FULL/LONG TITLE OF THE STUDY
Improving the care people with learning disabilities receive in hospital: an ethnographic study examining the experiences of people with learning disabilities and the organisation and delivery of their care

SHORT STUDY TITLE / ACRONYM

Care4Me

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 20.03.25

RESEARCH REFERENCE NUMBERS

IRAS Number:	331917
SPONSORS Number:	RHM MIS0083
FUNDERS Number:	NIHR206167

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature: 

Date: 27.01.25

Name: (please print):

Dr Joanna Hope.....

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KEY STUDY CONTACTS

Chief Investigator	Dr Joanna Hope +44 23 8059 5292 j.l.hope@soton.ac.uk
Study Co-ordinator	CI above will cover these duties
Sponsor	University Hospital Southampton NHS Foundation Trust Mandy Ross University Hospital Southampton NHS Foundation Trust Tremona Road Southampton SO16 6YD Tel: 02381205044 sponsor@uhs.nhs.uk
Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	NIHR
Key Protocol Contributors	Dr Joanna Hope: j.l.hope@soton.ac.uk Professor Katie Featherstone: katie.featherstone@uwl.ac.uk
Committees	The PPI Advisory Group is established. The Study Steering Committee will be in place by end of February 2025

STUDY SUMMARY

Study Title	Improving the care people with learning disabilities receive in hospital: an ethnographic study examining the experiences of people with learning disabilities and the organisation and delivery of their care
Internal ref. no. (or short title)	Care4Me
Study Design	This project will use ethnography (with 8 case study adults with learning disabilities and carers (estimated n=16-24) and staff (estimated n=64) involved in their care, using observation, interviews, document analysis) to understand how care is experienced by adults with learning disabilities and how it is organised and delivered by ward teams during a hospital admission.
Study Participants	Adults with learning disabilities who are admitted within two large general hospitals in England over a four-month period. We will include a range of participants who have had particular types of experiences (critical case sampling) to

	ensure we include people with learning disabilities who are typically excluded from research. Sampling will include adults with a learning disability who represent a range of factors that may influence care delivery, and where possible, socio-demographic factors: • Severity of learning disability (mild to profound) • Primary reason for the admission, including planned and unplanned admissions. • People from Black, Asian, and Minority Ethnic groups with a learning disability. • Expected length of stay • To include people attending hospital with differing levels of support, who have a full-time family or professional carer, and who have limited or no support.
Planned Size of Sample (if applicable)	8 adults with learning disabilities (4 per hospital) Anticipated 16-24 carers Anticipated 64 members of hospital staff Total sample size = 96
Follow up duration (if applicable)	n/a fieldwork will be carried out during their hospital admission.
Planned Study Period	September 2024-March 2026
Research Question/Aim(s)	This exploratory ethnographic study will examine the experiences of adults with learning disabilities and the organisation and delivery of their care during a hospital admission. Our objectives: 1. Understand care experiences from the perspectives of adults with learning disabilities and their family carers during a hospital admission, including people with complex needs and profound learning disabilities. 2. Examine how care is organised and delivered for adults with learning disabilities during a hospital admission including how ward teams understand and respond to their needs. 3. Use the findings to co-design guidance with adults with learning disabilities, their carers and ward staff to deliver initial strategies to improve support for adults with learning disabilities at the ward level during hospital admissions.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR	£148,994.00

ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor is University Hospital Southampton NHS Foundation Trust (UHS), which is the organisation that is taking legal responsibility for the research project.

NIHR has carried out a rigorous peer review of the study prior to funding approval. All requirements of an NIHR contract will be met, including provision of 6 month progress reports and the delivery of progress milestones as required.

The CI (JH) controls the final decision in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Steering committee: The study steering committee will be in place by end of February 2025. This is required by the NIHR and fulfills the role described in their guidance (https://www.nihr.ac.uk/documents/research-governance-guidelines/12154):

The role of the Steering Committee is to provide overall supervision for a project on behalf of the study's Sponsor and Funder and to ensure that it is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The role of the Study Steering Committee is as follows:

- To provide advice, through its Chair, to the study's funder, sponsor, Chief Investigator, host institution, and contractor
- To concentrate on the study's progress, adherence to the protocol, and patient safety (where appropriate), and to consider new information of relevance to the research question

- To uphold the rights, safety and well-being of the participants: these are the most important considerations and should prevail over the interests of the research
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the study

PPI advisory groups: Our PPI Advisory Groups of people with learning disabilities (Treat Me Well at Southampton Mencap and Southern Health's Patient Experience group) and carers are already established. Representatives (a person with a learning disability and a family carer) from the above Advisory Groups are co-applicants. The lead researcher has spent two days with a public contributor with a profound learning disability to learn about how this person communicates, their needs and what is important to them, which has been used to inform how involvement in our research could be improved for people with profound learning disabilities. We are paying for PPI contributors' time using NIHR PPIE rates.

A summary of PPI activities

- MB and AI will meet with the other co-applicants monthly except during the fieldwork phase (March-June 2025)
- Months 1-3 JH will identify and spend a total of two days with a person with profound and multiple learning disabilities and their carer(s), learning how they communicate including assent, dissent and distress.
- The PPI Advisory Groups with people with learning disabilities will meet monthly (except during the first two months of fieldwork) to ensure they are fully involved. This ensures they will have adequate time to be fully involved in the research design, implementation, analysis, and output development. We will meet with the carers' group every two months as their availability and support needs will be lower. Activities will be:

- Month 1: Agree terms and support required
- Month 2: Agree key principles for recruitment and accessible project materials
- Month 3-4: Test and critique accessible materials created by FL (PPI Lead)
- Months 5-6: Discuss responses to REC, develop toolkit for accessible interviews
- Month 9: Discuss initial findings and develop third order coding
- Months 9-18: co-design sessions to create outputs

JH and FL will support a PPI member with a learning disability to develop and present research findings at a conference (preference given to MB).

PROTOCOL CONTRIBUTORS

The Sponsor (University Hospital Southampton NHS Foundation Trust (UHS) is the organisation that is taking legal responsibility for the research study.

The funder NIHR has carried out a peer review of the study prior to awarding funding. All requirements of an NIHR contract will be met, including provision of 6 month progress reports and the delivery of progress milestones as required.

The PI (JH) is responsible for the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

This protocol has been developed in collaboration with people with learning disabilities and their carers. This includes the Treat Me Well group (Southampton Mencap), which includes people with severe learning disabilities, our carers group and our co-applicant, AI and staff at Southampton Mencap.

People with learning disabilities described their significant anxieties and fear of hospital care. They felt excluded from decision making and had been asked to sign forms they did not understand. They said staff spoke too fast for them to understand, long waits made them anxious, they were afraid of needles and cannulas after bad experiences. They identified pain management, eating and drinking and vital signs (particularly anxiety/discomfort around the use of blood pressure cuffs) as important research priorities.

