

A feasibility study to improve recovery after an episode of delirium

Submission date 27/10/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The word delirium describes a change in the brain which makes a person become suddenly more confused or more confused than usual. It affects a quarter of older people who come into hospital. Delirium is usually caused by an illness such as an infection. Many people take months to recover their memory and thinking skills, and some never recover completely. Previous research has looked at how to prevent and treat delirium while people are in hospital but there has been little research into how to improve people's recovery after delirium. This study aims to develop and test a package of activities (intervention) to help people recover from delirium.

Who can participate?

People aged over 65 years with delirium either with or without dementia, their carers, and professionals caring for them.

What does the study involve?

An expert panel with patient and public involvement (PPI) was asked to help design an evidence-based intervention. The intervention includes physical exercises, activities to improve memory and emotional support delivered in the participant's home by occupational therapists, physiotherapists and rehabilitation support workers. This study is a small study to test this approach. This is to test whether the intervention is acceptable and whether people are willing to take part. People who have had delirium and their care partners will receive the intervention for up to 12 weeks. Three and six months after discharge from hospital the researchers will assess daily living skills, memory and thinking skills, quality of life, use of health, social and care services and impact on well-being of carers. They will interview some participants and professionals involved to see how the intervention could be improved.

What are the possible benefits and risks of participating?

Benefits:

1. Structured physical exercise rehabilitation could lead to improved physical functioning and independence with daily activities such as getting out of bed.
2. Cognitive stimulation and/or talking therapy may lead to quicker recovery from delirium and can be cathartic.
3. Having the intervention at home provides greater convenience to patients and carers, i.e.,

there will not be any requirement to travel to additional community or hospital appointments as a result of taking part in the study.

4. Participants will have the option of completing follow-up visits at the acute hospital or at home, depending on their preference and abilities.

5. Inclusion of carers in the intervention could lead to long-term benefits for both patients and carers as a result of having a greater understanding of their condition and the rehabilitation activities.

Risks:

1. Patient participants may be considered to be vulnerable due to delirium and dementia and may lack the capacity to understand what the study involves and give informed consent.

2. Physical exercise in our participant population could lead to injury and potential re-admission to an acute hospital.

3. The intervention takes place in the participant's home where emergency medical assistance may not be immediately available, e.g., to manage falls and other medical problems.

4. Cognitive stimulation and/or talking therapy could cause emotional distress.

5. The intervention has the potential to put a greater burden on patient and carer participants than usual care alone (i.e., if not taking part in the study).

6. There is a risk of COVID-19 infection from home visits from healthcare professionals who wouldn't otherwise be visiting the home.

Where is the study run from?

The University of Exeter Clinical Trials Unit, on behalf of the Royal Devon University Healthcare NHS Foundation Trust (UK)

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

April 2022 to October 2024

Who is funding the study?

National Institute of Health and Care Research Programme Grants for Applied Research Programme (UK)

Who is the main contact?

Prof. Louise Allan, L.Allan@exeter.ac.uk

Study website

<https://blogs.exeter.ac.uk/recovered/>

Contact information

Type(s)

Scientific

Contact name

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302675

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53796, IRAS 302675

Study information

Scientific Title
A multi-centre, single-arm feasibility study of a complex intervention to improve Recovery after an Episode of Delirium in adults over 65 years: the RecoverED study

Acronym
RecoverED

Study objectives
To conduct a feasibility study of the rehabilitation intervention in older adults who have had delirium to determine if it is acceptable to patients and their carers and if it is possible to test the effectiveness and cost-effectiveness of the intervention in a future definitive randomised controlled trial (RCT).

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 24/10/2022, London -South East Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8085, +44 (0)20 710 48120, +44 (0)207 104 8265; londonsear.ethics@hra.nhs.uk), ref: 22/LO/0613
2. Approved 28/10/2022, Scotland A REC (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131465 5680; Manx.Neill@nhslothian.scot.nhs.uk), ref: 319555, 22/SS/0080

Study design

Non-randomized; Interventional; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Management of Care, Rehabilitation

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Delirium

Interventions

Study design:

1. A feasibility study to see if the intervention is acceptable to participants, sufficient numbers of participants can be recruited and given the intervention and sufficient outcome data can be collected
2. Recruiting male and female adults aged over 65 years diagnosed with delirium for more than 48 hours during admission to hospital, and their informal carers (patient/carers participant pairs)
3. Rehabilitation programme (intervention) delivered in the patient's home by NHS community staff
4. Single group (all participants will be offered the intervention)
5. Multi-centre (recruiting at 6 acute NHS sites)
6. 60 participant/carers pairs
7. Stop/go criteria for progressing to a separate definitive randomised controlled trial comparing the intervention with usual care
8. The primary outcome for the randomised controlled trial would be the Activities of Daily Living, measured using the proxy-reported Disability Assessment for Dementia (DAD) tool. This feasibility study will look at our ability to collect that data at baseline and 3- and 6-months post-discharge home.

