ISRCTN25294519 https://doi.org/10.1186/ISRCTN25294519

Exploring the acceptability and feasibility of delivering a wide-ranging resilience-building Intervention for people with dementia living at home in their own community

Submission date
26/09/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Resilience refers to one's ability to 'bounce back' and cope successfully in the face of life challenges. Strengthening the ability of people with dementia to bounce back in the face of a dementia diagnosis may provide the building blocks to create an environment that maximises their functioning, social connectedness and social performances. This study seeks to find out if it is possible to create such an environment.

Who can participate?
Older people over the age of 60 with memory problems/dementia who live at home in the community and their primary carers

What does the study involve?
All participants will receive a special programme of activities which will run over 15 weeks. These activities will have 3 key things:
1) A 7-week programme, (1 hour twice a week), for people with memory problems/dementia which consists of group activities, focused on promoting and maintaining their mental ability. There will be an average of 5 people in each group and the programme will be delivered by a health professional
2) An 8-week physical exercise programme, (1 hour per week for 4 weeks and 2 hours per week for 4 weeks), for people with memory problems/dementia delivered by an exercise expert. Participants will be supported by older people in the community to complete the exercises.
3) An educational programme which will have three parts (i) a 1-hour programme on dementia for members of the public delivered by a person trained in dementia care (ii) a 6-week educational programme for carers (1 hour 40 mins for the first week and 2 hours for remaining 5 weeks) delivered by members of the research team (iii) a dementia training workshop for GPs (1.5 hours) delivered by a GP trained in dementia care.

What are the possible benefits and risks of participating?
Taking part in this study will help us find out whether people with memory problems/dementia and their primary carers feel that the different activities are acceptable, that it is possible to deliver them in the community and that the way we measure the impact of the activities is not too difficult. The information we get will also help us plan a much larger study to gauge how effective the activities might be in helping people with memory problems/ dementia to live well with their dementia. It is not expected that people with memory problems/dementia and their carers will have any side effects from carrying out the different activities.

Where is the study run from?
National University of Ireland Galway, Ireland

When is the study starting and how long is it expected to run for?
The study commenced on 14th November 2016 and is due to end on 31st October 2020

Who is funding the study?
Health Research Board Ireland

Who is the main contact?
Priscilla Doyle (CREST Project Manager),
priscilla.doyle@nuigalway.ie
Prof. Dympna Casey (scientific contact),
dympna.casey@nuigalway.ie

Study website
http://www.nuigalway.ie/crest/

Contact information

Type(s)
Scientific

Contact name
Prof Dympna Casey

ORCID ID
http://orcid.org/0000-0001-5341-597X

Contact details
School of Nursing & Midwifery
Áras Moyola
National University of Ireland Galway
Galway
Ireland
H91 TK33
+353 (0) 91 493652
dympna.casey@nuigalway.ie

Type(s)
Public

Contact name
Ms Priscilla Doyle

Contact details
Room 338
School of Nursing & Midwifery
Áras Moyola
National University of Ireland Galway,
Galway
Ireland
H91 TK33
+353 (0) 91 493611
priscilla.doyle@nuigalway.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DEM-2015-1439

Study information

Scientific Title
The feasibility of a Comprehensive Resilience-building psychosocial Intervention (CREST) for people with dementia living at home in the community

Acronym
CREST

Study objectives
To determine the feasibility of the CREST complex psychosocial intervention for people with dementia and their carers living in the community. Quantitative and qualitative feasibility assessment data will be collected to inform the decision to proceed with a future RCT and its optimal design

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/08/2019, National University of Ireland, Galway Research Ethics Committee (Research Office, Research and Innovation Centre, National University of Ireland Galway, University Road, Galway, H91 TK33, Ireland; +353 (0) 91 495312; vpresearach@nuigalway.ie), ref: 16-Feb-03; Amend 1912 (updated 28/04/2020, previously: Amend 1907).

Study design
Non-randomized feasibility study

Primary study design
Interventional

Secondary study design
A non-randomized feasibility study

Study setting(s)
Community

Study type(s)
Other

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
Current interventions as of 24/10/2023:
CREST is a multi-level complex psychosocial intervention. All participants will receive the intervention. The intervention will run over 15 weeks and is comprised of various interrelated components targeting different participants and will include:
1) A 14-hour cognitive stimulation programme 'Making a difference' delivered over 7 weeks (1 hour twice a week), to people living with dementia
2) A 12-hour physical exercise programme, delivered over 8 weeks, (1 hour a week for 4 weeks and 2 hours a week for 4 weeks), by an exercise specialist to people living with dementia who will be supported by older people from the community
3) A dementia education programme which consists of three elements (a) a 1 hour one-off Community dementia awareness programme, delivered by trained dementia/community champions to members of the public (b) a 12-hour, educational programme delivered over 6 weeks (1 hour 40 mins for the first week and 2 hours for remaining 5 weeks) by members of the research team to the carers of people with dementia (c) a 1.5-hour one-off continuing professional development (CPD) and accredited GP workshop delivered by a trained GP facilitator