Family carers told us that they do all of the basic care but it is difficult to get their concerns taken seriously. They felt they had to take a hands-on approach to care and be available 24-7 as advocates and could be excluded from providing support when their son or daughter had requested it (e.g. during an MRI scan).

This has informed the research focus and the methods we are using, including our informed consent approaches and our approach to co-production. This includes the use of EasyRead, Photosymbols, Widgit symbols, simple language, providing questions ahead of time, use of graphics, role play scenarios and stories, embedded throughout the design of this study and in the PPI work.

KEY WORDS: Hospital, learning disabilities, nursing, ward care, reasonable adjustments, ethnography.

NHS
University Hospital Southampton
NHS Foundation Trust

STUDY FLOW CHART

	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25	Aug-25	Sep-25	Oct-25	Nov-24	Dec-25	Jan-26	Feb-26	Mar-24
Project setup	■																		
Write HRA application	■	■	■	■	■														
Co-applicant meetings	■	■	■	■	■	■					■	■	■	■	■	■	■	■	■
Negotiate local site approvals	■	■	■	■	■	■	■												
Development of accessible materials & review by advisory groups		■	■	■															
Pre-fieldwork PPI group meetings (TMW & SHPEG)	■	■	■	■	■	■													
Pre-fieldwork PPI advisory group (carers)		■		■		■													
Submit HRA application		■	■	■	■														
Respond to REC/HRA changes				■	■	■													
Ethnographic fieldwork across two sites							■	■	■	■									
Analysis								■	■	■	■	■	■	■	■				
Analysis discussion and co-design process with PPI groups (people with learning disabilities and carers) & staff									■	■	■	■	■	■	■	■	■		
Draft and submit final report														■	■	■	■	■	■
Dissemination of outputs															■	■	■	■	■

Commented [JH1]: I have amended as agreed with our grant manager for spending longer on PPI and writing application

STUDY PROTOCOL

Improving the care people with learning disabilities receive in hospital: an ethnographic study examining the experiences of people with learning disabilities and the organisation and delivery of their care

1 BACKGROUND

Population and literature review

Adults with learning disabilities are a key population within our hospitals (total estimated population 930,400: 2.16% of adults in England) (3). They require significantly more hospital care than the general population (4), with 1.9 times the expected number of episodes of admitted-patient care (5), 2.6 times the bed day rates of other patients (5) and have a longer than average length of stay (5,6) of between 3.7 (5) and 5.75 days (7). People with profound and multiple learning disabilities are significantly more likely to have an unscheduled emergency readmission than other people with learning disabilities (8).

In addition to their higher rates of admissions, people with learning disabilities experience poorer care in comparison to the general population within this setting. This has led to avoidable deaths during hospital admissions (9–15). During a hospital admission, people with learning disabilities experience higher levels of avoidable adverse events and poor safety outcomes compared to the general population (7,10,16) including poor quality of care and postoperative outcomes (16) and have a 2.7-fold higher incidence of experiencing five key avoidable hospital patient safety incidents - adverse drug reactions, hospital-acquired infections, pressure ulcers, postoperative pulmonary embolism, deep vein thrombosis, and postoperative sepsis (7).

When people with learning disabilities have communication difficulties, even if they are able to communicate with support or with a communication system, carers are typically expected to make decisions on their behalf (17) and a number of reviews have identified it is also common for people with mild learning disabilities to be ignored by healthcare staff (17,18), who instead communicate with their carers (18–20).

Despite commitments to learning disability care and the introduction of Learning Disability Liaison Nurses, ward staff often rely upon family carers and specialist nurses to ‘prop up services’, rather than adapting their care to meet the needs of people with learning disabilities. This includes staff misunderstanding the requirement to make reasonable adjustments (required under The Equality Act, 2010) (9,10,15,21–24) or expecting implementation to be carried out by specialist staff (13,15,22,24–27).

Research has shown that family carers are expected by ward staff to provide 24-hour bedside care for family members with learning disabilities (16–18,22,24,28–35), despite the RCN’s emphasis that carers should not be used as substitutes for nursing staff (36). Nonetheless family carers routinely provide physical nursing care (1,12), with the majority of fundamental care people carried out and overseen by carers who are visitors to the ward (16,33–35). This has resulted in fundamental care being missed by nursing teams who assumed carers were providing this (15,22). Furthermore it has been linked to wards failing to prioritise or oversee care (15,22,33) resulting in care omissions (15,17,22,33,35) and carers being expected to carry out procedures they are unqualified to provide (35). While ward staff may delegate oversight and provision of care to carers, when carers attempt to raise concerns about a patient’s condition this can be ignored by ward nursing teams (10,11,17,18,22,24,30,32,35,37). This has led to fatal failures in the identification and prevention of avoidable deterioration (10,11,35). In addition, this reliance on families poses significant risks given

fluctuating restrictions on entering hospital settings. Carers are often unable to enter or remain on wards, including due to Covid and infection risk (C.Diff, D&V, and Norovirus) restrictions (13,24,38), which has resulted in people with learning disabilities being left without support or monitoring (24,38) which Susan Sullivan's parents believe led to her death in 2020 (39).

Care continues to be 'haphazard' at the ward level, even within the same hospital (22). Reviews have identified that the care experienced by people with learning disabilities during a hospital admission is highly variable and unsafe (18–20,25,27,30,37). An integrative review of the hospital experiences of people with learning disabilities (19) found that reasonable adjustments were not consistently provided, while another key review found many examples of care failures, and failures to make reasonable adjustments at ward level (37). In their NIHR mixed-methods study, Tuffrey-Wijne and team (22) found evidence of a range of serious care omissions, including problems with nutrition, hydration, and delays in care and treatment, which were not included in incident reports. They concluded that care quality was "haphazard" throughout hospitals, with poor practice found even when there was good hospital management support and policies to support care for people with learning disabilities (40). Although they identified pockets of good practice, this varied significantly by ward, suggesting that poor care is not inevitable for patients with learning disabilities and that good care is attainable under the right conditions - however, to date these conditions remain unclear.

Reviews conclude that detailed research is needed to provide the evidence required to understand this variation (1), how reasonable adjustments are implemented and evaluated in practice (2,3) and how care is organised, adapted, and delivered for people with learning disabilities at ward level during a hospital admission (1,4–6). This includes a need for research into the care of patients known to be at higher risk of poor healthcare experiences (patients with complex needs and people from Black, Asian and minority ethnic groups and people who communicate non-verbally) (6,7). Ethnographic research is required to explore what happens to individual patients (4,7), following them to examine the "issues faced… at each point along the hospital journey" (2). However our systematic search identified only one ethnographic study that observed the hospital care of children with learning disabilities (8,9) and one study utilising a small number of very brief observations of children and adults' care (5).

People with learning disabilities have also been under-represented in research about their care. Methods that exclude people with severe or profound learning disabilities (10–15) are common and can be poorly implemented with people with mild learning disabilities (16–18).

Brief description of the study

In response, this exploratory study will provide a detailed examination of the experiences of adults with learning disabilities and the organisation and delivery of their care during a hospital admission. Objectives are to:

1. Understand care experiences from the perspectives of adults with learning disabilities and family carers during a hospital admission, including people with complex needs and profound learning disabilities.

2. Examine how care is organised and delivered for adults with learning disabilities during a hospital admission including how ward teams understand and respond to their needs.

3. Use the findings to co-design guidance with people with learning disabilities, carers and ward staff to deliver initial strategies to improve support for people with learning disabilities at the ward level during hospital admissions.

Methods

We will carry out ethnographic research following 8 case studies of adults with learning disabilities and their carers and hospital staff supporting and caring for them across a hospital admission, which will provide the detailed understanding of how care is organised, adapted and delivered at ward level, including how reasonable adjustments are made. We will include people from minority ethnic groups and people with profound learning disabilities in our sample, broadening our understanding of the hospital experience for both groups and developing new methodological approaches to the inclusion of people with profound learning disabilities in hospital research.

We will carry out the research in two hospitals using ethnographic methods: observation, interviews and document analysis. We will use a toolbox of accessible interview supports and spend time with people with profound and multiple learning disabilities during a hospital admission to learn about, include and interpret their non-verbal communications with the support of their carers.

Finally, we will create and adapt co-design methods and a methods toolkit that supports the inclusion of people with a range of needs, including people who communicate non-verbally. This will draw on and develop existing and adapted co-production techniques, tailoring them to the specific needs of people within these groups and including augmentative and alternative communication (AAC).

2 RATIONALE

We developed this study protocol following consultation with people with learning disabilities and carers. People with learning disabilities described their significant anxieties and fear of hospital care. They felt excluded from decision making and had been asked to sign forms they did not understand. They said staff spoke too fast for them to understand, long waits made them anxious, they were afraid of needles and cannulas after bad experiences. They identified pain management, eating and drinking and vital signs (particularly anxiety/discomfort around the use of blood pressure cuffs) as important research priorities. Family carers told us that ‘we do all of the basic care but it is difficult to get our concerns taken seriously’. They felt they had to take a hands-on approach to care and be available 24-7 as advocates and could be excluded from providing support when their son or daughter had requested it (e.g. during an MRI scan).

Contextual framing

For over 20 years government inquiries, inquests, and NHS reports have identified higher rates of systemically poorer care (9–12,15,16,18,19,21,22,24,28,30,31,37,38,67–72) leading to avoidable deaths of people with learning disabilities during hospital admissions (10,11,13,73,74), with Black, Asian and minority populations experiencing higher rates of early deaths (75). These reports identify tragic and repeated failures to provide routine and essential care that have led to avoidable deaths in hospital. Recent cases include 21-year-old Laura Booth, who died from malnutrition during a hospital admission for an eye operation (76); 14-year-old Christina Saleh, who developed a DVT following immobility in hospital after being admitted to hospital with constipation, where she also experienced inadequate nutrition and poor hydration checks, despite concerns raised by her family and the hospital learning disability liaison nurse (77); 61-year-old Guiseppe Ulleri, admitted to hospital where staff failed to provide adequate nutrition and treated him while supine, which led to his death from

pneumonia (78). The nature of these recent avoidable deaths bear striking similarities to the 2009 report into the deaths of six patients with learning disabilities (11) which also involved inadequate nutrition and monitoring in hospital. The majority of avoidable deaths of people with learning disabilities are due to treatable causes (by timely and effective health care interventions). In 2019, treatable causes accounted for 507 per 100,000 deaths in people with learning disabilities, compared with 80 per 100,000 in the general population (75) and a 2022 Care Quality Commission report concluded NHS hospital care for people with learning disabilities remains a 'critical patient safety issue' (24).

The poor care experienced by people with learning disabilities during hospital visits has been identified within the NHS since the National Patient Safety Agency's (NPSA) report on patient safety for people with learning disabilities in 2004 (31). Following Mencap's report, *Death by Indifference,* in 2006, and the resulting investigation into the deaths of people with learning disabilities (11) the independent inquiry into hospital care for people with learning disabilities *Healthcare for All* (in 2008) made a series of recommendations of which the following have been put into practice: adding reasonable adjustments to care to NHS core standards, the establishment of a Learning Disabilities Public Observatory, a Confidential Inquiry into the premature deaths of people with learning disabilities (completed in 2013) (9) and the tracking of the pathways of care of people with learning disabilities (partly: the Reasonable Adjustment Flag on the National Care Records Service was introduced last year) (79). Learning Disability Liaison Nurses were appointed in response to this inquiry and the NPSA report in the early 2010s (22,30) and the Learning Disabilities Mortality Review (LeDeR) programme was set up in June 2015 to review the deaths of people with learning disabilities. People with learning disabilities are a key group highlighted in the NHS Long Term Plan (80), which has committed to: reducing health inequalities for people with learning disabilities, taking action to prevent avoidable deaths, making reasonable adjustments to care, making sure "the whole NHS has an awareness of the needs of people with a learning disability" and improving the quality of inpatient care. National NHS learning disability improvement standards were introduced in 2018 (81) and are benchmarked each year by NHS Improvement. Relevant standards are: respecting and protecting rights (including making reasonable adjustments), inclusion and engagement of people with learning disabilities and their families and carers as partners in care, and workforce having the skills and capacity to meet the needs of people with learning disabilities. Mandatory training in learning disabilities and autism was introduced for healthcare workers recently under the Health and Care Act (2022).

3 THEORETICAL FRAMEWORK

Symbolic interactionism is the theoretical framework used for this study. This aims to provide an interpretive understanding of the social world, with an emphasis on interaction. We will use ethnography, which studies people's actions and accounts within their natural everyday settings and collect relatively 'unstructured' data from a range of sources (including observation, informal interviews and documentary evidence) (95). The aim is to explore the detail of often unnoticed everyday life, trying to read the tacitly known scripts and schemas that organise ordinary activities. The aim of our approach is to uncover original insights into the everyday ward care of people with learning disabilities (including people with profound learning disabilities) within the acute hospital setting and to understand how the wide range of social

actors within these settings (hospital staff) actively respond to these conditions through their actions. Ethnography allows us to examine these elements and the interplay between them. The value of this approach is the depth of understanding and original theory generation it can provide, including findings which are transferable more widely to other settings (96) that examine how context shapes and influences the quality, safety and delivery of care (97,98).

