Protocol

Full title:	The HOME Study: A study comparing two different ways of looking after older people in hospitals to see if we can improve how quickly they go home
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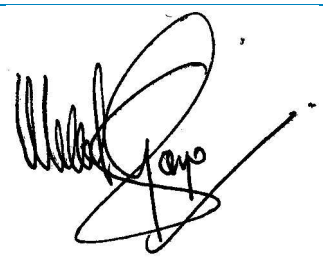
Chief Investigator Signature:	

Protocol version control			
Version Number	**Author**	**Effective Date**	**Reason for Change**
2.0	Jane Walker	15/10/2017	Investigators updated, Glasgow site and relevant procedures removed
3.0	Jane Walker	30/11/2017	Statistical analysis section updated with new text from Prof Chris Frost
4.0	Jane Walker	05/03/2018	ISRCTN added Synopsis updated with revised sample size Process data section updated following TSC/DMC meeting PLP/PPM description updated
5.0	Jane Walker	20/03/2018	Process data section updated
6.0	Jane Walker	09/09/2018	Data collection windows updated Investigator institution updated Qualitative analysis section updated Typos corrected
7.0	Jane Walker	01/10/2019	Investigator institution updated Statistical analysis section updated
8.0	Jane Walker	13/03/2020	Option of verbal (telephone) consent added for carer interviews

Contents

1 General information

1.1 Protocol use

This document describes The HOME Study and the procedures relevant to patients recruited to this study. The protocol should not be used to guide the treatment of other patients.

1.2 Compliance

The study will be undertaken in accordance with the study protocol, Good Clinical Practice (GCP) guidelines, the Data Protection Act (1998), the Research Governance Framework and the Mental Capacity Act 2005. Standard Operating Procedures will be implemented at all times.

1.3 Sponsor

The study sponsor is the University of Oxford.

1.4 Funder

This study is funded by the National Institute for Health Research Health Services and Delivery Research (HS&DR) Programme.

1.5 Conflicts of interest

The research team have no potential conflicts of interest.

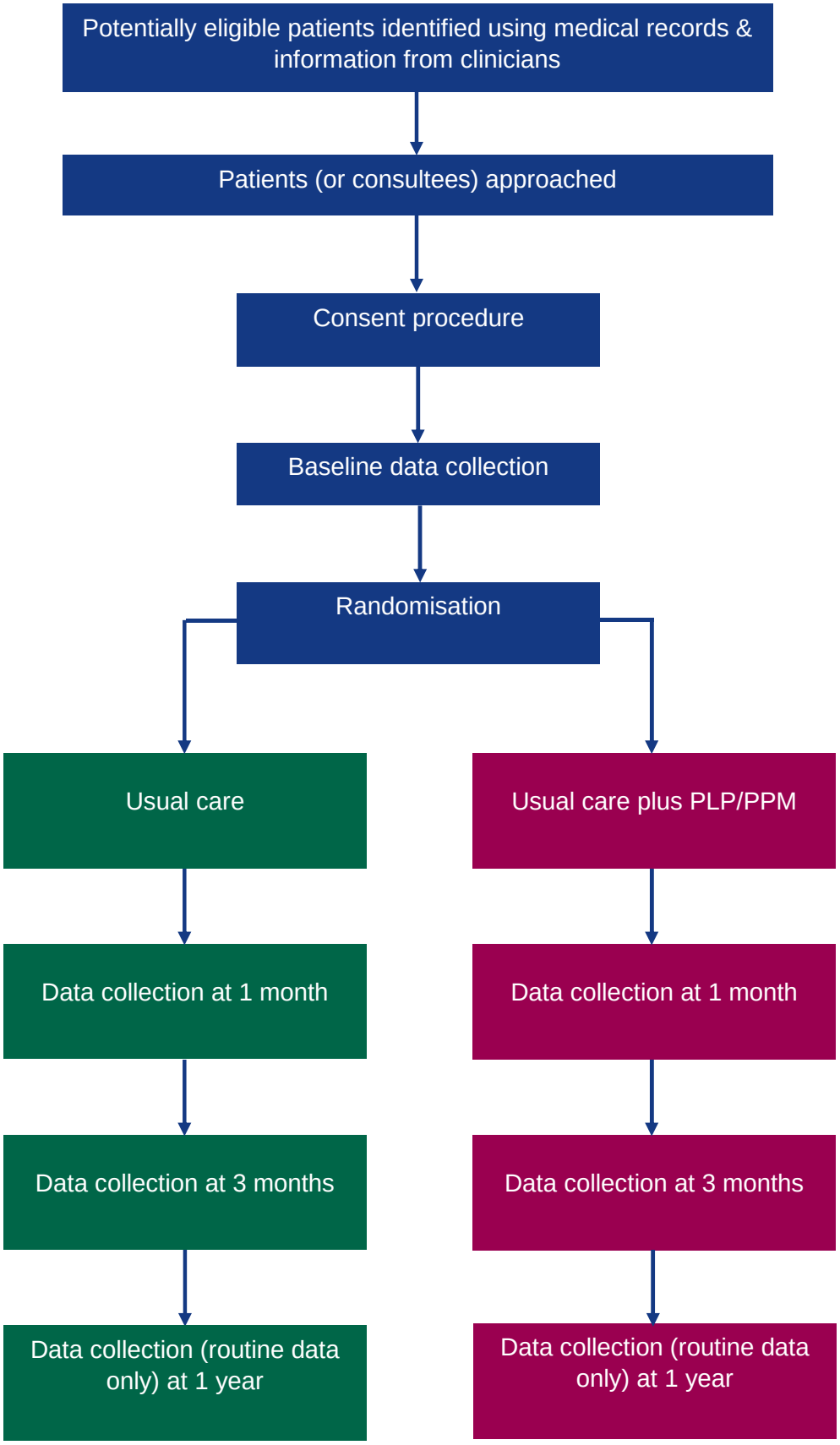
2 Abbreviations

CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
EQ-5D-5L	EuroQol 5D Questionnaire
GCP	Good Clinical Practice
GP	General Practitioner
MOCA-T	Montreal Cognitive Assessment - Telephone Version
NHS	National Health Service
NIHR	National Institute for Health Research Health Services
PHQ-4	Patient Health Questionnaire - 4 items
PI	Principal Investigator
PLP	Proactive Liaison Psychiatry
PPM	Proactive Psychological Medicine
SAE	Serious Adverse Event
TMG	Trial Management Group
TSC	Trial Steering Committee
UC	Usual care

3 Synopsis

Title	The HOME Study	
Clinical Phase	Effectiveness trial (Phase 3 equivalent)	
Design	Two arm parallel group randomised controlled trial	
Participants	Patients aged 65 or older who have been admitted non-electively to the acute wards of UK NHS hospitals.	
Planned Sample Size	2,680 to 3,588	
Experimental intervention	Usual Care (UC) plus Proactive Liaison Psychiatry / Proactive Psychological Medicine (PLP/PPM)	
Comparator	Usual Care (UC)	
Follow up duration	1 year	
	Objectives	Outcome Measures
Primary	To determine whether adding PLP/PPM to UC reduces time in hospital for older acute hospital inpatients.	Days in hospital in the 30 days post-randomisation
Secondary	To determine whether adding PLP/PPM affects the following variables compared with UC alone: Cognitive function, independent functioning, health-related quality of life symptoms of anxiety and depression, overall quality of life, experience of hospital stay, view of length of hospital stay, time spent in hospital, discharge destination, deaths	MOCA-T, Barthel Index of Activities of Daily Living, EQ-5D-5L, PHQ-4, study-specific items (for quality of life, experience of hospital stay, view of length of stay), medical records & routinely collected clinical data

4 Flow of patients through the study



5 Background

5.1 Problem to be addressed

The problem of prolonged acute hospital stays for older people

Acute NHS hospitals have more than two million unplanned admissions of people aged 65 and older every year. The greater length of stay of older patients (average of 9 days for those aged 65 and over compared with 3 days for those under 65) means that these admissions account for most (70%) of the available emergency bed days [1].

Ten years ago the UK Department of Health set out a policy to shift care from hospitals to community settings [2]. But despite this, the last decade has seen a 37% increase in emergency admissions, the majority of those being of people aged over 65, a trend likely to continue as the population ages [3]. Length of stay in hospital fell over the last 20 years but has now plateaued and international comparisons suggest potential for further improvement [4].

Excessive time in hospital is bad for patients: it leads to hospital acquired illnesses, demoralisation and loss of independence after discharge [5]. It is also bad for the NHS as it reduces the availability of beds for other people and increases costs. Indeed the pressure on hospital bed capacity is one of the key challenges currently facing the NHS [6]. Strategies to reduce length of stay as well as to reduce admissions are considered to be essential to address this problem [4].

We therefore urgently need evidence on how best to reduce prolonged stay in hospital by older people. A recent review found that, whilst many of the initiatives which aimed to achieve this showed promise, none were of proven effectiveness and that scientifically robust evaluations of carefully targeted interventions were needed [7].

The importance of medical-psychiatric multimorbidity in prolonging hospital stay

A key target for intervention is the psychiatric morbidity that complicates the medical condition of the majority of older acute hospital inpatients. It includes psychiatric illnesses such as delirium, dementia, and depression as well as psychological issues such as minor cognitive impairment or anxiety that may slow patients' discharge from hospital [8, 9]. Failure to effectively manage this medical-psychiatric multimorbidity is a well-documented cause of prolonged hospital stay [3].

