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Reminiscence groups for people with dementia and their family care-givers: pragmatic eight-centre trial of joint reminiscence and maintenance v usual treatment

Submission date
21/08/2007

Recruitment status
No longer recruiting

Registration date
23/08/2007

Overall study status
Completed

Last Edited
21/04/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia is a term given to a group of conditions that involve the gradual decline of a person's mental faculties. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. This can make it very difficult to deal with daily life and so many sufferers are eventually placed in nursing homes so that they can receive round-the-clock care. Reminiscence therapy (thinking and talking about past experiences) is a type of therapy which encourages patients to talk about their life experiences using "memory prompts" such as photographs, recordings and personal objects. Although it is a popular treatment for people with dementia, especially in nursing homes, there is still little evidence for its effectiveness. Some studies have shown that if these activities are completed with care-givers as well as patients (joint reminiscence) can benefit both parties. The aim of this study is to investigate the effectiveness and cost-effectiveness of joint reminiscence therapy in improving the quality of life of people with mild to moderate dementia.

Who can participate?
Adults with mild to moderate stage dementia who are able to communicate with others and their care-givers.

What does the study involve?
Couples (patients and their care-givers) are randomly allocated to one of two groups. Those in the first group attend 12 two-hour sessions of joint reminiscence therapy in social settings. Each session is structured around a specific theme, such as childhood, schooldays, working life, marriage, and holidays. Couples are encouraged to bring their own memory prompts to the sessions, relating to the topic being covered. In each session, couples take part in large and small group work which involves a range of activities, such as art, talking about their experiences and physically re-enacting their memories. Participants in the second group continue to receive usual care for the 12 weeks of the study. At the start of the study and then after 3 and 10 months,

patients and care-givers in both groups complete a number of questionnaires in order to assess the patients' quality of life and the care-givers' wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Eight mental health services in North Wales, Gwent, London, Bradford, Hull and Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2007 to November 2010

Who is funding the study?
National Institute for Health Research (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
HTA 06/304/229

Study information

Scientific Title
Reminiscence groups for people with dementia and their family care-givers: pragmatic eight-centre trial of joint reminiscence and maintenance v usual treatment

Acronym
REMCARE (REMiniscence CARE)

Study objectives
Research objectives:
1. To compare the effectiveness (in ameliorating the quality of life of people with dementia and the stress on their carers) of joint reminiscence groups with participants and carers followed by reminiscence-based maintenance with that of 'usual treatment'.
2. To compare the incremental cost-effectiveness (in ameliorating the quality of life of people with dementia and the stress on their carers) of joint reminiscence groups with participants and carers followed by reminiscence-based maintenance with that of 'usual treatment'.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/06304229
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51344/PRO-06-304-229.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-centre Research Ethics Committee for Wales, 14/11/2007, ref: 07/MRE09/58

Study design
Interventional pragmatic eight-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Interventions

Joint Reminiscence Groups (JRGs):
This approach is known as Remembering Yesterday Caring Today (RYCT). It places emphasis on active, as well as passive forms of reminiscence, involving both care-givers and the person with dementia. Couples will attend 12 two hour sessions, held, where possible, in a social as opposed to a clinic-based setting. Each session is structured around a different theme for example; childhood, schooldays, working life, marriage, and holidays and journeys. Couples are encouraged to contribute with materials brought from home. Each session involves a blend of large and small group work. Typical activities include art, cooking, physical re-enactment of memories, singing and verbal reminiscence. The emphasis is firmly placed on the inclusion of the person with dementia. In the joint reminiscence groups care-givers are guided by facilitators and volunteers into allowing time for the person with dementia to respond and to value the contributions of the person with dementia.

There is a maximum limit of 12 couples to two trained facilitators in each group, together with a number of trained volunteers.

Control group: 'usual treatment'

Intervention Type
Behavioural

Primary outcome measure
The following will be assessed at baseline, 3 and 10 months after randomisation:

1. Quality of life for the person with dementia, self-assessed by the Quality of Life in Alzheimer's Disease (QoL-AD), which has been shown to be reliable and valid for people with mild and moderate degrees of dementia. The scale is completed in a structured interview with the person with dementia and covers 13 domains of life quality.

