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PROTOCOL VERSION HISTORY

Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update
1.0	16-MAR-2022	Christian Dalton-Locke	First version
1.1	11-MAY-2022	Christian Dalton-Locke	Adding NIHR clause
1.2	11-MAY-2022	Christian Dalton-Locke	Removal of study Component which require CAG approval i.e. Component 4
1.3	07-JUN-2022	Christian Dalton-Locke	Addition of section STAFF SIGNATURES for Master File version of the research protocol

SIGNATURES

The Chief Investigator and Priment have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, GCP, the UK Data Protection Act (2018), any applicable EU/UK amended acts to the Data Protection regulation, the Trust Information Governance Policy (or other local equivalent), the UK Policy Framework for Health and Social Care Research, Priment's SOPs, and other regulatory requirements as amended.

Chief investigator Prof Helen Killaspy		11-MAY-2022
	Signature	Date
Sponsor Nicholas Portman	*Nicholas Portman*	11-MAY-2022
	Signature	Date

STAFF SIGNATURES

By signing the below, I confirm I have read, understood, and will comply with this research protocol.

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Hellen Killaspy	Chief Investigator		07JUN2022
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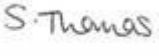
Sophie Thomas	Research Assistant		07JUN2022

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2 LIST OF ABBREVIATIONS

Term	Definition
ACER	Assessing the Clinical and cost-Effectiveness of inpatient mental health Rehabilitation services provided by the NHS and independent sector
APR	Annual Progress Report
CEA	Cost-Effectiveness Analysis
CUA	Cost-Utility Analysis
EQ-5D-5L	EuroQol 5-Dimension 5-Level health related quality of life questionnaire
C1	Component 1
C2	Component 2
C3	Component 3
C4	Component 4
C5	Component 5
CAG	Confidentiality Advisory Group
CANSAS	Camberwell Assessment of Needs Short Appraisal Scale
CAT	Client Assessment of Treatment
CCG	Care Commissioning Group
CEAC	Cost-Effectiveness Acceptability Curve
CEP	Cost-Effectiveness Plane
CQC	Care Quality Commission
CRF	Case Report Form
DAGs	Directed Acyclic Graphs
DE	Design Effect
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HoNOS	Health of National Outcome Scale
HRA	Health Research Authority
LSP	Life Skills Profile
MANSA	Manchester Short Assessment of Quality of Life

MAR	Missing At Random
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OAT	Out-of-Area-Treatment
PIS	Participant Information Sheet
PMG	Project Management Group
PPI	Patient and Public Involvement
QuIRC	Quality Indicator for Rehabilitative Care
REAL	Rehabilitation Effectiveness for Activities for Life
REC	Research Ethics Committee
ReQOL	Recovering Quality of Life questionnaire
SD	Standard Deviation
SOP	Standard Operating Procedure
UCL	University College London
UK	United Kingdom
VIF	Variance Inflation Factor

3 STUDY PERSONNEL

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4 SUMMARY

Previous research has shown that when people have access to local NHS rehabilitation services, the majority improve and are able to manage with less support over time, graduating from inpatient care to higher, and then lower, supported accommodation without subsequent readmission (1, 2). However, in recent years many NHS rehabilitation services have been closed and, increasingly, people with complex problems receive inpatient rehabilitation in the independent sector, funded by the NHS. The Care Quality Commission (CQC) reported in 2018 that the independent sector provided over half of the 4,400 mental health inpatient rehabilitation beds in England and raised concerns about the quality and costs of care provided (3). However, there have been no studies to date investigating the clinical or cost effectiveness of inpatient mental health rehabilitation that have included independent sector provision. We aim to address this evidence gap through a study composed of five Components (C1 to C5) that will be conducted over 42 months. This protocol describes the methods and procedures for C1 to C3 and C5, a separate protocol describing C4 will be drafted at a later date. The reason for this is that C4 involves the use of patient data without the patient's explicit consent and therefore requires approval from the Confidential Advisory Group (CAG) which will be sought at a later date. C1, C2, C3 and C5 will be conducted separately from C4. The five Components are:

C1 Survey of a sample of inpatient mental health rehabilitation services provided by the NHS and independent sector across England

C2 Qualitative assessment of these services from patient, staff and carer perspectives

C3 Cohort study comparing patient outcomes for users of this sample of services using multivariable regression to adjust for potential confounding

C4 Instrumental variable analysis using anonymised electronic NHS data to compare outcomes for all patients in NHS or independent sector inpatient rehabilitation units in England on a specific census date

C5 Health economic evaluation comparing cost effectiveness of inpatient rehabilitation services provided by the NHS and independent sector

5 BACKGROUND AND RATIONALE

The majority of people diagnosed with a severe mental illness such as schizophrenia recover at least partially, but around 20% will develop longer term, complex problems that require mental health rehabilitation services. These include persistent, severe 'positive' symptoms (delusions and hallucinations) and 'negative' symptoms (reduced motivation, verbal communication and emotional reactivity), alongside poor organisational skills due to specific cognitive impairments associated with the illness. Recovery is often further complicated by substance misuse and co-morbid physical health problems (such as obesity, diabetes, cardiovascular and pulmonary disease). Some people also have

pre-existing conditions such as intellectual impairment and/or developmental disorders, including those on the autism spectrum. These multiple problems impact negatively on the person's social and everyday functioning (self-care, housework, shopping, cooking, budgeting and interpersonal skills) and may lead to challenging behaviours (4). Many will struggle to engage in community activities or gain employment, and over half are vulnerable to self-neglect and exploitation (5, 6). In short, without appropriate treatment and support, quality of life for people with complex psychosis is poor.

Due to their complexity, admissions to inpatient rehabilitation services are longer than general ('acute') mental health admissions and community support costs for this group are high; it has been estimated that around half the total health and social care budget for mental health is spent on people with complex psychosis (7). Nevertheless, our previous research has shown that with access to local NHS rehabilitation services, most people can gain the skills to manage with less support over time, graduating from inpatient care to higher, and then lower, supported accommodation (1, 2). However, recent years have seen major disinvestment in NHS inpatient mental health rehabilitation services across England and increasing reliance on the independent sector.

In 2018, the Care Quality Commission (CQC) surveyed all providers of inpatient mental health rehabilitation services in England (3). They reported the cost of inpatient rehabilitation to be over £500m per year, with the independent sector providing around half the 4400 beds in the country. They noted that use of the independent sector varied greatly by Clinical Commissioning Group (CCG) and admissions to independent sector rehabilitation units were twice as long as to NHS units. Although the cost per day was similar, admissions to the independent sector therefore cost twice as much. The CQC also found that patients treated in the independent sector were much further from home than those receiving NHS care and they raised concerns about the social dislocation this caused for patients. They highlighted a lack of evidence based rehabilitation being provided in many units and questioned whether the current system represented an appropriate use of public funds, stating 'Too often, these…rehabilitation hospitals are in fact long stay wards that institutionalise patients, rather than a step on the road back to a more independent life in the person's home community.'

The CQC report (3) attracted considerable negative press (8, 9) and prompted a national initiative by NHS England ('Getting It Right First Time' – GIRFT) to encourage Clinical Commissioning Groups (CCGs) to invest in local NHS mental health rehabilitation services (www.gettingitrightfirsttime.co.uk/medical-specialties/mental-health/). The recently published NICE Guideline on mental health rehabilitation modelled the potential cost savings if all inpatient rehabilitation were to be provided by the NHS and estimated this at £52,000 per patient (an estimated total saving of over £100m per year) (10). However, this may be overly optimistic since there have been no studies comparing the quality and outcomes of NHS and independent sector providers of rehabilitation. A reversal of the current system risks wasting the expertise gained by the independent sector and major investment may be required to rebuild NHS services. Furthermore, there may be bias in the CQC data since NHS Trusts may be sending their most complex patients to the independent sector, necessitating longer admissions (11, 12).

