ISRCTN17993825 https://doi.org/10.1186/ISRCTN17993825

Journeying through dementia: exploring the clinical and cost-effectiveness of a group self-management intervention for people in the early stages of dementia

Submission date
26/09/2016

Recruitment status
No longer recruiting

Registration date
11/10/2016

Overall study status
Completed

Last Edited
11/05/2022

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 common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. In 2009 the UK government introduced the establishment of memory services in each health locality so that people experiencing symptoms of dementia can access expert diagnosis and help. The drive for earlier and better diagnosis continues, and was emphasised in the Prime Ministers Challenge on dementia. However the availability of services following early diagnosis has not kept pace. Some memory services provide assistance following diagnosis but others offer little more than medication. This may be because until recently, people only received help in the later stages of the condition or that some felt that nothing could be done to stop the condition after a person had been diagnosed. This view is now changing due to the availability of medication to alleviate symptoms combined with a growing societal movement to raise awareness and promote living well with dementia. Additionally there is a recent realisation that people with the condition can be helped to be independent for longer. Nevertheless, extent of unmet need among those who receive an early diagnosis is significant. This project involves examining the effectiveness of an intervention called Journeying through Dementia for those who are in the early stages of dementia. This program has been developed to help people to self-manage their condition and live their lives. The aim of this study is to explore the effectiveness and cost-effectiveness of the Journeying through Dementia program.

Who can participate?
Patients in the early stages of dementia. Participants can also choose for their supporter e.g. family member or friend (sometimes referred to as a carer) to also participate but this is not essential.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to

receive usual care for the duration of the study. Those in the second group also continue to receive their usual treatment as well as the Journeying through Dementia program. This consists of 12 1.5-hour long weekly group sessions and 4 individual sessions, all with trained NHS Facilitators. As part of the sessions people explore self-management techniques, with an emphasis on re-engagement with hobbies and interest. At the start of the study and then after eight and twelve months, participants in both groups complete a number of questionnaires in order to assess their quality of life and self-management skills.

What are the possible benefits and risks of participating?
The main benefit everyone participating in the trial will receive is the knowledge that they are supporting research which will help inform how to improve support to people in the early stages of their dementia. Those attending the Journeying through Dementia intervention may have additional benefits such as an improvement in self-management, however at this stage it is not known if the program is beneficial. There are no known risks involved with participating.

Where is the study run from?
13 NHS trusts across the North and East Midlands of England (UK)

When is the study starting and how long is it expected to run for?
December 2015 to May 2019

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

Who is the main contact?
Dr Jessica Wright
Jessica.Wright@sheffield.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Jessica Wright

Contact details
School of Health and Related Research
University of Sheffield
Regent Court
Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 222 4304
Jessica.Wright@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31981

Study information

Scientific Title
A randomised controlled trial of the clinical and cost-effectiveness of the Journeying through Dementia intervention compared to usual care

Acronym
JtD

Study objectives
The aim of this study is to evaluate the effectiveness and cost-effectiveness of a self-management group intervention called Journeying through Dementia, for people in the early stages of dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East National Research Ethics Service Board, 01/07/2016, ref: 16/YH/0238

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
Specialty: Dementias and neurodegeneration, Primary sub-specialty: Dementia; UKCRC code/ Disease: Neurological/ Other disorders of the nervous system

Interventions

Participants will be randomised on a 1:1 basis using a centrally based computer programme.

Intervention group: Participants receive the Journeying through Dementia intervention as well as usual care. The intervention consists of 12 weekly facilitated group sessions with 8-12 participants (all in the early stages of dementia) over 12 successive weeks, occasionally there may be a week's break, for example due to a bank holiday.

As part of the intervention, each participant also receives four individual sessions with one of the two facilitators to pursue their individual goals. The first individual session takes place before the commencement of the group and introduces the participant to one of the facilitators and enables discussion about their forthcoming involvement. The other three sessions are spaced over the 12 weeks including one at the end of the group sessions.
The content of the intervention includes (but is not limited to) the following topics:
1. Ways of thinking about dementia:
What is dementia, effects on everyday life, challenging stereotypes, sharing coping strategies
2. Keeping physically well
Relationship between physical and mental wellbeing, embedded health activity in everyday life, diet
3. Memory
Strategies to aid memory, impact on everyday life and learn and practice new techniques
4. Keeping mentally well
Relationship between anxiety and memory and dementia and stress
5. Endings
Celebration of achievements and how to move forward

There is flexibility within the intervention to select different topics and explore topics in the level of detail dictated by the group for example some groups may spend more time on memory with another group spending more time on keeping mentally well.. One essential component is enactment of activities, particularly in the community with participants being encouraged to support each other.
Participants are able to invite a supporter (e.g. family member, friend or neighbour) to participate in the group during sessions 1, 6 and 12, and in the individual sessions if the participant finds this helpful in achieving their goals. This is optional, e.g they do not have to bring along anyone. Nor does it have to be the same person each time or the participating supporter (if there is one).
The intervention is facilitated by two relevant NHS staff members experienced with working with people with dementia. Facilitators need to be at least a Band 3 on the Agenda for Change scale. Examples of relevant staff include nurses, occupational therapists, psychologists, social workers, occupational therapy assistants, assistant psychologists and support workers. Facilitators do not have to be registered health care professionals (HCPS). Additional staff will be trained in the intervention to provide cover for annual leave and sickness absence.
Facilitators at each site will initially receive a two day training course from Dr Claire Craig who devised the intervention. They will then be supported and supervised within their trust by someone experienced in supervision. This will usually be a HCP or social care professional who is a Band 7 on the NHS Agenda for Change scale. For example, someone who is a clinical psychologist or occupational therapist. The supervisors will receive supervision from a member of the trial team.