The need for better management of medical-psychiatric multimorbidity

The management of medical-psychiatric multimorbidity is currently inadequate. It relies on overburdened acute hospital medical and nursing teams who typically have limited expertise in this aspect of care [3]. Whilst they may seek help for conspicuous problems from a liaison psychiatry or psychological medicine service (this is usually an in-reach psychiatric service provided by a mental health trust), nationally fewer than 5% of patients are referred to such services [10]. Furthermore there is little robust evidence that such services are effective in reducing the duration of patients' hospital admissions [11]. A better approach to both the detection and management of medical-psychiatric multimorbidity is therefore required if we are to reduce its impact on length of stay.

5.2 Population to be studied

The population to be studied is patients aged 65 or older who have been admitted non-electively to the acute wards of UK NHS general hospitals.

5.3 New intervention (Proactive Liaison Psychiatry / Proactive Psychological Medicine, PLP/PPM)

Overview of PLP/PPM

We will test a new approach to identifying and managing psychological problems (sometimes called Proactive Liaison Psychiatry or Proactive Psychological Medicine, PLP/PPM). PLP/PPM has 4 main components:

a) Early proactive assessment of all patients to identify psychological problems including psychiatric illness.
b) Creation of a management plan to address these and overcome barriers to prompt discharge.
c) Proactive progress reviews and communication with relevant health and social care professionals to deliver the plan.
d) Integrated working with ward teams to ensure that the management plan is communicated to other providers at discharge.

Rationale for studying PLP/PPM

a) A report from the Nuffield Trust published in September 2015 suggested that factors important in reducing length of stay include early identification of needs, a proactive approach to care led by a senior decision maker, care targeted at need and close working between services [4].
b) Lessons from previous evaluations of liaison psychiatry include the need for better identification of psychiatric problems, robust interventions provided early in the hospital admission, a focus of intervention on timely discharge, and engagement with out of hospital care providers [11].
c) PLP/PPM is an innovative, more patient-centred, way of delivering liaison psychiatry / psychological medicine which includes the elements described above, and has been developed by our collaborators in the USA.
d) Studies of PLP/PPM in the USA have found it to be more effective than usual care in reducing length of stay (in adults of all ages the reduction in these studies ranged from 0.5 to 2.3 days) and to be overall cost-saving [12, 13].
e) A previous non-randomised evaluation of intensive liaison psychiatry in the UK that incorporated some elements of PLP/PPM was reported to reduce length of stay in older patients [14].
f) Our own feasibility study has found that PLP/PPM, in a form adapted for use in the UK NHS, is feasible to deliver and acceptable to patients, ward staff and liaison psychiatrists.
g) The NHS has made a commitment to parity of esteem of patients' mental and physical needs by providing integrated medical and psychiatric care [15]. To this end, the NHS has already committed to investing £30 million in liaison psychiatry services to acute

hospitals by 2020 [16]. We need to ensure that this, and future investment, is spent in the most cost-effective way.

5.4 Relevant published studies

The first study of PLP/PPM from Yale New Haven Hospital found that it was feasible to deliver and that the initial patient assessment component took less than 5 minutes. PLP/PPM achieved a one day reduction in length of stay [12]. In a subsequent larger study the same researchers compared 500 patients who had received PLP/PPM with 500 who had usual care in a before and after design [13]. PLP/PPM was welcomed by the hospital staff and reduced length of stay by 0.6 days. A study in a different hospital (Dartmouth-Hitchcock) found PLP/PPM to be feasible and acceptable to patients. In a small randomised pilot trial it reduced stay by over 2 days [Finn, personal communication].

In summary, three evaluations of PLP/PPM in the US have found it is feasible to deliver, welcomed by clinical staff and highly rated by patients. They indicate that it can reduce length of stay and may be overall cost -saving. The reduction in time in hospital achieved in these studies is consistent with the 1 day reduction used in our sample size calculation.

In considering the translation to the UK we note that inpatient care at these US hospitals does not differ greatly from that in an NHS hospital in that there are similar challenges of high numbers of elderly patients and limited out of hospital care provision.

5.5 Completed feasibility study

We have tested the feasibility and acceptability of delivering PLP/PPM in an NHS hospital (Horton General Hospital, Oxfordshire) and refined the intervention on the basis of our findings. Over a one month test period (February-March 2015) five consultant liaison psychiatrists delivered PLP/PPM to 242 patients admitted non-electively to three acute wards. They conducted early assessments (using a combination of medical and psychiatric record review, direct patient consultations and discussions with ward staff) and made plans to facilitate early discharge. We aimed to:

a) Assess the feasibility of delivering PLP/PPM to older general hospital inpatients.
b) Evaluate the acceptability of PLP/PPM to patients, medical and nursing staff and psychiatrists.
c) Identify ways to optimise the intervention for the NHS context.

We found that it was feasible to deliver PLP/PPM in the NHS setting. The PLP/PPM clinicians assessed all new admissions and identified a broad range of psychological problems that were impeding patients' discharge (by delaying their rehabilitation, treatment decisions or social care planning). These problems included anxiety, low mood, substance misuse disorders, confusion, lack of clarity about the patients' decision making capacity and patient and family anxiety about post-discharge care arrangements.

PLP/PPM was acceptable to patients, who engaged well with the team, and also to ward staff, who actively collaborated with the assessments and management plans. In open-ended interviews with the psychiatrists after the test period, they reported that PLP/PPM enabled them to intervene in the care of a broader range of patients than the traditional referral-based liaison psychiatry model, often by taking a more active role in the patient's care. They also noted differences in approach between psychiatrists. On the basis of this information we made the following changes to PLP/PPM:

a) To improve the sensitivity of the assessment it now always includes a brief initial consultation with the patient to provide information not available in medical records.
b) To ensure greater consistency in the assessment a checklist of potential psychological problems to be sought is now provided as part of the PLP/PPM manual.
c) To ensure that the post-discharge plan is being implemented and to reassure patients and family of follow-through of care, integrated working with the ward team ensures the hospital discharge summary includes any relevant information from the PLP/PPM team.

5.6 Research question

The study aims to determine whether adding PLP/PPM to usual care reduces the time spent by patients in acute hospitals in the month (30 days) after randomisation (primary outcome), when compared with usual care alone.

6 Aims and hypotheses

6.1 Aims

- To determine whether adding PLP/PPM to usual care reduces time in hospital for older acute hospital inpatients.
- To compare the cost-effectiveness of adding PLP/PPM to usual care with that of usual care alone.

6.2 Main hypothesis

Our hypothesis is that the addition of PLP/PPM will be associated with a substantial reduction in time spent in hospital (at least one day) in the month (30 days) after randomisation compared with usual care alone.

7 Study design

7.1 Type of design

A pragmatic multicentre 2-arm parallel group randomised controlled superiority trial with a linked health economic analysis and an embedded process evaluation.

7.2 Measures to minimise bias

Selection and allocation:

- Potential participants will be identified through a systematic process.
- Patients' eligibility to participate in the study will be assessed using a standardised procedure.

Outcome measurement and analysis:

- The primary outcome will be an objective measure to remove observer bias.
- Outcome data collection will be carried out by a team of researchers who are blind to group allocation.
- Data measuring participant and carer experience of the PLP/PPM intervention will be collected by researchers who are separate from the PLP/PPM treatment teams.
- Strenuous efforts will be made to minimise missing data.
- Outcome data analyses will be defined prior to closure of the study database and will be performed blind to treatment allocation on an intention-to-treat basis.

8 Participants

8.1 Hospital wards for recruitment

Participants will be recruited from the acute wards of general hospitals in NHS England.

Hospitals will be used for recruitment if they have a district general hospital function.

Hospital wards will be used for recruitment if they:

- Are either assessment units, general or appropriate specialist wards
- Admit patients non-electively

8.2 Selection criteria

To be included in the study a patient must:

- Be an inpatient in an acute ward where study recruitment is taking place (at the time of study enrolment, i.e. randomisation)
- Have been admitted non-electively (i.e. their hospital admission is unplanned)
- Be aged 65 or older
- Be expected (by their clinical team) to remain an inpatient for at least 2 days from the time of study enrolment
- Be able to give informed consent or if unable to give consent, a consultee advises that study participation is appropriate

Patients will be excluded if (at the time of enrolment):

- They are moribund (defined in this study as when the clinicians caring for a patient estimate that they are likely to die before discharge from hospital)
- Their participation in the study is judged to be clinically or practically inappropriate (e.g. the patient is not from the local area served by the hospital)
- They have already been enrolled in the study
- They have already been referred to the usual liaison psychiatry team
- They have been a general hospital inpatient continuously for 1 week
- They do not read or speak English

8.3 Identification of potential participants

Screening will be used to identify potential participants, in order to obtain a representative sample of the relevant population and to give all potentially eligible patients the opportunity to participate.

To achieve this, study researchers, with appropriate training and experience, will be embedded in the clinical teams at each study centre and will carry out an eligibility screen for all patients admitted to the participating wards during the study period. Study researchers will log all new admissions to the participating wards. They will access these patients' medical records (electronic or paper) to determine which patients should be excluded on the basis of their age (excluding those younger than 65) or admission type (excluding those admitted electively) and will check whether the patient has already been enrolled in the study

using the study database. The study researchers will also obtain the relevant information from the patient's clinicians on other potential reasons for study exclusion and any clinical reasons that the patient should not be offered study information.