We propose to conduct the first study to compare the clinical and cost effectiveness of NHS and independent sector inpatient mental health rehabilitation services. Our findings will be of obvious

relevance to those who require these services and their families, and will help inform commissioners and policy makers about the most appropriate use of resources for this complex group.

6 RESEARCH QUESTIONS

Our overarching aim is to investigate the clinical and cost-effectiveness of inpatient mental health rehabilitation provided by the NHS and independent sector with the objective of investigating differences between them in terms of: patient characteristics; service quality; patient; carer and staff experiences; clinical effectiveness; and cost effectiveness.

Our specific research questions are:

1. Do sociodemographic and clinical characteristics of patients differ between people receiving inpatient rehabilitation in the NHS and the independent sector?
2. Does service quality differ between inpatient rehabilitation units provided by the NHS and the independent sector?
3. Do the experiences of treatment and care, from the perspectives of patients, informal carers and staff, differ between inpatient rehabilitation services provided by the NHS and the independent sector?
4. Is inpatient rehabilitation clinically more effective at preventing readmission when provided by the independent sector or the NHS, after adjusting for differences between the sectors in terms of patient characteristics and length of stay?
5. Is inpatient rehabilitation more cost effective when provided by the independent sector or the NHS, after adjusting for differences between the sectors in terms of key predictors of costs such as patient characteristics and length of stay?

7 METHODS

7.1 SCOPING OF INPATIENT MENTAL HEALTH REHABILITATION SERVICES

We will first contact all NHS Mental Health Trusts and our local collaborators at our independent sector provider partners to identify potentially eligible inpatient rehabilitation services for the study. In terms of the independent sector, we already have agreements in place with Cygnet Health Care, Priory Group, and St Andrew's Healthcare, for their eligibly services to be available for selection in this study. We will confirm details of the number and types of inpatient rehabilitation units provided and use the typology of inpatient rehabilitation services developed by the Royal College of Psychiatrists (13) to categorise units. We will also collect information about their location (urban, suburban, rural), size (number of beds) and gender mix (mixed or single sex). We aim to recruit similar numbers of different unit types in both sectors and will consider the need for stratified random sampling (by provider, unit type, size, location etc.) once the initial scoping is completed.

7.2 SERVICE ELIGIBILITY CRITERIA

Only high dependency, community, or longer term high dependency rehabilitation units will be eligible for the study. Community rehabilitation units will only be included if they are registered with CQC as an inpatient unit (rather than supported housing or residential care). We will exclude highly specialist

units that focus on sub-groups (such as people with a diagnosis on the autism spectrum or those with neurodegenerative disease). We will also exclude specialist forensic mental health units (i.e. low secure rehabilitation units) as they do not form part of the standard mental health rehabilitation care pathway and are subject to specialist commissioning by NHS England. We will consider excluding very small units (less than 10 beds) to ensure adequate patient recruitment and an average cluster size of 8, in keeping with the number of patients per unit recruited in the REAL study, a previous national programme of research in NHS inpatient rehabilitation services led by HK (1, 5).

7.3 LOCAL APPROVALS

NHS Trusts and independent sector providers of eligible services will be approached by the research team about potential participation in the study. The research team will work together with organisations who agree to take part in this study to put in place all the necessary local approvals.

7.4 COMPONENT 1: SURVEY OF NHS AND INDEPENDENT SECTOR INPATIENT MENTAL HEALTH REHABILITATION SERVICES

Component 1 (C1) addresses research questions 1 and 2.

1. Do sociodemographic and clinical characteristics of patients differ between people receiving inpatient rehabilitation in the NHS and the independent sector?
2. Does service quality differ between inpatient rehabilitation units provided by the NHS and the independent sector?

7.4.1 MEASURES AND DATA COLLECTION

Data for C1 will be collected from patient participants, key staff and patients' healthcare records.

Research interviews will take place at the inpatient service where the participant is receiving treatment at the time of recruitment into the study. The following measures will be collected through interviews with patient participants and will take around 30 minutes:

- The amended version of the Manchester Short Assessment of Quality of Life (MANSA) (14), known as DIALOG (15), comprises 11 aspects of daily life that are rated on a scale from 1 (couldn't be worse) to 7 (couldn't be better), generating a total mean score between 1 and 7.
- The Recovering Quality of Life (ReQOL) (16) 10-item version, assesses quality of life in terms of personal recovery with each item rated 0 to 4 and a total possible score of 40. A new tariff has recently been published (17) and we will use this to calculate patients' utility scores from the questionnaire responses.
- The EQ-5D-5L (18) is a 5-item generic preference-based health-related quality of life measure, from which patients' utility scores are calculated using standard methods.
- The Resident Choice Scale (19) measures autonomy. The patient rates the degree to which they have choice over 22 aspects of daily activities and the running of the inpatient unit on a four-point scale ('I have no choice at all about this', 'I have very little choice about this', 'I can

express a choice about this but I do not have the final say', 'I have complete choice about this'), generating a maximum possible score of 88.

- The Time Use Diary (20) assess the patient's engagement in activities and can be completed by the patient or a staff member. Engagement and complexity of activities are assessed for the previous week during four periods each day – morning, lunchtime, afternoon and evening and rated on a scale from 0 to 4 for each time period, giving a maximum possible score of 112 with higher scores denoting greater activity.
- The Client Assessment of Treatment (CAT) (21) measures satisfaction with care. The patient rates their satisfaction with seven aspects of their inpatient treatment on a scale from 0 (not at all satisfied) to 10 (totally satisfied), generating a total mean score out of 7.
- Contacts with healthcare professionals external to the inpatient rehabilitation service over the last three months.

Patients will be paid £20 for giving their time to participate in the research interview.

A staff member at the inpatient service who knows the patient well will be asked to complete the following assessments about them, which together, will take less than 30 minutes to complete:

- The Life Skills Profile (LSP) (22) assesses social functioning. It comprises 39 items, each rated on a four-point Likert scale with the most positive response scoring 4 and the least scoring 1, giving an overall score ranging from 39 to 156.
- The Special Problems Rating Scale (23) assesses the presence and severity of 16 challenging behaviours on a scale of 0 (no problem) to 2 (frequent and/or extremely difficult to manage).
- The Clinical Alcohol and Drug Scale (24) is a 5-point scale that can be used to rate separately alcohol and other substance use over the previous six months (1 = abstinent; 5 = dependence resulting in institutionalisation). The degree of severity can also be summarised as a binary variable (problematic or non-problematic).
- The Camberwell Assessment of Needs Short Appraisal Scale (CANSAS) (25) assesses 22 domains of mental health and social need over the previous month as absent (0); met (1) or unmet (2). A need may be rated as unmet (whether receiving treatment or not) if it remains problematic. The scale generates a total score and the proportion of met and unmet needs.
- Time Use Diary (20) (see patient interview measures).
- Whether the patient is being treated 'out of area' (i.e. outside the catchment area of their responsible CCG) at their current inpatient rehabilitation service.
- How much per week the CCG are being charged for the patient's care at the inpatient rehabilitation service (£ per week). If the staff member being interviewed does not know this information, the researcher is to collect this from another member of staff.

The researcher will also collect the following information from the patient's healthcare records:

- Sociodemographic details (age, sex, ethnicity, civil status, highest level of education achieved).
- Health data (responsible CCG, primary and comorbid mental health diagnoses, comorbid physical health conditions using ICD-10 classification)
- Healthcare service use history (length of contact with mental health services, number of previous mental health admissions, date current inpatient admission started, date of admission to current rehabilitation unit, current Mental Health Act 1983 status).

- Current (within the last three months) and previous (any known historical incident/record) risks, including: self-harm, suicide, self-neglect, vulnerability to exploitation, risk posed to others. The researcher will also collect what was the most severe incident of aggression/violence to others ever recorded, whether they have previously been admitted to a forensic mental health facility and whether they have ever been in prison.
- Engagement in community based activities over the last month, including attending work, educational courses, or leisure activities.

