

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

<b>Submission date</b> 26/09/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/11/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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),

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## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Protocol serial number

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; vpresearch@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

### Study type(s)

Other

### 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(s)

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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

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**Study participating centre**

**Ballinfoile Castlegar Neighbourhood Centre**

Ballinfoile

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H91PN50

# Sponsor information

## Organisation

National University of Ireland Galway

## 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

National government

## Location

Ireland

# Results and Publications

## 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?
<a href="#">Results article</a>		09/11/2024	20/11/2024	Yes	No
<a href="#">Protocol article</a>		16/11/2020	10/08/2022	Yes	No

<a href="#">Other publications</a>	An embedded qualitative study of the experiences	25/09/2024	26/09/2024	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes