FULL/LONG TITLE OF THE STUDY

Mixed methods study to understand the scale, impact and care trajectory for patients who have a long lie after a fall.

SHORT STUDY TITLE / ACRONYM

Impact of having a long lie after a fall

PROTOCOL VERSION NUMBER AND DATE

Version 1.5 25th March 2025

RESEARCH REFERENCE NUMBERS

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Work package	Approvals	Reference number
1	University of Sheffield REC	061049 (approved)
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3	HRA & NHS REC	**336914 (in progress)**
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5	HRA	350537 (approved)
6	HRA & NHS REC	**336914 (in progress)**
7	Not applicable	

This protocol has regard for the HRA guidance and order of content

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FUNDED BY

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 publically 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:
06/03/2025

Name (please print): FIONA BELL

Position: HEAD OF RESEARCH

Chief Investigator:

Signature:

Date:
06/03/25

Name: (please print): FIONA SAMPSON

KEY STUDY CONTACTS

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Key Protocol Contributors	Fiona Sampson, University of Sheffield, Fiona Bell, Yorkshire Ambulance Service NHS Trust Joanne Coster, University of Sheffield, Maxine Kuczawski, University of Sheffield Lyn Wilson, Mid Yorkshire NHS Teaching Trust Richard Pilbery, Yorkshire Ambulance Service NHS Trust Jen Lewis, University of Sheffield, Suzanne Mason, University of Sheffield, Stephen Elsemere, Public contributor Liz Jones, National Care Forum Valentine Ngwa, Mid Yorkshire NHS Teaching Trust Phil Gleeson, Public contributor Simon Dixon, University of Sheffield,
Oversight group	Steering Group Alison Porter (Chair, Associate Professor of Health Services Research, University of Swansea, mixed methods and pre-hospital expertise), Professor Jo Knight, Professor of Data Science, Lancaster University, expertise in user of routinely collected datasets to improve health outcomes), Cathryn James (Clinical Support Manager for AACE, NASMED, coordinates ongoing development of UK Ambulance Services Clinical Practice Guidelines (JRCALC)), Saiqa Ahmed (PPI, lived experience as carer, public adviser for NIHR ARC NWC), Sally Davies, (Falls Specialist, Mid Yorkshire Hospitals NHS Trust - not independent, acute trust and rehab falls expertise), Helen Press (Head of Quality Improvement, Methodist Homes MHA, care home expertise).

	Andy Collen (Consultant Paramedic, South East Coast Ambulance Service NHS Foundation Trust, expertise in falls in ambulance service Jason Madan, Professor of Health Economics, University of Warwick, health economics expertise

STUDY SUMMARY

Study Title	Mixed methods study to understand the scale, impact and care trajectory for patients who have a long lie after a fall
Internal ref. no. (or short title)	Impact of long lies after a fall
Study Design	Mixed methods WP1 and WP2: Understanding characteristics and care trajectory of ambulance service patients who have been unable to get up after a fall, and understanding healthcare resource use by patients after their fall. WP3: Understanding the mechanisms for impact of a long lie, will build on early work from WP1. WP4: Identifying how health and social care organisations manage and mitigate for long lies. WP5 and WP6: Understanding how key stakeholders mitigate for long lies, and exploring the impact of long lies on patients and carers. Data analysis and integration will take place once WP1-6 are completed. WP7: Co-production of guidance and recommendations, and dissemination of findings will take place in the last 3 months of the study.
Study Participants	WP1 and WP2 - All YAS ambulance calls for patients who have been unable to get up following a fall over a period of 24 months (estimated at a minimum of 115,000 cases, with approximately 16,000. having a documented long lie) and use corresponding CUREd+ data from 1st April 2019 to 31st March 2023. WP3 - Patients whom YAS identify as having a long lie will be consented for follow up across 4 NHS acute hospital sites. WP4 - Ambulance service clinical leads (or equivalent), homecare, residential or care home staff. WP5 - Key stakeholders across 3 NHS ambulance trust areas, from across hospital departments (ED, frailty, acute medicine), community falls response teams, residential and care home staff. WP6 - Ambulance patients who have fallen and identified as having a long lie and their carers, identified either by WP3 hospital sites, care homes, patient care carer forums, or research cohorts.

Planned Size of Sample (if applicable)	WP1&2 - 16,000 patient cases in CUREd+ database WP3 - 200 patient participants WP4- 13 Ambulance service emergency operations centre clinical leads. Up to 500 residential and nursing home managers. WP5 - 22-26 NHS and social care staff WP6 - 18-24 ambulance patients and their carers
Follow up duration (if applicable)	WP3 - follow up period 3 months
Planned Study Period	27 months - 1st April 2024 to 30th June 2026
End of study date	30th June 2026
End of study definition	The date of the last workshop with stakeholders (WP7)
Research Question/Aim(s)	Research Question What is the scale, impact and care trajectory for patients who have a long lie after a fall and what interventions might mitigate the impact of a long lie? Aims and Objectives Aim**:** This study aims to understand the characteristics of patients who have a long lie, their care trajectory and the health, psychological and economic impact of the long lie, as well as understand potential interventions to mitigate the impact of a long lie. Objectives: ● To characterise the frequency and duration of long lies in ambulance patients using data from one UK region held within the CUREd+ routine linked dataset; ● To understand the care trajectory, health outcomes, and health resource use of patients after a long lie using the CUREd+ linked dataset; ● To understand the mechanisms by which a long lie impacts care trajectories using hospital notes review for a subset of 200 patients identified from ambulance service data; ● To identify interventions used to mitigate the impact of long lies before arrival at hospital using a survey of ambulance services and social care providers; ● To understand how key stakeholders mitigate long lies using staff interviews; ● To understand the impact of long lies on patient and carers using interviews with patient and carers; ● To refine the definition of a long lie that is likely to cause harm and identify actions to reduce their consequences for patients.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health and Care Research - Health and Social Care Delivery Research Programme (HSDR).	NIHR158676

ROLE OF STUDY SPONSOR AND FUNDER

Yorkshire Ambulance Service NHS Trust (YAS) is the sponsor of this study. The Chief Investigator is employed by the University of Sheffield and holds an Honorary Contract with YAS. YAS will undertake all sponsor responsibilities outlined in the UK Policy Framework for Health and Social Care Research.

The funder, the NIHR, has requested that the final study report will be received by NIHR 14 days after the completion date of the project. The CI will submit a final report to the required authorities (REC/) with the results, including any publications within one year of the end of the study. The CI is also required to submit a financial reconciliation statement and transaction report of expenditure (in an Excel format), no later than 3 months after the completion date of the project.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Project Oversight - Steering Group

Alison Porter (Chair, Associate Professor of Health Services Research, University of Swansea, mixed methods and pre-hospital expertise),

Professor Jo Knight, Professor of Data Science, Lancaster University, expertise in user of routinely collected datasets to improve health outcomes),

Cathryn James (Clinical Support Manager for AACE, NASMED, coordinates ongoing development of UK Ambulance Services Clinical Practice Guidelines (JRCALC)),

Saiqa Ahmed (PPI, lived experience as carer, public adviser for NIHR ARC NWC),

Sally Davies, (Falls Specialist, Mid Yorkshire Hospitals NHS Trust - not independent),

Helen Press (Head of Quality Improvement, Methodist Homes MHA).

Andy Collen (Consultant Paramedic, South East Coast Ambulance Service NHS Foundation Trust, expertise in falls in ambulance service

Jason Madan, Professor of Health Economics, University of Warwick, health economics expertise

The project oversight group wil meet up 4 times over the duration of the study via videoconference and will approve the protocol and SAP for WP1. They will adhere to terms and conditions for project oversight set out by NIHR.

Patient and Public Involvement Group

The Patient and Public Involvement Group will:

1. Provide service user and lived experience input and perspectives to the research design, research processes, interpretation of the research findings and dissemination, through regular meetings and discussion.
2. Provide guidance and input to ensure our patient recruitment and sampling strategies and research materials are inclusive.
3. Be included as active members of the project oversight group (responsible for study implementation). We will also have independent PPI representation on the project advisory group
4. Contribute to the assessment of the impact of PPI on the research and co-produce dissemination activities and materials.

PPI members recruited to the study are:

Stephen Elsemere, part of the YAS Critical Friends Network, a study co-applicant and Long lies PPI group member

Phil Gleeson, part of the YAS Critical Friends Network, Advonet Group, Chair of the Leeds involving people board. the Change Group (which develops easy read resources) and involved with the Pressure Ulcer Research Service User Network (PURSAN), a study co-applicant and Long Lies PPI group member

Alice Riddell, a member of the Sheffield Emergency Care Forum and a Long Lies PPI group member

Martin Pickthall, part of the YAS Critical Friends Network and a Long Lies PPI group member

Chandrika Kaviraj, a NICE Expert Panel Group lay representative, NIHR EME Funding Committee member, NHS England Cardiac Transformation Board, former member of NHSE's Allied Health Professional Strategy Board and a Long Lies PPI group member.