Service-level data will also be collected by the researcher from the inpatient rehabilitation unit manager at baseline, using the Quality Indicator for Rehabilitative Care (QuIRC) (26), a standardised quality assessment tool for inpatient mental health rehabilitation services. The QuIRC comprises 145 items covering: the setting (hospital or community) and size (number of beds) of the unit; the average length of stay; the proportion of male and female patients; the proportion detained under the Mental Health Act; patients' degree of disability/need for staff assistance; staffing (including numbers of full time equivalent staff of different disciplines); staff training in rehabilitative skills (including cognitive behaviour therapy, family interventions, recovery-based practice and motivational interviewing); the provision of staff supervision; staff turnover, vacancies and disciplinaries; the provision of evidence-based pharmacological and psychosocial interventions, occupational therapy and the facilitation of community activities (education, employment and leisure); interventions for physical health care and promotion (such as smoking cessation programmes, dietary advice, and support to access exercise); the therapeutic culture of the service; the degree to which patients are involved in developing their treatment and care plans; patient involvement in decisions about the running of the unit; the protection of patients' human rights; the response to challenging behaviours including the use of de-escalation, restraint and seclusion; and the quality of the built environment. The QuIRC produces percentage ratings on seven domains of care, has excellent psychometric properties and takes around one hour to complete. The QuIRC will be collected on paper and then entered by the researcher into the QuIRC website (quirc.eu/).

7.4.2 PATIENT ELIGIBILITY CRITERIA

All patients of inpatient rehabilitation units that are participating in the study will be eligible for participation (see section 7.2 for service eligibility criteria), with the exception of those on leave (with or without formal permission) at the time of recruitment (this comprised 8% of patients in the REAL study (5)) and those who lack adequate English to give informed consent (1% in the REAL study (5)). The vast majority of patients at these units have a diagnosis of schizophrenia or bipolar affective disorder (89% in the REAL study (5)).

We will include patients who are assessed as lacking capacity in C1. All efforts will be made to maximise the capacity of each patient to be able to provide informed consent for the study (for example, by explaining the purpose and process of the study in simple terms and over a number of meetings), and any patient with capacity who declines participation will not be included. However, for eligible patients who lack capacity to give informed consent we will seek advice from a consultee on their participation. Further detail on the procedure for seeking informed consent and assessing capacity is provided in section 8. Research data for participants lacking capacity will be collected via staff interview and healthcare records (as described in section 7.4.1), but these participants will not be asked to

participate in an interview themselves. We expect only a minority of eligible patients to lack capacity (around 8% based on the REAL study (5)) but it is important they are included in the study in order to prevent sample bias (13).

7.4.3 PROCEDURES FOR PATIENT RECRUITMENT AND DATA COLLECTION

Managers of inpatient services selected for potential participation will be contacted by the research team via telephone and/or email to explain the purpose of the study, why their service has been selected, and what would be required of the manager, the staff, and the patients if they agree to participate in the study.

Once a service has agreed to participate, the research team and service manager will arrange a time for the researcher to visit the inpatient service to recruit participants and collect data. It is expected that the researchers will spend approximately one week in each service. The research will interview the service manager to collect service level data as described in Section 7.4.1. The researcher will also meet with the rehabilitation unit staff to explain the purpose and processes of the study. Staff will be asked to approach eligible patients and asked if they would like to meet the researcher to discuss the study.

Patients who have capacity and agree to participate will be asked to confirm this by completing the 'Patient Participant Consent Form'. The patient research interview will then be conducted as described in Section 7.4.1 and once completed, the patient will be offered £20 cash for their participation (27). The researcher will then meet with a staff member who knows the patient participant well, and recruit and consent staff who are willing to take part in the study. Consented staff will then take part in a research interview as described in Section 7.4.1.

Further detail on the procedure for seeking informed consent of participants is described in Section 9.

7.5 COMPONENT 2: QUALITATIVE INVESTIGATION OF PATIENT, RELATIVES/CARE AND STAFF EXPERIENCES OF INPATIENT REHABILITATION SERVICES

Component 2 (C2) addresses research question 3 by exploring differences in the experiences of inpatient rehabilitation provided by the NHS and independent sector, from the perspectives of patients, informal carers and staff. C1 will provide quantitative evidence on potential differences between the NHS and independent sector rehabilitation services for a range of domains; the qualitative component will elaborate on these aspects of service provision and their relative importance to different stakeholders to obtain a more comprehensive picture of these services.

7.5.1 SAMPLING AND RECRUITMENT OF SERVICES

We will purposively select and invite 10 inpatient rehabilitation units (5 NHS and 5 independent sector) participating in C1 to participate in C2. Our selection will aim to ensure a range of quality (QuIRC ratings) and unit size; selection by geographic location (urban/suburban/rural and distance from home) will assist our understanding of: a) the experience and impact of 'out-of-area-treatment' (OAT);

and b) proximity to non-clinical, community based amenities that may influence people's recovery in inpatient rehabilitation.

7.5.2 SAMPLING AND RECRUITMENT OF PATIENTS, STAFF AND RELATIVES/CARERS

We will invite all staff of these units to participate in a staff focus group. There will be one focus group per participating service, therefore 10 focus groups in total. In our previous research we have found that an open invitation ensures 6-10 staff attend and avoids complex selection processes that may alienate staff. We will also conduct additional individual staff interviews with staff who were unable to attend the focus group.

We will purposively select 3-5 patients in the participating units (i.e. 15-25 NHS and 15-25 independent sector patients), who also participated in C1, to participate in individual interviews, aiming to recruit a mix of gender, age and ethnicity. Patient participants will need to have been in the unit for at least one month to be eligible, as any shorter would not give them adequate experience of the service, and they must be assessed as having capacity to provide informed consent (see Section 9 for further detail). We will ask patient participants for their permission to contact a relative/informal carer to take part in a separate qualitative interview. We aim to recruit two family members/informal carers per unit (i.e. 20 in total). Any relative/carer identified by the patient participant will be eligible for participation. A maximum of one relative/carer will be recruited per patient participant.

We will also invite the patient's community care co-ordinator or care manager to participate in an in-depth interview to explore their views on the patient's care in the inpatient rehabilitation unit. We will also invite key decision makers from the person's CCG area services, such as the local mental health commissioner and senior service managers, to participate in in-depth interviews about their use of NHS and independent sector rehabilitation services, how their system operates and how decisions are made about where patients who require inpatient rehabilitation receive this care.

The procedure for seeking informed consent for C2, including how consent is sought from relatives/carers, is described in Section 9.

7.5.3 INTERVIEW CONTENT

Topic guides have been developed by the Project Management Group and reviewed and revised through consultation with our patient and public involvement (PPI) and Expert Reference Group members. Separate topic guides have been developed for inpatient rehabilitation service staff patients, relatives/carers, community staff, and senior managers and commissioners.

Topic guides for staff cover multilevel factors, key factors, and processes that illuminate relationships between context and outcomes. Thus, interviews with senior managers and commissioners will explore the 'external system' (economic, political, and professional milieu) (28) and decision-making processes related to transfers to the independent sector compared with those who remain in the NHS (e.g. capacity, funding, patient characteristics) and how these are negotiated. Focus groups and interviews with unit staff will explore contextual, 'internal' factors (culture, ethos, attitudes, resources, prioritisation and intensity resource allocation: staffing levels, recruitment, skill mix, training; structure and organisation). Transfers to the independent sector are criticised for the social dislocation of

patients and the failure to maintain connections to NHS services, family and neighbourhood. We will specifically explore this issue, taking into account NHS and independent sector perspectives. Our in-depth interviews with patients will cover: satisfaction with the unit's facilities; the content of the rehabilitation programme provided; staff attitudes (e.g. communication, helpfulness, service user empowerment); barriers to accessing community resources; maintaining contact with family/friends; joint decision making and discharge planning. Interviews with family/informal carers will explore satisfaction with services and any barriers to their involvement. Interviews with community staff will explore their perspectives on the patient's current care in the inpatient rehabilitation unit and any barriers to their involvement. We do not anticipate any of the interviews or focus groups to include topics that might be sensitive or upsetting, nor do we expect the disclosure of criminal or other activities which require action.