2. Care-giver's mental health, evaluated using the 28 item, self-report General Health Questionnaire GHQ-28 which has been widely used in care-giver research; the Likert scoring system 0-1-2-3 will be used. The scale includes indicators of anxiety, depression, insomnia, social dysfunction and somatic symptoms. This is preferred as the primary care-giver outcome to the Relatives' Stress Scale in this study, in view of its more general focus and wide usage.

Secondary outcome measures
The following will be assessed at baseline, 3 and 10 months after randomisation:

1. Autobiographical memory, assessed using an extended version of the Autobiographical Memory Interview (AMI). The extended AMI assesses recall of the person with dementia's personal memories relating to both factual (semantic) information for example, names of schools or teachers and specific incidents. In the trial platform, we validated an additional section on middle-age to retirement, to give systematic coverage to the life-span of our participants.

2. Measure of relationship quality, self-completed by both person with dementia and carer: Quality of the Care-giving Relationship (QCPR). Originally developed in the Netherlands this scale comprises 14 items (with 5 point Likert scales) designed to assess the warmth of the relationship and the absence of conflict and criticism.

3. Depression and anxiety for both people with dementia and carer:
3.1. Cornell Scale for Depression in Dementia (CSDD): A 19-item interviewer administered

measure, using information from interview with the person with dementia and their carer. Signs and symptoms are described to the carer as they appear on the scale. Where there is a discrepancy between the carer and clinician's ratings the carer is re-interviewed before the interviewer makes the final judgment.
3.2. Rating for Anxiety In Dementia (RAID): An 18 item rating scale to measure anxiety in a person with dementia based on a structured interview with the carer and the person with dementia.
3.2. Hospital Anxiety and Depression Scale for carer: a 14-item, self-report well-validated scale, which provides an index of both anxiety and depression, and is suitable for use with adults of all ages.

4. Stress specific to the care-giving situation, assessed using the Relative's Stress Scale: self-report scale for the care-giver, contains 15 items rated on a 5-point Likert scale.

5. Quality of life of person with dementia, rated by the care-giver, assessed using the proxy version of the QoL-AD, identical in structure and content to the self-report version above.

6. Costs, using the validated Client Services Receipt Inventory (CSRI). The CSRI has been used extensively in studies of mental health and dementia care and comprehensively gathers data on accommodation, medication and services accepted. In this case, the data collected will reflect the previous 3 months (at baseline and post-treatment) and 7 months (at follow-up).

7. Quality of life of care giver and person with dementia will also be measured using EQ-5D. EQ-5D is a standardised instrument for use as a measure of health outcome, applicable to a wide range of health conditions and treatments. It provides a simple descriptive profile and a single index value for health status. EQ-5D was originally designed to complement other instruments but is now increasingly used as a 'stand alone' measure. EQ-5D is designed for self-completion by respondents and can be used in face-to-face interviews. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire. We did not include the EQ-5D originally, in view of concerns that use of a generic quality of life measure such as EQ-5D might not be sufficiently sensitive for use as the primary outcome measure with people with dementia. Our team has previously used the EQ-5D to evaluate the concurrent validity of the QoL-AD, and the two scales showed moderate correlation (0.54), but rather less of the sample of people with mild to moderate dementia were able to complete it, even though it was administered in an interview. Care-givers will be asked to complete the measure from their own perspective and for the person with dementia. The self-report of the person with dementia will also be obtained wherever possible.

Overall study start date
01/12/2007

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Participants with dementia will meet the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM-IV) criteria for dementia. All types of dementia will be included, including Alzheimer's, vascular dementia, Dementia of Lewy Body type and mixed dementias.
2. Participants with dementia will be in the mild to moderate stage of dementia (Clinical

Dementia Rating).
3. Participants with dementia will have some ability to communicate and understand communication: a score of 1 or 0 on the relevant items of the Clifton Assessment Procedures for the Elderly Behaviour Rating Scale.
4. Participants with dementia will be living in the community at the time of the baseline assessment, and will have a relative or other care-giver who maintains regular contact, can act as an informant, and would be willing and able to participate in the intervention with the person with dementia.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
576

Key exclusion criteria
Participants will not have a major physical illness, sensory impairment, disability or a high level of agitation which could affect participation.

Date of first enrolment
01/12/2007

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
United Kingdom

Wales

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Sponsor type
University/education

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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

Intention to publish date
30/06/2012

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	30/07/2009		Yes	No

Results article	results	01/07/2012	Yes	No
Results article	results	19/04/2016	Yes	No