This research builds on work undertaken by this team to increase the inclusion of people with profound learning disabilities in research (62,84), NIHR ethnographies examining the hospital care of vulnerable populations (85–87), a systematic review of interventions to include people with learning disabilities and other cognitive impairments in care decisions (88), reasons for ward-level care omissions (89,90), and the difficulties in implementing individualised care at ward level (91). Our work to date has explored and theorised why nursing care for vulnerable people is more likely to be missed (91), and to explore and understand care omissions within the wider ward and hospital context, where difficult decisions are made to balance different kinds of care tasks (90), but which can reflect the underlying prioritisation of certain kinds of care for certain kinds of patients, and care rationing and allocation that can disadvantage certain groups and/or the time required to carry out personalised fundamental care (92–94).

4 RESEARCH QUESTION/AIM(S)

This exploratory ethnographic study will examine the experiences of adults with learning disabilities and the organisation and delivery of their care during a hospital admission.

4.1 Objectives

1. Understand care experiences from the perspectives of adults with learning disabilities and family carers during a hospital admission, including adults with complex needs and profound learning disabilities.
2. Examine how care is organised and delivered for adults with learning disabilities during a hospital admission including how ward teams understand and respond to their needs.
3. Use the findings to co-design guidance with adults with learning disabilities, carers and ward staff to deliver initial strategies to improve support for adults with learning disabilities at the ward level during hospital admissions.

4.2 Outcome

The goal is to provide insights into an “intractable problem” – the need to improve hospital care for adults with learning disabilities. This study will provide insights into key areas of the organisation and delivery of care and the appropriate methodological approach to inform a programme of research that includes adults with severe and profound learning disabilities. The outputs described below would encourage change in clinical practice at site level, policy level, and through building greater inclusion of adults with learning disabilities (including profound learning disabilities) in research that will influence policy and practice in the future.

Outputs will be co-produced in collaboration with our PPI groups (adults with learning disabilities, carers) and in workshops with nursing staff from both hospitals.

For NHS hospitals we will deliver:

- Recommendations for the organisation and delivery of appropriately adapted care for adults with learning disabilities at ward level (shared with local sites, NHS England and national Mencap).
- A masterclass for ward staff in each site to promote care that supports the needs of adults with learning disabilities during a hospital admission, with a focus on the needs of adults with profound learning disabilities (this may include the recognition of deterioration, distress and pain in adults who communicate nonverbally). The feasibility, acceptability and initial evaluation of this training will be assessed to explore its implementation in future research.
- A briefing to NHS England and the Care Quality Commission to improve the monitoring and oversight of the care of adults with learning disabilities at ward level

To support the development of the next stages of this research programme and the wider research community (including current NIHR research (NIHR205211)) we will:

- Co-produce guidance in collaboration with adults with learning disabilities, and adults with complex needs and their carers on their inclusion in healthcare improvement research, which we will share with the research community and UKRI funding bodies
- Develop co-design methods and a methods toolkit that supports the inclusion of adults with a range of needs, including adults who communicate non-verbally.

We will also produce an academic paper on care experiences and ward organisation of care for adults with learning disabilities.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This project will use ethnography (with embedded case studies, observation, interviews, document analysis) to understand how care is experienced by adults with learning disabilities and how it is organised and delivered by ward teams during a hospital admission. JH will carry out all data collection and analysis with the support and mentoring of KF. As described below, PPI groups will also be involved in the analysis and interpretation of data.

In response to objective 1 we will recruit 8 case studies of adults with learning disabilities (4 per hospital) who are admitted within two large general hospitals in England over a four-month period and their carers and hospital staff supporting and caring for them.

For each case study, ethnographic in situ interviews with adults with learning disabilities and family carers will be carried out to explore their experiences of care during their hospital admission. We estimate carrying out a series of at least four ethnographic interviews with each person with a learning disability and/or their family carers during their admission (total n=>32 interviews) as well as spending time ‘alongside’ adults with profound and multiple learning disabilities observing and interpreting their non-verbal communication with the support of their carer(s).

Drawing on team expertise (JH) in supporting, interviewing, and observing the care of adults with learning disabilities (including adults with profound learning disabilities), and involving vulnerable populations in research during a hospital admission (KF), we will use tailored methods of augmentative and adaptive communication for each participant and accessible interview tools. These will be agreed in discussion with the person and (if appropriate) their carer. For adults who communicate nonverbally or with few words, JH will work with their carer to interpret how they express assent, dissent and a range of emotions.

For all participants including those with varying degrees of verbal communication we will build on existing good practice in the use of interviews with people with learning disabilities (22,42,54,59). Our toolbox of adapted and augmentative supports will include adaptations that have already been successfully used on hospital studies with people with learning disabilities:

- Talking Mats (www.talkingmats.com),"a facilitated conversation approach used to supplement interviews by moving graphic images around to make options more concrete" (22,54,59)
- Use of pictures to guide discussion (59)
- Pictures and stories about care experiences (following (40))
- Use of a sticker activity about interactions with staff using happy and sad faces (59)
- Use of symbols including Makaton to support questions about care (following (22))

For people with profound learning disabilities these methods will not be appropriate, however, with support people may be able to express preferences or emotional responses to the here and now (54) Building on the most innovative work to date with people with profound and multiple learning disabilities, JH will spend significant periods of time 'being with' (62) each individual during their hospital admission to understand the meaning of each participant's "personalised forms of action" and through negotiating and interpreting meaning with their carer (60) We will be guided by their carer(s)' advice on how best to spend time with and interact with the person (61) and how they express a range of emotions (fear, pain, boredom, frustration, contentment) (60). This will involve recording detailed 'micro-descriptions' of their body and facial movements, with interpretations discussed with their carer(s) during the admission (60,61,64)

This will produce detailed understandings of care experiences from the perspectives of adults with learning disabilities and family carers during a hospital admission, including people with complex needs and profound learning disabilities.

In response to objective 2,

At ward level, for each case study participant, we will observe (where possible) the routine bedside care they receive during their admission. Ethnographic observations will focus on:

- routine care at the bedside including: mealtimes and hydration; personal care (we will not observe intimate care); observations and medication rounds (including vital signs); to provide understandings of the routine organisation and delivery of care.

- staff attending the bedside and visits from specialists (including Learning Disability Liaison Nurses, medical teams, Speech and Language Therapists, and Physiotherapists) to examine interactional approaches during everyday care.

- nursing handovers, medical rounds, and MDTs (as they relate to the case studies) to examine decision making, involvement of the person and family, any adaptions, and discharge plans.

In addition:

-Ethnographic in situ short interviews with ward staff attending the bedside (approximately 8 per case study) and directly caring for participants to explore how they understand the participant's care and communication needs.

-Documentary examination of hospital passport and medical records to examine care across the admission and how it is recorded.

-Ward level documentation on staffing levels and patient acuity during the periods of observation to provide context.

The four-month period of data collection will deliver 160 hours of detailed ethnographic observations, across the two hospital sites. Observation periods will be carried out over three days/shifts a week across their admission, providing approximately 20 hours per case study. Observational fieldnotes and in situ short interviews will be taken during observation periods and written up into more detailed data on the same day (producing approximately 175,000 words of data). No identifiable data (individual names, ward names, hospital name) will be recorded during data collection. All notes will use pseudonyms for patients and carers, and staff role only will be used in notes.

This will produce new understandings of how care is organised, adapted, and delivered for adults with learning disabilities during a hospital admission including how ward teams understand and respond to their needs.

Analysis

Data sets will be transcribed by JH into anonymised word documents or collected using handwriting software on a tablet and converted into Word files. Data will be checked and cleaned in Word. All tablets are provided by University of Southampton and password protected. These word documents will be entered into NVivo for analysis. The goal of analysis will be to create a conceptual model of how care is organised, adapted, and delivered for people with learning disabilities during a hospital admission via: (1) a narrative approach to deliver a series (n=8) of detailed case studies (interviews, observation, document analysis) that illuminate individual trajectories during an admission. This will illustrate the experiences of a range of people with learning disabilities across different clinical contexts, experiences, and outcomes. These case studies will be used to inform theory development to support and extend the ethnographic analysis of everyday care. They will also be used to inform output development including anonymised case scenarios.

(2) To analyse the ethnographic data (observation, in situ interviews, document analysis) an inductive process will be used, drawing on a grounded theory approach. To develop concepts and theories from the data we will develop initial ‘sensitising concepts’, using the constant comparative approach to deliver understandings about the provision of hospital care for people with learning disabilities that are transferable beyond local contexts (100)

(3) The ethnographic and case study analyses will be examined, refined, and brought together during the process of co-production to develop strategies to support hospital care. We will use NVivo to manage data and analysis, enabling us to develop a wider conceptual analysis and detailed case studies that illuminate key concepts and theory development.

We will also use this study to provide an analysis of the practicality and acceptability of the research methods used (inclusive interview and observational approaches). Ethnography is appropriate to support this through detailed recording in-situ of the methodological approach in practice.

Participant details will remain confidential as per the requirements of the Data Protection Act (2018) and the University Hospital Southampton NHS Foundation Trust data management policy. Linked anonymity will be guaranteed (each participant will be allocated an ID on entry to the study and code and participant list will be stored separately). The code sheet that links codes with individual identifying

details will be stored on a password protected file on a password protected computer, and in a locked filing cabinet, separate to any research data storage. Any research data stored will be associated with individual codes not identifying details. All physical data will be stored in a locked cabinet at the University and all electronic data on a password protected file on a network drive that is accessible only through the research team members' password protected accounts. This will only be accessed by members of the research team. Files relating to the project may sometimes be stored on researchers' local laptop disks, which are protected by a university login. All sensitive files will be stored on the network drive where feasible, or if away from network access and access is critical, saved to the local laptop disk with a password known only to the research team. Before being shared in reports or published in articles, details of participants will be limited to ensure individuals cannot be identified and quotes will be attributed to pseudonyms.

6 STUDY SETTING

This is a multicentre study. Data collection as described above will be carried out within two large general acute hospitals in England.

These settings are appropriate as they will allow us to explore how care of people with learning disabilities, including people from minority ethnic backgrounds, is carried out in acute general hospitals.

Local site approvals following NHS regulations will be sought to undertake research through the R & D departments of the two hospital sites, including completing a Research Passport, following HRA and REC permissions.

The same activities will be carried out at both sites with four patients recruited at each site.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Adults with a learning disability (over the age of 18)
- Receiving inpatient care in the hospital site during the data collection period

7.1.2 Exclusion criteria

- Children and young people with learning disabilities (under 18 years of age).
- People living with other kinds of cognitive impairment (not learning disability) e.g. head injury
- People not receiving inpatient care in the hospital sites during the recruitment period
- Patients on the end-of-life care pathway at the point of recruitment into the study
- Patients in intensive care units at the point of recruitment into the study

7.2 Sampling

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7.2.1 Size of sample

Our decision to recruit eight patients represents a feasible number to recruit and observe over a four-month period at both hospitals concurrently for the purposes of this exploratory study. The rationale for our sample size was based on the known populations of people living with learning disabilities in hospital, our discussions with learning disability liaison nurses working in hospital settings, and expert advice received during the NIHR peer review process during the submission of our grant application.

Our discussions with local learning disability liaison nurses have identified that they have an average admission rate of 20 people with a learning disability every month. This reflects the average admission rates identified in the literature (101). Using GP records and national statistics of hospital admissions, a screening study estimated that within an average-sized local health area approximately 5 adults with learning disabilities will be in hospital every day, each staying for an average of 3.7 days, or as long as 7.4 days in some departments, with significantly longer stays in medical and surgical specialties than members of the general population (102), but this was likely to be an underestimate due to low recording of people with learning disabilities on GP records compared to estimated prevalence in the population. People with severe and profound learning disabilities, a key group of interest in this study, are the most likely people with a learning disability to be identified by hospitals (5,22).

Using this data, extrapolated from the study above, even with longer stays of 7.4 days (30 days/7.4 days stay*5 people= 20) we estimate there will be 80 admissions within each hospital site over the 4 month period of data collection – 160 eligible patients in total – allowing for a cautious 5% recruitment rate.

In addition, we will also be recruiting carers and staff supporting and caring for these eight case study patients. We anticipate this will involve 16-24 carers and 64 members of hospital staff, creating a total sample size of 96.

7.2.2 Sampling technique

Sampling in ethnography requires a flexible, pragmatic approach, using a range of variables that may influence the phenomena, and what is known based on the available literature. Probability sampling is not appropriate, instead non-probability sampling will generate analytically - rather than statistically - generalizable findings (103). The number of sites and participants are considered appropriate on the basis of the quality and appropriateness of the sample and when data saturation has been achieved, rather than on the basis of sample size (103).

We will initially use maximum variation sampling (104) to ensure we include people with learning disabilities who are under-represented in work exploring health inequalities, such as the LeDeR reports (75), and are more likely to have a poor experience of health services (17,23). Given the high representation of research with or through carers, we will also approach people with a range of carer support, including people who attend hospital without carers. However, as the study progresses, this approach will be refined to identify a purposive sample, to ensure our sampling reflects the patient population. Thus, sampling will include people with a learning disability who represent a range of factors that may influence care delivery, and where possible, socio-demographic factors:

- Severity of learning disability (mild to profound)
- Primary reason for the admission, including planned and unplanned admissions.
- People from Black, Asian and Minority Ethnic groups with a learning disability.

