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Living well with dementia groups in primary care

Submission date
17/07/2013

Recruitment status
No longer recruiting

Registration date
25/10/2013

Overall study status
Completed

Last Edited
16/09/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
It is important that people who are affected by dementia receive an early and timely diagnosis. It is hoped that this will allow people affected by dementia to plan ahead and to take control over their illness. However, it is only possible for patients to do this if they realise the impact of the illness on them. This presents a huge emotional and social challenge. Although it is now relatively easy for people who are diagnosed with dementia to get appropriate written material, few services in the UK provide structured, clear and accessible emotional support that focuses directly on supporting people to come to terms with their illness. An initial study is comparing changes in quality of life for people with early diagnosis dementia who attend a "Living Well with Dementia" support group compared to people who are on a waiting list to attend. Although we havent yet been able to analyse our results, the early signs are that people enjoy attending the groups and find them helpful. However, one problem has become clear. These groups have been run by nurses who work for memory clinics. Due to an increasing demand for memory clinics to reduce the waiting time, it is now much harder for the clinics to support people once they have a diagnosis. Increasingly, people with dementia and their families are turning to the GP for support. In this study, we are looking to see whether it is possible to run the groups in GP practices.

Who can participate?
The groups are open to anyone in the local area who has received a diagnosis of Alzheimers disease, vascular dementia or Lewy-Body dementia less than 18 months before the start of the group, who has good enough communication skills and who would like to join.

What does the study involve?
This study involves training psychologists working in GP practices to provide the support groups. We will then support the psychologists to set up two groups, each of which will last for 10 weeks, and provide opportunities for people with dementia and their families to meet others in a similar position. We will collect information about how the groups run from the participants, their families and also from the group facilitators.

What are the possible benefits and risks of participating?
Our experience is that side effects to attending the groups are extremely rare. However, the sessions involve participants discussing their dementia, including their symptoms and the prognosis. By its nature, dementia is distressing, and people living with dementia often feel

embarrassed and uncomfortable in talking openly about their memory lapses. In general we have found that most people who attending the groups benefit from the sessions, and as a result feel more able to manage the illness and to cope with the embarrassing and frightening aspects of their condition.

Where is the study run from?
The study is being run as part of the LIFT psychology service, based in Swindon (UK).

When is the study starting and how long is it expected to run for?
The study will run from October 2013 until March 2014.

Who is funding the study?
The study is funded by Avon and Wiltshire Mental Health Partnership Trust, UK.

Who is the main contact?
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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
July 17th, 2013, v1.1

Study information

Scientific Title
A feasibility study to translate LIVing Well with DEMentia groups into a primary care context

Acronym
LIVDEM

Study objectives
The main aim of this feasibility study is to translate the Living Well with Dementia (LIVDEM) group intervention from its current use by memory clinic nurses into a primary care context. This broad objective can be broken down into a series of subsidiary questions, including:
1. Do therapists believe that the training delivered to therapists equips them to lead the LIVDEM intervention?
2. Do our methods of recruitment provide sufficient numbers of participants to make a group viable?
3. Is the collection of the Minimum Data Set (MDS) acceptable to group participants?
4. Is the LIVDEM model of intervention acceptable to group participants within primary care?
5. Are the research methods of identifying, enrolling and gaining informed consent developed for the LIVDEM memory clinic project, suitable for a primary care context?
6. What is the response rate to the MDS questionnaires?
7. What is the level of attendance at the groups ?
8. What is the compliance with the tasks given to participants during the intervention?
9. Are participants and their carers able to complete the Quality of Life in Alzheimers disease scale as a self-report instrument?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 10/10/2013 ref: 13/SC/0440

Study design
Pre- and post-intervention assessment with a subsidiary qualitative study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Dementia (Alzheimer's disease, vascular dementia and Lewy-body disease)

Interventions
Participants will attend one of two Living Well with Dementia groups, with between 4 and 12 participants attending each group, each of which runs for 10 weeks. The Living Well with Dementia (LIVDEM) group 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 LIVDEM groups attempt to achieve these goals by:
1. Helping people with dementia to share their feelings about the diagnosis itself, the problems they face and their fears for the future
2. Providing education and training to help people to develop skills in managing their memory problems
3. Encouraging participants and their families to talk about what is happening to them and to set goals for their future

In the first and the final session, family members and friends are invited to accompany the person with dementia. Each weekly session will last for 75 minutes. In order to facilitate adaptation to the illness, at the end of every session participants are given a one or two page handout. These summarise the contents of the session and outline possible homework tasks to be completed with carers.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life is measured using the Quality of Life in Alzheimers disease scale (QoL-AD) during the first and the final sessions.

Secondary outcome measures
The LIFT psychology service, like all Improving Access to Psychological Therapies (IAPT) services, are required to administer the Minimum Data Set (MDS) for all therapy participants at the end of every session. This includes:
1. Demographic information (e.g., ethnicity, address, religion, economic status)
2. The Patient Health Questionnaire (PHQ-9)
3. Generalized Anxiety Disorder 7-item (GAD-7) scale
4. Work and Social Adjustment Scale (WSAS)

Overall study start date
01/06/2013

Completion date

31/03/2014

Eligibility

Key inclusion criteria
The principal inclusion criteria are that participants:
1. Must have received a diagnosis of dementia within the previous 18 months. This diagnosis may be of
1.1. Probable Alzheimers disease according to the National Institute of Neurological and Communicative Disorders and Stroke - Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria (McKhann et al. 1984)
1.2. Probable vascular dementia according to the NINDS-AIREN criteria (Roman et al. 1993)
1.3. Dementia with Lewy bodies according to the consensus guidelines for the clinical and pathologic diagnosis of dementia with Lewy bodies (DLB) (McKeith et al. 1996)
2. Participants should acknowledge, at least occasionally, that they have a memory problem
3. Be willing to attend a group program
4. Have adequate communication skills to enable group participation
5. Have a MMSE (Mini-Mental State Examination; Folstein, Folstein & McHugh, 1975) score of at least 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
We will set up two groups, each of between six and eight participants

Key exclusion criteria
Participants will be excluded from the study if:
1. They have a significant pre-morbid history of functional mental health problems (e.g., psychosis)
2. Received a diagnosis of frontotemporal dementia (Neary et al. 1988)
3. If participants have taken part in similar research or dementia group projects in the past

Date of first enrolment
01/09/2013

Date of final enrolment
17/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Old Town Surgery
Curie Avenue
Swindon
United Kingdom
SN1 4GB

Sponsor information

Organisation
Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0379k6g72

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Avon and Wiltshire Mental Health Trust (Research and Capability Funding) (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No
HRA research summary			28/06/2023	No	No