Recruitment:

1. Screening (from medical records & discussion with the direct care team, non-invasive)
2. If eligible, the research nurse/clinician discusses the study with the patient, provides a PIS and ascertains their capacity to provide informed consent
3. If eligible, has the capacity and is willing to take part - written informed consent obtained
4. If eligible, but lacks capacity - consultee identified, research nurse discusses the study with the patient (to their maximum ability) and consultee and obtains consultee opinion of patient's wishes (or, consent obtained from nearest relative/welfare guardian if in Scotland)
5. Carer participant identified and if eligible, research nurses discusses the study and provides carer PIS. If willing to take part, written informed consent is obtained.
6. The consent form includes the process evaluation (interview) and audio recording of an intervention session as optional items so that participants don't have to complete two separate forms.

Baseline (patient):

1. Demographics, contact details and preferences, medical history (including dementia diagnosis), clinical frailty score, Charleson co-morbidity index, APACHE II, discharge destination, length of hospital stay
2. Detailed delirium assessment (4 'A's Test [4AT], Diagnostic and Statistical Manual of Mental Disorders [DSM5], Observational Scale of Level of Arousal [OSLA], Memorial Delirium Assessment Scale [MDAS])
3. Forward and backward digit span test
4. Timed up and go mobility assessment
5. Verbal fluency assessment
6. Participant reported outcome measures (paper booklet) (EuroQol [EQ-5D-5L], ICEpop CAPability measure for Older people [ICECAP-O], Dementia Quality of Life Instrument [DEMQOL], Identity self-continuity)

Baseline (carer):

1. Demographics, contact details and preferences
2. Proxy participant reported outcome measures (paper booklet) (DAD, DEMQOL, EQ-5D-5L, Informant Questionnaire on Cognitive Decline in the Elderly [IQCODE], Health Resource Use)
3. Carer participant reported outcome measures (paper booklet) (EQ-5D-5L, ICEpop CAPability measure for Adults [ICECAP-A], Zarit burden interview-12)

Intervention (at patients' home post-discharge):

1. Initial home assessment visit with the patient, carer and an occupational and/or physiotherapist from the community services team. Up to 90 minutes.
2. Intervention rehabilitation sessions with a rehabilitation support worker, up to 10 sessions over 12 weeks from the date of the home assessment visit. Each session is up to 60 minutes.
3. Intervention sessions will be tailored to the individual needs and personal goals and will involve a combination of physical rehabilitation, cognitive exercises, emotional support and delirium education and sense-making.
4. Participants will be given a paper rehabilitation diary to keep. The support worker will use the diary during sessions to plan the session and orientate the patient (e.g. by asking them to write in the day, date, time of day). The patient and carer will be able to use the booklet to look back on sessions and also make their own entries between sessions if they wish (optional). The diary will include basic guidance on good nutrition and hydration and some information on delirium.
5. If doing physical exercises, the participants will be given paper printouts of the exercises to keep and refer back to.

Follow-up (at patients' home or in the acute hospital 3- and 6-months post-discharge):

1. Visit with a research nurse/clinical researcher from the acute Trust
2. Verbal confirmation of continued consent

Patient participant:

1. Detailed delirium assessment (either 4AT + mini - Addenbrooke's Cognitive Examination (mini-ACE) OR, 4AT + DSM5, OSLA, MDAS)
2. Timed up and go mobility assessment
3. Forward and backward digit span test
4. Verbal fluency assessment (if mini-ACE is not required)
5. Participant reported outcome measures (paper booklet) (EQ-5D-5L, ICECAP-O, GDS-4, DEMQOL, Identity self-continuity)

Carer participant:

1. Proxy participant reported outcome measures (paper booklet) (DAD, DEMQOL, EQ-5D-5L, IAgED, Health Resource Use)
2. Carer participant reported outcome measures (paper booklet) (EQ-5D-5L, ICECAP-A, Zarit burden interview-12)

End of participation in the study. The patient continues with standard NHS care.

Optional elements of study:

Process evaluation (qualitative interviews):

1. If the patient and/or carer participant consented to an interview, they will be contacted by a researcher from the University of Exeter shortly after their final intervention session
2. The patient and carer can undertake an interview separately or together depending on their preference (and if they have both consented)
3. The interview will take up to 60 minutes, with breaks if needed, and will be guided by key interview topic guides
4. Interviews will be conducted by telephone or video call, depending on participant preferences
5. Health and social care professionals who are involved in intervention delivery and decision-making will be invited to take part in an interview
6. Health and social care professionals will be provided with an information sheet and consent form using DocuSign. This will be managed by the qualitative researcher at the University of Exeter
7. 15-20 patient/patient-carer pairs will be interviewed and 20-24 professionals

Audio recording of an intervention session:

1. If both the patient and carer participants have consented to the audio-recoding of an intervention session, one of their intervention sessions may be purposively sampled for recording. This is to monitor intervention fidelity (i.e. to make sure the rehabilitation support worker is delivering the intervention as intended)
2. Rehabilitation support workers will be asked to provide written consent using DocuSign for their intervention session to be recorded
3. The protocol section 6.6. describes the sampling plan in detail
4. The rehabilitation support worker will bring an encrypted audio-recording device to the session and record the session after verbally re-confirming consent
5. 15-20 intervention sessions will be audio-recorded
6. The audio recording will be securely uploaded to the University of Exeter and then the rehabilitation support worker will delete the recording from the device and their computer

Intervention Type

Other

Primary outcome measure

1. The number of people with delirium identified on hospital wards will be measured with a screening log pre-baseline
2. The proportion (and number) of people with delirium who meet the eligibility criteria will be measured with a screening log pre-baseline
3. The proportion of eligible people with delirium who agree to participate in the study will be measured with a screening log pre-baseline
4. The proportion of carers who agree to participate in the study will be measured with a screening log pre-baseline
5. The proportion of participating people with delirium who start the intervention will be measured with an intervention case report form (CRF) at 2 weeks post-discharge
6. The proportion of participating people who complete $\geq 60\%$ of the intervention sessions will be measured with an intervention CRF at 3 months post-discharge
7. The proportion of participating people with delirium who remain in the study until the final follow-up at 6 months
8. The proportion of people with delirium providing valid outcome data for each primary and secondary outcome measure at 3 and 6 months post-discharge
9. The acceptability of the intervention will be assessed using a qualitative process evaluation post-intervention
10. The estimated standard deviation and 6-month follow-up rate for the proposed primary outcome, in order to either verify or inform the revision of the proposed sample size calculation for the definitive RCT

The primary outcome measure for the randomised controlled trial:

1. Activities of daily living (ADL) measured using the Disability Assessment for Dementia (DAD) tool at baseline and 6 months

Secondary outcome measures

1. Activities of daily living (ADL) measured using the Disability Assessment for Dementia (DAD) tool at baseline and 3 months
2. Mobility assessed using the Timed Up and Go (TUG) at baseline, 3 and 6 months
3. Delirium persistence or recurrence based on the protocol previously published for the Delirium and Cognitive Impact in Dementia (DECIDE) study in which diagnosis is made according to DSM5 criteria, with some additional enhancements including the use of the Informant Assessment of Geriatric Delirium scale (I-AGeD), at baseline, 3 and 6 months
4. Attention assessed by reciting the number of months of the year backwards at baseline, 3 and 6 months
5. Arousal assessed using the Observational Scale of level of Arousal (OSLA) at baseline, 3 and 6 months
6. Cognition assessed with mini ACE at baseline, 3 and 6 months
7. Verbal fluency assessed using the 'Animals' assessment from the mini-ACE assessment at baseline, 3 and 6 months
8. Identity self-continuity assessed using a single question scored on a Likert scale (Strongly disagree/disagree/neither agree nor disagree/agree/strongly agree) at baseline, 3 and 6 months
9. Verbal short-term and working memory assessed with the Digit span test (Forward Digit Span and Reverse Digit Span) at baseline, 3 and 6 months
10. Mood assessed with the Geriatric Depression Scale-4 (GDS-4) at 3 and 6 months
11. Wellbeing assessed with the ICEpop CAPability measure for Older people (ICECAP-O) at baseline, 3 and 6 months

12. Residence category assessed using a record of whether the patient participant is living in their own home, living with family, assisted living/warden supported, care home without nursing, care home with nursing or other residence type at 3 and 6 months
13. Patient health-related quality of life (HRQL) assessed with the EQ-5D-5L and EQ-5D-5L proxy at baseline, 3 and 6 months
14. Patient HRQoL assessed with the DEMQOL and DEMQOL-Proxy at baseline, 3 and 6 months
15. Carer burden assessed with the Zarit burden interview 12 (ZBI-12) at baseline, 3 and 6 months
16. Carer quality of life assessed with the EQ-5D-5L at baseline, 3 and 6 months
17. Carer wellbeing assessed with the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 3 and 6 months
18. Resource use collected via a proxy Resource Use Questionnaire (RUQ) designed specifically for this study at baseline, 3 and 6 months

Overall study start date

01/04/2022

Completion date

09/10/2024

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 01/11/2023:

