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A feasibility study to improve recovery after an episode of delirium

Submission date
27/10/2022

Recruitment status
No longer recruiting

Registration date
13/12/2022

Overall study status
Completed

Last Edited
06/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact information

Type(s)
Scientific

Contact name
Prof Louise Allan

Contact details
University of Exeter
Exeter
United Kingdom
EX1 2LU
+44 (0)1392726025
L.Allan@exeter.ac.uk

Type(s)
Scientific

Contact name
Dr Abby O'Connell

Contact details
Exeter Clinical Trials Unit
University of Exeter
Exeter
United Kingdom
EX1 2LU
+44 (0)7866139629
RecoverED-Study@exeter.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
302675

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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;

londonsoutheast.rec@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

Study type(s)
Treatment

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/carer 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/carer 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(s)
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 ≥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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
All

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
United Kingdom

England

Scotland

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

Funder(s)

Funder type
Government

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

Results and Publications

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 article		15/09/2023	18/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	26/01/2023	20/02/2023	No	No
Protocol file	version 4.0	16/05/2023	23/08/2023	No	No
Protocol file	version 5.0	17/10/2023	01/11/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes