

The effects of helping and supporting an adult who experienced harm in the NHS and/or social care

Submission date 22/08/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Involving carers (family or close friends) in the aftermath of physical or psychological harm in NHS or adult social care settings is important. Such events can have a negative effect on carers' health and wellbeing. These effects can be direct or indirect, due to increased intensity or scope of caring after the harm. They often also play a vital role in supporting decisions and taking action after harm (e.g. whether to make a complaint or pursue litigation). Carers often adopt the important role of primary representative and decision-maker in the aftermath of harm, especially where the person harmed cannot speak for themselves.

The project will explore the carers' perspectives when someone (who they provide care for) has been physically and/or psychologically harmed in the NHS or adult social care settings. The study will find out how carers experience and are impacted by harm, what support needs they have, and the support they give their loved one (e.g., making complaints) after harm.

There has been little research on carers' insights into harm. This study seeks to address this gap. Understanding carers' perspectives will be used to develop recommendations for policy and practice designed to improve carers' experiences and support health and wellbeing after harm.

Who can participate?

Adults (18 years or older) who provide care and support to a family member or close friend who was harmed in the NHS or social care in England. The harm needs to have happened in the last 5 years. Participants need to be able to participate in an interview (reasonable adaptations can be made with language and disability support).

What does the study involve?

One-to-one interviews will be conducted with up to 30 carers of people, who have experienced physical or psychological harm in the NHS or adult social care settings. The researchers will analyse the interviews to understand carers' experiences, what effect it had on them, and what helped (or could have helped) in the aftermath of harm. They will also develop recommendations.

What are the possible benefits and risks of participating?

There are no immediate benefits to carers who take part, but some people find it helpful to reflect on their experiences and talk about them. For some people, however, it may be upsetting to recall and share experiences of supporting a family member or close friend who was harmed. The researchers will be attentive to any potential upset or distress, and if needed, will stop the interview. Details of who can give any further support (if needed after the interview) will be given.

Where is the study run from?

The study is run by researchers from the University of Oxford and the University of Kent, as part of the programme of work by the National Institute of Health Research Quality Safety and Outcomes Policy Research Unit (NIHR QSO PRU)

When is the study starting and how long is it expected to run for?

May 2024 to April 2026

Who is funding the study?

This project is funded by the National Institute of Health and Care Research (NIHR) through the Quality, Safety and Outcomes of Health and Social Care Policy Research Unit (QSO-PRU) (ref: NIHR206117)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

University of Oxford Ethics MS IDREC 674605, NIHR206117

Study information

Scientific Title

Experiences, outcomes and actions of family or friends ("carers") when someone is harmed in the NHS or social care

Study objectives

To explore the perspectives of family or close friends' ("carers") when someone (who they provide care for) has been physically and/or psychologically harmed in the NHS or adult social care settings. The study aims to understand their experience and effects of harm, their support needs and the support they give their loved one (e.g., making complaints) after harm.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/10/2025, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) University of Oxford (Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: 674605

Study design

Qualitative interview study

Primary study design

Observational

Study type(s)

Quality of life, Safety

Health condition(s) or problem(s) studied

Carer experiences (e.g. unmet need) and outcomes (e.g. quality of life) when they are supporting a family member or friend (with any type of physical and/or mental health problems) who was harmed in the NHS or social care

Interventions

One-to-one interviews will be conducted with up to 30 carers of people, who have experienced physical or psychological harm in the NHS or adult social care settings. Researchers will analyse the interviews to understand carers' experiences, what effect it had on them, and what helped (or could have helped) in the aftermath of harm. They will also develop recommendations.

Intervention Type

Other

Primary outcome(s)

The experiences and outcomes of unpaid carer who help and support an adult with long-term health problems who experienced harm in the NHS and/or social care. Interviews will explore the impact of the harm on the carer, their actions after harm, and any support needs they have.

Method: Qualitative one-to-one interview (a single interview) that will be analysed by thematic analysis.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

01/04/2026

Eligibility**Key inclusion criteria**

1. A family member or close friend, who provides or provided help, care or support to an adult (aged 18 years or older) due to their care and support needs ("carers"), where the adult experienced harm in the NHS or Adult Social Care contexts in the last 5 years
2. Aged 18 years or older at the time of the harm
3. Able to participate in an interview. Reasonable support and adaptations can be made (e.g. language or disability support)
4. Able to give informed consent to participate in the study
5. Living in England

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. The harm was experienced outside of England – whether one of the other UK nations or another country
2. The harm was experienced in private healthcare settings, outside of NHS care
3. Aged under 18 years (now or at the time when the harm occurred)
4. Unable to communicate in English, even with support or adaptations

Date of first enrolment

06/10/2025

Date of final enrolment

15/02/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

No specific participating centre (participants are recruited across England)

United Kingdom

OX3 7LF

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets (anonymised interview transcripts) generated and analysed from this study will be available upon request from the Principal Investigator Dr Michele Peters (michele.peters@dph.ox.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes