ISRCTN01423159 https://doi.org/10.1186/ISRCTN01423159

Evaluation of exercise on individuals with dementia and their carers

Submission date	Recruitment status
22/04/2009	No longer recruiting
Registration date	**Overall study status**
26/05/2009	Completed
Last Edited	**Condition category**
28/08/2018	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.evidem.org.uk/projects/evidem-e

Contact information

Type(s)
Scientific

Contact name
Dr David Lowery

Contact details
Central and North West London NHS Foundation Trust
Greater London House
Hampstead Road
London
United Kingdom
NW1 7QY
+44 (0)20 3214 5889
d.lowery@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled evaluation of exercise as a therapy for the behavioural and psychological symptoms of dementia

Acronym
EVIDEM-E

Study objectives
The introduction of a tailored excercise programme will significantly reduce behavioural and psychological symptoms of dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London R&D Consortium, submission planned for June 2009 (as of 22/04/2009).

Study design
Pragmatic single-blind randomised single-centre trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Behavioural and psychological symptoms of dementia

Interventions
A 6-week supervised incremental course of walking outside, at a pace and distance to suit the participant and carer for at least 5 days per week. Walking is a useful exercise which is considered acceptable by participants, and is easily delivered and measured (in terms of time and distance) but rarely incorporated in a daily routine. A physiotherapist or exercise therapist will oversee the delivery of the exercise programme. The sustainability of this intervention will

be assessed by evaluating adherence and impact during an unsupervised interval (weeks 6-12) and by further telephone contact at 6 months.

Control group: No exercise training

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Behavioural and psychological symptoms measured by NPI at baseline, week 6 and 12.

Secondary outcome measures
1. Participants' mental health (General Health Questionnaire) at baseline, week 6 and 12
2. Participants' quality of life (DemQOL-Proxy) at baseline, week 6 and 12
3. Caregivers' burden of caring (short Zarit Caregiver Burden Inventory) at baseline, week 6 and 12
4. Participants' level of physical activity and compliance with the intervention (diaries and heart rate monitors, to be completed by the participant and their carer)
5. Participants' and carers' views about the intervention (Diaries and semi-structured questionnaires to be carried out after the trial)
6. Mortality and domiciliary status at 6 months

Overall study start date
01/08/2009

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Diagnosis of:
2.1. Dementia in primary or secondary care OR
2.2. Suspected dementia confirmed by the researcher to ensure the International Classification of Diseases 10th Revision (ICD-10) research criteria for dementia (DCR-10) are met
3. Presence of a carer (professional, friend or family member, who does not necessarily have to live with the participant)
4. Neuropsychiatric Inventory (NPI) score in any one sub-set except only hallucination or delusion more than or equal to 2 in severity and more than or equal to 2 in frequency
5. Consent of participant, or in the case of an individual who is not capable of giving informed consent, the assent of the participant with agreement of carer
6. Consent of carer

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
145

Key exclusion criteria
1. Cardio-respiratory condition, neurological or musculo-skeletal condition of a degree that prevents participation to even the modified exercise regime unsafe or not possible
2. A score of three or more assessed using the Falls Risk Assessment Tool or less than one minute as assessed by the Timed Unsupported Steady Stand test
3. Uncontrolled medical problems, which the GP considers would exclude participants from undertaking the exercise programme; for example, acute systemic illness such as pneumonia, poorly controlled angina, acute rheumatoid arthritis, unstable or acute heart failure
4. Sensory impairment to an extent that prevents dyad facilitated exercise
5. Participant or carer dissent to engage in the exercise programme
6. Acute confusional state

Date of first enrolment
01/08/2009

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central and North West London NHS Foundation Trust
London
United Kingdom
NW1 7QY

Sponsor information

Organisation
Central and North West London NHS Foundation Trust (UK)

Sponsor details
Greater London House
Hampstead Road
London
England
United Kingdom
NW1 7QY

Sponsor type
Hospital/treatment centre

Website
http://www.cnwl.nhs.uk

ROR
https://ror.org/05drfg619

Funder(s)

Funder type
Government

Funder Name
EVIDEM-E is funded as part of a wider programme of Research & Development via the National Institute for Health Research (NIHR) (UK) - Programme Grants for Applied Research (ref: RP-PG-0606-1005)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/05/2010		Yes	No
Results article	results	01/08/2014		Yes	No

Results article	results	01/04/2015	Yes	No
Results article	cost-effectiveness results	01/06/2016	Yes	No