Staff focus groups and individual interviews will last no more than one hour. In our previous research we have found that in-depth interviews with patients of rehabilitation services tend to be much shorter (30 minutes maximum) due to the cognitive difficulties that many patients experience. We will offer patient participants £20 for their time (27). We have not included interviews with relatives/carers in our previous research but we estimate these will take no longer than one hour. Interviews and focus groups with patients and staff at the selected inpatient rehabilitation service will take place face-to-face at the service. We will offer to conduct our interviews with relatives/carers and staff working outside the unit (such as senior managers and commissioners) using a secure videoconferencing platform (Zoom or Teams) to minimise travel and time burden since they may be based many miles from the patient's rehabilitation unit. All face-to-face interviews will be recorded using encrypted recorders compliant with the relevant service provider requirements. All recordings will be transcribed with identifiable information such as names and locations removed. It will be explained to participants that their quotes may be used in publications, but that they will not be identifiable.

7.5.4 QUALITATIVE DATA ANALYSIS

Data will be professionally transcribed verbatim and entered into qualitative software (NVivo version 12) (29) for analysis, to be done independently by two researchers and, initially, without reference to the quantitative findings to maximise objectivity. To guide this process, we will use a framework approach (30) with pre-defined themes which can accommodate additional emergent themes and sub-themes. Co-investigator GL will review the analyses where any dissonance arises between the findings. In this first stage, we will highlight apparent differences and similarities within the NHS and independent sectors as experienced and described by our participant groups (e.g. quality of care, ethos, resources). We will also critically examine perspectives 'within sectors', e.g. contrasting patient views and experiences with those provided by staff. As in our past research, we will describe both strengths and weaknesses within clinical services. These findings will be presented to the wider team and discussed in relation to C1 and C3, with the aim of triangulating both qualitative and quantitative findings. We will assess consensus within and between groups and validate these through review by our internal and external PPI groups.

7.6 COMPONENT 3: ASSESSMENT OF CLINICAL EFFECTIVENESS OF NHS AND INDEPENDENT SECTOR REHABILITATION SERVICES

Components 3 (C3) addresses research question 4 using different approaches to quantitative analysis of an important outcome - successful rehabilitation. We know that admissions to the independent sector tend to be longer and therefore more costly (3, 30), but if they result in fewer readmissions they may be more effective. We will therefore compare NHS and independent sector patients in terms of the primary outcome, total inpatient days, and the main secondary outcome, the proportion readmitted after discharge to the community. The preferred approach to compare effectiveness of two services is a randomised controlled trial, which ensures that all variables (except for the services received) that may explain the outcomes (i.e. all known/unknown confounders) are balanced between groups. As randomisation is not feasible here, in C3 we will use an observational design employing multivariable regression and propensity scores to adjust for confounding.

We will follow participants recruited in C1 for 18 months and compare total inpatient days from recruitment, including any readmissions, for those in NHS and independent sector units. To account for the fact that independent sector patients are likely to have less time to relapse (due to longer admissions) than those in NHS units, our main analysis will compare readmissions for those discharged during the 12-month recruitment period in C1. However, we will also conduct a supportive analysis including all patients discharged during the 18-month follow-up period. Full details of the approach to data analysis are provided in Section 10.3.1.

We have experience of successful tracking of similar patient cohorts and will gain participants' consent for this at recruitment in C1. We plan to follow their progress through contact with key staff and will record contact details for these staff at recruitment into C1 (including the participant's local CCG and NHS Trust and their community care co-ordinator or care manager). We will contact the manager of inpatient rehabilitation units that participated in C1 every month to confirm whether any patient participants have been discharged or transferred to another inpatient unit. Where this is the case, we will record the date of transfer/discharge and details of where the patient has moved to and confirm contact details for key staff involved in their ongoing care such as their community care co-ordinator. This staff member will be the patient participant's 'key staff contact' for the remainder of the study and we will continue to keep in contact with them monthly to track the patient's progress and the dates of any further admissions. We will collect from the key staff contact at six, 12 and 18 months details following discharge about the patient's use of mental health supported accommodation (residential care, 24 hour supported housing, < 24 hour supported housing), the number of hours and cost per week of any additional 'care packages' funded by the NHS or social services that are in place to support them in the community and the length of time any such care packages have been in place, any readmissions (including general medical admissions), number of visits to Accident and Emergency, and the number of community contacts.

For all participants recruited to C1, we will also attempt to complete the 10-item version of the Recovering Quality of Life measure (ReQOL) and the EQ-5D-5L at six, 12 and 18 months after recruitment. We will explain to patient participants during the consent procedure for C1 that we will ask them to take part in brief follow-up interviews six, 12 and 18 months later by telephone or video call (Teams or Zoom). We will ask participants for their contact number at baseline (i.e. data collection

for C1) and attempt to contact them directly at follow-up. If we are unable to make contact this way, we will contact them through their healthcare team i.e. the member of staff researchers are contacting monthly; for inpatients this will be the ward manager and for those who have been discharged, their community care co-ordinator.

7.7 COMPONENT 5: HEALTH ECONOMIC ANALYSIS

Component 5 (C5) will address research question 5 primarily using data collected for C1 and C3, and will also use data from C4 pending HRA and CAG approval for C4. As described in Section 4, this protocol describes the methods and procedures for C1–C3 and C5. A separate protocol will be written at a later date. See Section 10.3.3 for further details of the health economic analysis plan.

The main cost-utility analysis (CUA) will use information from C1 and C3 to calculate the incremental cost per quality-adjusted life-year (QALY) gained by using independent sector rehabilitation services instead of NHS rehabilitation services, over the 18-month period. The most significant costs are expected to be due to inpatient rehabilitation days (i.e. the primary statistical outcome), but the cost perspective will also include other NHS and Personal Social Services resource use to describe the wider support provided to participants.

The supporting cost-effectiveness analysis will calculate the incremental cost per readmission avoided (this is the secondary statistical outcome) for those discharged during the 12-month recruitment period in C1/C3. We will also conduct a supportive analysis including all patients discharged during the 18-month follow-up period of C1/C3.

Quality-adjusted life-years (QALYs) will be calculated from patients' utility scores captured in C1 and C3, calculated in turn from EQ-5D-5L responses using standard methods and a secondary analysis will calculate these from ReQOL responses. We will use the resource use data gathered via the key staff contact about patient participants discharged from the inpatient rehabilitation unit they were receiving treatment in at recruitment, as well as the inpatient costs pre-discharge, to calculate costs and quality-adjusted life-years per patient. These resources include the length of the baseline inpatient rehabilitation admission from the study baseline date (i.e. the date the patient participant was interviewed for C1), any readmissions in days, the use of supported accommodation services (including the length of time the participant has lived there, the level of support provided [residential care, 24 hour supported housing, <24 hour supported housing] and the weekly costs) and any individual 'care packages' provided, including the number of hours of support per week, the cost per week and the length of time provided. Unit costs for inpatient bed-days will be calculated using a bottom-up microcosting in the first instance so that the independent and NHS services are assessed according to the cost to the provider of providing the services.

C5 will also include analyses using information on inpatient rehabilitation bed-days from C1 and C3, and C4 pending the necessary approvals (as described above), calculating the mean and marginal costs per patient across the two types of service provision, to further investigate the impact of service type around the primary statistical outcome of total inpatient days.

8 COVID-19 SAFETY AND ADAPTATIONS

Researchers will be required to follow local and national COVID-19 guidance and will be provided with the appropriate personal protective equipment, including face masks and hand sanitiser. Whilst we aim to recruit and interview all study participants for Components 1 and 2 face-to-face, given the uncertainty of the COVID-19 pandemic, we can adapt our processes if necessary using secure videoconferencing (e.g. Microsoft Teams). All inpatient units provide such facilities to enable patients and staff to attend Mental Health Review Tribunals (for patients detained under the Mental Health Act). Interviews with relatives/carers and staff working outside the inpatient unit can also be conducted through videoconferencing. Colleagues at UCL's Division of Psychiatry have made such adaptations to study processes during the pandemic successfully and we are confident that we will be able to continue the study in such circumstances.

9 INFORMED CONSENT PROCEDURE

It will be the responsibility of the researchers delegated by the Chief Investigator, to obtain informed consent from each participant prior to their participation in the study, following adequate explanation of the voluntary nature of their participation, the purpose of the study, what their participation will involve, and the potential benefits and risks of taking part.

9.1 COMPONENTS 1 AND 3

9.1.1 PATIENTS

Once a service has agreed to take part in C1 and C3, the researcher will schedule with the service manager when they will visit the service to recruit participants and collect research data. These visits will usually last around one to two weeks. Upon their arrival, they will meet the service manager or a delegated member of staff and be introduced to other members of staff. They will explain the purpose of the study and what it will involve for participants. They will be asked to approach eligible patients at the service and ask them if they would be willing to meet with the researcher. The staff member will introduce patients to the researcher patients who are willing to meet. The researcher will explain to the patient the purpose of the study, the voluntary nature of their participation, what their participation would involve, and the potential risks and benefits of participating. The researcher will then provide the patient with a Patient Participant Information Sheet (PIS), and invite them to ask any questions they have about the study. They will give them at least 24 hours to decide whether they wish to participate or not. Researchers will then meet with the potential participant again, providing another opportunity for them to ask any questions. Those who agree to participate will be asked to confirm this by completing the Patient Informed Consent Form. This will include consenting to the following:

- To participate in a research interview
- To be invited by the researcher either directly or via their healthcare team to participate in brief follow-up research interviews via telephone or videoconference at six, 12 and 18 months later
- To have data relating to their participation collected from staff

- To have data relating to their participation collected from their healthcare records
- To have data relating to their participation collected from staff at regular intervals for the duration of the study (18 months)

Consent from patient participants will always be collected in person and recorded in writing. The original copy of the completed and signed consent form will be kept by the researcher and filed at the UCL Division of Psychiatry. A copy will be given to the patient participant to keep and a further copy will be given to staff at the inpatient service for them to add/upload to the patient's healthcare records. The researcher will also contact the patient's community care co-ordinator to explain that the patient has been recruited to the study and send them a copy of the completed consent form.

9.1.2 PATIENT CAPACITY

Patients will be asked to consent to continue to taking part in the study even if they later lose capacity to make this decision. Where it is clear from the key staff contact (the service manager or other healthcare professional) that a patient participant has lost capacity at six-, 12- and 18-month follow-up point, the researcher will not invite them to complete the follow-up interview.

At recruitment and during the consent seeking procedure for Components 1 and 3, the researcher will assess the patient's capacity to provide informed consent in accordance with Good Clinical Practice (GCP) and national guidance associated with the Mental Capacity Act 2005, considering the following: they will assume each potential participant has capacity to agree or disagree to take part in this study; they will provide sufficient information about the study; they will then ask the participant their understanding of what their involvement in the study means and the pros and cons of participating.

If the researcher judges the patient to lack capacity, they will attempt to identify a personal consultee for the patient and seek their advice on whether they believe the patient would like to participate or not. The patient will be asked who they would like to be their personal consultee. It should be someone who knows the patient well and who is trusted by the patient. A personal consultee cannot be someone who is in a paid role and will usually be a close relative or friend. If a personal consultee is identified, the patient's clinical team at the inpatient rehabilitation service will be asked by the researcher to contact the consultee and to ask them if they would be willing to act as a consultee and speak with the researcher. If a personal consultee cannot be identified because the patient does not have someone close to them suitable for the role, or contact cannot be established with the person identified, the researcher will nominate a consultee. The nominated consultee will be a member of staff at the inpatient rehabilitation service who knows the patient well and is not part of the research team (i.e. not a Local Collaborator).

Once a personal/nominated consultee is identified, the researcher will discuss with them the study, explaining its purpose, what it will involve for the patient, and the potential risks and benefits. It will also be explained that they are being asked to provide their opinion on whether the patient would object or not to taking part in this study. They will be provided with a Consultee Information Sheet and given at least 24 hours to consider their opinion. The Consultee Information Sheet will be given to the consultee in person or via email or post if they are not able to meet in person. If the consultee believes the patient would not object, they will be asked to confirm this by completing the Consultee

Declaration Form. This may take place in person and recorded in writing or in cases where it is not feasible for the researcher to meet with the consultee in person, it will be completed remotely via telephone or video call and recorded verbally. Three copies of the completed Consultee Declaration Form will be generated, one will be kept by the researcher and filed securely at UCL Division of Psychiatry, one will be given to the consultee for them to keep, and one will be given to the patient's healthcare team to be added/uploaded to the patient's healthcare records.

Where a consultee has been identified the patient participant will not be invited to take part in any research interview. Their research data will be collected solely via interviews with staff and from their healthcare records.

9.1.3 STAFF AND MANAGERS

A staff member at the inpatient service who knows the patient participant well will then be approached by the researcher and invited to take part in the study during the researcher visit. Again, the voluntary nature of their participation, the purpose of the study and what their participation would involve will be explained to them. There are no specific anticipated benefits or risks to taking part other than giving the time to complete the research interviews. The staff member will be provided with a Staff Information Sheet and invited to ask any questions about the study. It will be explained to them that any patient participant we ask them about has either consented to this themselves or a consultee (for patient participates who lack capacity to give informed consent to participate) is of the opinion that the patient would not object to participating. It will be explained that the healthcare team have already been provided with a copy of the completed and signed consent form or consultee declaration form, and the researcher can show the staff member a copy if they wish. Staff who complete the staff research interview will be deemed as providing consent to taking part. The Staff Information Sheet will include the following statement: 'Completing the research interview with the researcher will be deemed as you consenting to taking part in this study.'

The service manager will also be approached during the visit by the researcher and invited to take part in the study. The voluntary nature of their participation, the purpose of the study, and what their participation would involve will be explained. The manager will be provided with a Manager Information Sheet and invited to ask any questions about the study. Managers who complete the manager research interview will be deemed as providing consent to taking part. The Manager Information Sheet will include the following statement: 'Completing the research interview with the researcher will be deemed as you consenting to taking part in this study.'

9.2 COMPONENT 2

Of the services taking part in C1 and C3, 10 will be selected for participation in C2. Separate informed consent will be sought for C2 but will follow the same procedure as described for C1 and C3, except that patients who lack capacity will not be invited to take part. PISs and Consent Forms will be specific to the component(s) of the study the individual is being invited to take part in. Therefore, there will be one Patient PIS and Patient Consent Form covering C1 and C3, and a separate Patient PIS and Patient Consent Form for C2.

Patients participating in Component 2 will be asked for their consent to invite a relative or friend who is involved in their care to also participate in C2. We will ask for the relative's/carer's name, contact details (e.g. telephone number, email address or home address), so that they can be invited. If the patient is unsure of these details, they will be collected from staff or their healthcare records. The researcher will then attempt to make contact with the relative/carer by telephone and/or email. As explained in Section 7.2, interviews with carers/relatives will take place remotely. Therefore, the Relative/Carer PIS and the Relative/Carer Informed Consent Form will be sent via email or post. It will be explained that the consent form can be completed by posting/emailing the form back (wet signatures will not be required for electronically completed forms, but the email in which they are received will be saved as a record of the consent, as well as the electronically completed consent form), or recorded verbally over telephone/ video call (Teams or Zoom) by the researcher reading out each item on the consent from and asking the relative/carer to say whether they agree or disagree to each item, and asking them to state their name and date.

