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Managing, living, remembering

Submission date
05/07/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
04/10/2018

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
Encouraging self-management is helpful in many long-term health conditions. Self-management interventions provide people with information about their condition, educates them on how to live as well as possible with the illness and gain a greater degree of control over the condition. It also helps the person take on more responsibility for managing the condition. This study aims to test a group self-management programme for people with early stage dementia. We believe the self-management programme will improve participants confidence (self-efficacy), mood and well-being and reduce caregivers stress levels.

Who can participate?
Participants will be drawn from people attending a memory clinic in North Wales (Glan Traeth). The primary participants will be people in the early stages of dementia. The secondary participants will be their caregivers. Caregivers may be spouses, partners, siblings or children of people with early-stage dementia who are involved in providing day-to-day support.

What does the study involve?
Potential participants will be identified by clinic staff working with the researcher and people will be invited to participate by the clinical team.
People who consent to take part will complete an initial assessment and will then be randomly allocated into one of two conditions: group self-management programme or care as usual. The self-management group (working title: Managing, Living, Remembering) will involve eight 90-minute weekly sessions held at Glan Traeth Day Hospital, Rhyl. It will be led by two members of the clinical team. Seven people with dementia will attend each group and caregivers (a friend or relative) will be invited to attend the first and final sessions. Caregivers may also, if they wish, join the group at the end of each session to hear an overview of what theme has been covered. Each person with dementia will receive a group manual which will cover the content of each session. The manual will allow space for additional notes and comments to be made. The idea is that the people with dementia can share this resource with the caregiver between sessions. Each session will cover a particular theme and participants will discuss the theme with each other and the facilitators. Within each theme participants will be able to focus on aspects that are meaningful to group members. The first session will include an orientation to the group and its approach, and information about memory difficulties. Subsequent sessions will cover themes which include: practical memory strategies, managing and coping with difficult emotions, managing relationships, planning ahead, how to find and access additional help and staying well.

At the end of the group self-management programme everyone who participated in the intervention will be interviewed to provide feedback on the group. All participants will be reassessed by a research assistant 3 months after the first assessment. The research assistant will not know if the participant attended the group self-management programme or had care as usual. Final follow-up assessments will be conducted 12 weeks later by the research assistant. All assessments will take place at a venue convenient for participants (their home, Glan Traeth or Bangor University).

What are the possible benefits and risks of participating?
Participants may enjoy the assessment sessions and we hope the group self-management programme will be helpful and informative for participants. We do not anticipate that the research poses any risks.

Where is the study run from?
Glan Traeth Day Hospital, Rhyl.

When is the study starting and how long is it expected to run for?
Recruitment for the self-management programme will start in August 2013. It is expected that the study will end in December 2014.

Who is funding the study?
The study is funded by the National Institute for Social Care and Health Research.

Who is the main contact?
Gill Toms (Research Officer)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Funders reference; RFS 12-35

Study information

Scientific Title
Self-MAnagement in dementia: a pilot Randomised controlled Trial of the efficacy and cost-effectiveness of a self-management group intervention (The SMART study) - Phase Two

Acronym
SMART- Phase Two

Study objectives
It is envisaged that people with dementia who attend the eight-week self-management group will show improvements in self-efficacy in comparison to the care as usual group. The intervention may also result in improvement in mood, well-being and cognitive test scores. The self-management group attendees are also likely to show a reduction in health service use, in accordance with previous research findings. Caregivers of people with dementia are expected to show a reduction in caregiver stress and general distress. Finally, it is anticipated that the feasibility of the group will be demonstrated in terms of acceptability to and ease of use by, the clinical team.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC committee: North Wales- West
REC Reference: 13/WA/0174
REC approval: 24/06/2013
R&D approval: 25/06/2013

Study design
Single-site single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format; please contact Gill Toms (g.toms@bangor.ac.uk) to request copies of the participant information sheets

Health condition(s) or problem(s) studied

Early-stage Dementia (MMSE > 20)

