed consent to take part in an interview.
- Practitioners are not over 18 years of age.
- Practitioners are not working with people experiencing, or who have experienced, homelessness and other facets of multiple exclusion homelessness.

10 Study procedures

10.1 Participant recruitment

Practitioner Interview participants in study sites (WP4) will be recruited via emailed call outs via study site contacts, including service networks and leads. Interviews will be carried out online, so Information Sheets and Consent Forms will be emailed to potential participants in advance, to allow them time to request further information and address any queries. Participants will return a completed and signed Consent Form by email prior to the online interview. Practitioner interview participants will not be offered a voucher or payment; it is anticipated that interviews will take place within their working hours. For all study site interviews, snowballing and other personal recruitment approaches will also be used to recruit under-represented groups, if gaps are identified within interviews or through the on-going monitoring of participant recruitment. Interview numbers will be extended if data saturation is not reached. Interview participants in WP4 will be asked at Information/Consent stage if they are willing to be contacted to consider participation in the Tool piloting and in feedback interviews (WP6); 30 of the 45 practitioners interviewed for WP4 will be selected and re-interviewed for WP6.

Interviews with adults with lived experience of MEH in study sites (WP5) will be recruited via local homelessness provider organisations/services, including day centres, specialist accommodation and support, which may be third sector or statutory sector led. The research team will build early relationships with organisations who may be able to assist identification and recruitment of potential participants. These conversations will include identifying people who are less likely to be visible within mainstream homelessness services, such as individuals who may be further marginalised in relation to their ethnicity or race, sexual identity or gender, or neurodiversity.

The service lead/managers will review their client list against the study eligibility (inclusion / exclusion) criteria, and key workers familiar with individuals will be consulted for input into initial screening for possible participation. Potential participants will then be approached by the service lead or key worker to assess their interest and capacity to consent to study participation. Services will be provided with accessible information about the study to prompt initial conversations. Researchers will spend time at services engaging informally with clients to make themselves known, and to offer further opportunities for potential participants to hear about the study. Those who are believed to have capacity to consent and who agree to be approached by the researchers, will be introduced in a confidential space, for example a meeting room or unused communal space within the service, in order to discuss the study and the process of being involved. We will be guided by key workers if, for example, an individual may be better placed to participate at particular times, eg times of day. Potential participants will be provided with a (large print) information sheet and will then be talked through the sheet by the researchers. We will not assume high levels of literacy or good eyesight (optical care is often not available) so the written information will be a starting point and prompt, not the end of the information sharing process.
Capacity to consent to participate will be assessed by the researcher (who has undertaken MCA assessment training) and the PPI peer-researcher during this initial contact and discussed after the meeting, to reach agreement. Participants will be asked to initial and sign the printed Consent Form, but audio-recorded verbal consent will be an option for those unable or uncomfortable with the signing process. Interviews will be led jointly by a researcher and Peer Researcher, so the information and consent process will always have two team members present. The capacity to agree to take part will be re-considered when the researchers re-meet the participant at the start of the interview, and will remain under consideration throughout, including if the interview is paused and needs to be re-started or to be completed at a later time. If a participant chooses to withdraw from a study, any interview data collected up to the point of stopping will only be used if participant consent is explicitly obtained. Interview participants will be offered an opportunity of having someone of their choice accompany them in the interview. We are aware that payment raises ethical issues, for example, it may be construed as exerting influence on decisions whether to take part, however a shopping voucher will be offered to lived experience interview participants to reimburse them for their time and expertise and thank them for contributing to the study.

10.2 End of Study Definition

The study will be completed when fieldwork has been completed, data analysed and written up, the Toolkit has been finalised and a study report produced. The NIHR funding end date is 31.3.26.

11 Regulatory Approvals

The study protocol and other documentation will be submitted to an HRA Research Ethics Committee (REC) before the start of the study site fieldwork. All correspondence with the REC will be retained. For any amendment to the study, the Chief Investigator(s), in agreement with the Sponsor, will submit information to the relevant regulatory bodies for review. Substantial amendments that require review by the REC will not be implemented until that review has been completed with a favourable outcome, and other mechanisms are in place to implement at site. The Chief Investigator will work with the sites to put in any necessary arrangements to implement the amendment & confirm their continued support.

11.1 Progress Reporting

A progress report will be submitted to the REC within 30 days of the anniversary of the date on which the favourable opinion was given and annually until the end of the study is declared.

11.2 End of Study Reporting and Declaration

The end of the study will be declared to the REC that gave a favourable opinion (as per the above Regulatory Approvals section) within 90 days of the study ending.

The end of the study report will be submitted to the REC that gave a favourable opinion within 12 months of the study ending.

12 Safety & Adverse Events Reporting

The study does not anticipate any Serious Adverse Events (SAEs) but any that occur (for example a data breach) will be reported (signed and dated and completed by the Chief Investigator) to KCL's RGO, following the guidance on Adverse Event Reporting In Research, as the Sponsor, and to the SCREC, following the HRA's guidance on adverse events.