8.4 Approaching potential participants

As soon as possible during their admission, patients identified as eligible through this screening process will be approached by an appropriately trained study researcher and offered both verbal and written information about the study and an opportunity to discuss their questions and concerns about the research. They will be given a full explanation of the two treatment allocations and the procedures for randomisation and outcome data collection. Patients will be given sufficient time to read the information leaflet and discuss it with their carers or others if they wish to do so. We will tailor the time that patients have to decide about participation to individuals: A study researcher will approach the patient and explain the research. If the patient is interested in taking part the study researcher will ask whether they would like them to (a) stay whilst they read the information leaflet and answer any questions there and then, or (b) return later the same day or the following day, so that the patient can read the leaflet alone and can discuss the study with their relatives and friends if they wish to do this.

8.5 Informed consent

If the patient agrees to participate the study researcher will obtain written informed consent. If the patient is able to give verbal informed consent but is physically unable to sign the consent form, the signature of a witness will be obtained.

8.6 Recruitment and consent where patients lack capacity

8.6.1 Principles

In this protocol, 'capacity' refers to a patient's ability to make the decision whether to participate in The HOME Study. Assessment of capacity conducted as part of the study procedures will refer to this specific decision only and should not be used for any other purpose.

In accordance with the principles of the Mental Capacity Act 2005:

- Patients will be assumed to have capacity to make their own decisions unless there is evidence otherwise.
- Patients will not be treated as unable to decide unless all practicable steps have been taken, without success, to help them to do so.
- Decisions whether to enrol patients in the study and whether to continue collecting data about them will take into account their past and present wishes.
- Nothing will be done to which a patient appears to specifically object unless it is to prevent him/her from harm, or reduce or prevent pain or discomfort.
- Any advance statements will be respected.
- Patients lacking capacity who are recruited to the study will be treated, as far as possible and with appropriate help where necessary, in the same way as other study participants

(for example, we will explain the study procedures to all participants using language they can understand, and will ask all participants to contribute data where they are able and willing to do so).

8.6.2 Identification of patients who lack capacity

Clinicians at each participating ward will alert the study researchers if, in their opinion, a patient does not have capacity. In addition, members of the study team will be trained to assess capacity if they are concerned, during the consent process, that a patient is unable to make an informed decision about participation. This brief assessment will focus on the patient's understanding of what participation involves, their ability to retain this information, to weigh the pros and cons of participation, and to communicate their decision. A psychiatrist with appropriate expertise will be available at each study centre to advise on capacity assessments and to formally assess patients' capacity as required.

8.6.3 Recruitment and consultation regarding participation for patients who lack capacity

Recruitment of patients who lack capacity will be in accordance with the Mental Capacity Act 2005 with specific reference to Sections 30 to 34.

A personal consultee will be identified for the patient, where possible. A personal consultee will be defined as someone who:

- Is a family member, carer or friend; an attorney under a Lasting Power of Attorney; or a court appointed deputy provided that they had a relationship with, or personal knowledge of, the person lacking capacity before their appointment as deputy.
- Can advise on the patient's likely thoughts and feelings about the research and whether they should be enrolled in the study.
- Is not caring for, or interested in the welfare of, the patient in a professional capacity or for remuneration (N.B. remuneration does not cover family members receiving some of the person's pension or other benefits as a payment towards their share of the household expenses).

Personal consultees will be identified through discussions with patients and their clinical teams.

Personal consultees will be approached (either in person or by telephone) by a suitably qualified member of the research team, who will explain the study and what it would involve for the patient. They will also be provided with a study information leaflet. The researcher will explain that, because the patient lacks capacity, it is important that we seek the advice of someone who knows them. They will make it clear that the consultee would not be providing consent on the patient's behalf, nor are they being asked their own views on the research. Rather, the researcher would like their views on what the patient's wishes and feelings about participation might be.

If the personal consultee agrees to the patient's participation in person, the researcher will obtain their signature on a consultee declaration form. If they agree by telephone the researcher will complete a consultee verbal declaration form and ask the consultee to confirm their agreement to a witness, who will sign the consultee verbal declaration form to

confirm this. A copy of the verbal declaration form will be returned to the personal consultee by post or in person according to their preference.

If a personal consultee cannot be identified (either because the patient does not have someone such as a family member who could act in this role, or because these persons exist but are not able or willing to take on the role) or cannot be contacted within 24 hours, a nominated consultee will be approached for advice. Nominated consultees, with no connection to the research, will be identified at each centre. They will attempt to seek the views of any family, friends, carers or professionals on whether the patient would wish to participate. If the nominated consultee advises that the patient should be enrolled in the study, a written record of consultation will be made. If the advice is given face-to-face the researcher will ask the nominated consultee to sign a consultee declaration form. If the advice is given by telephone, the researcher will complete a consultee verbal declaration form and ask the consultee to confirm their agreement to a witness, who will sign the consultee verbal declaration form to confirm this. A copy of the verbal declaration form will be returned to the consultee by post or in person according to their preference.

If a study researcher subsequently becomes aware that the patient has regained capacity, they will provide full information about the study and seek the patient's informed consent to continue to participate.

8.7 Changes in capacity status

8.7.1 Participants who regain capacity

If a participant did not have capacity to decide to participate at the time of their recruitment to The HOME Study, but the study team is alerted that they have subsequently regained capacity, a study researcher will discuss the study with the participant and, if they agree, obtain their consent in person to continue in the study. If the participant, having regained capacity, declines to give consent the procedures for study withdrawal will be followed.

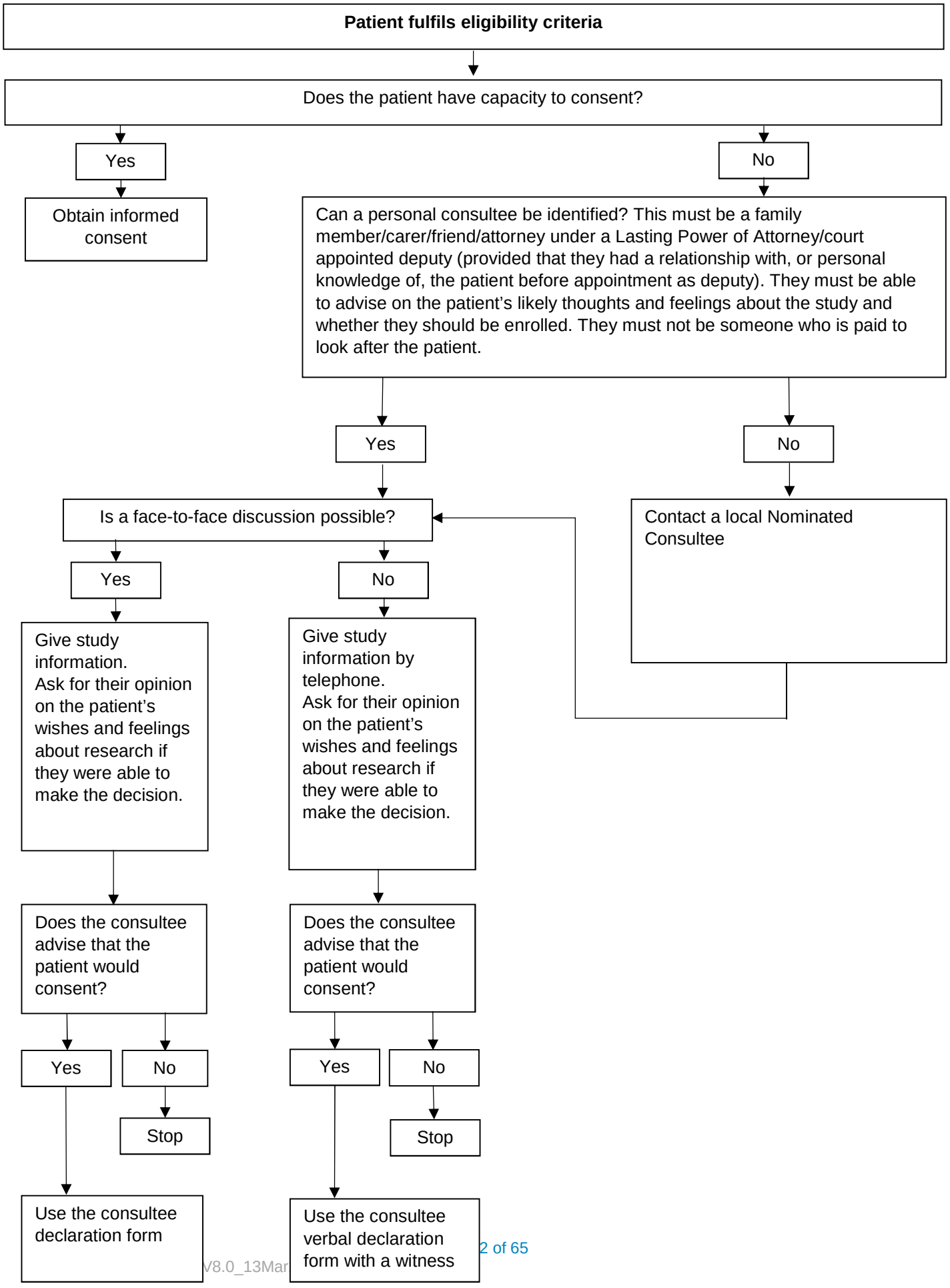
8.7.2 Participants who lose capacity

The Mental Capacity Act 2005 preserves the English common law principle that consent does not survive loss of capacity. Therefore, if it becomes clear, during the collection of outcome data, that a participant has lost capacity, a consultee will be identified to advise the study team regarding their continued participation in the telephone or in-person collection of data using questionnaires (i.e. whether they can be involved in this aspect of the study, if they are willing, with appropriate support or whether data should be collected, where possible, from their carer). Data will continue to be collected from the participant's medical records and routinely collected clinical data unless the consultee advises that the participant should be withdrawn from the study.