Interventions
The self-management group (working title: Managing, Living, Remembering) will involve 8, 90-minute weekly sessions held at Glan Traeth Day Hospital, Rhyl. It will be led by two members of the clinical team. Seven people with dementia will attend each group and caregivers (a friend or relative) will be invited to attend the first and final sessions. Caregivers may also, if they wish join the group at the end of each session to hear an overview of what theme has been covered. Each person with dementia will receive a group manual which will cover the content of each session. The manual will allow space for additional notes and comments to be made. The idea is that the person with dementia can share this resource with the caregiver between sessions.
The group is based on a self-management approach and draws on Social Cognitive Theory and self-regulation models. We will employ a flexible approach to the organisation and structure of the sessions. Each session will cover a particular theme and participants will discuss the theme with each other and the facilitators. Within each theme participants will be able to focus on aspects that are meaningful to group members. The first session will include an orientation to the group and its approach, and information about memory difficulties. Subsequent sessions will cover themes which include: practical memory strategies, managing and coping with difficult emotions, managing relationships, planning ahead, how to find and access additional help and staying well. Based on the findings from Phase One of the study, the group will be facilitated in an informal manner and time will be included for more social activities. Facilitation techniques will include discussion, collaborative problem-solving and goal-setting as well as creating situations where participants can experience mastery.

The control group will receive care as usual.

Follow- up measures will be conducted at three and six months after the baseline assessment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Added 06/09/2013: This is a pilot study intended to supply an initial evaluation of the self-management intervention so that a full-scale randomised controlled trial may be powered from the best evidence available. It will assess the feasibility of the intervention, the study design and the recruitment strategies adopted. The primary research questions to be answered in a follow-on full-scale randomised controlled trial are outlined below. Our study aims to establish the relevant parameters and their confidence intervals, as well as reporting on the wider feasibility questions.

Perceived self-efficacy at three months post baseline assessment is the primary outcome measure. Self-efficacy is commonly recognised as a crucial factor in self-management. This will be measured with the General Self-Efficacy Scale with is a 10 item measure with established reliability and validity.

Secondary outcome measures
Participant with early-stage dementia:
1. Addenbrookes Cognitive Examination- III (ACE-III)

2. Hospital Anxiety and Depression Scale (HADS)
3. Clinical Outcomes in Routine Evaluation- Outcome Measure (CORE-OM)

Caregiver:
1. Neuropsychiatric Inventory Questionnaire
2. Relatives Stress Scale (RSS)

Person with dementia and caregiver:
1. Client Service Receipt Inventory (CSRI)
2. EuroQOL (EQ-5D)
3. ICECAP-O

Acceptability:
Participant dyads randomised to the self-management programme will be asked to provide feedback on the course. A short (20 minute) semi-structured interview will be conducted with each person in the dyad to explore their perceptions and views. This interview will be audio-recorded.

Overall study start date
01/08/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/09/2013:
1. Participants will be diagnosed with early-stage Alzheimers, vascular or mixed dementia as indicated by a score of 20 or more on the Mini-Mental State Examination (MMSE)
2. Participants must be able to give informed consent
3. Participants may be either taking or not taking medication for their memory problems. To ensure that change is not confused by medication effects, participants receiving memory medications must have been stabilised on their current dose for a minimum of one month prior to the first assessment, with no plan to change dosage/medication during the course of the study.
4. Participants must have a caregiver (close friend/ relative) who is willing to participate in this study

Previous inclusion criteria:
1. Participants will be diagnosed with early-stage Alzheimers, vascular or mixed dementia as indicated by a score of 20 or more on the Mini-Mental State Examination (MMSE)
2. Participants must be able to give informed consent
3. Participants may be either taking or not taking medication for their memory problems. To ensure that change is not confused by medication effects, participants receiving memory medications must have been stabilised on their current dose for a minimum of two months prior to the first assessment, with no plan to change dosage/medication during the course of the study.
4. Participants must have a caregiver (close friend/ relative) who is willing to participate in this study

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
We aim to recruit 42 participant- caregiver dyads

Key exclusion criteria
1. A history of stroke, significant neurological or psychiatric conditions (e.g. psychosis) or brain injury. These conditions may affect cognitive, emotional and behavioural functioning and thus make the study results difficult to interpret
2. Current significant anxiety or depression that would affect cognitive, emotional and behavioural functioning
3. Inability to speak English sufficiently well to allow completion of the assessment measures

Date of first enrolment
01/08/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Bangor University
Bangor
United Kingdom
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Sponsor information

Organisation
Bangor University (UK)

Sponsor details

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Sponsor type
University/education

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ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
National Institute for Social Care and Health Research- Health Award 2012. Ref: RFS-12-35 (UK)

Alternative Name(s)
Sefydliad Cenedlaethol ar Gyfer Ymchwil Gofal Cymdeithasol ac Lechyd, NISCHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	08/03/2014		Yes	No
Results article	results	01/05/2016		Yes	No
HRA research summary			28/06/2023	No	No