Informed consent will also be sought from all other participants in C2, including staff based at the participating service (focus groups and interviews with these participants will be conducted in person and thus consent will also be sought in person and recorded in writing), community staff, senior managers, and commissioners (we anticipate these interviews to be a mix of in person and remote). Like patients and their relatives/carers participating in this study, staff, senior managers, and commissioners who agree to take part will be asked to confirm this by completing a consent form. This may be completed in person or via telephone, video call, email, or post as described above for relatives/carers.

10 DATA MANAGEMENT

According to GDPR legislation, Camden and Islington NHS Foundation Trust is the data controller for this study and UCL is the data processor. The legal basis for processing personal is performance of a task in the public interest. The legal basis for processing special category personal data is scientific and historical research or statistical purposes.

10.1 DATA COLLECTION TOOLS AND SOURCE DOCUMENT IDENTIFICATION

A data management plan will be created which will include details of the data collection tools, methods of completing case report forms (CRFs), sign off of finalised CRFs, source document identification and methods to maximise completeness of data collection.

It will be the responsibility of the Chief Investigator (CI) and research team to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the study database.

10.2 DATA COLLECTION AND HANDLING

All data will be collected and handled in accordance with Priment's Data Handling standard operating procedure (SOP). Each participant will be assigned a participant ID and this will be used to link

completed data collection forms relating to the same participant. Identifiable data such as names or NHS numbers will not appear with any of the data collected. Therefore, participant data is pseudonymised. The Participant ID Log, which will be the only electronic file which contains both the participant ID and the participant's name, will be password protected and stored on the UCL network drive only accessible to the research team and stored within the UCL firewall. In addition to the participant's name and participant ID, the Participant ID Log will also include the participant's NHS number (only for patient participants, not staff or relative/carer participants; so that the researcher can access their healthcare records and be able to track participants who are discharged and move between service providers), and their contact telephone number and email address (for patients and staff participating in C3, to facilitate establishing contact for follow-up interviews). For patient participants participating in C2, who agree to their relative/carer being invited to also take part in this study, their relative's/carer's name and their contact details will also be included in this file.

The data collection forms will be prepared for electronic use by Priment CTU with technical support from Sealed Envelope, an independent company which provides Red Pill, an online data management system that collects and manages data in partnership with Priment's data management team. The data will be collected at interview on paper versions of the CRFs, which will then be entered electronically to the Red Pill database system.

Information on study participants will be kept confidential and managed in accordance with the Data Protection Act 2018, the General Data Protection Regulation (GDPR), NHS Caldicott Guardians, Research Governance Framework for Health and Social Care, and the Research Ethics Committee approval. During each site visit for participant recruitment, researchers will complete a paper based Recruitment Log. This will include all the information needed to complete the electronic Participant ID Log described above (the participant's name, their participant ID, NHS number, contact number, email address, and carer/relative name and contact details for a sub-set of patient participants in C2). The information recorded on the Recruitment Log will be transferred by the researcher to the Participant ID Log at the earliest opportunity, and once transferred, the Recruitment Log will be safely destroyed (i.e. shredded). This will usually be at the end of each day of the researcher's site visit. All other data collection forms and consent forms completed during the researcher visit will be filed by the researcher upon their return to UCL each week in locked filing cabinets accessible only to the research team and located on UCL premises only accessible to UCL staff.

10.3 DATA MANAGEMENT FOR COMPONENTS 1 AND 3

The secure online database that we will use for C1 and C3, the Red Pill database system, is hosted by Sealed Envelope, is fully GCP compliant and all data entered will be pseudonymised. All access will be via encrypted channels and limited to the research teams. Sealed Envelope is registered as a data controller with the UK Information Commissioner's Office and has been inspected by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK clinical trials regulator.

10.4. DATA MANAGEMENT FOR COMPONENT 2

Interviews and focus groups will be recorded on encrypted voice recorders or via the platform in which the interview was conducted (Teams or Zoom). The recording will then be transferred from the voice

recorder, Teams or Zoom to the secure UCL network drive (within the institution's firewall and only accessible to the research team), and the recording on the voice recorder, Teams, or Zoom will be deleted. An external third party transcription agency will transcribe the interviews. This transcription agency will be in compliance with the Data Protection Act 2018 and General Data Protection Regulation. A data processing agreement between the relevant parties will be put in place and will ensure that the transcription agency will only use UK based servers, and that all data will be transferred, handled, stored and processed securely. During the transcription process, all identifiable information (e.g. names, mentions of specific locations, etc.) will be removed. Once transcribed, all recordings will be deleted. Transcriptions will be stored on the secure UCL network drive in the study's electronic files.

10.5 DATA OWNERSHIP

Data ownership rests with the study sponsor, Camden and Islington NHS Foundation Trusts. The Chief Investigator will be the data custodian.

11 STATISTICAL AND HEALTH ECONOMICS CONSIDERATIONS

11.1 OUTCOMES

11.1.1 PRIMARY OUTCOMES

- C1 will provide descriptive data on patient and service characteristics in the NHS and independent sector inpatient rehabilitation units and there is no primary or secondary outcome.
- C2 is a qualitative study.
- In C3 our main outcome is successful discharge from inpatient rehabilitation i.e. being discharged to the community without readmission.
- In C3 our primary outcome is total inpatient days in the 18 months since recruitment to C1.
- In C5 our primary outcome is the incremental cost-effectiveness ratio (ICER) calculated using cost-utility analysis (CUA) where the QALYs are calculated from patients' EQ-5D-5L responses, comparing rehabilitation in the independent sector vs. rehabilitation in an NHS service.

11.1.2 SECONDARY OUTCOMES

In C3 our main secondary outcome is the proportion of patients readmitted in the 18 months since recruitment to C1. We will also investigate potential predictors of successful discharge that we will assess at recruitment that have been identified in previous research: length of time in the inpatient rehabilitation unit; engagement in activities (Time Use Diary score); social function (LSP total score and sub-domain scores); needs (CANSAS total and unmet needs score); current risk of self-neglect (yes/no); current vulnerability to exploitation (yes/no); past history of fire setting (yes/no); Recovery Based Practice of the service (QuIRC domain score); service's promotion of Human Rights (QuIRC domain score); degree to which the service promotes social inclusion (QuIRC domain score).

11.2 SAMPLE SIZE AND RECRUITMENT

11.2.1 COMPONENTS 1 AND 3

We aim to recruit 500 participants over a period of 12 months. A sample of 294 (half from NHS and half from independent sector units) will allow us to detect a mean difference in inpatient days of 0.38

SD (REAL study SD =113, i.e. around 6 weeks) (1) between NHS and independent sector rehabilitation units, using a two-sample t test with 90% power and 5% significance level. Based on a bed day cost of £3503, 6 weeks is an important difference, representing a potential saving of £14,700 per patient.

To perform the multivariable regression analysis described below, this sample size is increased to 350 after inflating, using a variance inflation factor (VIF) of 1.19 (derived using a multiple correlation coefficient of 0.16, the assumed proportion of variance in the service type explained by its association with the confounding variables). We do not have estimates available for the VIF from previous studies and thus assumed a moderate strength of association between service sector and the confounding variables (31). The sample size further increases to 497 after allowing for a design effect (DE) of 1.42 (based on an average cluster size of 8 and an intracluster correlation of 0.06) (5).

Based on the REAL cohort study findings (1) and CQC report (3, 32), we estimate 160 NHS and 80 independent sector patient participants will be discharged during the 12 month recruitment period in C1 (without readmission) and around 33% NHS patients will be readmitted during follow-up. Thus, for our main secondary outcome, this sample size (240 patients) will allow us to detect a difference in readmission of 22.3% between NHS and independent sector units with 90% power and 5% significance level assuming the same VIF and DE as above, or 19.7% with 80% power (based on a Z-test comparing two proportions).

11.2.2 COMPONENT 2

In C2 we aim to recruit from 10 services between 25 and 50 patients, and 20 relatives/carers for one-to-one interviews, and between 60 and 100 staff for either focus groups or one-to-one interviews. We also aim to recruit around 10 community based staff and 10 commissioners/ senior managers involved in inpatient rehabilitation services for one-to-one interviews.