8.8 Non-participation

At all stages the research team will endeavour to record reasons for non-participation. However the right of patients to refuse to participate in the study without giving reasons will be respected.

8.9 Consent flowchart



9 Baseline data

9.1 Data to be collected

We will collect the following baseline data (see table below for methods of data collection):

- NHS and hospital numbers (to allow matching with routine data)
- Date of birth
- Sex
- Ethnicity
- Relationship status (whether the patient has a partner or spouse)
- Usual place of residence (private home, care home etc)
- Postcode (to calculate deprivation index & urban/rural residence)
- Whether the participant lives alone
- Employment status
- Reason for hospital admission (presenting complaint or working diagnosis)
- Diagnoses (medical and psychiatric) recorded on admission
- Medication prescribed
- Date of hospital admission
- Date of admission to specified acute ward
- Days in hospital prior to enrolment
- Cognitive function (MOCA-T) [17]
- Independent functioning (Barthel Index of Activities of Daily Living) [18]
- Health-related quality of life (EQ-5D-5L) [19]
- Depression & anxiety symptoms (PHQ-4) [20]
- Overall quality of life (study-specific item)
- Secondary healthcare use (including number of admissions to hospital) in the year prior to randomisation

9.2 Methods of baseline data collection

9.2.1 Medical records

Clinical (and where possible demographic) data will be collected from the participant's medical records (paper or electronic).

9.2.2 Participant report

Demographic data, cognitive function, independent functioning, health-related quality of life, symptoms of anxiety and depression and overall quality of life will be collected from the participant using a brief face-to-face interview. Data collection will be as soon as possible prior to randomisation.

9.2.3 Proxy report

Some participants will be unable to give reliable data, even with help. In this instance, data will be collected from proxies wherever possible. Data collection will be as soon as possible prior to randomisation.

9.2.4 Routinely collected clinical data

Demographic and clinical data and data on secondary healthcare use in the year prior to randomisation will be obtained from national datasets of routinely collected clinical data (Hospital Episode Statistics, HES) and from local hospital datasets.

9.2.5 Summary of baseline data collection

Variable	Method of data collection
NHS and Hospital numbers	Medical records
Date of birth	Medical records
Sex	Medical records
Ethnicity	Medical records / routine data
Relationship status	Medical records / patient / proxy
Residence type	Medical records / patient / proxy/ routine data
Postcode	Medical records
Living alone	Medical records / patient / proxy
Employment status	Patient / proxy
Reason for hospital admission	Medical records
Diagnoses	Medical records / routine data
Medication prescribed	Medical records
Date of hospital admission	Medical records
Date of admission to specified acute ward	Medical records
Days in hospital pre-enrolment	Medical records
Cognitive function (MOCA-T)	Patient
Independent functioning (Barthel)	Patient / proxy
Health-related quality of life (EQ-5D-5L)	Patient / proxy
Depression & anxiety symptoms (PHQ-4)	Patient / proxy
Overall quality of life (study-specific item)	Patient / proxy
Secondary healthcare use in the year prior to randomisation	Routine data

10 Randomisation

10.1 Randomisation algorithm

A database software algorithm was designed by the study statistician. The algorithm allocates participants to usual care plus PLP/PPM or usual care alone in a 1:1 ratio with stratification by putative prognostic variables: hospital, sex and age (65-74, 75-84, ≥85). The algorithm is based on Stata's "ralloc" command, and utilises random permuted blocks of variable size. The required random seed was selected by the Oxford Clinical Trials Unit, which will implement the randomisation system.

10.2 Randomisation procedure

The participant's details will be entered into a database via a secure website. Their treatment allocation will be automatically generated once the participant's baseline data have been entered. A study researcher will inform the patient of their allocation.

11 Blinding

Study statisticians and staff who collect outcome data will be blinded to participants' allocated interventions.

HOME Study researchers who recruit participants will carry out the randomisation procedure described above, will inform participants of their treatment allocation, and will inform the PLP/PPM teams about participants who have been allocated to usual care plus PLP/PPM. These researchers will therefore not be blinded to allocation. Nor will it be possible to blind participants and their clinicians because of the nature of the study interventions.

12 Study interventions

12.1 Experimental intervention (Proactive Liaison Psychiatry / Proactive Psychological Medicine)

The PLP/PPM intervention will be given in addition to usual care. Each PLP/PPM team will be led by a consultant in liaison psychiatry/psychological medicine. Other team members will be junior doctors, nurses or allied health professionals with experience of working in liaison psychiatry/psychological medicine.

PLP/PPM comprises:

a) An early assessment to identify psychological problems

Patients will be assessed by a PLP/PPM team member as soon as practicable after randomisation. This will take approximately 30-40 minutes and will focus on identifying psychological problems (e.g. psychiatric disorder, confusion, alcohol and substance misuse, psychological distress, unclear decision-making capacity, fragile care arrangements, family or ward team concerns). The assessment will be carried out by or supervised by the consultant. The assessment may comprise any combination of the following elements: further face-to-face patient assessment focussed on the identified problems; review of medical records; review of psychiatric records; eliciting observations of medical and nursing staff; collateral history from the patient's GP or carer.

b) A specific plan to address these problems in order to facilitate discharge

The PLP/PPM team will develop a clear written plan using a PLP/PPM checklist, in collaboration with the patient (where able), carers, relevant ward staff, GP and other out of hospital care providers as appropriate. This will form part of the patient's overall management and discharge plans. The plan will focus on the active management of factors that might impede discharge. It will include both in-hospital care and the coordination of appropriate post-discharge care. The plan can comprise any combination of the following elements: optimising psychotropic medication; delivering or coordinating delivery of psychological treatment; facilitating communication between patient, family and health and social care providers; ensuring early and accurate resolution of decisions on the patient's capacity to make decisions about their care; and coordination of psychological care plans with out of hospital care providers.

c) Proactive progress reviews and communication with care partners

Progress toward discharge will be reviewed daily by the PLP/PPM team and the plan amended as needed to ensure discharge targets are met. The team will communicate with the patient's out of hospital care providers (by telephone, email or electronic record) prior to or at the time of discharge where appropriate.

d) Follow-up post-discharge

If the patient is readmitted to hospital within one month of the initial assessment, the PLP/PPM team will review their plan with them and relevant health and social care providers, adjusting this as needed to ensure prompt discharge.

PLP/PPM teams will be trained during a two day workshop. Teams will be trained to deliver PLP/PPM according to a manual to ensure standardisation of delivery, and will participate in regular telephone supervision to troubleshoot difficulties.

12.2 Comparator (usual care alone)

Participants allocated to usual care will receive usual medical care, including the option for the patient's medical team to request a consultation from the hospital's usual liaison psychiatry team.

13 Outcome data

13.1 Primary outcome

The primary outcome is the number of days spent as an inpatient in a general hospital in the month (30 days) post-randomisation.

13.2 Secondary outcomes

Secondary outcomes are:

- Cognitive function (MOCA-T) [17]
- Independent functioning (Barthel Index of Activities of Daily Living) [18]
- Health-related quality of life (EQ-5D-5L) [19]
- Symptoms of anxiety and depression (PHQ-4) [20]
- Overall quality of life (study-specific item)
- Patient's experience of hospital stay (study-specific item)
- Patient's view on the length of their hospital stay (study-specific item)
- Discharge destination
- Secondary healthcare use in the year post-randomisation (including total length of index admission, number of readmissions, number of days in hospital)
- Death in the year post-randomisation

13.3 Measures of cost and health-related quality of life

The following economic outcome measures will be assessed:

- Cost of secondary healthcare use.
- Cost of PLP/PPM
- Health related quality of life (measured by EQ-5D-5L) [19].

13.4 Methods of outcome data collection

13.4.1 Routinely collected clinical data

Data describing the participant's hospital stay, their discharge destination, subsequent hospital admissions, secondary healthcare use and mortality data will be obtained from national datasets of routinely collected clinical data (HES) and from local hospital records and datasets.

13.4.2 Participant report at 1 month and 3 months post-enrolment

At 1 month (30 days) and 3 months (90 days) post-randomisation, a member of the research team will contact the participant (or an appropriate proxy – see below) to administer questionnaires regarding cognitive function, independent functioning, health-related quality of life, symptoms of anxiety and depression, overall quality of life, experience of hospital stay

and views on length of stay. The questionnaires will be delivered by telephone or face-to-face (at the participant's home, the hospital or other location chosen by the participant) and will take approximately 15 minutes. The time windows for data collection are as follows: 1 month data will be collected between day 30 and day 75 post-randomisation (inclusive of these dates) and 3 month data will be collected between day 90 and day 135 post-randomisation (inclusive of these dates).

13.4.3 Proxy report at 1 month and 3 months post-enrolment

Some participants will be unable to give reliable data even with help. In this instance, data will be collected from proxies wherever possible (see table below).

13.4.4 Summary of outcome data collection

Variable	1 month (30 days)	3 months (90 days)	1 year	Method of data collection
Number of days in hospital in the month (30 days) post-randomisation	■			Routine data / medical records
Cognitive function (MOCA-T)	■	■		Patient
Independent functioning (Barthel)	■	■		Patient / proxy
Health related quality of life (EQ-5D-5L)	■	■		Patient / proxy
Depression & anxiety symptoms (PHQ-4)	■	■		Patient / proxy
Overall quality of life (study-specific item)	■	■		Patient / proxy
Experience of hospital stay (study-specific item)	■			Patient / proxy
View on length of hospital stay (study-specific item)	■			Patient / proxy
Discharge destination	■	■	■	Routine data / medical records
Secondary healthcare use in the year post-randomisation			■	Routine data / medical records
Death	■	■	■	Routine data / medical records

13.5 Missing data

Active measures will be taken to minimise missing data. These will include:

- The use of routinely collected clinical data to provide the primary outcome.
- Obtaining full contact details from participants.
- Obtaining a back-up ‘best contact’ address (i.e. contact details of a friend/relative nominated by the participant).
- Recording participants’ discharge destination from hospital.
- Collection of data from proxies where participants are unable to give reliable data.
- Reminder telephone calls and letters.
- Checks with the patient’s GP to determine if they are alive and/or have moved address.

14 Process data

14.1 Data to be collected

We will collect the following process data:

Relevant care received by participants during their hospital stay

- PLP/PPM intervention components received
- Other contacts with mental health professionals
- Medications prescribed at discharge
- New Mental Health Act detentions
- Incidents during hospital stay (e.g. falls)

Experiences of PLP/PPM

- Patient experiences of receiving PLP/PPM, particularly what they found helpful and what they would change.
- Carer experiences of receiving PLP/PPM, particularly what they found helpful and what they would change.
- PLP teams' experience of delivering PLP/PPM including their views of the barriers and facilitators to their new way of working.
- Healthcare professionals' experience of PLP/PPM including implications for the way that they provide care for admitted patients and changes that PLP/PPM leads to in their working practices.

Experiences of relevant aspects of usual care

- Patient experiences of receiving liaison psychiatry as part of usual care.
- Carer experiences of receiving liaison psychiatry as part of usual care.
- Healthcare professionals' experience of delivering usual liaison psychiatry.
- Healthcare professionals' experience of referring to usual liaison psychiatry.

Description of the context in which PLP/PPM is delivered during the study

- Description of the acute medical wards and hospitals where recruitment takes place, including the nature of the usual liaison psychiatry services.
- Relevant changes in the wards, hospitals and NHS during the study, including relevant structural changes and local and national initiatives.

14.2 Methods of process data collection

14.2.1 PLP/PPM documentation

The PLP/PPM teams will record the duration and content of all consultations, telephone calls and related administrative time.

14.2.2 Medical records

Data on contacts with non-PLP mental health professionals and medications prescribed at discharge will be obtained from the participant's medical records.

14.2.3 Mental health act detention records

Any new mental health act detentions will be obtained from the hospital detention records.

14.2.4 Incident reports

Incidents during the participant's hospital stay (e.g. falls) will be obtained from the hospital incident reporting system.

14.2.5 Documentation of context

The study team will record a description of the acute medical wards and hospitals where recruitment takes place and any relevant activities and events related to the delivery of care at each centre. Data will also include summaries of correspondence from PLP/PPM teams, relevant meetings, local and national initiatives and structural changes.

14.2.6 Interviews with participants

We will interview 40-80 participants to find out about their experiences of PLP/PPM and of relevant aspects of usual care. At the time of recruitment, the researcher will explain this part of the study, that we will only ask a sub-sample of study participants to take part in an interview and that the patient can take part in the study but decline to take part in an interview. The study information leaflet for patients will also include this information. Informed consent will be obtained from patients at the time of study enrolment for participation in an interview.

We will ask participants to take part in an interview if they:

- Have received PLP/PPM.
- Have been allocated to usual care and have been referred to the usual liaison psychiatry team.

We will not ask participants to take part in an interview if they have substantial cognitive impairment or do not understand and speak English sufficiently to participate in a qualitative interview.

Interviews will be conducted by a trained member of the study team and will take approximately 30 minutes. Interviews will take place at the hospital, participant's home, other location or by telephone depending on participant preference. Interview topic guides will focus on participants' experiences and views of their care during their hospital stay, in particular psychiatric care received and the duration of their hospital stay.

14.2.7 Interviews with carers

We will interview 40-80 carers to find out about their experiences of PLP/PPM, relevant aspects of usual care and, where appropriate their experience of being a personal consultee for this study. At the time of recruitment, the researcher who obtains informed consent from the participant (or seeks advice from a personal consultee) will explain this part of the study and determine whether the participant has a carer who might be able and willing to be interviewed.

We will identify carers to approach regarding an interview using the relevant participant's study data. We will ask carers to take part in an interview if:

- The relevant participant has received PLP/PPM.
- The relevant participant has been allocated to usual care and has been referred to the usual liaison psychiatry team.
- They have acted as a personal consultee in this study.

Carers will be approached (in person, by telephone, by email or by post) by a suitably qualified member of the research team, who will explain this part of the study and what it would involve. They will also be provided with a study information leaflet. If the carer agrees to participate in an interview in person, the researcher will obtain written informed consent. If they prefer a telephone interview, informed consent will be obtained either by giving them a consent form (by email, post or in person depending on their contact with research team members) and asking them to return this to the study team or by asking them to confirm their consent to a witness. The carer will be provided with a copy of the consent form

(countersigned by the researcher who conducts the interview) or the verbal consent form (signed by the researcher who conducts the interview and countersigned by the witness).

Interviews will take approximately 30 minutes. They will take place at the hospital, carer's home, other location or by telephone depending on carer preference. Interview topic guides will focus on carers' experiences and views of the participant's care during their hospital stay, in particular psychiatric care received and the duration of their hospital stay, and if appropriate their experience of acting as a personal consultee for this study.

14.2.8 Interviews with healthcare professionals delivering PLP/PPM and usual liaison psychiatry

We will seek to interview all (anticipated 10 to 20) healthcare professionals who deliver PLP/PPM and usual liaison psychiatry to The HOME Study participants. Interviews will be conducted by a trained member of the study team, who will obtain informed consent, and will take approximately 30 minutes. Interviews will take place at the hospital, other location or by telephone depending on preference. If the healthcare professional prefers a telephone interview, informed consent will be obtained by giving them a consent form (by email, post or in person depending on their contact with research team members) and asking them to return this to the study team. A copy of the consent form (countersigned by the researcher who conducts the interview) will be returned to the healthcare professional. Interview topic guides will focus on healthcare professionals' experiences and views about delivering PLP/PPM, including barriers and facilitators to its implementation.

14.2.9 Interviews with other healthcare professionals

We will interview 30-60 healthcare professionals who are substantially involved in the care of participants in The HOME Study. We will identify potential interviewees using the documentation of context data and will approach them by email, in person or by post. Interviews will be conducted by a trained member of the study team, who will obtain informed consent, and will take approximately 30 minutes. Interviews will take place at the hospital, clinic, other location or by telephone depending on interviewee preference. If the healthcare professional prefers a telephone interview, informed consent will be obtained by giving them a consent form (by email, post or in person depending on their contact with research team members) and asking them to return this to the study team. A copy of the consent form (countersigned by the researcher who conducts the interview) will be returned to the healthcare professional. Interview topic guides will focus on healthcare professionals' experiences and views about PLP/PPM and usual liaison psychiatry, including barriers and facilitators to PLP/PPM implementation, perceived differences from usual care (including usual liaison psychiatry), and implications for the care they deliver.

15 Withdrawal of participants

15.1 Withdrawal from questionnaire data collection only

If a participant wishes to withdraw their consent to providing questionnaire data their decision will be respected. Data will continue to be collected from healthcare records and relevant databases unless the participant specifies that they also wish to withdraw from this aspect of the study (see below). All data collected up to that point will be retained unless the participant wishes these data to be destroyed. If the participant subsequently changes their mind, questionnaire data collection will be re-instated.

15.2 Withdrawal from all study data collection

If a participant wishes to withdraw their consent to all study data collection (that is, both questionnaire data and data collection from healthcare records and relevant databases) their decision will be respected. All data collected up to that point will be retained unless the participant wishes these data to be destroyed.

15.3 Refusal of interventions

This is a pragmatic study comparing two approaches to the identification and management of psychological problems in older general hospital inpatients. Patients (or their representatives on their behalf) may decide, during their participation in the study, to refuse relevant interventions. For example, a patient (randomised to either study intervention) may refuse medications prescribed for their anxiety, or a follow-up consultation with a psychiatrist. These refusals will be noted but will not be considered withdrawals from the study.

15.4 Participants who are unable to be contacted for questionnaire completion

All efforts will be made to minimise missing data. However, if a participant cannot be contacted (that is, they are 'lost to follow-up'), data will continue to be collected from their healthcare records and relevant databases.

15.5 Deaths

Deaths are anticipated in this study and will not be considered as withdrawals. If a participant dies during the follow-up period, data will be collected as planned from their healthcare records and relevant databases.

16 Definition of end of study

The end of this study is defined as the last date on which data are collected on a study participant.

17 Safety

17.1 Risk

This study involves negligible risk to participants. Due to the intention to facilitate prompt discharge there is a potential risk that patients allocated to PLP/PPM will receive less secondary medical care by taking part in the study. However PLP/PPM aims to facilitate only effective discharge – patients will not be denied any form of care that would be beneficial to them during their hospital stay and the PLP/PPM teams will ensure that post-discharge arrangements are appropriate.

17.2 Definition of Serious Adverse Events

A serious adverse event (SAE) is any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or consists of a congenital anomaly or birth defect. Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

17.3 Recording of Serious Adverse Events in this study

The participants in this study are patients aged 65 or older who have been admitted to an acute ward of a general hospital – these patients will, by definition, be unwell. The Serious Adverse Events (SAEs) which will be recorded and reported in this study are deaths by any cause in the 30 days post-randomisation. Re-hospitalisations, life-threatening illness and significant disability are to be expected in this group of patients and will not, therefore, be recorded as SAEs.

17.4 Reporting Procedures for Serious Adverse Events

SAEs will be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs will be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form.

18 Statistical analyses

18.1 Sample size

A total of 3,588 participants is required to detect a reduction of 1 day (from 9 to 8 days, standard deviation 9) in mean number of days in hospital with 90% power at the 5% significance level and allowing for 5% loss to follow-up. A total of 2,680 participants is required to detect the same reduction with 80% power.

This sample size differs from that originally calculated for two reasons, one a consequence of a necessary change to the planned statistical analysis as a consequence of information found during detailed planning of the study, the other from an analysis of historical data on time spent in hospital from the hospitals that will be involved in study. These are explained below.

Initially it had been intended to give the trial 90% statistical power to detect a reduction of 1 day using a statistical analysis that allowed the effect of the intervention to be a random effect, differing in magnitude in each of the 16 independent PLP/PPM teams that it had been anticipated would deliver the intervention across the centres. The aim of an analysis that includes random treatment effects is to give a result which is generalisable to a wider population of PLP/PPM teams than are actually studied in the trial. Given that other assumptions remain the same such an analysis requires a larger sample size than a fixed effect analysis which allows the effect of the intervention to differ by PLP/PPM team but where the aim is simply to estimate the average effect across these specific PLP/PPM teams, without any explicit generalisation to a wider population. However at the planning stage of the study it became apparent that there will, in fact, not be independent PLP/PPM teams operating within each of the three study centres: so there will only be three independent PLP/PPM teams involved, making a random effects analysis inadvisable. Accordingly we have switched to an analysis where treatment effects are fixed.

Also, consideration of data collected at the three study centres suggested that our original estimate of the standard deviation of the length of stay (7 days) was an underestimate, with a standard deviation of 9 days being a more plausible estimate.

18.2 Overview of statistical analyses

A single main analysis will be performed at the end of the study when all outcome data have been collected. A detailed Statistical Analysis Plan will be developed prior to closure of the study database and prior to the unblinding of the treatment allocations. Primary analysis of the primary and secondary outcomes will follow the intention to treat principle (i.e. the participants will remain in the group they were randomised to and not analysed according to the interventions actually received).

18.3 Primary outcome

For the primary outcome (number of days spent in hospital in the 30 days post randomisation), the difference between the means with a 95% confidence interval will be reported. This will be obtained from a linear regression model. This model will include i) centre (Cambridge, Exeter, Oxford) by treatment interaction terms, ii) stratification factors

(hospital, gender and age: which will be treated as continuous in the analysis model, but in three categories for stratification) as fixed effects and iii) wards as either fixed or random effects (the final choice being dependent on the number of wards included). The primary outcome will be a weighted mean of the three centre-specific treatment effects, with weights proportional to the number of people randomised at each centre. In the event of substantial departure from normality assumptions non-parametric bootstrap (bias corrected and accelerated, 2000 replications, with allowance for stratification) methodology will be used to construct the confidence interval.

18.4 Secondary outcomes

Secondary continuous outcomes will be analysed in an analogous fashion to the primary outcome. For binary outcomes risk ratios and risk differences will be estimated. These will be obtained from generalised linear models (with adjustment for stratification factors). Further secondary analysis will consider time until leaving hospital as a survival time, with Cox models used to estimate hazard ratios.

19 Economic evaluation

19.1 Approach

Cost-effectiveness will be assessed from the perspective of the NHS with outcomes expressed in terms of quality-adjusted life-years (QALYs), in line with current UK guidance for economic evaluations [21]. In the case of one form of management being more costly and more effective, incremental cost-effectiveness ratios will be presented for the alternative options and compared with appropriate cost-effectiveness thresholds [21, 22].

19.2 Time horizon

For the base case, cost-effectiveness will be assessed over the one year study period. If there are found to be differences over this period which may result in the cost-effectiveness result being expected to differ over the longer term, extrapolation of study results will be conducted using a decision analytic modelling approach to synthesise the evidence from the study with other external evidence [23, 24]. Full uncertainty analyses in line with those proposed for the clinical analysis will be undertaken.

19.3 Resource use

Resource use will be estimated from a number of sources. Secondary care resource use, including hospitalisations, outpatient appointments and A&E visits will be estimated using routine data (HES). Liaison psychiatry resource use (in both study l arms) will be estimated using information from participants' medical records. Costs will then be calculated by applying appropriate unit costs to this resource use [25, 26].

19.4 Health related quality of life

Health related quality of life data will be collected at baseline and during the study follow-up (by telephone or face to face) using the EQ-5D-5L measure [19]. The scores will be used to estimate QALYs for the patients based on the area under the curve method and linear interpolation between time points [24]. We plan to capture the EQ-5D-5L at 1 month and at 3 months when possible so that we will be able to measure both initial and longer term effects on participants' quality of life. We will use these, along with mortality data, to estimate the QALYs over the one year period based on linear interpolation which is standard practice. Regression analysis will be used to control for any baseline differences in covariates and EQ-5D-5L score.

19.5 Analysis

The within study analyses will be conducted using appropriate statistical techniques to control for any baseline differences in covariates between patient groups and for issues with non-normality of cost and outcome data [27]. The choice of covariates to control for will be specified in advance following discussions with the study clinicians and statisticians. Further, any subgroup analyses being considered for the main clinical analysis will be replicated for

the health economic analysis. Missing data will be handled using imputation with chained equations [28]. Decision uncertainty resulting from the estimation of the within study analysis cost-effectiveness will be presented using cost-effectiveness acceptability curves [29].

If differences in costs or outcomes between the management strategies are found over the study period which would be expected to differ over the longer term, extrapolation of the study l results will be conducted. This will involve the development of a decision analytic model to capture the costs and QALYs over an appropriate time horizon (the time over which costs and QALYs could be expected to differ between the management strategies, which may be lifetime) [23, 24]. The model structure will be developed with clinical input and will synthesise data from the study with other external sources to estimate cost-effectiveness. Uncertainty in the parameters in the model will be reflected using probability distributions with the resulting overall decision uncertainty presented using cost-effectiveness acceptability curves [29]. The economists and clinicians on this study have previously collaborated on a decision analytic model to extrapolate the results of a study over a longer period [30].

20 Process evaluation

20.1 Analysis of care received

Data on care received will be reported in narrative form and using descriptive statistics.

20.2 Analysis of interview data

Data generated from the qualitative interviews with participants, carers and healthcare professionals will be analysed using qualitative description.

21 Data monitoring and quality assurance

21.1 Direct access to data

The CI and PIs will permit study-related monitoring, audits, ethics committee review and regulatory inspections by providing direct access to source data and documents. Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

21.2 Confidentiality

All data collected, processed and stored for the purposes of the study will remain confidential at all times and comply with GCP guidelines and the principles of the Data Protection Act 1998. The sponsor organisation (University of Oxford) is registered under the Data Protection Act (Registration Number Z575783X).

The study staff will ensure that the participants' anonymity is maintained. Personal data will be stored separately from research data (identifiable only by participant number and initials) at the main office (see below). All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

21.3 Data collected at study centres

Paper case report forms (CRFs) will be used to collect participants' demographic and clinical details and their questionnaire responses at baseline as well as the details of relevant usual care received during their hospital stay. These CRFs will be securely stored in locked filing cabinets at each study centre (NHS premises) and will only be accessible to members of the study team. During this brief stage, the paper CRFs will contain both personal and research data as we have found that the increased risks of misidentification from separating these during the hospital stay outweigh the risks to data protection.

Separate forms will be used by PLP/PPM teams to record the care that they provide (these will be duplicates of the information that they provide to the patient's medical team). These will be securely stored in locked filing cabinets at each study centre (NHS premises) and will only be accessible to members of the PLP/PPM team. These forms will include patient's identifiers (such as name and NHS number) in order that care can be provided safely and in accordance with usual clinical care guidelines.

Audio-recordings of interviews (with participants, carers and healthcare professionals) will be stored on audio-recorders, kept in locked filing cabinets at each study centre.

The CRFs, PLP/PPM forms and audio-recordings, as well as study logs, will be transferred to The HOME Study main office (at the University of Oxford's Department of Psychiatry) as soon as practicable after they are no longer required at the study centre. Transfer will be done securely, either by a member of the study team or by secure courier delivery. Copies of consent forms will be retained at the study sites until the end of the studyl.

21.4 Paper data storage at The HOME Study main office

On arrival at The HOME Study main office from the study centres, CRFs, PLP/PPM forms and study logs will be checked for completeness and consistency. Data will be entered in the study database. The paper CRFs obtained from the study centres will contain personal and research data – they will be separated so that personal data can be stored separately from research data (identifiable only by participant number and initials). Similarly, CRFs used to collect study outcome data will be identifiable only by participant number and initials.