Control group: Participants receive treatment as usual for the duration of the study.

Both groups will be followed-up for a year, with outcome measure collection at 8 and 12 months post-randomisation.

Intervention Type
Other

Primary outcome measure
Dementia related quality of life is measured using the DEMQOL questionnaire at baseline and 8 months.

Secondary outcome measures
1. Dementia related quality of life measures using the DEMQOL questionnaire at baseline and 12 months.
2. Mood, specifically symptoms of depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline and 8 months
3. Mood, specifically symptoms of anxiety is measured using the Generalized Anxiety Disorder 7 questionnaire (GAD-7) at baseline and 8 months
4. Quality of life is measured using the EQ-5D-5L questionnaire at baseline, 8 and 12 months
5. Self-efficacy (sense of control of one's life) is measured using the General Self-Efficacy Scale at baseline and 8 months
6. Having the skills to self-manage is measured using the Self-Management Ability Scale at baseline and 8 months
7. A person's wellbeing is measured using the Diener's Flourishing Scale at baseline and 8 months
8. A person's ability to perform functional tasks is measured using the Instrumental Activities of Daily Living at baseline and 8 months
9. Health and social care service use including medication is measured using the Health and Social Care Resource Use Questionnaire a, 8 and 12 months. This is to inform the cost effectiveness analysis
10. Family and friends' ability to support someone with dementia is being measured by the Sense of Competency in Caregiving questionnaire administered at baseline and 8 months to people supporting the participant

Overall study start date
01/12/2015

Completion date
30/11/2019

Eligibility

Key inclusion criteria
People with dementia:
1. People diagnosed with dementia for example Alzheimer's disease, vascular dementia or mixed Alzheimer's/vascular dementia
2. A Mini Mental State Examination (MMSE) score of 18 or over (conducted less than 2 months pre consent)
3. Can make informed decisions (assessed by the Capacity Assessment Form)
4. Living in the community or in sheltered accommodation, alone or with others
5. Able to converse and communicate in English
6. Willing to engage in a 12 week group self-management intervention

Supporters (carers of a person with dementia):
1. Aged 18 years or older
2. Named by the person with dementia as their supporter
3. Able to converse and communicate in English
4. Ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 486; UK Sample Size: 486

Total final enrolment
519

Key exclusion criteria
People with dementia:
1. Not been diagnosed with a form of dementia
2. Being in more moderate stages of dementia. Measured by having a MMSE score of < 18
3. Is assessed as lacking capacity (assessed by the Capacity Assessment Form)
4. Living in residential or nursing care
5. Not able to converse or communicate in English
6. Is taking part in any other pharmacological or psychosocial intervention studies

Supporters:
1. Under 18 years old
2. The person with dementia they provide support to is not participating in the trial
3. Unable to converse or communicate in English
4. Unnot able to give informed consent

Date of first enrolment
01/11/2016

Date of final enrolment
28/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Health and Social Care NHS Foundation Trust
Old Fulwood Road
Sheffield
United Kingdom
S10 3TH

Study participating centre
Bradford and District Care Trust
Fieldhead House
2-8 St Martins Avenue
Bradford
United Kingdom
BD7 1LG

Study participating centre
Leeds and York NHS Partnership Trust
2150 Century Way
Leeds
United Kingdom
LS15 8ZB

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Leicestershire NHS Partnership Trust Riverside House
Bridge Park Plaza
Bridge Park Road
Thurmaston
Leicester
United Kingdom
LE4 8PQ

Study participating centre
South West Yorkshire NHS Foundation Trust
Fieldhead
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
Tees, Esk and Wear NHS Foundation Trust
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Humber NHS Foundation Trust
Willerby Hill
Beverley Road
Willerby
United Kingdom
HU10 6ED

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Lincoln
United Kingdom
LN1 1FS

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Mary’s Hospital
London Road
Kettering
United Kingdom
NN15 7PW

Study participating centre

North Staffordshire Combined Healthcare NHS Trust
Bellringer Road
Stoke-on-Trent
United Kingdom
ST4 8HH

Study participating centre
University Hospitals of North Midlands NHS Trust
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Northumberland Tyne and Wear NHS Foundation Trust
St. Nicholas Hospital Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Sponsor information

Organisation
Sheffield Health & Social Care NHS Foundation Trust

Sponsor details
Fulwood House
Old Fulwood Road
Sheffield
England
United Kingdom
S10 3TH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings of the trial will be actively publicised and disseminated. The main trial findings are likely to be published in 2020.

Intention to publish date
31/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator Professor Gail Mountain (G.Mountain@bradford.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative study results	04/02/2021	15/02/2021	Yes	No
Other publications	fidelity assessment	11/02/2021	18/02/2021	Yes	No
Other publications	trial challenges	29/01/2020	18/02/2021	Yes	No
Protocol article	protocol	13/09/2019	18/02/2021	Yes	No
	DEMQOL instrument results				

Results article		01/06/2021	14/06/2021	Yes	No
Basic results		09/08/2021	09/08/2021	No	No
Results article	Efficacy results	01/04/2022	08/04/2022	Yes	No
Funder report results		01/05/2022	11/05/2022	Yes	No
HRA research summary			28/06/2023	No	No