Emily Lam, part of the Health Data Research UK North PPIE group and a Long Lies PPI group member.

(Up to 3 additional members to be recruited)

Stakeholder group

Dr Andrew Pountney, Emergency Medicine Consultant, Mid Yorkshire NHS Trust

Portia Chikwanha, Improvement Lead UEC community pathways, NHSE

James Goulding, EOC Clinical Lead, Yorkshire Ambulance Service NHS Trust

Christine Chaffin, Community falls response, ICB - NHS Herts and West Essex

Imogen Gunson, Paramedic and PhD student, West Midlands Ambulance University Teaching Trust

Sally Davies, Falls Specialist Physiotherapist, Mid Yorkshire Hospitals NHS Trust

Sandra Prew, ENRICH National Coordinator, NIHR Clinical Research Network West Midlands

Jane Nixon, Chair in Tissue Viability, University of Leeds

The stakeholder group will:

- Provide clinical and practical advice where needed
- Advise on study plans
- Support trouble shooting with practical study delivery
- Identify other relevant stakeholders
- Support study data integration and promote final workshops among networks

PROTOCOL CONTRIBUTORS

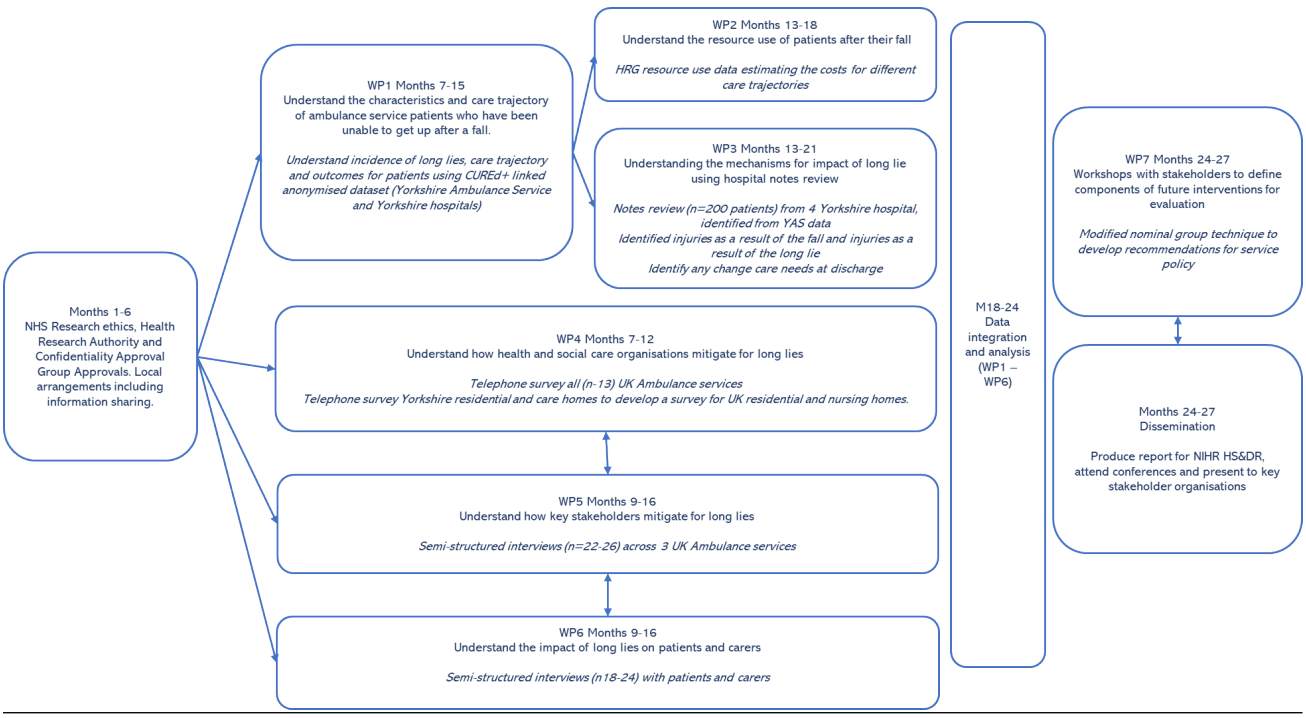
Fiona Sampson drafted the initial proposal. Jen Lewis and Richard Pilbery drafted WP1 and WP2, with methodological advice from Suzanne Mason with Simon Dixon. Richard Pilbery and Lyn Wilson drafted WP3, supported by Valentine Ngwa. Joanne Coster, Liz Jones, Fiona Bell and Fiona Sampson drafted the remaining workpackages. Stephen Elsemere and Phil Gleeson as public contributors advised on all aspects of the protocol, in particular the lay summary and dissemination strategy overseen by Jo Coster. All members of the PPI group have reviewed the lay summary.

The sponsor is responsible for the study design, for monitoring study conduct. Leaders of each workpackage are responsible for data analysis, and manuscript preparation. The sponsor and funder must be informed of all manuscripts being submitted for review, and must review the final study report. The sponsor must agree any changes to the protocol and the funder controls the final decision regarding any changes to the protocol.

KEY WORDS:

EMERGENCY MEDICAL SERVICES (MESH)
AMBULANCES (MESH)
Paramedic
Fall
Lie or Lay

STUDY FLOW CHART



1 BACKGROUND

1.1 Epidemiology and burden

Falls and fall-related injuries are a leading major global public health problem, leading to significant mortality and morbidity (WHO 2008, Slade 2017). Risk of falling increases with age, with 30% of people older than 65 and 50% of people older than 80 having at least one fall a year (Bergland 2005, NICE 2013, Rubenstein 2006). Risk of falling events and associated injuries are also high for people with chronic conditions such as Parkinson's disease and dementia, as well as sensory disorders (Morris 2004, ASHA 2021). Falls are a major cause of hip fracture and hospitalisation with adverse consequences of falls including pain, injury, loss of independence, increased use of social care and increased mortality (NHS Overview 2021, Slade 2017). NHS costs due to falls are estimated at around £2.3 billion per annum (NHS Overview 2021, Healey 2008). In Yorkshire Ambulance Service NHS Trust (YAS), falls make up 8% of the total 999 call volume, with over 50,000 calls receiving an on scene response annually. There were 223,000 emergency admissions for falls in people aged 65 in England in 2020/21, with an estimated increase in volume of ED attendance emergency admissions for falls of 13% over the period 2010 to 2020 (Hollinghurst 2022, Fingertips PHE).

Due to the high level of morbidity after a fall, there has been significant investment in research and falls prevention strategies delivered from a range of healthcare settings (Scottish Government 2014, Logan 2010, Honaker 2021, Montero-Odasso 2022, NICE 2013, Scott 2020). Guidelines and research focus on understanding causes of falls and risk-assessment for prevention of future falls, but there is limited evidence related to optimal management of a patient once they have fallen. Existing guidance on falls management focuses on the management of inpatient falls rather than on the majority of falls that occur outside the hospital setting (Montero-Odasso 2021, NICE 2017, NPSA 2011).

Many older people who fall cannot get up off the floor without help but are likely to be triaged as a low priority call (Category 3 or Category 4) in the absence of any apparent life-threatening signs or symptoms. An ambulance response may take time to arrive due to other higher priority calls, with the result that the patients may be on the floor for extended periods of time, experiencing a long lie. People who are unable to get up off the floor after a fall for over an hour may suffer a number of complications, in part due to delayed medical treatment. Complications of a long lie include potential association between long lies and rhabdomyolysis, hypothermia (primary and secondary), pneumonia, pressure injuries, dehydration, muscle and tissue damage, higher risk of admission to hospital and adverse psychological effects as well as subsequent move into long term care. (Blackburn 2022, Kubitza 2022, Fleming 2008, Tinetti 1993, Wongrakpanich 2018, Ryynanen 1992).

Data from YAS January-June 2023 identified 39% of patients from 999 calls triaged with a complaint of falls were on the floor at the time of call and/or crew arrival, 35% of whom had a documented long lie (approximately 8,000 long lies per annum in Yorkshire region). Previous studies have suggested that long lies (typically defined as >1 hour spent on the floor) occur in around 13-30% of cases (Simpson 2014, NHS Overview 2021, Fleming 2008). These long lies have long been a subject of concern but increasing pressure on ambulance services and longer ambulance response times means that patients are being left for increasingly long periods of time, potentially leading to significantly worsened health outcomes. Mean ambulance response times for category 3 and 4 calls have increased from 64 minutes and 90 minutes respectively in 2017/18 to 107 minutes and 139 minutes respectively in Q1 2023/24 (NHS England AQI). Community-based falls response services have recently been implemented to be dispatched to these ambulance calls due to concerns about harm associated with potential delayed response times. (NHS England 2022)

1.2 Current approach

Current ambulance call handler advice for patients who have fallen is to give no or limited oral fluids until assessment, due to the potential risk of fractured neck of femur and need for subsequent surgery. However, this can lead to significant consequences for patients who are being left for extended time periods without water, including dehydration and resultant acute kidney injury (AKI). It is likely that this advice is inappropriate for the majority of patients who will not require surgery after a fall. Although some organisations are now recommending sips of water, the advice provided is inconsistent across different areas of the UK (NFPGC 2020, NHS Inform 2023, NI Direct 2023). Current guidance for falls management emphasises the importance of avoiding hospital admission where possible, but the relationship between length of lie and increased risk of hospital admission is not yet known (AACE 2020).

Despite the recognised impact of falls on patient experience and health and social care resource use, and significant research into falls prevention (e.g. NICE 2013, Charlton 2017, Gunn 2018, Logan 2010, Scott 2020, Snooks 2017) there is limited evidence about what happens to patients who fall, particularly those who have a long lie after a fall. Nationally and internationally, the extensive falls literature and guidance focuses almost solely on falls prevention, with post-fall management plans focussing on identifying cause of fall for future risk (Vance 2012, Montero-Odasso 2022, Montero-Odasso 2021, WHO 2008). NICE recommendations for preventing falls in older people lack any specific evidence regarding long lies, despite recommending that advice for avoiding long lies should be a priority. (NICE 2013, NICE 2019) Similarly, the NHS England guidance document that recommends community-based falls response teams be dispatched to ambulances due to concerns about harm from long lies references only the 2008 Fleming study (40 patients with a long lie, mean age 94) (NHS England 2022).

Although we know that long lies are increasing in incidence, we do not understand which patients have a long lie, the health and economic impact of these long lies, which patients experience higher morbidity from the long lie or whether anything can be done to mitigate their impact. The evidence base behind any existing guidance on management of long lies is weak.

1.3 Published evidence

A systematic review by Blackburn et al aimed to explore the impact of experiencing a long lie fall on physical, and clinical outcomes in older people requiring an ambulance (Blackburn 2022). They identified that this impact remains poorly understood, with a particular lack of evidence of the psychological and long-term impact of long lies. They identified only two cohort studies that explored the long term outcomes of long lies (Fleming 2008, Scott 2020). Fleming et al (2008) reported a small observational study of 110 patients (90 female, 20 male) from the Cambridge City over-75s cohort, who were aged over 90 at the time of the study (mean age 94). They identified that patients experiencing a long lie (n=40) were more likely to suffer subsequent serious injury, hospital admission or move into long term care. Scott et al (2020) identified that patients who contacted the ambulance service after a fall were more likely to re-contact the service within 6 months if their original fall had involved a long lie.

Kubitza et al (2022) undertook a scoping review to identify therapy options for people affected by a long lie after a fall and noted the paucity of research on the treatment of patients who experience long lies. Existing evidence about problems following a long lie is old, with the Kubitza et al review referencing papers from 1981 and 1983. There is some evidence that inability to get up after a fall is associated with increased mortality but limited evidence to show the link between long lies and outcomes. Cannon et al (2016) found no statistically significant evidence of mortality in patients who had waited longer for an ambulance but the study was underpowered with only 38 deaths amongst 500 patients. Bloch et al (2012) included 3 studies in a non peer-reviewed systematic review (from 1981,1993 and 2009) and concluded that long lie increased risk of mortality by 1.75. However, confidence intervals were wide (1.15-2.67) and the definitions of long lie varied significantly (Bloch 2009, Wild 1981, Tinetti 1993).

Data indicating whether increased risk of mortality or adverse events is a consequence of the lie itself, or the mechanisms that resulted in the lie is sparse. Morbidity may be due to the fracture itself, with an estimated 10% of falls resulting in fracture and 5% resulting in serious soft tissue injury or head trauma (Berry 2008) Morbidity is also significant due to frailty or psychological factors. The psychological impact of falling is significant and the fear of falling has been demonstrated to lead to reduced physical activity amongst at-risk patient groups, leading to further increased morbidity (Schoene 2019, Tischler 2005). The fear of falling is higher in individuals who have already fallen, particularly those with previous injurious falls (Chippendale 2018), which may be exacerbated in those who have experienced a long lie. Fear of falling, particularly fear of falling outdoors, is associated with feelings of embarrassment and anxiety about future falling (Nyman 2013) with suggestions that the fear is due to fear of being unable to get up more than the fall itself (Cox 2016).

No studies have been identified that specifically explore psychological consequences of long lies, yet complications associated with long lies are likely to increase the psychological fear of falling, particularly when dignity is compromised. Swancutt et al 2020 undertook interviews and focus groups with 16 older people and their spouses, and 12 healthcare professionals to understand their knowledge, skills and attitude about getting up from the floor after a

fall. Although they did not report older people having a long lie, therapists identified that a long lie could induce significant physical and psychological damage, with fear following a previous fall leading to unwillingness to learn how to get up from the floor.

The lack of evidence around the consequences of long lies is currently limiting the potential to produce evidence-based guidance in this area. This mixed methods research study will address this gap in evidence.

1.4 Plain English Summary

When a person is unable to get up off the floor for a prolonged period of time after a fall, this is referred to as a 'long lie'. Around 1 in 3 adults over 65 have at least one fall a year and around one in 5 of these will be a long lie (over 1 hour). People who have a long lie may suffer a number of complications, including dehydration, pressure injuries, muscle and tissue damage and psychological harm. Longer ambulance response times due to growing pressure on ambulance services means that people are being left on the floor for increasing periods of time. The problem of long lies may therefore be leading to worse health outcomes for an increasing number of people. Whilst there has been a lot of research to understand how to prevent people falling, there is currently little information about how to manage people once they have fallen. Existing advice given to patients who have fallen assumes that an ambulance will arrive quickly. It is also based around concerns that the patient may have a hip fracture and need surgery. However, most people who fall do not have a fractured hip, and current advice that people should not be moved or should restrict fluids may be more dangerous for people who have a long lie.

We wish to understand more about what happens when people have a long lie and how people can be helped whilst waiting for an ambulance. We will work with patients and the public as well as relevant health and social care organisations. We will do this using 7 different research activities:

1. We will analyse an anonymised dataset of linked ambulance, emergency department and hospital patient records to understand which patients have a long lie and what happens to them after they have fallen. We will look at what health and social care services patients used during the 12 months after their fall and whether this is different for people who had a long lie. We will also use this data to understand the length of lie where the risk of long-term damage is increased. This will help ambulance services when deciding how to prioritise calls in future.
2. We will apply standard NHS and social care costs to the linked dataset to estimate the cost of care for people following their fall. We will compare costs of people who have a short lie with those who have a longer lie.
3. We will look in detail at hospital notes for a subset of 200 patients. This will help us understand exactly how the long lie affected their health and care required after their fall (e.g. whether longer hospital stays are due to kidney injury).
4. We will understand how health and social care organisations currently manage patients after a fall to reduce the harm from a long lie. We will do this using a telephone survey of ambulance services and a survey of residential or care home staff.
5. We will speak to people who advise patients (ambulance clinicians, hospital staff, social and residential home staff) when they are awaiting help to understand what advice they currently give people when they have fallen, and what they feel could be improved.
6. We will speak to people who have had a long lie and their relatives or carers to understand the impact that long lies have had on their lives.
7. We will discuss the findings from this research in a national workshop with key people from the ambulance service and social care organisations. We will use this workshop to help develop clear guidance for managing people who have fallen and are awaiting assessment.

2 STUDY RATIONALE

The specific service-led need for this research has arisen due to a lack of consistent advice or evidence over management of long lies, which has been exacerbated over recent months by the increase in ambulance response times.

This research will create new knowledge about what happens to patients after they have a long lie, how outcomes after a long lie may differ (or not) than after a fall without a long lie, and aims to create a definition of a 'harmful long lie'.This will be key to supporting future policy around falls management and prevention. By understanding how service use differs for patients with a long lie versus those without, we can help to understand whether ambulance services need to change the triage priority given to people who have fallen, or whether there are particular subgroups of patients who have fallen who should receive an escalation of care. Depending on the findings, this may lead to a review of ambulance triage and dispatch systems being made more sensitive to factors associated with harm from long lies (i.e. ambulance response times changed for certain subgroups of patients). The findings will also enable more consistent implementation of falls response services, by enabling services to understand which patients they need to prioritise.