Paper data stored at The HOME Study main office will be stored in locked filing cabinets in locked premises at the University of Oxford's Department of Psychiatry, accessible only to members of the study team.

21.5 Electronic data storage

Electronic data will be stored on a secure, password protected University of Oxford database, accessible only to the study team. Interview audio-recordings will be uploaded to a secure University server and deleted from the audio-recording devices. Interviews will be transcribed by a member of the study team and the audio-recordings deleted after study analysis is complete.

21.6 Data transfer for linkage and analysis

Minimal data will be sent securely to NHS Digital to allow linkage for the return of relevant routine clinical data. All data will be anonymised prior to leaving the University of Oxford for statistical and health economic analysis.

21.7 Archiving

The Chief Investigator will keep a copy of all consent forms, case report forms and study documents for five years from the end of the study. All files and data will be securely stored in a University of Oxford data archive.

21.8 Quality assurance of recruitment procedures

To ensure these procedures are conducted according to protocol, researchers will receive regular supervision from the centre PI. In addition, researchers will receive feedback from quality assurance centre visits which will include observation of practice, interviews with staff and checks of clinical records.

21.9 Quality assurance of PLP/PPM delivery

Teams will be assisted in maintaining fidelity to PLP/PPM by feedback from quality assurance centre visits which will include observation of practice, interviews with staff and checks of clinical records.

21.10 Quality assurance of primary outcome

HES data are generally accurate and complete for simple and easily measured variables such as length of stay. However, as a validity check, we will compare the HES length of stay data against each hospital's own data.

21.11 Quality assurance of other outcome data collection

Outcome data collectors will receive weekly supervision from a member of the TMG.

21.12 Data quality

The TMG will be responsible for overseeing the handling and management of all study data. This includes collection of outcome data. A dedicated study database, developed by the Oxford Clinical Trials Research Unit will be used to record all study information. To ensure that all data are reliable and have been processed correctly, Standard Operating Procedures (SOPs) will be implemented at each stage of the data handling process and all electronic data collated will be checked for accuracy as follows: 100% check on the primary outcome measure and a random minimum 10% sample check on all other outcome measures.

22 Ethical considerations and approval

22.1 Ethical considerations

22.1.1 Recruiting patients who lack capacity

This research will include adult participants who are unable to consent for themselves. This is necessary because the PLP/PPM intervention is designed to benefit older patients with medical-psychiatric multimorbidity, such as delirium or dementia. Patients who lack capacity to consent to study enrolment may therefore benefit directly from participation and the research will improve our knowledge of the best way to provide care to similar patients in the future. The research involves negligible risk to participants, will not interfere significantly with their freedom or privacy, and is neither unduly restrictive nor invasive.

Patients will be assumed to have capacity unless there is reasonable cause to believe this is not the case (e.g. the patient appears unable to understand or retain information about the research). Researchers who provide information to potential participants will be trained to identify patients who may lack capacity to consent and an appropriately trained research clinician will be available to provide further assessment as needed.

The consent process will take into account the implications of Sections 30-33 of the Mental Capacity Act (2005). A personal consultee (a family member, carer or friend; an attorney under a Lasting Power of Attorney; or a court appointed deputy provided that they had a relationship with, or personal knowledge of, the person lacking capacity before their appointment as deputy) will be identified where possible who can advise on (a) the patient's likely thoughts and feelings about the research and (b) whether the patient should participate. Nominated consultees, with no connection to the research, will be trained at each centre to provide advice regarding patients for whom we are unable to identify a personal consultee.

22.1.2 Identifying and approaching potential participants

We have carefully considered the best way to identify patients who are eligible to take part in this study. In order to give as many patients as possible the opportunity to participate, and to recruit a representative sample to answer the research question, we will need to screen patients for eligibility as soon as possible after their admission to the ward.

This process cannot be completed effectively by patients' clinicians because: (a) the broad selection criteria means that a large number of records will need to be checked daily and this would interfere with usual clinical care, and (b) acute wards are staffed by a large number of rotating clinicians making it unfeasible to train them all to screen and approach patients for this study. For the same reasons, and because it may cause distress and burden to patients, it is also not feasible for the clinicians to ask all admitted patients if they consent to the study researchers accessing their records. We are therefore seeking approval from local Caldicott Guardians and the Confidentiality Advisory Group for study researchers to carry out the screening procedure and to approach potential participants.

22.1.3 Time given to decide about participation

We will tailor the time that patients have to decide about participation to individuals. Patients have told us that they consider the interventions in this study to be low risk (relative to those in drug trials for example). They told us that they would like to be able to decide whether to participate during their discussion with a study researcher rather than be burdened by extra visits at a time when they are likely to be seeing multiple professionals. To accommodate this request, whilst ensuring that patients do not feel pressured to take part, we will use the following procedure: A study researcher will approach the patient and explain the research. If the patient is interested in taking part the study researcher will ask whether they would like them to (a) stay whilst they read the information leaflet and answer any questions there and then, or (b) return later the same day or the following day, so that the patient can read the leaflet alone and can discuss the study with their relatives and friends if they wish to do this.

22.1.4 Telephone consultation and consent from consultees regarding patients' participation

We will give consultees the option to give their opinion about the patient's participation in the study by telephone. Carers told us that, given the nature of the study, they would be happy to receive a telephone call from a study researcher to discuss the study and to give verbal advice or consent. They highlighted that, if we were to insist that they returned a postal form, this would place additional burden on carers at an already difficult time and would mean that some patients would miss out on participating.

22.1.5 Follow-up of participants who may lose capacity

Participants may lose capacity during the study follow-up period. It is important that we obtain information about these participants to find out whether they benefit from the new approach we are testing. Therefore, if it becomes clear, during the collection of outcome data, that a participant has lost capacity, we will identify and contact a consultee or carer to advise whether the patient can continue to be involved in telephone or in-person collection of data using questionnaires (with appropriate support and if the participant is willing), or whether data should be collected where possible from the carer. Information will continue to be collected from the participant's medical records and routinely collected clinical data unless a consultee advises that the participant should be withdrawn from the study.

22.2 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

22.3 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

23 Insurance and indemnity

The University of Oxford, has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment which is provided.

The study participant information leaflet will include information on how participants can complain about any aspect of the way in which they have been approached or treated during the course of the research, or regarding the care they have received as an NHS patient.

24 Finance

This study is funded by the National Institute for Health Research Health Services and Delivery Research (HS&DR) Programme, project reference number: 15/11/16

25 Trial committees

25.1 Trial management group (TMG)

The TMG will be responsible for the day-to-day running of the study, including recruitment monitoring and outcome data collection, and will meet at least monthly. The TMG will be led by a senior clinical researcher and will be accountable to the CI. Observers may be invited to attend meetings at the discretion of the TMG.

25.2 Trial steering committee (TSC)

The study will be overseen by an independent TSC. The TSC will meet at least annually to consider and address strategic issues. Representatives of the Sponsor and Funder and members of the TMG may attend TSC meetings at the invitation of the TSC Chair.

25.3 Data monitoring committee (DMC)

The DMC will monitor data and make recommendations to the TSC on whether there are any ethical or safety reasons why the study should not continue. Members will act independently of the TSC, TMG and Funder. The DMC will communicate at least annually as requested by the chairman and will receive a report from an independent statistician who will attend only by invitation. The DMC will monitor unblinded data; its members will have knowledge of the study arm that each participant has been allocated to (PLP/PPM or usual care) as well as the study centre where they have been recruited. The DMC will monitor the occurrence of serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs), i.e. serious adverse events that are likely to be due to the implementation of PLP/PPM. The DMC will focus particularly on the number of participant deaths that occur within 30 days of study enrolment. Interim analyses of the primary outcome data will not be undertaken because these require data that will not be available during the relatively short recruitment period. There are therefore no statistical stopping rules for this study related to the primary outcome and the DMC will recommend stopping only on safety grounds.

25.4 Patient and Public Involvement (PPI) panel

The PPI panel will include at least four patients and carers. The majority of members will be aged 65 or over. The panel will be actively involved in the design of study procedures, the development of information for potential participants and their carers, discussion of issues that arise during the study and interpretation of the research findings. Members of the PPI panel will be invited to attend TSC meetings. The PPI panel will also be invited to meet at least every six months (either face to face or by telephone) with members of the TMG. Additional PPI members will also be recruited through local forums at each centre to ensure involvement in specific decisions and local progress monitoring.

26 Ancillary studies

The value of the study may be enhanced by smaller ancillary studies. Any plans for such studies will be discussed by the TMG in the first instance and agreed with the TSC. Ethical approval will be sought for any such additional proposals.

27 Publication policy

The results of the study will be analysed and published as soon as possible. The results will be reported in the first instance to the funding body and study collaborators. A writing committee, chaired by the CI, will be constituted.

A lay summary of the study findings will be made available on the study website.

