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Maintaining independence in people with dementia who had a fall

Submission date
22/05/2023

Recruitment status
No longer recruiting

Registration date
06/06/2023

Overall study status
Completed

Last Edited
09/02/2024

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
People with dementia fall over up to ten times more often than people who do not have dementia. When they fall over, they are more likely to hurt themselves. They are less likely to recover than people without dementia. After a fall people with dementia may need a lot more help and they, and their carer, may have a poorer quality of life. Researchers have designed a rehabilitation programme (intervention) for people with dementia aged over 50 years who have had a fall in the past 6 months. They aim to test the intervention in a two-group pilot randomised controlled trial of 60 patient and carer participant pairs.

Who can participate?
People living with dementia aged over 50 years who have fallen in the past 6 months, their carers, and professionals caring for them.

What does the study involve?
Patient and carer pairs will be recruited through community settings (primary care, paramedics, admiral nurses), secondary care settings (emergency departments, supported discharge teams, rehabilitation outreach teams, memory clinics) and research registers. If a patient is found to lack mental capacity to give informed consent, the researchers will approach a consultee (close family or friend). At their homes, participants will have an initial assessment visit followed by up to 19 rehabilitation sessions over a 12-week period with booster sessions at weeks 16, 20 and 24. The rehabilitation programme will be personalised to each participant, taking into account their physical abilities, their preference for activities and goals agreed upon by the therapist, the patient participant and their unpaid carer. A clinical researcher will follow up participants at 3 months over the phone and at 6 months at the participants' home.

What are the possible benefits and risks of participating?
As the patient population is made up of people living with dementia, they may lack the capacity to give informed consent and therefore be considered vulnerable. The intervention is comprised of physical activity which could result in injuries being sustained. Patient participants will undertake the intervention at their homes without medical assistance available if injuries occur, such as if the participant falls. There is the potential impact of increased burden on both the patient participant and the carer participant when taking part in this study compared to usual

care. Visits from research support workers and therapists to the patient participant's home introduce the risk of COVID-19 infection during these home visits.
Structured physical exercise rehabilitation could lead to improved physical functioning and independence with a reduced prevalence of falls. The intervention will be undertaken at patient participants' homes, eliminating the need for travel to community or hospital appointments. The 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 rehabilitation activities.

Where is the study run from?
The University of Exeter Clinical Trials Unit

When is the study starting and how long is it expected to run for?
December 2022 to November 2024

Who is funding the study?
Alzheimer's Society

Who is the main contact?
Prof. Louise Allan, maintainstudy@exeter.ac.uk

Study website
https://sites.exeter.ac.uk/maintainstudy/

Contact information

Type(s)
Scientific

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323555

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56040, IRAS 323555

Study information

Scientific Title
An intervention to maintain independence in people living with dementia, living in their own homes, who have already fallen: a multi-centre, two-arm pilot cluster randomized controlled trial

Study objectives
Is it feasible to conduct a research study of an intervention, in people with dementia aged over 50 years old, whilst demonstrating benefits in other patient-reported, professional-reported and cost-effectiveness outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2023, Wales REC 6 (c/o Public Health Wales, Building 1, Jobswell Road, St David’s Park, SA31 3HB, UK; +44 (0)1267 611164; Wales.REC6@wales.nhs.uk), ref: 23/WA/0126

Study design
Randomized; Interventional; Design type: Process of Care, Education or Self-Management, Complex Intervention, Physical, Management of Care, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Dementia

Interventions
Study design:
- Deliver a pilot cluster randomised control trial of an intervention to maintain independence in People With Dementia (PWD), living in their own homes, who have already fallen
- Recruiting male and female PWD aged over 50 years old, and their unpaid carers (patient/carer participant pair)
- Rehabilitation programme delivered in patient participants' homes by NHS community staff
- Sites are randomly allocated to provide participants with the rehabilitation programme (intervention) or to provide participants with care as usual. Half of the participants will receive the intervention and the half with receive care as usual.
- Multi-centre (recruiting at 6 sites)
- 60 patient/carer participant pairs
- The primary outcome is the Activities of Daily Living, measured using the proxy-reported Disability Assessment for Dementia (DAD) tool. This pilot study will look at our ability to collect that data at baseline and 6 months post-baseline.