3 THEORETICAL FRAMEWORK

The overall design is an observational mixed methods study, following a parallel design, with data from six inter-related work packages being integrated prior to co-development of guidance with key stakeholders (WP7) (O'Cathain 2010). The research addresses a recognised research gap and is problem-driven rather than theory-driven, arising from a long-standing service-led need for information about management of patients with long-lie that has been exacerbated by contextual factors such as increasing ambulance service pressures and resulting ambulance delays.

We also draw on partnership approaches to co-production of research, involving a diverse group of stakeholders to understand different perspectives of the problems associated with long lies at each stage of the research process. We then aim to develop a shared understanding of the potential solutions, using workshops that are designed to give all stakeholders a voice and sense of ownership (O'Cathain 2019a, Grindell 2022).The research will draw on theoretical and evidence approaches to designing complex interventions when developing the final outputs (O'Cathain 2019b. Sekhorn 2017). Inclusion of PPI and patient and carer voices within the study are key as consideration of individual preferences in fall prevention recommendations made to patients are lacking and patient and caregiver perspectives not consistently incorporated in clinical guidelines. (Hameen-Antilla 2016, Montero-Odasso 2021)

The research aims to increase understanding of the care trajectory of patients and current management of patients who have a long lie and specifically to identify the mechanisms for impact of a long lie. By understanding more about the care trajectory we can assess the health and social care burden of long lies, particularly the impact on patients and carers and we can assess suitability of current guidance. By identifying the mechanisms for impact, we can understand more about the importance of intercepting long lies. Our initial programme theory assumes that long lies are harmful, and that length of lie will have an impact on the degree of harm. We will refine this theory throughout the research project. Details of sampling, data collection, data analysis, description of patients/carers as research participants and description of PPI involvement are described separately for each work package.

4 RESEARCH QUESTION/AIM(S)

Research Question

What is the scale, impact and care trajectory for patients who have a long lie after a fall and what interventions might mitigate the impact of a long lie?

Aim**:** To understand the characteristics of patients who have a long lie, their care trajectory and the health, psychological and economic impact of the long lie, as well as understand potential interventions to mitigate the impact of a long lie.

4.1 Objectives

- To characterise the frequency and duration of long lies in ambulance patients using data from one UK region held within the CUREd+ routine linked dataset;
- To understand the care trajectory, health outcomes, and health resource use of patients after a long lie using the CUREd+ linked dataset;
- To understand the mechanisms by which a long lie impacts care trajectories using hospital notes review for a subset of 200 patients identified from ambulance service data;

- To identify interventions used to mitigate the impact of long lies before arrival at hospital using a survey of ambulance services and social care providers;
- To understand how key stakeholders mitigate long lies using staff interviews;
- To understand the impact of long lies on patient and carers using interviews with patient and carers;
- To refine the definition of a long lie that is likely to cause harm and identify actions to reduce their consequences for patients

4.2 Outcomes

- Describe the frequency and duration of lies in ambulance patients and refine the definition of a harmful lie.
- Understand the care trajectory of patients who have fallen with and without a long lie, their health resource use and care outcomes within 12 months of their fall and long lie.
- Improve understanding of morbidity associated with the injury resulting from the fall, and that relating to the long lie.
- Understand how key stakeholders currently manage and mitigate for long lies and where there is variation in practice/understanding that may be harmful
- Understand the patient and carer perspective of long lies, the psychological impact and areas where advice about how to manage a long lie are required

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS, SAMPLE and RECRUITMENT

We propose to undertake a mixed methods study incorporating 7 linked work packages over 27 months.

WP1: Understand the characteristics and care trajectory of ambulance service patients who have been unable to get up after a fall.

WP1 - Data collection

Data from a linked dataset (CUREd+) will be used to describe the characteristics of ambulance service patients who have been unable to get up after a fall and quantify patients' care trajectory and resource use. The CUREd+ dataset incorporates data including 999 ambulance calls, NHS 111 calls, ED, hospital admissions and basic mental health services data from 2017-2023 with additional demographic data (i.e. postcode), medications and prescriptions data, death registry data and improved data from mental health services and ambulance electronic patient record data (Feb 2019 onwards) which will provide a richer understanding of health and social care use.

All YAS ambulance calls for patients who have been unable to get up following a fall over a period of 24 months will be identified (estimated at a minimum of 115,000 cases, with approximately 16,000 having a documented long lie) and use corresponding CUREd+ data from April 2019-March 2023 Twenty-four months' worth of index cases will be provided, enabling a minimum of 12 months' follow up for all cases. This data will be used to understand the incidence of long lies after a fall, where and when they happen and the estimated length of time waiting for an ambulance, using standardised ambulance dataset parameters including time of injury/illness. When time of injury/illness has been completed, this will be considered as the lie start time, acknowledging that self-report may not be accurate. The fields for 'time of call/ incident time' to 'crew arrival at scene' may also be used where time of injury/illness is not available. The condition of the patient upon initial ambulance clinician assessment will be assessed (e.g. estimate hypothermia rates, suspected fracture, frailty, weight etc.).

The resulting dataset will be used to quantify patients' care trajectory and resource use. Outcomes will include: mortality, ambulance service use, ED resource use (tests, re-attendance), hospital resource use (initial length of stay, reattendance), outpatient use (e.g. tissue viability services), discharge location (including escalation of care needs) and any subsequent ambulance re-contact or hospital reattendance. Data on service factors such as ED wait and hospital occupancy will be collected as these may impact on care. This data will enable an understanding of any differences in care trajectories between patients who have had a long lie, and those whose fall did not result in a long lie.

The relationship between length of lie and key outcome variables will be explored using descriptive and visualisation methods. The impact of the length of lie on key outcomes via a series of regression models will be explored (logistic,

Poisson and other), using different definitions of long lie (including the 1 hour NICE definition) and adjusting for appropriate demographic covariates. This will quantify the impact of a long lie on patient health outcomes, and indicate whether 1 hour is the most appropriate threshold to consider a long lie in terms of health outcomes. The analysis will explore the impact of environmental, geographical and seasonal variables on the length of lie to provide an indication of the factors driving the likelihood of a long lie and enable understanding of targets for future interventions that may influence key outcomes.

Due to the period of analysis including the Covid-19 pandemic, analyses will account for Covid-19 in two ways. Firstly, a categorical covariate will indicate whether a covid lockdown was in place nationally at the time of the long lie. Secondly, a continuous variable consisting of the number of Covid hospital beds will indicate the severity of the pandemic at the time of the long lie. Although it is acknowledged that the impacts of covid are likely to be highly complex, this should not differentially affect those who do and do not have a long lie at a given date (although may affect the balance of those groups). To explore this a sensitivity analysis will be performed including the month of the long lie as a covariate. This will allow us to gain an understanding of any change in the effect of a long lie over time, which will indicate any differences associated with covid lockdowns or pandemic severity.

A full Statistical Analysis plan will be developed and submitted to the Study Oversight Group for approval.

WP1 - Analyses

Length of lie is of interest as both an outcome (under what circumstances is a long lie more likely) and as a predictor of health outcomes and future resource use.

WP1.1 We will provide a descriptive analysis of length of lie, stratified by patient demographics and the characteristics of calls and resulting attendances, including features which have implications for the care trajectory of the patient (e.g. time of day of the call/attendance, seasonality) to examine seasonal pressures. We will explore the relationship between length of lie and key outcome variables using descriptive and visualisation methods.

WP1.2 We will examine the impact of the length of lie on key outcomes via a series of regression models. Key outcomes will include ambulance conveyance (vs see and treat); number of investigations at ED; acute admission to hospital; number of treatments received; discharge to care home or ‘step down’ or intermediate care; 12-month mortality; number of and time to first readmission within 12 months; number of and time to first unplanned ED attendance within 12 months; number of and time to first NHS 111 call within 12 months. These will consist of logistic, Poisson, and other regression models as appropriate. Key outcomes will be discussed with both the project management group and the PPI group to ensure all potential relevant outcomes have been included.

These analyses will include length of lie as a continuous variable, as a dichotomous variable based on the NICE 1-hour definition of a long lie in logistic regression, and dichotomised based on other possible explanatory thresholds identified in WP1.1. This will quantify the impact of a long lie on patient health outcomes, and indicate whether 1 hour is the most appropriate threshold to consider a long lie in terms of health outcomes.

These analyses will be carried out as adjusted and unadjusted analyses, including appropriate demographic covariates such as age, sex, ethnicity, deprivation indices, care home residence, indications of frailty and/or comorbidities, time of day, season and any key clinical observations recorded by ambulance crew.

Analysis will provide an estimate of association between length of time lying after a fall and outcomes. However, the assessment of clinical risk undertaken initially will partly determine the length of time left lying after a fall (i.e. ambulance response times may be shorter where a patient has additional risk factors). This means that a confound in terms of fall severity/clinical risk is possible. Since the data is not currently available to assess what analyses may be possible, we planned a cautious associative analysis in the first instance. This will remain the primary analysis; an assessment of clinical risk will be included as a covariate in the analyses where available.

The possibility of additional causal inference methods will be assessed on receipt of the data and if feasible will be undertaken as a supplementary analysis. This may involve the use of matching (although if systematic differences in

clinical severity exist between groups this may reduce sample size dramatically). Alternatively approaches such as the use of instrumental variables may be used (e.g., distance of event from nearest ED may be an appropriate instrument).

WP1.3 Will explore the impact of environmental, geographical and seasonal variables on the length of lie. This will be undertaken with length of lie as a continuous variable in linear regression and as a dichotomised variable based on results from WP1.2. This will provide an indication of the factors driving the likelihood of a long lie. Results from this analysis in context with those from WP1.2 will facilitate an understanding of targets for future intervention in order to address key outcomes.

PPI will discuss definitions of a long lie at the start of the WP to enable their views to feed into the analysis and the variables used, as there may be PPI perspectives that are relevant that have not been documented in the literature. Their views on the parameters of what is a long lie and how this may vary in different contexts e.g. a fall in the home vs a fall outside. This may help inform any scenario analysis. Results will then be fed back to PPI, their views on the findings discussed and different definitions validated. Proposed definitions will then be fed into the workshops (WP7).

Early analyses from WP1 will be used to feed into WPs 3-6.

WP2 Understand the resource use of ambulance service patients after their fall

WP2 - Data collection

Urgent and Emergency Care service access events in the 12 months following an ambulance call after a fall will be assigned a unit cost based on Healthcare Resource Group (HRG) reference costs. These events include ambulance journeys, ED attendances, acute, non-elective inpatient admissions and subsequent hospital stays and outpatient events (where available). Where possible, this will be calculated using the NHS National Schedule of Costs (NHS England 2021/22 cost data) for the appropriate year. In the event that HRG codes are unavailable in CUREd+, estimated costs will be calculated based on average costs by specialty, attendance type, or ambulance service level. Where costs for that year may not be available, costs for the most recent available year will be used and adjusted using the NHS Cost Inflation Index (Jones 2023). Costs will be aggregated on a monthly basis to produce a total cost per patient per month for the 12 months following a fall.

In the event additional fall events occur within the 12-month fall follow-up period for a given patient, the additional fall will be considered a new 'index' event. The initial 12-month follow-up period related to the first fall will be censored and costs subsequent to the second fall will be modelled as occurring in the new 12-month follow-up. This will be adjusted for in the regression models. This is likely to result in wider confidence intervals for later months in the follow-up period. Confidence intervals will also be impacted for the loss of patients to follow-up, through either missing data, migration, or death during the follow-up period.

WP2 - Analysis

Aggregated, monthly cost data per patient will be modelled using two-part 'hurdle' Gamma regression models, with length of lie as a primary independent variable. Models will explore the influence of length of lie as a continuous and dichotomised variable as described in WP1. The use of monthly cost data as the primary outcome supports estimates of costs associated with length of lie for each month following the index fall event, facilitating an understanding of whether cost differences increase, decrease, or remain stable over the 12 month follow-up period.

A series of models will be developed to explore the influence of length of lie on resource use. Unadjusted models with only length of lie and month number as predictor variables will give a crude estimate of the influence of length of lie. Patient ID will be included as a random effect to account for individual level clustering.

Second, covariate-only models will establish a 'baseline' against which to assess the adjusted influence of length of lie on cost outcomes. These will include demographic data including age, sex, deprivation decile and ethnicity; clinical characteristics including comorbidities; and features of the incidence including time of year, time of day and distance to nearest ED. The precise list of covariates will depend on data quality and learning from WP1.

Finally, fully adjusted models will include length of lie as a main predictor in conjunction with covariates listed above. This will give adjusted estimates of the effect of length of lie. Likelihood ratio tests will compare the adjusted models with the baseline models to determine the impact of including length of lie as a predictor over and above the covariates. The above models will be developed for all healthcare related costs, and separately for costs related to ED attendances, acute admissions, ambulance calls, NHS 111 calls and outpatient costs.

The primary analysis will consider 'Month 1' to be the calendar month in which the index fall occurs. This will therefore consider month 1 to be the same for falls occurring on the first or last day of the month. This may result in issues around the accuracy of predictions of monthly costs (although distribution is expected to be the same for long and short length of lie). Sensitivity analysis will examine a different date alignment , whereby 'Month 1' will be considered the same calendar month for a fall occurring in the first half of a month, and the subsequent calendar month for a fall occurring in the second half of a month.

WP3: Understanding the mechanisms for impact of long lie using patient notes review

WP1 will provide an overview of the patient journey for a cohort of patients who have had called 999 after a fall. Within WP3 a more detailed and nuanced description of the patient journey will be described by undertaking detailed notes review to understand the post-fall management and treatment pathway, and the aspects of their care that could be attributed to the long lie rather than the injuries resulting directly from the fall.

A detailed hospital notes review for a subset of 200 patients (50 patients at each of the four hospitals with an Emergency Department within the Yorkshire and Humber region) to understand which complications from the long lie lead to changes in patient care trajectory will be undertaken (i.e the mechanisms for impact of long lie). Ambulance records will be used to identify a sample of 50 patients who had a long lie (as defined by CUREd+ WP1 analysis) who were transported to each of four participating hospitals within the YAS area. We will invite expressions of interest from all eligible hospitals (i.e those with an Emergency Department) within the Yorkshire and Humber region and select hospitals with the highest incidence of long lie, ensuring a wide geographical spread. We will sample consecutively until we have a mixture of short and long lies (as defined by WP1).

WP3 - Data collection

A research paramedic (member of the patient's usual care team) from YAS will identify patients who have fallen, been unable to get up off the floor, and are conveyed to one of the four study hospitals, on at least a bi-weekly basis. The research paramedic will then screen for and exclude patients who have either registered with the NHS Data Opt-out or who have already been approached to participate in the study. If the patient matches the screening criteria for the study, they will be allocated a unique study ID, which will be sent along with demographic and incident details relating to the fall to the research team at the admitting hospital via secure NHS email using a study-specific inbox. We will continue to sample and pass on details of patients until we obtain data for 50 patients at each hospital.

Data will be extracted for all data items during the 90 days following the fall. A full health and social care record review of each patient will be undertaken by the respective research team members who routinely have access to patients' ambulance, ED, hospital and community health and social records. This notes review will identify evidence of injury as a consequence of the fall e.g. fractures and surgery, and injuries associated with the lie time (e.g. acute kidney injury, pressure injury), and provide additional detailed information about any change in patient care needs following hospital admission (e.g.outpatient appointments, discharge to an escalated care facility (from home to nursing home or 'step down care'), social care referrals or packages). The period of 90 days has been chosen as a period of time to capture immediate effects of the fall/long lie, including change in residential status. Whilst this may miss some of the later changes in residential status (e.g. due to step-down care), it was felt to be feasible for research nurses and to ensure that we capture the date relating specifically to the long lie.

Demographic data, including frailty score at the time of the fall, will be collected to understand its potential influence on the patient's care trajectory, as this has been shown to be an important predictor of outcome. This WP will understanding, for example, whether the current advice to avoid food or drink in this population is appropriate and to understand whether there are any important variables that are not available from the CUREd+ dataset.

In all cases, a member of the patient's usual care team who is supporting the research at each site will submit electronic case report forms for ambulance, hospital and community phases of the patient journey, which may include multiple instances of contact with services from the initial fall. These online forms will only be accessible by NHS staff and all access and submissions will be logged. Data will be sent to and stored securely by YAS. A similar process will be followed for electronic consent forms. Paper forms which are subsequently scanned in, will be sent by secure NHS email from the recruiting hospital to YAS.

WP3 - Patient consent process

On receiving details about a patient from YAS, a member of the patient's usual care team atthe hospital site will check the patient's details and confirm eligibility for the study within two weeks of their initial hospital attendance and request permission to access their notes from initial ambulance contact up until 90 days after their fall. They will also assess the patient's mental capacity. If the patient has mental capacity, a member of the patient's usual care team in the hospital site will speak to the patient and provide verbal and written information about the study. The patient will be given time to consider whether they wish to take part. If a patient does wish to take part, a member of the patient's usual care team who is supporting the research in the hospital site will seek informed consent (written or electronic) from patients during their initial hospital attendance and request permission to access their notes relating to the time from initial ambulance contact to 90 days after their fall. The patient's usual care team in the hospital site will have access to hospital translators for patients who require translators to ensure we do not exclude patients who do not have English as a first language, including if the participant requires additional assistance, such as a British Sign Language interpreter. The information sheet and consent form will be made in different formats for accessibility. This will include large text and easy to read formats provided upon request.

If a patient does not have capacity, but the lack of capacity is likely to be temporary, a member of the patient's usual care team in the hospital site will periodically visit the patient to determine when mental capacity has returned. Upon return of mental capacity, procedures for patients with mental capacity will be followed.

If a patient does not have capacity, a member of the usual care team at the hospital site will determine whether there is a family member and/or legal representative who can provide consent on the patient's behalf. If there is no family member or legal representative, then a nominated/ professional consultee in the patient's medical care team will be asked to approve the patient's participation in the study.

The study team will seek Confidentiality Advisory Group (CAG) approval to access patient medical records where we are unable to obtain patient consent or nominated / professional consultee consent when the patient lacks capacity, does not have a representative who can be approached to consent on their behalf, is seriously ill and unlikely to be able to consent during the timescale required or who dies during the care episode.

In the event that a patient has been discharged prior to a clinical member of the research team in the hospital site being able to speak to them in hospital, a member of the patient's usual care team at the hospital site will make up to two attempts to contact the patient by telephone. They will then send the participant information sheet and consent form by post or electronically depending on patient preference.

If a patient does not wish to take part (or where the family member/legal representative/nominated consultee has decided the patient should not take part) no data will be collected about the patient but the patient details will be sent back to YAS and logged so that the patient does not appear again during future screening.

Electronic consent forms will be completed where possible. Where written consent is obtained, the form will be scanned and stored securely at the hospital site.

Patients will be given the opportunity to withdraw from the study any time up to 90 days after their initial fall. Patients who withdraw will be asked whether they a) wish to withdraw from further participation but will allow data collected up until the date of withdrawal to be used or b) wish to withdraw from future data collection and withdraw all data collected to date. After 90 days the data will be aggregated into a wider dataset and will be unable to be removed.

WP3 - Analysis

This is an exploratory work package aiming to understand the mechanisms by which a long lie impacts upon the care trajectory and a broader understanding of the morbidity associated with the long lie itself, rather than from injury relating to the fall. A detailed description of healthcare use data, social care information and details of tests or observations that may indicate injury or harm from the long lie will be created (e.g. hydration status, derangement of physiological observations). Baseline co-morbidities and initial fall risk will be considered to identify changes in patient care needs and understand whether changes can be attributed to pre-existing conditions.

Outcomes from WP3 will be the creation of a descriptive model of different care trajectories, highlighting which aspects of the different patient care trajectories may influence outcomes. We will try to develop typologies of patient trajectory and example summary cases. Where possible we will explore any areas that are identified as potential points where intervention is required within later interviews in WP5 and WP6.

Findings from WP1–3 will not include patients who do not call an ambulance, but have a long lie. These patients are likely to have lower morbidity than those for whom an ambulance was called. We will estimate the significance of this underestimation within WP4–6.

WP4 – Identify how health and social care organisations mitigate for long lies

WP4 - Data collection

WP4a) Structured survey of all UK NHS 999 Emergency Operations Centre ambulance service clinical leads will be undertaken (n=13) to understand what interventions are currently in place to reduce the impact of a long lie after a fall, local guidance and any local initiatives for crews to understand how to manage long lies.

WP4b) An initial survey of residential and nursing homes managers in the Yorkshire area (using the 18+ Wakefield Research Hub networked research-active residential homes) will be undertaken to understand any initiatives used within care facilities to manage patients whilst awaiting ambulance services.

In WP4a and b) potential participants will be contacted by direct email, with up to two reminders for non-response. Participants will be sent the consent and information sheet within the initial invite and asked to either return the signed consent form via email or clarify consent verbally at the start of the interview. Consent will be confirmed verbally for all participants prior to the survey taking place. The information sheet and consent form will be made available in different formats for accessibility. This will include large text and easy to read formats provided upon request. If a participant requires additional assistance, such as British Sign Language because they are deaf, we can arrange for an interpreter to be present with the participant. The surveys will be conducted by a researcher from the University of Sheffield and take place in different formats (i.e. online, telephone); they will be recorded either using in-built recording applications (e.g. Google Meet) or using an encrypted digital recording device to enable detailed notes to be made. Recordings will be deleted once the notes are complete.

Survey responses for WP4a and WP4b will be stored in Excel or Word and the data will be used to develop the survey for WP4c.

WP4c) Survey results will be used to inform and update the draft survey (submitted as part of the regulatory approvals) to produce a simple online Qualtrics national survey for wider participation of residential and nursing homes and other providers of social care. Electronic consent will be obtained before the start of the survey. We will develop the survey in collaboration with the NIHR CRN managed ENRICH network (NIHR ENRICH) which currently has around 1000 care homes in England signed up to undertake research. ENRICH will share the survey via their networks.

Potential participants working in sheltered housing and social care providers will be contacted via social media and via Local Authority Link networks (LARks). Local Clinical Research Networks will also be asked to identify any similar research hub models that include residential and nursing homes and other social care providers. The National Care Forum will support this work package by disseminating the survey to not-for-profit care providers.

Up to two reminders will be sent and we will leave the survey open for up to 2 months. Participants will be asked to confirm that they have read the information sheet and provide consent prior to undertaking the online survey.

All participants will be paid at an hourly rate of £25 and be offered a CPD certificate. Online survey participants will be offered the chance to win one of 4 x £50 Love2Shop vouchers.

WP4 - data analysis

A descriptive analysis of interventions from ambulance services and care providers including current practice after a fall, individual ambulance service/care home policies, interventions used, training and barriers to change will be created. Data on routinely collected outcomes from each ambulance service to understand context to interventions, including numbers of calls to falls, response times, length of time at scene and conveyance rates will be collated.

WP5 – Understand how key stakeholders mitigate and manage long lies. (Months 9-16)

WP5 - Data collection

To understand the perspectives of key stakeholders who manage long lies, and understand how they currently mitigate long lies, semi-structured telephone/online interviews will be conducted with 22-26 key stakeholders across 3 ambulance service areas. Around 8 stakeholders from ambulance service, hospitals and care homes within each of the ambulance service areas will be interviewed.

The National Ambulance Research Group (NARSG) will be approached to identify sites who express an interest in participating. Hospitals within the participating ambulance regions will be invited to participate by the corresponding Clinical Research Network, and hospital sites will be invited to identify staff that are involved throughout the process of care such as ED, frailty and acute medicine departments (dependent upon the findings from WP1). Residential and care home staff via the ENRICH Network, LARks and National Care Forum will be recruited (as with WP4c).

Research leads at the ambulance services and research teams at the hospitals will send invitations out via mailing lists and by advertising within their bulletins. They will send up to two reminder emails and bulletin reminders. We will aim to include different ambulance clinician roles, including frontline clinicians and 999 call handlers due to concerns expressed in providing what they perceive as inadequate advice or inappropriate triage outcomes for people who have fallen (Coster 2021). Participants will be asked to contact the research team directly so that the organisations do not know who has agreed to participate.

Participants will be sent the consent and information sheet within the initial invite and asked to either return the signed consent form via email or clarify consent verbally at the start of the interview. Consent will be confirmed verbally for all participants prior to the interview taking place. The consent process and interview are expected to take up to one hour. Each participant will receive a £25 Love2shop e-voucher via email and be offered a CPD certificate. There will be no further contact with the participant unless they would like to receive a copy of the results of the study at the end.

Semi-structured interviews will aim to understand the impact of long lies on participant's work perceptions, workload, experiences and patient care trajectories. Understanding of management of patients who have had a long lie, how this impacts on staff and strategies used to avoid harm whilst awaiting ambulance attendance, ED admission or during hospital stay will be explored. Draft topic guides will be developed in consultation with the stakeholder group, and guided by the early findings from WP4a and WP4b. We will speak to a purposive sample of staff, sampling primarily for role but also aiming to cover a diverse population in terms of rural/urban mix, deprivation and ethnicity.

WP5 - Data analysis

All interviews will be digitally recorded and transcribed verbatim, with detailed notes and post-interview reflexive summaries typed up straight after interviews. Data will be managed using NVivo (™) qualitative software. The aim of WP5 is to understand how individuals understand management of long lies, rather than motivations or experience and analysis will be more descriptive than interpretative. We will undertake analysis using the first stages of Framework approach (Gale, 2013).