- Expected length of stay
- To include people attending hospital with differing levels of support, who have a full-time family or professional carer, or no or limited support.

We will use translation services in NHS settings where required.

7.3 Recruitment

Before recruitment begins the researcher will meet with matrons representing different clinical specialty areas in the hospital, to inform them about the study and answer any questions. The researcher will arrange to visit medical and surgical wards and any other wards known to have significantly more admissions among people with learning disabilities. She will provide study information and discuss the study with the ward leader and with ward staff teams where this is possible (e.g. at handover meetings).

7.3.1 Sample identification

Two forms of identification of potential case study patient participants will be carried out concurrently during recruitment periods to maximise identification of potential patient participants.

1. Every weekday morning during data collection periods (except when active data collection is happening with a case study participant) Learning Disability Liaison Nurses at both hospitals will be asked to identify wards with potential participants (adults with a learning disability who are current inpatients) and wards with a planned admissions of an adult with a learning disability within the same week.
2. With the permission of matrons in both hospitals, JH will make weekly visits (except when active data collection is happening with a case study participant) to the nurses in charge of the medical and surgical wards on each site (due to greater lengths of stay and numbers of people with learning disabilities in these specialisms (5)) and any other wards identified by each site as having more people with learning disabilities attending. She will ask the ward leader to screen their records for any patients with a learning disability currently on the ward (rather than directly through access to care records, which only the patient team can access).

In screening for potential participants, Learning Disability Liaison Nurses and Ward Leaders and Nurses in Charge will be asked to identify people with a learning disability using:

- The reasonable adjustments flag (used nationally) (79) and any further information recorded within it about the nature of ‘patient impairment’ to identify people with a learning disability.
- The ‘hospital learning disabilities flag’ used within one of our sites
- Anyone whose record identifies a condition associated with a learning disability (if any one of the following was documented in their medical notes: (a) a diagnosis of learning disability (b) a condition always accompanied by a degree of learning disability (e.g. Down syndrome, Rett syndrome) (c) global developmental delay (following method successfully used by (59))
- Someone identified by the Learning Disability Liaison team or any other relevant professional (e.g. GP, member of a Community Learning Disability Team) as having a learning disability

As the study progresses, learning disability liaison nurses and ward managers will be asked to identify people in line with recruiting a range of people following the sampling criteria described in 7.2.2 (e.g. by ethnicity and by planned or unplanned admissions).

We will work with both hospitals concurrently to maximise recruitment opportunities with the support of staff (including collaborators).

In all cases of patient identification described above, the researcher will only be told which ward to visit for recruitment and will ask the ward manager to screen her current patient list for any adult with a learning disability. No identifying patient details will be shared with her. The researcher will always discuss the study with the ward manager or 'nurse in charge' on the relevant ward and seek initial verbal consent for her to be present on the ward to carry out observations of care should consent be gained from the patient and their carer. If the nurse in charge agrees, she will ask them to gain initial verbal consent from the patient and/or their carer (if supporting) for the researcher to approach the patient to discuss the study. If they provide consent for her to approach to discuss the study, she will discuss the project when a carer involved in their hospital support is present. If they are alone, she will ask if they would like a friend, carer or supporter to be there when she discusses the study and if so, she will return when that person is available.

7.3.2 Consent

People with learning disabilities

In discussion with ward managers, JH will approach eligible patients and their carers following the screening process described above. She will provide accessible information sheets about the study developed with the PPI groups and PPI lead (FL) and available in either EasyRead or Widget, according to preference) and share a link to a video that outlines the information on information sheets (via a private link on YouTube). There will an opportunity for people to ask questions about the study. For patients with learning disabilities who are assessed to lack capacity to consent, we will seek advice from an appropriate consultee in line with the Mental Capacity Act. The personal consultee cannot also participate in the study as a carer. This means if a carer wishes to participate in the study an alternative personal consultee who knows the person well will be consulted instead. For all participants with a learning disability, we will also use Dewing's model of process consent (105), which conceptualises consent as a continuous process with researchers considering whether a study participant is consenting to each decision across the course of the study. In practice, this means that even if someone has already consented to be observed, every time the researcher starts an observation period, she will remind them of the study and provide details of what it involves and check they are still willing to participate.

For people with learning disabilities who are also non-verbal, this will involve asking carer(s) how the person expresses dissent, fear or other negative emotions. Following approaches used within previous ethnographic research with people with profound learning disabilities JH will continually monitor assent, checking her interpretations with the participant's carer. If the participant or potential participant shows dissent to JH's presence, she will cease data collection or not proceed with the recruitment process.

The researcher will seek verbal and written consent from the patient to access and take brief notes from their medical records and for the researcher to attend and take notes during staff meetings about their care. If they lack capacity to make these decisions, advice will be sought from their consultee.

Patients can participate in the research without giving consent for their medical notes to be accessed by the researcher and/or for the researcher to make notes during staff meetings about their care. This will be made clear in discussion and is clear on the information and consent sheets. If consent is given for accessing medical records, or a consultee advises that they can be accessed, brief notes will be taken to outline the treatments and assessments undertaken. These will be used to support the interviews with patients, who may, due to their learning disability, find it difficult to remember the details of their hospital treatment and assessment

At the beginning of each planned data collection session the researcher will check if the person and (if relevant) their carer(s) are happy for her to continue, including a discussion about whether the person feels too unwell to participate in observations or interviews that day or too unwell to continue participating in the study. This will be done in a way appropriate to that person's ability to communicate and understand. If anyone shows signs of not wanting the reseacher to carry out the study with them at that time, she will stop collecting data that day. If this happens again the next day, the researcher will withdraw that person from the study completely. If a patient or carer says at any point they don't want to be in the study anymore, or it is their view (or the view of their personal consultee) that the patient does not wish to participate any longer the researcher will withdraw that person from the study completely.

It is possible that existing participants may move onto an End-of-life care pathway or into an Intensive Care Unit. If this happens, we will review their participation with them with the support of their carer or personal consultee if relevant and withdraw them from the study at this point if they wish.

If a participant with a learning disability wishes to withdraw their data from the study, they can do so during the data collection period, but not afterwards. This is made clear on the information sheets and will be discussed with all potential participants.

Carers

If the participant with a learning disability says they are happy for their carer(s) to be included, the researcher will provide the carer(s) with information and consent forms and discuss the study with them too. The carer will be required to give written consent to participate. If the carer does not wish to take part but the patient does, the researcher won't collect any data about them, including during observations of the patient's care if they are present.

Staff

The study focus is on observing the everyday care provided to people with learning disabilities by nursing and HCA staff (and other clinical staff from a range of disciplines and roles when they are involved in the care of our participants with learning disabilities). We have built on the approaches

used in previous NIHR grants using observations, approved by the HRA (NIHR13290; NIHR170503) and agreed this process with guidance from our NHS collaborators.

When consent has been gained for a patient to participate in the study, written consent will be sought from the ward manager or nurse in charge for the researcher to be present on the ward and observe care. The researcher will put up posters about the research in prominent places and leave information sheets at the nurse's station. The researcher will request that the relevant member of staff add a research entry to the patient's medical notes documenting their consent process according to local standard research policy.

The researcher will sit near the patient participant during her observations, explain the study and seek verbal consent from staff. Staff members can cease participation at any point during the study.

Nursing staff will be approached at a time that does not interrupt care to ask for full written consent to participate. Should a staff member decline to give written consent, any data collected about or from them during that observation period will be destroyed and they will not be observed in any subsequent care observations. However as notes on care provided by staff are anonymous, it will not be possible to remove data about prior observations on different shifts.

Written consent from the ward manager will be sought for attending meeting discussions about the patient's care. The researcher will ask for verbal consent from all staff in the meeting and if all staff do not agree, she will not take notes of their contribution. It is not practical to take consent from staff from other parts of the hospital as this may entail interrupting ward processes or interventions. Instead, posters giving information about observations on the ward will be prominently placed at the entrance to the room where observation of the patient is taking place. As described above, a note will be added to the patient's medical record to identify them as a participant in research, according to local standard research procedures. The researcher will carry information sheets and be available to answer questions and will take verbal consent from all staff when it does not interfere with clinical care processes or the work of the ward. An observation will be ceased should any staff member raise any concerns about being observed.

If the patient participant moves to another ward during data collection (including into an Intensive Care Unit or after moving onto an End-of-life care pathway), the researcher will explain the study to the new ward manager and seek initial verbal consent to continue the study on that ward if the patient participant (or on advice from a consultee) wishes to continue. She will check that the patient and their carers (if relevant) are happy to continue with the study on this new ward. She will then use the same recruitment and consent process for the ward manager and staff as described above, for this new ward.

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RIGHT TO WITHDRAW

The participant will remain free to withdraw at any time from the study without giving reasons and without prejudicing his/her further treatment and will be provided with a contact point where he/she may obtain further information about the study. Participant withdrawal of consent from the study will be explicitly documented in the source documents.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

While undertaking observations of ward staff delivering care, the delivery of an unacceptable standard of clinical practice may become apparent or be strongly suspected by the researcher (JH), who does not hold a clinical qualification. If this occurs, the researcher (JH) will discuss these concerns with the nurse in charge of the ward. Furthermore, the one-to-one conversations as part of fieldwork may reveal disclosures that require action. We do not expect these situations to occur frequently but acknowledge that they are possible. Information sheets include a disclaimer that the researcher has a duty to report harmful or abusive care practices. This will be discussed with those taking part before data collection begins. The researcher will have completed courses in Safeguarding Adults (Levels 1 and 2) prior to commencement of this study. Should participant disclosures or observations of care reveal criminal acts, including acts of abuse or neglect, appropriate safeguarding procedures will be immediately followed.

We recognise the possible effects of Covid-19, and other infections on the execution of the research:

- The proposed research relies on direct access to wards, and we will follow local regulations to access required (e.g. masking, use of LFTs before entering wards)
- The ethnographic observations require a physical presence of only 1 team member (JH). Permissions and governance will be prioritised early (see gantt chart)
- Sampling and data collection is designed to require only limited support from NHS systems and frontline resources and is informed by ongoing discussions with our collaborators
- Remote working can be used when required for some project communication, PPI Advisory Group and Project Steering Group meetings
- The project prioritises the delivery of open access outputs, and the team have expertise in delivering blended learning and online resources where preferred

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study we will seek ethics committee approval through the HRA process and through a Mental Capacity Act trained NHS REC. Both KF and JH have expertise in obtaining REC (15/WA/0191,18/WA/0033, IRAS 313816) approval to involve vulnerable populations in research in hospital settings and the application of the Mental Capacity Act (2005).

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. The Chief Investigator (JH) will produce the annual reports as required and notify the REC of the end of the study. 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 study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator will ensure that appropriate approvals from participating organisations are in place – specifically site agreements with the two hospitals where recruitment and data collection will take place.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration with the express agreement and cooperation of the Chief Investigator (JH) using the process described below. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

- The process for making amendments is that the sponsor should discuss any wishes to make substantial amendents with the Chief Investigator (JH)
- Substantive changes will be communicated by the Chief Investigator (JH) to relevant stakeholders (e.g., REC, R&D, regulatory agencies).
- The amendment history will be tracked in the site files, with protocol version numbers showing the most recent protocol version and previous protocol(s) archived and marked as outdated in the title.

8.3 Peer review

The details provided in this protocol were reviewed as part of the NIHR RfPB grant submission process.

8.4 Patient & Public Involvement

This proposal has been developed in collaboration with people with learning disabilities and their carers. One of our co-applicants has lived experience of having a learning disability (MB) and another of our co-applicants is a parent of a woman with a learning disability (AI). This has informed the research focus and the methods we are using that supports the inclusion of people with severe and profound learning disabilities, and our approach to co-production. This includes the use of EasyRead, Photosymbols, Widgit symbols, simple language, providing questions ahead of time, use of graphics, role play scenarios and stories, embedded throughout the design of this study and in the PPI work.

A summary of PPI activities

• Our co-applicants MB and AI will meet with the other co-applicants monthly except during fieldwork when there will be no meetings

Months 1-3 JH will identify and spend a total of two days with somebody with profound and multiple learning disabilities and their carer(s), learning how they communicate including assent, dissent and distress. This will inform the research protocol and co-design outputs.

The PPI Advisory Groups with people with learning disabilities will meet monthly (except during fieldwork) to ensure they are fully involved. This ensures they will have adequate time to be fully involved in the research design, implementation, analysis, and output development. We will meet with the carers' group every two months as their availability and support needs will be lower.

Activities will be:

- Month 1: Agree terms and support required
- Month 2: Agree key principles for recruitment and accessible project materials
- Months 3-4: Test and critique accessible materials
- Months 5-6: Discuss responses to REC, develop toolkit for accessible interviews
- Month 9: Discuss initial findings and develop third order coding
- Months 9-17: co-design sessions to create outputs

JH and FL will support a PPI member with a learning disability to develop and present research findings at a conference (preference given to MB).

We will hold a series of workshops with our advisory groups of people with learning disabilities, carers and families. The workshops will discuss and 'member check' initial findings (100) and co-design and develop guidance and study outputs, using initial findings from the data.