Recruitment:
- Screening and recruitment via community settings (primary care, paramedics, admiral nurses), secondary care settings (emergency departments, supported discharge teams, rehabilitation outreach teams, memory clinics) and research registers.
- If eligible, potential participants in secondary care settings will be sent an information sheet and invitation letter. A clinical research will then follow up by phone. Potential participants in community settings and on research registers will be given an information sheet and invitation letter with an opt-in form they will return to the clinical researcher. The clinical research will then follow up by phone.
- If eligible, has capacity and is willing to take part - written informed consent obtained.
- If eligible, but lacks capacity - consultee identified, the clinical researcher discussed the study with the patient (to their maximum ability) and consultee. The consultee's opinion of the patient's wishes was obtained.
- Carer participant identified and if eligible, the clinical researcher discussed the study and provided a carer information sheet. If willing to take part, written informed consent is obtained.
- The consent form includes the process evaluation (interview and observation) as optional.

Baseline (patient):
- Demographics, contact details and preferences, medical history (including dementia diagnosis), falls history and mini-ACE
- Timed Up and Go test
- Physiotherapy and occupational therapy assessment (intervention only)
- Goal Attainment Scaling (GAS) (intervention only)
- Participant reported outcome measures (paper booklet) (EQ-5D-5L, Short-FES-I, QOL-AD)

Baseline (carer):
- Demographics, contact details and preferences
- Proxy participant reported outcome measures (paper booklet) (proxy EQ-5D-5L, DAD, QOL-AD and HUQ)
- Carer participant reported outcome measures (paper booklet) (EQ-5D-5L, ZBI-12 and QOL-AD)

Intervention group:
- Up to two initial home assessment visits with OT and/or PT. Each visit will take approximately 60 minutes.
- Intervention rehabilitation sessions with a rehabilitation support worker (RSW and/or therapist), up to 19 sessions over 12 weeks with booster sessions at weeks 16, 20 and 24. Each session will take approximately 60 minutes.
- Intervention sessions will be tailored to the individual needs and personal goals of the patient participant.
- Patient participants will be given a fall diary to complete with the aid of their unpaid carer if required. This diary is for participants to record any falls they have during the study and the date on which the fall(s) occurred. This diary also allows the participant to note any health services utilised during the study. This will take approximately 10 minutes to complete per day.
- Patient participants will also be given an activity log to keep a record of which activities they have undertaken during the study.

Usual care group:
- Continue with standard NHS care
- Patient participants will be given a fall diary to complete with the aid of their unpaid carer if required. This diary is for participants to record any falls they have during the study and the date on which the fall(s) occurred. This diary also allows the participant to note any health services utilised during the study. This will take approximately 10 minutes to complete per day.

Follow-up (patient):
- At 6 months, a visit from the clinical researcher
- Timed Up and Go test
- Participant reported outcome measures (paper booklet)(EQ-5D-5L, Short-FES-I, QOL-AD)
- End of study participation (patient continues with standard NHS care)

Follow-up (carer):
- At 3 months post-baseline the clinical researcher will call the carer participant to complete the health and care service and resource use utilisation questionnaire (HUQ).
- At 6 months, a visit from the clinical researcher at the patient participant's home.
- Proxy report outcome measures (paper booklet) (proxy EQ-5D-5L, DAD, QOL-AD, HUQ)
- Carer participant reported outcome measures (paper booklet) (EQ-5D-5L, ZBI-12)
- End of study participation

Optional elements of study (Interviews):
- 18 face-to-face or online interviews will be conducted with patients and their unpaid carers in the intervention group.
- Interviews will be semi-structured and guided by topic guides.
- 24 healthcare professionals involved in the study will be interviewed online or by telephone.
- Interviews will be semi-structured and guided by topic guides.
- 6 clinical researchers involved in screening/recruitment/data collection (e.g. research nurses) will be interviewed online or by telephone.
- Interviews will take no longer than 60 minutes and will be video/audio recorded with participants' permission. If permission is not given, notes will be taken.

- Encrypted voice recorders will be used to record interviews where conducted face-to-face or by telephone.

Optional elements of study (Observations):
- 6 non-participant observations of intervention sessions will be conducted to investigate the feasibility and implementation of the intervention.
- Sessions will be sampled to include those delivered by PT, OT and RSW across different sites.
- 4 supervision meetings between RSW and either the PT or OT will be observed.
- 4 multidisciplinary team (MDT) meetings will be observed
- Observations will take place in person if possible and may be recorded using an encrypted audio recorder. Notes will be taken during and immediately after observations.
- Recordings will be carried out by a practitioner and sent to the study qualitative researcher via secure file transfer at the earliest opportunity.
- The study qualitative researcher will listen to the recording and take notes. Selected sections of the recordings may be transcribed in full for more detailed analysis.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Activities of daily living (ADL) assessed with the Disability Assessment for Dementia (DAD) at baseline, and 6 months

Secondary outcome measures
1. Mobility assessed using the timed up and go at baseline and 6 months
2. Patient participant rated quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) at baseline and 6 months
3. Patient participant rated quality of life assessed with the Quality of Life - Alzheimer's Disease (QOL-AD) at baseline and 6 months
4. Psychological consequences of falling assessed with the International short form Falls Efficiency Scale (Short-FES-I) at baseline and 6 months
5. Cognition assessed with mini ACE (Mini-ACE) at baseline
6. Assessing the extent goals are achieved using Goal Attainment Scaling (intervention only) at baseline and 6 months
7. Number of falls assessed with the falls diary throughout 6-month follow-up
8. Carer burden assessed with the Zarit burden interview 12 (ZBI-12) at baseline and 6 months
9. Carer participant rated quality of life assessed with the European Quality of Life Instrument (EQ-5D-5L) at baseline and 6 months
10. Carer-rated patient participant quality of life assessed with the EQ-5D-5L proxy at baseline and 6 months
11. Carer-rated patient participant quality of life assessed with the Quality of Life - Alzheimer's Disease (QoL-AD) Proxy at baseline and 6 months
12. Health and social care utilisation assessed with the Health and social care Utilisation Questionnaire (HUQ) at baseline, 3 month follow up and 6 month follow up

Overall study start date
01/12/2022

Completion date
30/11/2024

Eligibility

Key inclusion criteria
Patients:
1. A diagnosis of dementia made prior to entry into the study. PWD must be on the Primary Care Quality Outcomes Framework (QOF) Dementia register.
2. Must have sustained at least one fall within 6 months prior to identification as a potential study participant. A fall is defined as an event whereby a person comes to lie on the ground or another lower level with or without loss of consciousness.
3. Must be dwelling in their own home at the time of the index fall and returning to their own home at the time of the intervention
4. Must have an unpaid carer available to assist with the completion of the diaries
5. Either has the capacity to consent to participation, or a personal or nominated consultee who is able to give an opinion on the participation of the PWD
6. Able to communicate in English
7. Aged over 50 years

Carers:
1. Family member or friend of the PWD patient participant
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)
Patient, Carer

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
Patients:
1. Diagnosis of dementia cannot be confirmed by the primary care team within 4 weeks of their being identified
2. PWD found to be dwelling in a care home or to have been a hospital inpatient at the time of the index fall
3. PWD refuses consent or lacks capacity and does not have a personal or nominated consultee, or their personal or nominated consultee declines participation
4. Unpaid carer declines participation in the study

Carers:
There are no exclusion criteria for carer participants

Date of first enrolment
26/09/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
United Kingdom
NW1 3AX

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Rice - the Research Institute for the Care of Older People
The RICE Centre
Royal United Hospital
Combe Park
Bath
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BA1 3NG

Study participating centre
Lincolnshire Partnership NHS Foundation
Research Department
Welton House
Limekiln Way
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LN2 4WH

Sponsor information

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Royal Devon University Healthcare NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Alzheimer's Society; Grant Codes: 586 (AS-PG-21-010)

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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.

The researchers 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.

Intention to publish date
30/09/2025

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?
HRA research summary			20/09/2023	No	No
Protocol article		01/02/2024	09/02/2024	Yes	No
Protocol file	version 3.0	08/11/2023	09/02/2024	No	No