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The living well with dementia pilot randomised controlled trial

Submission date	Recruitment status
15/01/2013	No longer recruiting
Registration date	**Overall study status**
17/01/2013	Completed
Last Edited	**Condition category**
06/07/2018	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia is often a difficult subject to discuss. People in the early stages of the illness can benefit from talking about what is happening to them. There is little research evidence as to how best to do this. Government policy makes it clear that people with dementia should have opportunities to discuss their problems; and learn effective ways to cope with dementia. Recently a new approach has been developed in mental health: called the Recovery Model, it aims to help inform and empower people to help them live as well as they can despite their illness. This research project is being led by experienced Clinical Psychologists and will allow us to look at whether groups based on the recovery model are of benefit to people with dementia and their carers. The different groups will be lead by nurses working in memory clinics who have undergone a training programme. The overall aim of this project is to establish a base from which a full trial of recovery group work can be carried out.

Who can participate?
Those people eligible to take part in the study are those who have received within the previous 18 months of entry into the study a diagnosis made by a Consultant Psychiatrist of either probable Alzheimers disease, probable Vascular Dementia, or Dementia with Lewy bodies. Participants should also acknowledge, at least occasionally, that they have a memory problem; be willing to attend a group program; and have adequate communication skills to enable group participation. Participants should also have a Mini-Mental State Examination (MMSE) score of at least 18.

What does the study involve?
We will train nurses and to lead six different recovery groups for people with dementia. Each of these groups will last for 10 weeks. Researchers from the University of Southampton will interview those people with dementia who attend these recovery groups. They will gather information about the impact of the group on participants quality of life their levels of depression, and the level of care-giver burden.
We will do this prior to, at the end of the group and then after a 10 week interval. We can then compare this data with information from people who have been waiting to attend a recovery group.

What are the possible benefits and risks of participating?
This project is an initial small study. The effectiveness of recovery group work cannot be fully assessed in this study due to the small numbers of people involved. The information from this study will allow us to go on to carry out a full trial research project that can provide the answers that are needed.
We anticipate that the Living Well with Dementia group intervention program will produce no more potential adverse effects than would naturally occur in routine clinical practice of this kind. During participation in the Living Well with Dementia groups there is a likelihood that participants may discuss experiences that are emotionally upsetting, however groups will be supervised by mental health practitioners (trained memory clinic staff) and participants will have the backup and support of either their community mental health team or their memory service throughout and following the completion of the intervention.

Where is the study run from?
The Study is a collaborative research project involving NHS clinicians from two trusts (Southern Health Foundation trust based in Hampshire, and Avon and Wiltshire Mental Health Care trust) and researchers from the Psychology department at Southampton University

When is the study starting and how long is it expected to run for?
The study will be running for two years, from the 1st January 2012, to the end of December 2014. The time period in which we are recruiting participants varies according to where the groups are being held, but we will finish recruiting our final group early in the New Year of 2013.

Who is funding the study?
The National Institute for Health Research (NIHR)

Who is the main contact?
Dr Ann Marshall
Ann.Marshall@southernhealth.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr John Spreadbury

Contact details
School of Psychology
Faculty of Social & Human Sciences
University of Southampton
Southampton
United Kingdom
SO17 1BJ
+44 7867 627805
jhs101@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11077

Study information

Scientific Title
A pilot randomised controlled trial to compare changes in quality of life for participants with early diagnosis dementia who attend a 'Living well with dementia' group compared to waiting-list control

Acronym
LIVDEM

Study objectives
The main aim of this research will be to assess the impact and effectiveness of a standardised, non-pharmaceutical, 10 week group intervention program called Living Well with Dementia, for people with an early diagnosis of dementia and their families.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Ethics Committee South Central - Oxford B, 18th November 2011, ref: 11/SC/0363

Study design
Pilot randomised controlled trial with a subsidiary qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

Interventions
There are two arms to this study: an active intervention (10 week Living well with dementia group programme); and a waiting list control.

The Living Well with Dementia groups involves 10 weekly sessions, each one of which lasts for 75 minutes. The sessions are led by nurses and other health professionals working within a memory clinic setting who have attended a training course, and who receive regular supervision from the project leaders. The intervention is manualised to ensure consistency across the six different venues where it is being delivered.

The Living Well with Dementia intervention is based on a recovery model of mental health and places an emphasis on helping participants to find meaning in life, achieve acceptance of their illness and through this to renew hope. Central to this approach to well-being is the importance of challenging stigma and helping people with dementia to work with their family to take responsibility for recovery. The Living Well with Dementia group aims to achieve these goals by helping people with dementia to share their feelings about the diagnosis itself, the problems they face, and their fears for the future. The program will also provide education and training to help people to develop skills in managing their memory problems and encourage participants and their families to talk about what is happening to them and to set goals for their future.

Those participants allocated to the waiting list control arm of the study will not receive an active intervention but will be provided with an opportunity to take part in a Living Well with Dementia group once data collection has finished.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of Life in Alzheimers disease scale (QOL-AD; Logsdon et al. 1999). The QOL-AD is a brief, 13-item measure designed specifically to obtain a rating of the participant's Quality of Life. It was developed for individuals with dementia, based on input from the person, their family and from experts in the field, to maximize construct validity, and to ensure that the measure focuses on quality of life domains thought to be important in cognitively impaired older adults. It uses simple and straightforward language and responses & includes assessments of the individual's relationships with friends and family, concerns about finances, physical condition, mood, and an overall assessment of life quality.

Secondary outcome measures
1. Mood will be measured using the Cornell Scale for Depression in Dementia (CSDD; Alexopoulos, Abrams, Young, & Shamoian, 1988) for the person with dementia, and the General Health Questionnaire (GHQ; Goldberg & Hillier, 1979) will be used to assess mood changes in the spouse/care-giver.
2. Self esteem will be measured using the Rosenberg self-esteem scale (Rosenberg, 1989)
3. Cognitive changes will be measured using the Modified Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975)

4. General Quality of Life of both care-giver and person with dementia will be measured using the EQ-5D (Rabin & de Charro, 2001).
5. Costs and resources used will be measured using a modified version of the Client Services Receipt Inventory (CSRI; Beecham & Knapp, 1992)
6. In addition, changes in the person with dementias ability to discuss dementia at pre and post intervention will be rated using the Marker of Assimilation of Problematic Voices (Honos-Webb, Stiles, & Greenberg, 2003) - a technique used in psychotherapy process research and adapted by a member of the research team for assessing changes in awareness in groups for people with dementia (Watkins, Cheston, Jones, & Gilliard, 2006).
7. Domain non-specific changes will also be measured. Additional information will be collected using semi-structured interviews with group participants and their carers.

Overall study start date
16/04/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. A diagnosis made by a Consultant Psychiatrist of either probable Alzheimers disease according to the NINCDS-ADRDA criteria (National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer's Disease and Related Disorders Association) (McKhann et al. 1984) or probable Vascular Dementia according to the NINDS-AIREN criteria (National Institute of Neurological Disorders and Stroke - Association Internationale pour la Recherche et l'Enseignement en Neurosciences) (Roman et al. 1993) within the previous 6 months of entry to the study.
2. Male & Female; Upper Age Limit 100 years ; Lower Age Limit 50 years
3. Acknowledge, at least occasionally, that they have a memory problem
4. Be willing to attend a group program
5. Have adequate communication skills to enable group participation
6. Have a MMSE (Mini-Mental State Examination; Folstein, Folstein & McHugh, 1975) score of at least 18

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 66

Key exclusion criteria
1. Participants will be excluded from the study if they have a significant pre-morbid history of functional mental health problems (e.g. psychosis)

2. Participants will be excluded from the study if they have taken part in similar research or dementia group projects in the past

Date of first enrolment
16/04/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
Southern Health NHS Foundation Trust (UK)

Sponsor details
Newtown House
2a/b Newtown Road
Eastleigh
England
United Kingdom
SO22 6RE

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03qesm017

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Grant Codes: PB-PG-0610-22005

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?
Results article	results	01/07/2015		Yes	No