11.3 STATISTICAL AND HEALTH ECONOMIC ANALYSIS PLAN

11.3.1 COMPONENTS 1 AND 3

We will conduct two statistical analyses using the information collected from C1 and C3 (as well as the health economic analysis, which is detailed in 11.3.3 below):

i) Multivariable regression

We will conduct linear regression using total inpatient days (since recruitment to C1) as our primary outcome and logistic regression using proportion of patients readmitted as our main secondary outcome, allowing for clustering within inpatient rehabilitation units. Service sector (independent or NHS) will be included in the model as the main explanatory variable. We shall adjust for relevant sociodemographic and clinical confounding variables, including inpatient days up to recruitment, (gathered in C1) which may account for differences in outcomes between the two service types. We will use Directed Acyclic Graphs (DAGs) to ensure a logical and consistent approach to identifying potential confounders (33). Suitable transformations will be used if assumptions of normality for linear regression are not satisfied. In addition, we will conduct exploratory analysis to investigate the relationship between the length of the inpatient rehabilitation admission (i.e. 'dose' of rehabilitation

assessed in inpatient days), readmission and the service sector (NHS/independent), through a mediation analysis. Bias due to missing data in the explanatory variables (gathered in C1) will be investigated and we will use multiple imputation based on chained equations to impute missing values for these variables as appropriate.

ii) Multivariable regression with propensity score

In this two-stage approach, an initial regression generates a propensity score, the probability of 'exposure' (admission to an independent sector unit) conditional on sociodemographic and clinical covariables identified in C1. The propensity score is then included in a second appropriate regression, accounting for clustering, in which the main outcome variable is successful rehabilitation at 18 months (defined as before). This approach allows us to account for the principal confounders influencing why (e.g. the patient's health state) a person is admitted to an independent sector unit rather than an NHS unit (i.e. confounding by indication). A major issue when estimating propensity scores is the presence of missing values in the explanatory variables. Multiple imputation will be used to handle missing data under missing at random (MAR) assumption, and the two stage analysis will be performed in each imputed dataset. The results are then combined using Rubin's rule to obtain an overall estimate of the effect of service sector on successful rehabilitation. We will also conduct sensitivity analyses following the methods recommended by Blake et al (34) if the MAR assumption is not considered plausible.

11.3.2 COMPONENT 5: HEALTH ECONOMIC ANALYSES

Using data collected in C1 and C3, cost-utility analyses will be performed, aiming to calculate the incremental cost per quality-adjusted life-year (QALY) gained using utility scores calculated from the EQ-5D-5L (a 5-item generic health-related quality-of-life questionnaire plus visual analogue scale) over the 18-month period, of using independent sector versus NHS for rehabilitation. The ReQOL (the 10-item Recovering Quality of Life questionnaire designed for users of mental health services) will be used to perform a secondary cost-utility analysis. These two quality-of-life questionnaires will be completed with patient participants at recruitment (C1) and through telephone or videoconferencing at 6, 12 and 18 months follow-up (C3).

The primary analysis perspective will be that of the NHS plus Personal Social Services, so rehabilitation costs for users of NHS services will be captured as number of inpatient days, monetised using unit costs that we will calculate from a bed-day micro-costing across the two arms. Secondary analyses will use (i) published NHS unit costs also for the inpatient rehabilitation costs in both arms, and (ii) the cost charged to the relevant CCG costs for users of independent sector rehabilitation services. Other health and social care resource use provided after discharge will be costed according to NHS Reference Costs and Personal Social Service Research Unit (PSSRU) unit costs (35) for all analyses. QALYs will be calculated from utility scores using standard area-under-the-curve methods and adjusted for baseline values.

The bed-day micro-costing will use certain items from the QuIRC (avoiding duplication of questions), supplemented by other information from the key staff contact or team in order to provide a mean unit cost per patient for the two settings, including: staffing levels and salaries (mean cost per hour, also consider holiday pay, sick leave, etc.); staff to patient ratios; number of patients per ward; number of patients on ward with similar diagnosis; estates costs and other overheads (including ward floor square

metres); medication costs; 'hotel' facilities (food, laundry etc.); travel or other similar costs (e.g. to visit local area, to access community resources). The questions will be developed with the independent providers and staff at NHS sites to ensure they are appropriate and will yield meaningful information.

Bootstrapping will be used to calculate means and 95% confidence intervals for costs and QALYs to show the probability that rehabilitation in the independent sector is cost-effective compared to in the NHS for a range of cost-effectiveness threshold values. We will report a cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC) using the bootstrapped results.

We will conduct secondary cost-efficiency analyses (36) using the patient-level bed-day data collected in C1 and C3, and C4 pending the necessary approvals for C4 (see Section 7.7), calculating the cost per patient and marginal cost per patient incurred over the study time period, according to their assigned inpatient rehabilitation group (NHS or independent sector). These analyses will use the same unit costs and cost perspective as for the cost-per-QALY analysis (see above), although the NHS cost perspective will be narrower as the C4 cohort will not have direct information on resources used beyond those reported in the Mental Health Services Data Set (MHSDS).

Adjustment covariates will include relevant sociodemographic and clinical confounding variables captured in C1 (for the main cost-utility analyses) or provided with the MHSDS (for the cost-efficiency bed-day analyses). Predictors of any missingness will be assessed and also included as adjustment covariates, and sensitivity analysis will assess the impact of uncertainty in assumptions and input parameters.

12 RECORD KEEPING AND ARCHIVING

At the end of the study, all essential documentation will be archived securely for a minimum of 10 years from the declaration of end of study, which will be declared once the final research data is collected.

Essential documents are those which enable both the conduct of the study and the quality of the data produced to be evaluated and show whether the research team complied with the principles of Good Clinical Practice and all applicable regulatory requirements.

All archived documents will continue to be available for inspection by appropriate authorities upon request.

13 OVERSIGHT COMMITTEES

13.1 PROJECT MANAGEMENT GROUP (PMG)

The PMG will include the Chief Investigator and Co-Applicants. The PMG will be responsible for overseeing the successful progress and completion of the study. The group will meet once every two months and will send updates to the local collaborators after each meeting.

The PMG will review and agree any substantial amendments to the protocol prior to submission to the REC and/or MHRA. They will also agree any necessary substantial amendments during the course of the study and submit these to the REC for approval. All local collaborators will be kept informed of any substantial amendments through their nominated responsible individuals.

13.2 PROJECT OVERSIGHT COMMITTEE

The independent Project Oversight Committee will be chaired by Professor Tom Craig of King's College London and will include Professor Stephen Bremner (statistician at Brighton and Sussex Medical School), Aodan Mulholland (PPI representative at Praxis Care in Northern Ireland), and the Chief Investigator.