Patients:

1. Aged over 65 years
2. Admitted to an acute hospital
3. Clinical diagnosis of delirium while admitted to hospital
4. Expected to be living in a private dwelling after discharge from hospital or immediate care (a period of 4 weeks of intermediate care will be allowed before discharge home)
5. Has a carer who could be approached for the study
6. Has the capacity to provide informed consent to participate, OR, has a consultee who is able to give an opinion on the participation of the person with delirium (in England), OR, has a relative /welfare guardian who is able to give informed consent on behalf of the person with delirium (in Scotland).
7. Lives within the geographical boundary of the local intervention delivery team

Carers:

1. Family member or friend of the person with delirium
2. In contact with patient participant for at least one hour per week
3. Able to communicate in English sufficiently well to complete the proxy outcome measures
4. Has the capacity to provide informed consent.

Previous participant inclusion criteria:

Patients:

1. Aged over 65 years
2. Admitted to an acute hospital
3. Clinical diagnosis of delirium lasting for more than 48 hours
4. Expected to be living in a private dwelling after discharge from hospital or immediate care (a period of 4 weeks of intermediate care will be allowed before discharge home)
5. Has a carer who is willing to assist with the completion of outcomes
6. Has the capacity to provide informed consent to participate, OR, has a consultee who is able

to give an opinion on the participation of the person with delirium (in England), OR, has a relative /welfare guardian who is able to give informed consent on behalf of the person with delirium (in Scotland)

Carers:

1. Family member or friend of the person with delirium who is going to take part in the study
2. In contact with patient participant for at least 1 hour per week
3. Able to communicate in English sufficiently well to complete the proxy outcome measures
4. Has the capacity to provide informed consent

Participant type(s)

Mixed

Age group

Adult

Lower age limit

65 Years

Sex

Both

Target number of participants

60 patients + 60 carers

Total final enrolment

38

Key exclusion criteria

Current participant exclusion criteria as of 01/11/2023:

Patients:

1. Diagnosis of delirium cannot be confirmed during the patient's hospital visit
2. Unable to communicate verbally due to advanced dementia or aphasia
3. Carer declines participation in the study
4. Undergoing end-of-life care
5. Participating in another intervention study

Carers:

There are no exclusion criteria for carer participants

Previous participant exclusion criteria:

Patients:

1. Diagnosis of delirium cannot be confirmed during the patient's hospital visit
2. Unable to communicate verbally due to advanced dementia or aphasia
3. Carer declines participation in the study
4. Undergoing end-of-life care
5. Participating in another intervention study

Carers

There are no exclusion criteria for carers

Date of first enrolment

28/04/2023

Date of final enrolment

31/03/2024

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre**Uclh**

250 Euston Road

London

United Kingdom

NW1 2PQ

Study participating centre**The Royal Victoria Infirmary**

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

TS1 4LP

Study participating centre**Freeman Road Hospital**

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Study participating centre**Sandwell General Hospital**

Lyndon

West Bromwich

United Kingdom

B71 4HJ

Study participating centre**Queens Medical Centre**

Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre**Nottingham City Hospital**

Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre**Royal Infirmary of Edinburgh at Little France**

51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre**Royal Devon and Exeter Hospital**

Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation

Royal Devon University Healthcare NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.rdehospital.nhs.uk/>

Funder(s)

Funder type

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR Programme Grants for Applied Research

Results and Publications

Publication and dissemination plan

The researchers aim to publish the findings in peer-reviewed scientific and clinical journals and via presentations at local, national and international meetings. They aim to publish the results in an open-access journal within 24 months of study completion, in line with NIHR guidelines. They will work with their PPI group to provide a lay-accessible summary of the results to all study participants. Participants will be asked to provide their contact method preferences so that they receive the results in a format of their choice (i.e. hardcopy by post or digital copy by email).

The results will be posted on the publicly available registry (ISRCTN). A summary of the results will be submitted to the HRA within 12 months of the end of the study in line with HRA guidelines. The study protocol will be published in a peer-reviewed journal before the end of the recruitment stage and will be publicly available in the NIHR Journals Library at the end of the study.

Intention to publish date

31/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. At the end of the study the researchers will store anonymised

research data and outputs in the University of Exeter's Open Research Exeter repository (<https://ore.exeter.ac.uk/repository/>) indefinitely. This approach has been approved by an independent NHS research ethics committee and consent will be sought from participants. All future research proposals must obtain the appropriate ethical and regulatory approvals.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	26/01/2023	20/02/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	16/05/2023	23/08/2023	No	No
Protocol article		15/09/2023	18/09/2023	Yes	No
Protocol file	version 5.0	17/10/2023	01/11/2023	No	No