Authors will acknowledge that the study was funded by the NIHR. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

28 Key study contacts

Name	Institution	Role in this study
Prof Michael Sharpe Professor of Psychological Medicine	University of Oxford	Chief Investigator
Dr Jane Walker Senior Clinical Researcher	University of Oxford	Study Management & Principal Investigator (Oxford)
Dr Cathy Walsh Consultant Psychiatrist	Cambridge & Peterborough NHS Foundation Trust	Co-Principal Investigator (Cambridge)
Dr Annabel Price Consultant Psychiatrist	Cambridge & Peterborough NHS Foundation Trust	Co-Principal Investigator (Cambridge)
Prof Chris Dickens Professor of Psychological Medicine	University of Exeter	Co-Principal Investigator (Devon)
Dr Colm Owens Consultant Psychiatrist	Devon Partnership NHS Trust	Co-Principal Investigator (Devon)
Prof Chris Frost Professor of Medical Statistics	London School of Hygiene & Tropical Medicine	Supervision of statistical analysis
Dr Ian White Professor of Statistical Methods for Medicine	University College London	Expertise in trials statistics
Prof Mark Sculpher Professor of Health Economics	University of York	Supervision of health economic analysis
Mr Simon Walker Research Fellow	University of York	Health economic analysis
Dr Bart Sheehan Consultant Psychiatrist	Coventry and Warwickshire Partnership Trust	Expertise in old age liaison psychiatry
Prof Sallie Lamb OCTRU Co-Director	University of Oxford	Expertise in trials in the frail elderly
Prof Dan Lasserson Professor of Ambulatory Care	University of Birmingham	Expertise in primary-secondary care interface
Prof Ray Fitzpatrick Professor of Public Health and Primary Care	University of Oxford	Expertise in patient-reported outcomes
Prof Sasha Shepperd Professor of Health Services Research	University of Oxford	Expertise in evaluation of services for older adults
Prof Tjeerd Van Staa Professor in Health e-Research	University of Manchester	Expertise in use of routine data
Prof Alistair Burns Professor of Old Age Psychiatry	University of Manchester	Expertise in dementia research and national implementation
Mr Paul Brennan Director of Clinical Services	Oxford University Hospitals NHS Foundation Trust	Expertise in hospital management
Prof Rowan Harwood Professor of Geriatric Medicine	University of Nottingham	Expertise in geriatric medicine research
Dr Vicki Barber OCTRU Hub Manager	University of Oxford	Trials Unit Manager
Ms Sue Pargeter Research Manager	National Institute for Health Research	Funder's Representative

29 Appendix 1: measures

29.1 Montreal Cognitive Assessment (MOCA)

Repeat list of words		Face	Velvet	Church	Daisy	Red	No points
	1st trial						
	2nd trial						

Repeat list of digits	*Forwards*	21854	/1
	Backwards	742	/1

Read list of letters. Participant must tap at each letter A. No points if ≥2 errors	F B A C M N A A J K L B A F A K D E A A A J A M O F A A B	/1

Serial 7 subtraction from 100 *4 or 5 correct: 3 points* *2 or 3 correct: 2 points* *1 correct: 1 point* *0 correct: 0 points*	Numbers given by participant					/3
	Tick if correct (each number = previous number -7)					

Ask participant to repeat	I only know that John is the one to help today	/1
	The cat always hid under the couch when dogs were in the room	/1

Name words that begin with letter F *≥11 in 1 minute: 1 point*	0	1	2	3	4	5	/1
	6	7	8	9	10	11	

What are the similarities? *(e.g. banana & orange = fruits)*	Train & bicycle	/1
	Watch & ruler	/1

Recall words	Face	Velvet	Church	Daisy	Red	/5

Orientation	Date	Month	Year	Day	Place	City	/6

29.2 Barthel Index of Activities of Daily Living

Mobility indoors (house or ward)	A	Independent	Walks around without anyone's help, may use stick or frame.	
	B	Walks with help of 1 person	Help can be physical, moral support, giving instructions.	
	C	Wheelchair independent	Moves around in wheelchair without help, including going round corners & through doors.	
	D	Immobile	Doesn't move around, or has help from at least 2 people, or uses wheelchair with help.	

Transfer (bed to chair)	A	Independent	Moves from bed to chair without any help.	
	B	Minor help	Able to sit up. 1 person can easily help to supervise moving from bed to chair.	
	C	Major help	Able to sit up. To transfer needs a lot of help (1 skilled or strong person or 2 normal people).	
	D	Unable	Unable to sit up. At least 2 people required to lift.	

Stairs	A	Independent	Walks up & down stairs without help. If they have a stick, they carry it.	
	B	Needs help	Has help or supervision. Includes using a walking aid, someone there to hold arm or stick.	
	C	Unable	Does not go up & down stairs.	

Grooming	A	Independent	Does own face-washing, hair, teeth-brushing, shaving (may have help getting implements).	
	B	Needs help	Has help or supervision for any of these tasks.	

Bathing	A	Independent	Washes self, gets in & out of shower/bath without help.	
	B	Dependent	Does not wash self, needs any help to get in & out of bath/shower, washed in bed.	

Feeding	A	Independent	Eats food (not just soft food) without help. Cuts own food, spreads butter etc.	
	B	Needs help	Has some help (e.g. cutting food) but feeds self.	
	C	Unable	Only eats soft food or does not eat without help.	

Dressing	A	Independent	Puts on all items of clothing and does own laces, buttons, zips etc.	
	B	Needs help	Puts some items of clothing themselves, but has some help to put on the rest.	
	C	Dependent	Does not dress themselves, or does not put on any item of clothing without help.	

Bladder	A	Continent	No accidents over the last 7 days or catheterised but able to manage the catheter alone.	
	B	Occasional accident	Maximum 1 accident per day over the last 7 days.	
	C	Incontinent	More than 1 accident per day over the last 7 days, or catheter managed by others.	

Bowels	A	Continent	No accidents over the last 7 days.	
	B	Occasional accident	Maximum 1 accident over the last 7 days.	
	C	Incontinent	More than 1 accident over the last 7 days or needs enema from nurse.	

Toilet Use	A	Independent	Gets to toilet/commode, undresses, cleans self, dresses & leaves without help.	
	B	Needs some help	Wipes self & can do some undressing or getting to toilet but needs some help.	
	C	Dependent	Does not use toilet/commode or needs help with most tasks involved.	

29.3 EQ-5D-5L

Mobility	A	I have no problems in walking about	
	B	I have slight problems in walking about	
	C	I have moderate problems in walking about	
	D	I have severe problems in walking about	
	E	I am unable to walk about	

Self-care	A	I have no problems washing or dressing myself	
	B	I have slight problems washing or dressing myself	
	C	I have moderate problems washing or dressing myself	
	D	I have severe problems washing or dressing myself	
	E	I am unable to wash or dress myself	

Usual activities (*e.g. work, housework, family or leisure activities)*	A	I have no problems doing my usual activities	
	B	I have slight problems doing my usual activities	
	C	I have moderate problems doing my usual activities	
	D	I have severe problems doing my usual activities	
	E	I am unable to do my usual activities	

Pain / discomfort	A	I have no pain or discomfort	
	B	I have slight pain or discomfort	
	C	I have moderate pain or discomfort	
	D	I have severe pain or discomfort	
	E	I have extreme pain or discomfort	

Anxiety / depression	A	I am not anxious or depressed	
	B	I am slightly anxious or depressed	
	C	I am moderately anxious or depressed	
	D	I am severely anxious or depressed	
	E	I am extremely anxious or depressed	

29.4 PHQ-4

Over the last 2 weeks how often have you been bothered by the following problems?			
Feeling nervous, anxious or on edge	A	Not at all	
	B	Several days	
	C	More than half the days	
	D	Nearly every day	
Not being able to stop or control worrying	A	Not at all	
	B	Several days	
	C	More than half the days	
	D	Nearly every day	
Little interest or pleasure in doing things	A	Not at all	
	B	Several days	
	C	More than half the days	
	D	Nearly every day	
Feeling down, depressed or hopeless	A	Not at all	
	B	Several days	
	C	More than half the days	
	D	Nearly every day	

29.5 Quality of Life

We've talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate your quality of life overall on a scale of 0 to 10?	

29.6 Experience of Hospital Stay

On a scale of 0-10, where 0 is terrible and 10 is excellent, how would you rate the care you received in hospital?	

29.7 View on Length of Hospital Stay

What do you think about your stay in the hospital?	A	Too short	
	B	About right	
	C	Too long	

30 Appendix 2: topic guides

30.1 Topic guide for interviews with patients

- Experience and views of care in the hospital
- Helpful and unhelpful aspects of care received in the hospital
- Experience of receiving psychiatric care
- Helpful and unhelpful aspects of psychiatric care in the hospital
- Views about healthcare professionals providing care
- Views of duration of hospital stay
- Experience of leaving hospital

30.2 Topic guide for interviews with carers

- Experience and views of participant's care in the hospital
- Helpful and unhelpful aspects of care received by participant in the hospital
- Experience of participant receiving psychiatric care
- Helpful and unhelpful aspects of psychiatric care received by participant in the hospital
- Views about healthcare professionals providing care to participant
- Views of duration of participant's hospital stay
- Experience of participant leaving hospital
- Experience of acting as personal consultee

30.3 Topic guide for interviews with healthcare professionals delivering PLP/PPM

- Experience and views of delivering PLP/PPM
- Barriers and facilitators to delivery of PLP/PPM
- Perceived differences from usual way of working
- Implications for their clinical practice
- Relationship with other healthcare professionals

30.4 Topic guide for interviews with other healthcare professionals

- Experience and views of PLP/PPM
- Barriers and facilitators to PLP/PPM implementation
- Perceived differences from and influences on usual way of working
- Implications for their clinical practice

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