Previous interventions:
CREST is a multi-level complex psychosocial intervention. All participants will receive the intervention. The intervention will run over 15 weeks and is comprised of various interrelated components targeting different participants and will include:
1) A 14-hour cognitive stimulation programme 'Making a difference' delivered over 7 weeks (1 hour twice a week), to people living with dementia
2) A 12-hour physical exercise programme, delivered over 8 weeks, (1 hour a week for 4 weeks and 2 hours a week for 4 weeks), by an exercise specialist to people living with dementia who will be supported by older people from the community
3) A dementia education programme which consists of three elements (a) a 1 hour one-off

Community dementia awareness programme, delivered by trained dementia/community champions to members of the public (b) a 10-hour, educational programme delivered over 6 weeks, (1 hour 40 mins a week), by members of the research team to the carers of people with dementia (c) a 1.5-hour one-off continuing professional development (CPD) and accredited GP workshop delivered by a trained GP facilitator

Intervention Type
Other

Primary outcome measure
Feasibility study outcomes (this line added 11/05/2020):
1. Number and proportion of participants (people with dementia, caregivers) who are screened, judged eligible and agreed to take part in the study
2. Follow-up rates outcome completion and adherence/compliance
3. Reasons for non-recruitment, non-adherence or attrition
4. Feasibility and acceptability of the intervention content, delivery, and fidelity assessments
5. Acceptability of the recruitment process, assessments, data collection tools, intervention content & delivery
6. Willingness of key gatekeepers to recruit participants (people with dementia and caregivers)
7. Calculate baseline score and variability of primary outcome measures among participants (updated 25/10/2023; previously secondary outcome measures)
8. Evaluation of the cost analysis process
9. Identification of barriers and enablers to stigma change in dementia
10. Identification of optimal strategy for recruitment of participants for future definitive trial

Secondary outcome measures
The feasibility and acceptability of the following secondary outcome measurement tools [for use in a future definitive trial] (added 11/05/2020) will also be explored:

1. Completed by carers pre and post the 15-week intervention:
1.1 Zarit Carer burden interview (ZBI) to assess the level of burden
1.2 Short sense of Competency Scale (SSCS) to measure the sense of competence
1.3 Dementia Knowledge 20 (DK20) to measure knowledge of dementia
1.4 Resource Utilisation in Dementia – (RUD-lite) to measure healthcare resource utilisation
1.5 Adult carer quality of life (AC-QoL) to measure the overall quality of life of adult carers

2. Completed by people with dementia pre and post the 15-week intervention:
2.1 Mini Mental State Examination (MMSE) to screen for dementia and measure changes in cognitive function
2.2 Quality of Life- Alzheimer's Disease (QoL-AD) to measure Quality of Life
2.3 Stigma Impact Scale (SIS) to measure self-perceived levels of stigma
2.4 Positive Psychology Outcome Measure (PPOM) to measure resilience
2.5 EQ-5D-5L to measure health status for economic appraisal
2.6 Fitbit to measure sleep quality and physical activity
2.7 The Geriatric Depression Scale – Short Form (GDS-S) to measure depression in older adults.

3. Completed by members of the public pre and post 15-week intervention:
3.1 Dementia Attitudes Scale (DAS) to measures attitudes towards dementia
3.2 Dementia Knowledge 20 (DK-20) to measure knowledge of dementia

Overall study start date

14/11/2016

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. People with dementia (of any gender):
1.1 > 60 years of age
1.2 Have either
1.2.1 A formal diagnosis of dementia (mild to moderate dementia)
1.2.2 Their GP believes they have memory problems and the person has a provisional diagnosis of dementia based on the DSM-IV criteria
1.2.3 Are prescribed dementia medications
1.3 Living in the community
1.4 Willing and capable of undertaking the exercise component of the intervention
1.5 Able to speak in and read English
1.6 Able to give informed consent
1.7 Their primary caregiver is also willing to take part in the study

2. Carers of People with dementia (of any gender):
2.1 Primary caregiver of a person with dementia who has also agreed to participate in the study
2.2 Does not have a diagnosis of dementia
2.3 Living in the community
2.4 Willing and able to participate in the 6 weeks Caregiver education programme
2.5 Able to speak in and read English
2.6 Able to give informed consent

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
A total of 20 participants - 10 people with mild to moderate dementia and their primary informal carers (n=10)

Total final enrolment
20

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
25/02/2019

Date of final enrolment
13/10/2019

Locations

Countries of recruitment
Ireland

Study participating centre
School of Nursing & Midwifery
National University of Ireland Galway
University Road
Galway
Ireland
H91 TK33

Study participating centre
Ballinfoile Castlegar Neighbourhood Centre
Ballinfoile
Galway
Ireland
H91PN50

Sponsor information

Organisation
National University of Ireland Galway

Sponsor details
University Road
Galway
Ireland
H91 TK33
+353 (0) 91 493652
dympna.casey@nuigalway.ie

Sponsor type
University/education

Website
http://www.nuigalway.ie

ROR

https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
15/12/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/11/2020	10/08/2022	Yes	No
Other publications	An embedded qualitative study of the experiences	25/09/2024	26/09/2024	Yes	No
Results article		09/11/2024	20/11/2024	Yes	No