WP6 – Explore the impact of long lies on patients and carers. (Months 9-16)

Semi-structured interviews with 18-24 patients who have fallen and identified as having a long lie (via a range of definitions) and/ or carers will be undertaken, sampling purposively for range of patient age, sex, ethnicity and location at time of fall (e.g. home, public place etc). Carers may participate without the patient, especially where patients lack the capacity to consent or feel the interview process would be emotionally demanding. Participants will undertake two short interviews, the first shortly after their fall and the second within 3-6 months. This will enable researchers to collect information as soon as possible following the fall and of its impact later in the participants life, it will also reduce the duration of the interviews for participants. Topic guides will be developed from existing literature and explore the impact of advice received, experiences of a long lie, ambulance waits, the impact on patient dignity, confidence, social functioning of the initial fall and the consequences of any subsequent changes in care needs. The PPI group will be used to help with recruitment and advise on developing sensitive topic guides.

Participants will be offered the option of face-to-face, online or telephone interviews, recognising that patients may have sensory difficulties (ASHA 2021). Previous studies have reported difficulties in recruiting patients for qualitative interview, particularly from minoritised groups (Perez 2022, Archibald 2015, Renert 2013) . We aim to mitigate for these difficulties by using a number of different recruitment approaches and ensuring that we have sufficient support from trusted individuals within recruiting organisations to enable us to reach our recruitment targets.

We will recruit patients from different sources. Firstly we will recruit patients from WP3. These patients are known to have had a long lie and will be recruited by the hospital research nurse, who will obtain consent from the patient for the research team to contact them about taking part in an interview. Secondly, we will use existing networks and registries, (such as the Care75+ cohort study group and other Yorkshire older adult research cohorts) or the Patient Experience Network (Patient Experience Network 2023) and via patient groups that the Wakefield Research Hub engagement officers have approached. Recruitment adverts will be sent out via these channels and contact details will be provided (mobile telephone number, landline telephone number and email address) so that people who are interested in taking part in an interview can easily get in touch with the research team for more information. We have worked with our PPI group to develop the recruitment materials and these include an advert/flyer that can be easily shared electronically or given to patients in hospital and a participant information sheet.

We will be mindful of including traditionally minoritised groups to ensure that we reach a diverse group of patients using Wakefield Research Hub Engagement officers whose role is specifically to reach into under-represented communities to enhance involvement in research. We have included costs of translation of information sheets into 3 languages, and costs of translators to undertake bilateral translation for participants who are unable to communicate in English. We will also seek support from the ethnic minority research inclusion (EMRI) network (NIHR EMRI 2023).

We will also use information from the semi-structured interviews in WP5 and WP6 to identify whether there are any aspects of the patient trajectory that have not been considered in WP1 and WP3. In order to maximise recruitment, all research participants in WP5-6 will be offered £25 Love2Shop vouchers as thank you for participating. Healthcare professionals will be offered a CPD certificate as a record of participation.

WP6 - data analysis

All interviews will be digitally recorded and transcribed verbatim, with detailed notes and post-interview reflexive summaries typed up straight after interviews. Data will be managed using NVivo (™) qualitative software. We will use an inductive approach, analysing data using thematic analysis according to the principles of Braun & Clarke (2021). PPI will be involved in the development of themes.

Integration of findings from WPs 1–6 (months 18–24)

We are using multiple methods to understand the scale, impact and care trajectory for patients after a fall. Each work package focuses on different aspects of the research question, from different perspectives. Integration of analysis from each work package will ensure that the whole is more than the sum of its parts and will be key to answering the overall research question, and identifying where gaps in knowledge remain that may need addressing in future. We have allowed additional time to undertake analysis of data and ensure full integration of findings prior to undertaking WP7. Findings from WP1-6 will be triangulated using joint displays to ensure integration of all data sources and improve

overall learning.(O'Cathain 2010, Farmer et al 2006). We will also ensure that learning from literature is identified throughout the research process, updating literature reviews using our pre-defined search terms, supported by MbCHB research attachment students at University of Sheffield (UoS)

The timing of the work packages is such that initial analysis can be undertaken 'blind' from the results of the other work packages. This is particularly important for the inductive analysis in WP6. However, early findings will be shared at project management group meetings and we will seek to ensure that we are covering areas of research that may have been previously overlooked (e.g. if WP1 identified patient groups who have high risk of morbidity we will aim to recruit further patients with this characteristic to help explain findings). From the integration phase we will develop a set of initial findings and potential recommendations for discussion with wider PPI and project advisory groups, prior to exploring these within WP7.

WP7: Make recommendations for service policy to reduce risk to patients (Months 24–27)

We will present our initial findings at workshops with key stakeholders to co-develop guidance for management of long lies that addresses key stages of the patient journey. To ensure all key actors are involved in the development of guidance we will undertake the workshops to ensure we include diverse stakeholders and provide the opportunity for different groups to be heard equally (Grindell 2022). We will hold three parallel workshops with separate groups of key stakeholders who have different roles in the management of long lies:

1) people who are at risk of falling or their carers (including care/residential home staff) to understand how fallers should be managed during the time whilst they are unable to get up.

2) ambulance service (ambulance clinicians plus call handling staff) to understand what advice to give people who have fallen, how to manage patients when helping them off the floor and considering whether conveyance to hospital is required, how to hand over care of conveyed patients to ED.

3) hospital (inpatient service/ED) to understand how to manage people conveyed after a long lie, what tests are required and who may need admission

We will include stakeholders from relevant key organisations within each of the workshops (e.g. AACE, NASMED, RCEM, ICBs, Healthwatch, National Care Forum, NICE and NHS England) as well as clinicians and PPI.

The workshops will present findings to key stakeholders using a modified Nominal Group Technique to obtain stakeholder views on interventions that could reduce the detrimental consequences of long lies after a fall for patients and healthcare systems. When presenting our findings, we will undertake process mapping to ensure that we have understood the 'reality' of each stakeholder's perspective and understand where barriers or problems with implementation will lie. We will present this back to stakeholders to ask them to confirm this 'reality'. Workshops will focus on stakeholder views on the usefulness and feasibility of implementing any interventions, identifying how interventions would work in practice, how interventions would be evaluated and which part of the system has responsibility for the intervention (Coster 2018, Van de Ven 1972).

We will then draw together findings in a joint workshop to present each perspective and ensure that there is a shared understanding of individual guidance with buy-in from each group. This final workshop will include wider stakeholders, including Integrated Care Boards to ensure findings are relevant to falls response planning. The final workshop will produce recommendations that span the different organisation types, and aim to give practical and easily implementable ways to reduce the risk to patients from long lies.

We will aim to co-produce simple guidance for hospitals (ED/inpatient), ambulance services and patients/carers/care professionals who manage people after they have fallen as well as for patients at risk of falling. When the content of the guidance has been agreed, we will co-develop simple infographics for the different sets of stakeholders. Results from workshops will include recommendations for service policy change to reduce the risk to patients from long lies.

6. STUDY SETTING

The study will be carried out in UK NHS Ambulance Trusts, NHS hospital Trusts, UK home care providers (including care homes, nursing homes and community care organisations), and using patient research cohorts.

7. ETHICAL AND REGULATORY COMPLIANCE

University of Sheffield Research Ethics approval has been obtained for WP1, WP2, WP4 and WP5 (UoS 061049). HRA approval has been obtained for WP4 and WP5 (IRAS 350537) including approval for a non-substantial amendment (09/04/2025). **We will obtain NHS Ethics and HRA approval for WP3 and WP6 separately (IRAS 336914).**

CUREd+ data has existing data sharing agreements in place with YAS and UoS and has in place existing approvals as an anonymised linked research database (HRA, CAG and NHS REC in place). We will apply to the Data Research Committee at Data Connect (UoS) who oversee CUREd+ data to obtain approval, ensuring data minimisation is optimed. A project specific data sharing agreement will be generated and data accessed and analysed via UoS secure virtual environment (AWS). We will ensure that patients who have requested their data not be used for research/sharing purposes will have their data removed from the study using the national data opt out system. This will happen prior to transfer of CUREd+ data.

For WP3, the main ethical issues are obtaining informed consent for accessing patient records, or approval from the Confidentiality Advisory Group for those who lack capacity, are seriously ill or die during the care episode. Good Clinical Practice (GCP) trained members of the patient's usual care team in the hospital sites will undertake the consent processes within each of the hospitals involved. People will be given the opportunity to withdraw consent until such a period as their data has been combined into a full dataset.

For WP4-6 the main ethical issue is informed consent for interviews and survey participants. Surveys will include provision of consent, with links to the approved information sheets in the online portal. We will obtain recorded verbal or written consent for semi-structured interviews, and enable participants to withdraw data prior to data analysis.

Data security, storage and retention

Information sharing and data sharing agreements will be put in place between UoS and the participating organisations. Data will be transferred using secure methods (FTP transfer with winzip 7 encryption) or nhs.net to nhs.net email transfer. All essential documentation and study records will be stored by YAS in conformance with the UK legal requirements and access to stored information will be restricted to authorised personnel.

In WP1 and WP2 the CUREd+ data on the specified cohort will be extracted and stored on a University of Sheffield virtual machine. All data is anonymised at the point it is included within the CUREd+ dataset. It will be made available to research staff with a University of Sheffield contract (JL and RP). Analysis will be performed using the statistics package, R. Data for this work package will be archived within 5 years of the study end date.

For WP1, 2, 4, 5 and 6 electronic data will be stored in a secure area of the server with access restricted to staff working on the study at the University of Sheffield. Any paper data forms will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. For WP3 all electronic data will be stored in a secure area of the service with access restricted to research team members. All databases containing identifiable information will be encrypted and password protected.

Data from interviews and structured surveys will be recorded either using in-built recording applications (e.g. Google Meet) or using an encrypted digital recording device to enable detailed notes to be made. Recordings will be deleted once the notes are complete. The study data for WP3 will be retained in accordance with the study sponsor's data retention guidelines of 5 years, with a 'clock start' date of 2 years following closure of study or publication of the final report or journal publication, whichever is longer. After a 7-year period has expired, the remaining study data (anonymised transcripts, analysis, etc.) will be deleted from the secure area of the server at the University of Sheffield, in accordance with University of Sheffield policy.

8. DISSEMINATION POLICY

Dissemination, outputs and expected impact

The project is being undertaken to address a service-led research need to understand how to best manage patients who are unable to get up after a fall. The dissemination strategy therefore needs to target key professional organisations to ensure the findings of the research are used to influence guidance and clinical decision-making and behaviour.

Dissemination of research findings and implementation of research findings into practice is improved when multiple methods are used, particularly when active methods are used (Grol 2003). Dissemination will include active methods (e.g. workshop), infographic dissemination and written publications. The research team is well placed to ensure widespread dissemination to the NHS and social care sector, academic audiences and the wider population, being well connected to a range of professional organisations within these sectors. The project advisory group will also advise on dissemination strategies. The PPI group will connect with the research team to ensure that engagement and dissemination strongly represents the voices and interests of patients at risk of falling/long lie and their carers. Progress and findings will be advertised on the project website (hosted at UoS) and shared by project-specific social media accounts.

Outputs: Co-produced outputs are described in WP7 above. We will write up findings for WP1-3, WP4, WP5 and WP6 as Open Access threaded publications as well as a mixed methods paper of overall findings, incorporating WP7 recommendations. High impact academic journals will include Age & Ageing, BMC Geriatrics, BMJ Open and Annals of Emergency Medicine. We will set up a study website and disseminate via social media accounts to update on study progress and dissemination activities. Findings will be presented at UK & international conferences (e.g. EMS2025, 999EMSResearch Forum, HSRUK).

We will work with key professional organisations (including National Ambulance Service Medical Directors (NASMeD) and other AACE sub-groups, Royal College Emergency Medicine, British Geriatric Society, College of Paramedics, NHS Pathways/AMPDS, National Care Forum) to disseminate summaries of the research findings, particularly recommendations and action plans generated from workshops in WP7 in order to maximise impact on policy. We will work with our PPI group to guide wider dissemination of lay research summaries, and will co-produce a publication with PPI about PPI findings, as well as delivering a PPI co-produced 2-3 minute long narrated animation and PPI co-produced easy read infographic.

Expected impact: Although based on regional / UK data, the findings will have international relevance for falls management in other countries. We expect our research to improve understanding and definitions of a problematic long lie, and inform call triage and dispatch prioritisation recommendations for the most at-risk patients in order to reduce the most harmful long lies. This will be key to supporting future policy around falls management. We will seek to produce optimal care guidance on managing a patient who cannot get up from the floor after a fall (e.g. fluid intake, movement, medications) for ambulance call handlers, ambulance crew members, ED and continuing care clinicians as well as patients and their carers (including care homes). This will include how information is communicated by the ambulance service call handlers and remote clinical advisors to the patient and their carer(s), including residential and care homes.

The production of evidence-based, co-produced guidance across a range of care settings will improve staff experience for those managing patients with a long lie, with consistent advice across different services and higher levels of confidence in advice given. Importantly, this will improve patient and family/carer experience for people who are at risk of falling so they understand what they can do whilst awaiting help. Improved understanding and management of long lies has the potential for significant reduction in long lie-related morbidity and resource use.

Success criteria: The success of the project will be measured against the aims and objectives outlined above and the timelines highlighted in the attached Gantt chart. We will work with the advisory group and PPI panel to ensure there is scrutiny and oversight of our objectives and timelines. We will consider the project successful if we:

- Describe the frequency and duration of lies in ambulance patients and refine the definition of a harmful lie.
- Understand the care trajectory of patients who have fallen with and without a long lie, their health resource use and care outcomes within 12 months of their fall and long lie.

- Improve understanding of morbidity associated with the injury resulting from the fall, and that relating to the long lie.
- Understand how key stakeholders currently manage and mitigate for long lies and where there is variation in practice/understanding that may be harmful
- Understand the patient and carer perspective of long lies, the psychological impact and areas where advice about how to manage a long lie are required
- Engage with and maintain PPI input throughout the project and understand and document the impact of PPI on the research process

Success will primarily be judged by the development of meaningful and accessible recommendations and principles that will help organisations and individuals to understand how long lies can be better managed.

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Version control table

Version and date	Changes made	
Version 1.1 22nd July 2024	Funders logo, funding acknowledgement and statement and version control table added. HSDR programme name correct. Funding and Gantt chart removed.	
Version 1.2 19th November 2024	Added in details about the work packages that are covered by University of Sheffield ethical approval to section 7 and UoS ethics reference number to front page. Added in study participant details about WP4 that were missing in the Study Summary table. P14. Changed time period of data collection from Jan 2020-Dec 2023 to April 2019-March 2023 to accurately reflect the available CUREd+ data. P17 WP3 Added in clarification that the 200 patients are at 4 different sites. P18 WP3 Patient consent process. Added further details about the patient consent process, after conversations with PPI group. P19 WP4 Data collection. Added further details, after conversations with PPI group, including provision for online surveys and consideration of inclusion. P20 WP5 Data analysis and P21 Data analysis. Removal of word 'audio'. P20 WP6 Added further details about the recruitment of patients and carers. Following conversations with PPI, and in response to other work undertaken in care homes, we decided to reduce the length of each interview but to undertake repeated interviews to capture data from a) the initial lie and b) the longer-term consequences of the lie. P23 Data security, storage and retention. Added details about data storage to match Data Access Management Plan.	
Version 1.3 4th February 2025	P4. Key study contact details: Changed Fiona Sampson's title to Professor P5. Study participants. Data collections dates updated to match other parts of protocol. p17. WP3 - Data collection: updated all references to research team/ research paramedic to 'member of the patient's usual care team in YAS/ hospital site' (as appropriate), providing further clarity. P18. WP3 - Patient consent process: updated all references to research team/ research paramedic to 'member of the patient's	

	usual care team in YAS/ hospital site' (as appropriate), providing further clarity. P18-19. WP3 - Patient consent process: Changed 'clinician' to 'nominated consultee' to align with study documentation (information sheets and consent forms) P23. **7. ETHICAL AND REGULATORY COMPLIANCE** Changed wording to match previous sections and provide further clarity.	
Version 1.4 4th March 2025	P1 RESEARCH REFERENCE NUMBERS Added ISRCTN ID. Added approvals and reference numbers for each work package in a table. IRAS approvals also added to Section 7 'Ethical and regulatory compliance'. P6 STUDY SUMMARY Added study end date. Footer Removed IRAS 336914.	
Version 1.5 24th March 2025	P1 PROTOCOL VERSION AND DATE Updated to v1.5, 25th March 2025 P6 STUDY SUMMARY Added end of study definition 'The date of the last workshop with stakeholders (WP7)'. Footer Updated to v1.5, 25/03/2025	
Version 1.5 10/04/2025	P1 University of Sheffield REC (061049) updated to 'approved' P23 ETHICAL AND REGULATORY COMPLIANCE Updated text to reflect approval of WP4 and WP5 from HRA, including approval for non-substantial amendment	