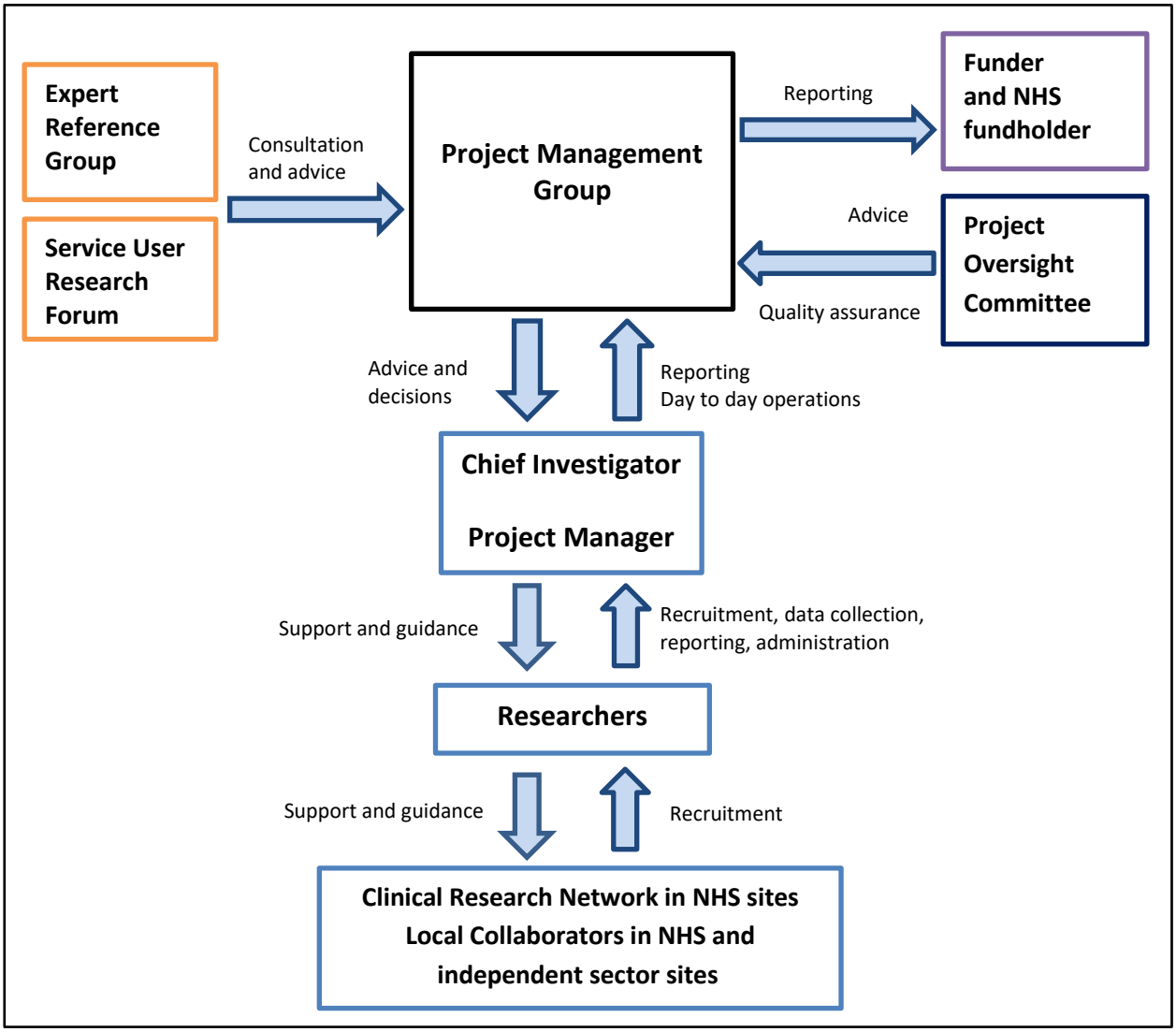
13.3 THE NORTH LONDON SERVICE USER RESEARCH FORUM (SURF)

SURF will be consulted throughout the study at four separate points on aspects of the project including any necessary substantial amendments to the study design, interpretation of findings and dissemination.

13.4 EXPERT REFERENCE GROUP

An expert reference group comprising national leaders in mental health rehabilitation service provision has been convened to provide advice to the PMG through the course of the study. Members include Dr Sri Kalidindi, Clinical Lead, NHS England's 'Getting it Right First Time' programme for mental health rehabilitation, and Dr Raj Mohan, immediate past Chair, Faculty of Rehabilitation and Social Psychiatry, Royal College of Psychiatrists. This group will meet on four occasions during the study.

13.5 ACER PROJECT MANAGEMENT ORGANISATION CHART



14 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The Chief Investigator will permit study-related monitoring, audits, research ethics committee (REC) review, and regulatory inspection(s), providing direct access to source data/documents. Study participants are informed of this during the informed consent discussion. Participants will consent to provide access to data collected related to them for the purposes of the study.

15 ETHICS AND REGULATORY REQUIREMENTS

C&I will ensure that the study protocol, participant information sheets, consent forms, consultee declaration forms and submitted supporting documents have been approved by the Health Research Authority (HRA) and an appropriate research ethics committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

Before any site can enrol participants into the trial, the Chief Investigator/ Principal Investigator or designee will apply for local confirmation of capacity and capability. It is the responsibility of the Chief Investigator/ Principal Investigator or designee at each site to ensure that all subsequent amendments gain the necessary approvals. This does not affect the individual clinician's responsibility to take immediate action if thought necessary to protect the health and interest of individual patients (see section for reporting urgent safety measures).

Within 90 days after the end of the study, the CI/Priment will ensure that the main REC are notified that the study has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The chief investigator will prepare the APR.

The CI will supply the Sponsor with a report of the clinical trial and a copy of the report will be submitted to the main REC, within 1 year after the end of the trial.

16 MONITORING REQUIREMENT FOR THE STUDY

The sponsor will determine the appropriate level and nature of monitoring required for the trial. Risk will be assessed on an ongoing basis and adjustments made accordingly.

The degree of monitoring will be proportionate to the objective, purpose, phase, design, size, complexity, blinding, endpoints and risks associated with the study.

A study specific oversight and monitoring plan will be established for studies. The study will be monitored in accordance with the agreed plan.

17 FINANCE

This research is funded by the National Institute for Health Research (NIHR), Health Service and Delivery Research programme (Award ID: NIHR130693). The fundholder is Camden and Islington NHS Foundation Trust. The CI and Project Manager will submit a financial report to the fundholder as requested.

18 INSURANCE

The NHS indemnity scheme will cover the potential legal liability of the sponsor arising from the design, conduct and management of the study.

19 DISSEMINATION AND PUBLICATION POLICY

We will use traditional and contemporary methods to raise awareness of our study and disseminate results to participants and relevant audiences (user and carer organisations, policy makers, service commissioners, provider organisations, mental health clinicians).

Our planned dissemination activities and outputs include: adding the study to the ISRCTN register, a study website (ucl.ac.uk/psychiatry/acer); a regular newsletter which will be published on the study website and send to participating services, and in the final issue will include a lay summary of the study findings; social media activities; journal publications; two webinars with participants to report key findings (Components 1 and 2, and 3-5); conference presentations; dissemination events in conjunction with key stakeholder groups.

In the first six months of the project, we will set up a stimulating and accessible study website, hosted by UCL, to promote interest in our project, and in addition to regular newsletters, will provide information about the project aims and progress. The website will also serve as the main contact point for external users and will contain a 'contact us' portal for interested stakeholders to pose questions to the research team. The website will also include links to our associated online dissemination activities, publications, and conference presentations.

We will disseminate our findings through peer reviewed scientific journal publications, two webinars for participating services (at completion of Components 1 and 2, and at the end of the study), and conference presentations. We will include anonymised quotes from patients and family/carers in our dissemination materials (publications, presentations, blogs etc) which are powerful aids to communicating the 'real life' impact of our results. Costs for open access publications and conference expenses have been included in the study budget. These activities will have a limited audience and thus we will broaden our reach through additional approaches. We will use social media, including the Twitter accounts of the study team and UCL Division of Psychiatry which, between them, have over 30,000 followers, to publicise the study, provide updates and links to publications. We will also invite the 'Mental Elf', a specialist social media enterprise, to profile our work and publications through targeted online activities such as Tweets and blogs, to inform and enthuse our stakeholder groups about the project and discuss the implications of our findings and recommendations for policy and practice. The Mental Elf has over 84,000 Twitter followers with an interest in mental health service research. Their support will assist us in building a following for the programme at an early stage and will work in tandem with conference presentations and other stakeholder events to extend participation to a wider audience. We will also disseminate information about the project and its findings to the McPin Foundation, a specialist mental health service user organisation that networks with other organisations that promote service user involvement in research across the UK.

20 NIHR CLAUSE

This study/project is funded by the National Institute for Health Research (NIHR) Health and Social Care Delivery Research programme (NIHR130693). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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