We will adapt Accelerated Experience-Based Co-Design (106) significantly in response to critiques about its use with people with learning disabilities and other vulnerable groups (57,58) for instance in using a set of principles derived from the approach rather than a series of rigid steps (58). We will also adapt these methods for the specific communication preferences, cognitive needs, and expertise of the people with learning disabilities in our advisory groups (54,107–110), using our 'toolbox of adapted and augmentative supports' and role play scenarios, developing this approach with our PPI representatives and PPI lead.

8.5 Protocol compliance

The Investigator agrees to comply with the requirements of the Protocol and Good Clinical Practice. Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials and must not be used e.g. it is not acceptable to enrol a subject if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol, which are found to frequently recur, are not acceptable and will require immediate action by the sponsor. Frequent non-compliances could potentially be classified as a serious breach

8.6 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Regulation and UK GDPR guidance with regards to the collection, storage, processing and disclosure of personal information and will uphold the Regulation's core principles. The PI will be the data custodian as part of her honorary contract with the sponsor, University Hospital Southampton NHS Foundation Trust. Participant details will remain confidential as per the requirements of the Data Protection Act (2018) and the University Hospital Southampton NHS Foundation Trust data management policy.

No identifiable data (individual names, ward names, hospital name) will be recorded during data collection. All notes will use pseudonyms for patients and carers, and staff role and ward speciality only will be used in notes. In all reporting and publication of findings individual participants will not be identifiable. Confidentiality will be ensured at all times. Patient pseudonyms (chosen by participants and agreed with the researcher to ensure they are not identifying) will be used for transcripts and in written reports. Direct quotes will not include any identifiable information. Methods of presentation that protect anonymity will be adopted including composite stories. In line with Caldicott Principles, only information necessary to the organisation and delivery of the study will be obtained from participants. This will be name (for consent forms) and name, email and address if patient or carer participants complete a request form to be sent a summary of the research findings (all documents with identifying details will be stored separately from their data).

Linked anonymity will be guaranteed (each participant will be allocated an ID on entry to the study and code and participant list will be stored separately). The code sheet that links codes with individual identifying details will be stored on a password protected file on a password protected computer, and in a locked filing cabinet, separate to any research data storage. Any research data stored will be associated with individual codes not identifying details. All physical data will be stored in a locked cabinet at the University (paperwork) all electronic data on a password protected file on a network drive that is accessible only through the research team members' password protected accounts. This will only be accessed by members of the research team. Files relating to the project may sometimes be stored on researchers' local laptop disks, which are protected by a university login. However all sensitive files will be stored on the network drive where feasible, or if away from network access and access is critical, saved to the local laptop disk with a password known only to the research team. Data will be archived for 15 years in accordance with the University Hospital Southampton NHS Foundation Trust's Research Data Management Policy, and the CI will retain anonymised data from the study for use in further publications.

All information sheets and consent forms state that participants in the research are guaranteed anonymity. All contact details will be stored securely and destroyed after the final key output or summary document from the study is shared with prior participants. This data will play no part in any dissemination or outputs of the study and will be managed in line with UK General Data Protection Regulation

8.7 Indemnity

The sponsor of the trial is University Hospital Southampton NHS Foundation Trust. For NHS sponsored research HSG (96) 48 reference no.2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the research. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

8.8 Access to the final study dataset

JH and KF will have access to the full anonymised dataset. We will not be making the dataset available for secondary analysis.

9 DISSEMINATION POLICY

9.1 Dissemination policy

- Data belongs to University Hospital Southampton NHS Foundation Trust.
- Full study report will be completed in line with NIHR requirements and published as per their requirements, available on their site
- JH as CI holds rights to publications and will publish with co-applicants. No co-applicants can publish data independently of JH
- NIHR will be acknowledged in all outputs from the study as study funder following their guidance on wording
- All publications arising from this work will acknowledge the organisations involved in the research - University of Southampton, University of West London, University Hospital Southampton NHS Foundation Trust, Portsmouth Hospitals University NHS Trust, Southampton Mencap and Southern Health NHS Trust's Patient Experience Group.
- All patient participants will be asked when consented if they wish to receive a summary of the findings, and the best way to share this (e.g. postal address or email). If they wish to receive a summary, they will be given a separate form to complete, which will be stored separately from research data. We will share a summary of the research with patient and carer participants in appropriately accessible formats after our final data analyses have been completed, if they have agreed they would like this. We will also share a brief summary of the findings with both hospital sites and wards and key staff who have participated in the study, in addition to the outputs described elsewhere.
- The protocol will be made publicly available via the ISRCTN site
- We will not be making our dataset publicly available

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the study report will include the CI, all co-applicants and our collaborators CM and RA. All will be individually named.

Monitoring, Audits and Inspections

This study will be monitored and may be participant to monitoring and audit by University Hospital Southampton NHS Foundation Trust, under their remit as sponsor and other regulatory bodies to ensure adherence to ICH GCP, UK Policy Framework for Health and Social Care Research, applicable contracts/agreements and national regulations. All study related documents will be made available on request for monitoring and audit by UHS, the relevant REC or other licensing bodies.

ARCHIVING

Archiving will be authorised by the Sponsor following submission of the end of study report.

Location and duration of record retention for:

- Essential documents: Patient case notes will be stored and maintained according to standard rules and procedures.
- Study data will be held for minimum of 15 years

Destruction of essential documents will require authorisation from the Sponsor.

Definition of End of Study

The study end will be defined by the completion of all data collection undertaken as part of this study's data collection. The Chief Investigator will inform the relevant Research Ethics Committee giving favourable opinion within 90 days of the study ending using the appropriate form.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

We will follow IRAS and local R&D guidance for site management, with all the relevant site file information including all study documents, IRAS form and approvals, REC approvals, CVs and permissions (research passports).

11.2 Appendix 2 – Schedule of Procedures (Example)

As described in section 7.3.1 we will be recruiting 8 case studies including patients, carers and staff and collecting data over a four month period in two hospitals. We are therefore unable to give an exact number of visits per week. In addition as this is an ethnographic study we will not be collecting baseline and follow-up data at specific times, but instead collecting data on 8 case studies using ethnographic methods. JH will make weekly visits to the nurses in charge of the medical and surgical wards (due to greater lengths of stay and numbers of people with learning disabilities in these specialisms (5)) and other wards identified as having higher admissions of people with learning disabilities on each site to screen their admissions through discussion with the ward leader (rather than directly through access to care records, which only the patient team can access). The PI (JH) will visit the hospital as often as required during this period to visit wards identified by learning disability nurses as having potentially eligible patients and their families and discuss the study with them. When somebody consents to participate in the study, JH will immediately begin ethnographic observations. Observation periods will be carried out over three days/shifts a week across their admission.

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.