13 Compliance and withdrawal

13.1 Withdrawal/ drop out of participants

If the researchers are of the opinion that a service user interview participant is unable to adequately understand or lacks the capacity to continue with an interview, once it is underway, their participation will be suspended. If we are unable to continue the interview at a later point, when their capacity to take part has been confirmed, they will be withdrawn from the study. We will replace the participant if there are fewer than 10 participants at that study site.
In the event of a participant choosing to withdraw, data already collected from an interview will only be used if consent is given by the participant.

13.2 Protocol Compliance

Any non-compliance with the protocol will be documented and reported to the Sponsor by email, and where relevant to the funder and the Research Ethics Committee.

14 Data

14.1 Data to be collected

Personal data collected from practitioner participants prior to interview will be name, job role, employer organisation and contact details (if they wish to be contacted directly with study reporting).
Personal data collected from lived experience participants will be name; age (within a 10-year range), gender/gender identity, ethnicity, contact details (if they wish to be contacted directly with study reporting), and an outline history of their experiences of multiple exclusion homelessness, which will be collected using a participant questionnaire (Appendix 2). All data will be collected by the research fellows undertaking the interviews. No data will be shared between organisations or services.

14.2 Data handling and record keeping

We will respect participant confidentiality. The study will be compliant with the Data Protection Act 2018 and General Data Protection Regulation (GDPR) guidelines.

Personal data relating to the study interview participants, will be stored in a password protected spreadsheet stored online on the KCL one-drive and accessed by the two research fellows (JH/SM) via password protected computers (including KCL laptops used at home), under the oversight of CI (KS). Paper copies of Consent Forms and demographic questionnaires will be stored at KCL in a locked cabinet. Digital Consent Forms signed by practitioner participants will be securely stored on the KCL OneDrive. Interview data will be audio recorded on encrypted, password protected digital recorders and sent to the KCL-contracted transcriber service (which has signed a confidentiality agreement) via a Secure File Transfer Service. Interview transcripts will be pseudonymised and stored on the KCL one-drive, accessed as described above. If applicable, identifiable data will be deleted following transcription, and a unique identifier will be used to identify the interview participant and the study site. The pseudonymised code breaker spreadsheet will be stored separately from any data collected and held on the KCL OneDrive. All data shared with the wider research team will be sent pseudonymised. The unique identifier will be used in any direct quotes in reports or academic articles. Any published output will not allow identification of any participant through deductive disclosure. Similarly, all survey responses will be anonymised with a unique identifier number, secured on the secure KCL OneDrive. All study data and records will be retained securely for 10 years from the date of the end of the study, in accordance with the KCL Records Retention Schedule.

14.3 Access to the final dataset

The final data set will be stored on a KCL secure drive (the cloud), and accessible only to the KCL members of the research team. Other research team members who may be writing up discrete elements of the study will have anonymised data shared with them via a secure data transfer route. The research team may use part of the data at a later stage for secondary analysis, for example, in relation to a follow-up study; the Information Sheets and Consent Forms make this point explicitly and offer participants the opportunity to opt out.

15 Ethical considerations

As the contracting organisation, sponsorship approval for the study will be secured from KCL.
Ethical approval for WP2 and WP3 will be obtained from KCL, whilst ethical approval for WP4, WP5 and WP6 will be obtained from the Social Care Research Ethics Committee (SCREC).
The study has undergone peer review throughout the NIHR bid process, and has been modified in response to the useful feedback received. All stages of the study development have been informed by the participation of advisors with lived experience of MEH, who met with the research team to shape the thinking and planning behind the study. This PPI Advisory Group will continue to meet six monthly throughout the study to inform the different stages of fieldwork and analysis, as well as having opportunities to contribute to dissemination and impact activities. This lived experience involvement is led by the PPI lead on the study team (SB).

16 Risk Management & Safeguarding

16.1 Risk Management

The study seeks to engage with a cohort with multiple and complex needs, therefore the research team undertaking interviews with individuals with lived experience of MEH will need to display empathy and respect at all times. We will ask homeless interview participants to reflect on their experiences and perceptions of assessments by practitioners. This may give rise to feelings of ‘stigma’, ‘shame’ and ‘distress’. It will be incumbent upon the research team to manage the emotional context of the interview with great sensitivity. Researchers will be alert to any distress triggered or evident, offering breaks, continuation at a later time, and pre-identified sources of local support if required. In the context of fieldwork, researchers spend a lot of time building rapport with front line workers. Where the researcher feels that the participant has unmet need or is distressed, we would check first if the participant is happy for us to raise this with their key worker. Where there is a refusal, following any reassurances offered, and the researcher suspects that the individual may lack the mental capacity to fully understand the implication of not accepting help for a serious physical or mental health concern or risk to themselves or others, the researcher would contact adult safeguarding or the ambulance service without their permission. Prior to the research we will have informed and briefed local adult safeguarding teams about the study. We will also inform research participants about the limits to confidentiality when seeking informed consent.

Interview location will often be pragmatic, but will prioritise the comfort and safety of the research participants and researchers, and maintaining the confidentiality of the conversation. It may be a service's meeting rooms or a local quiet public setting will be agreed if an individual does not wish to talk in a service setting.

In more positive terms, participation may be seen to offer an opportunity to openly discuss issues, to be heard, and to have their views valued. Participants will be made aware that at all stages of the research process they can pause or withdraw without explanation, and that any data that they wish will be withdrawn. All interviews with homeless participants will be carried jointly by a KCL researcher and a lived experience peer researcher, who will support the process of putting the interview participant at ease and reducing any feelings of power imbalance.

16.2 Safeguarding

The research team, including the peer researcher, are familiar with and will adhere to the KCL safeguarding policy. Prior to undertaking interviews with homeless participants the researchers will agree with the host organisation the appropriate point of contact for raising any safeguarding concerns that might arise during an interview. Members of the research team working with vulnerable adults will have an enhanced DBS check and will be working carrying out interviews and visiting study sites in pairs, not solo.

17 Financing and Insurance

17.1 Funding

This study is funded by the NIHR Health & Social Care Delivery Research (HSDR) Programme (project reference NIHR154668). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

17.2 Insurance

The study is sponsored by King's College London (KCL). The sponsor will, at all times, maintain adequate insurance in relation to the study through its professional indemnity and no fault compensation in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant *(with certain restrictions)*.

18 Publication and Dissemination

18.1 Publication

The study will report via a summary and full project report (which will be published by the funder); will publish a Tool with Guidance for practitioners, which will be disseminated widely through national professional and practice networks; will produce peer reviewed articles on main areas of study findings; and will undertake presentations to a wide range of audiences/stakeholders nationally and internationally. It will include brief, accessible reporting appropriate for homeless audiences, including study participants, including (if future funding allows) a short animation. It will comply with all reporting requirements of the funder. Whilst all investigators will be co-authors on all publications, only KCL study team members will have access to the raw study data.

18.2 **Informing participants**

The research team will feed back summary and accessible findings to participating organisations who facilitate access to people experiencing homelessness (eg day centres, specialist services). The team will offer to return to talk through (present) the study findings in person to service users and the staff who support them, and to thank them for their contributions to the study. We hope to secure additional 'impact' funding to commission a short animation of the key messages from the study. Contact details, such as an email address, will be taken if this is a preferred option for a lived experience participant to receive updates/feedback.

The team will offer presentations to study sites leadership/training/practitioner stakeholders in the study sites, and will email publications and invitations to dissemination events to all practitioner interview participants who express an interest in being informed.

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Appendix 1 – Information on Safety Reporting in Non-CTIMP Research

	Who	When	How	To Whom
SAE	Chief Investigator	Report to Sponsor within 24 hours of learning of event Report to the MREC within 15 days of learning of event	SAE Report form for Non-CTIMPs, available from NRES website.	Sponsor and MREC
Urgent Safety Measures	Chief Investigator	Contact the Sponsor Immediately MREC to be notified Within 3 days	By phone/email Initial notification must set out reasons for the urgent safety measures and plan for further action. Where required, Substantial amendment should be submitted as soon as it is possible to do so.	Main REC and Sponsor MREC will aim to give a formal opinion on the substantial amendment within 28 calendar days but will give an opinion in no more than 35 days.
Minor Protocol deviations or GCP non-compliance	Chief Investigator	Contact the Sponsor as soon as possible after learning of the event	By email using the file note template, protocol deviation log and/or file note log templates	Sponsor Voluntary notification to REC manager and to breaches@hra.nhs.uk for information
Serious Breaches	Chief Investigator	Contact the Sponsor immediately MREC to be notified within 7 days of Sponsor notification	By email including details of when the breach occurred, the location, who was involved, the outcome and any information given to participants. An explanation should be given, and the REC informed what action the sponsor plans to take.	Main REC and Sponsor Reports provided may be referred to the Health Research Authority breaches@hra.nhs.uk for consideration by the Main REC
Progress Reports	Chief Investigator	Annually (starting 12 months after date of favourable opinion)	Annual Progress Report Form (non-CTIMPs) available from the NRES website	Main REC
Declaration of the conclusion or early termination of the study	Chief Investigator	Within 90 days (conclusion) Within 15 days (early termination)	End of Study Declaration form available from the NRES website	Main REC with a copy to be sent to the sponsor
Summary of final Report	Chief Investigator	Within one year of conclusion of the Research	No Standard Format. The following should be included:- Where the study has met its objectives, main findings and arrangements for publication or dissemination including feedback to participants	Main REC with a copy to be sent to the sponsor