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The DECIDE study: dementia carers making informed decisions

Submission date
03/05/2016

Recruitment status
No longer recruiting

Registration date
14/06/2016

Overall study status
Completed

Last Edited
10/07/2023

Condition category
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 a common condition caused by the ongoing decline of the brain and its abilities with age. People with dementia and their relatives find it difficult to make decisions about whether they should live in a care home.The aim of this study is to develop and test a decision aid, known as the 'DECIDE manual', for carers of people with dementia to use when making decisions about living arrangements and place of care for their relative.

Who can participate?
Family/friend carers of people with dementia

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives the 'usual treatment', in this case being given a copy of the Alzheimer's Society factsheet 'Selecting a care home'. The other group receives the DECIDE manual, which the researcher takes participants through at the initial interview. All participants answer questions about decision-making and how they care currently feeling at the initial assessment, and 1 week and 10 weeks later.

What are the possible benefits and risks of participating?
We cannot promise the study will help participants but the information we get might help improve the support offered to carers of people with dementia and help healthcare staff discuss living arrangements and place of care with families in the future. We do not anticipate that there will be any disadvantages to taking part except for the inconvenience of making time for the interview, but it is possible that some topics discussed concerning the stresses of caring may be upsetting, so participants will be given details of appropriate, independent support services.

Where is the study run from?
This project is based at University College London and participants will be recruited from four memory clinics across three London boroughs: Camden Memory Service and Islington Memory Assessment and Treatment Service within Camden and Islington NHS Foundation trust; Haringey Memory Service within Barnet, Enfield and Haringey Mental Health trust and Tower Hamlets Diagnostic Memory Clinic within East London NHS Foundation trust.

When is the study starting and how long is it expected to run for?
August 2014 to April 2016

Who is funding the study?
UCL IMPACT studentship and the Division of Psychiatry (UK)

Who is the main contact?
Kathryn Lord

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The DECIDE study: dementia carers making informed decisions

Study objectives
Family carers who receive the DECIDE manual intervention will find the resource relevant and useful and to evaluate trial recruitment and retention in preparation for a full, pragmatic trial of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Research Ethics Service Committee North East – Newcastle & North Tyneside 2, January 2015; REC Reference: 15/NE/0015
2. Local approval was obtained from all regions where the study was conducted (East London and Camden and Islington NHS Foundation Trusts and Barnet, Enfield and Haringey Mental Health NHS Trust)

Study design
10-week pre and post design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

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
Carers of people with dementia

Interventions
Half of the cohort will receive the DECIDE decision aid we have created, the other half will receive 'treatment as usual'. In this instance that will be telling carers that if they want any further information they should speak with their healthcare professional.

Intervention Type
Behavioural

Primary outcome measure
The proportion of family carers who receive the DECIDE manual who report finding it relevant (defined a priori as a score of 4 or 5 on a 5 point Likert scale) and the proportion of family carers who receive the DECIDE manual who report finding it useful (defined a priori as a score of 8, 9 or 10 on a 10 point Likert scale).

Secondary outcome measures
To test the secondary hypothesis that family carers who receive the DECIDE manual intervention will report lower scores on the total Decisional Conflict Scale score and Informed sub-scale score, when compared to family carers in the treatment as usual group 10 weeks post baseline.

Overall study start date
07/08/2014

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Current, unpaid, main informal carer (e.g. a family member or friend in regular contact who is either next of kin or a 'key decision maker')
2. English language skills sufficient to participate in interviews. Whilst it is acknowledged that that the ideal would be to use the first language of all potential participants unfortunately there were not funds to provide interpreters

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
41

Key exclusion criteria
1. Carers under the age of 18 years
2. Carers where there are clinical concerns that may preclude them from being approached such as severe physical or mental illness or lack of capacity to give informed consent

Date of first enrolment
01/05/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
United Kingdom
W1T 7NF

Sponsor information

Organisation
University College London (UK)

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
Project that is part of a fellowship/personal award/research training award - PhD studentship funded by UCL IMPACT Award, cofunded by UCL Division of Psychiatry (Previously Mental Health Sciences Unit)

Results and Publications

Publication and dissemination plan
We intend to publish the results of the feasibility trial this summer/before the end of the year.

Intention to publish date
31/12/2016

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?
HRA research summary			28/06/2023	No	No
Results article		02/02/2017	10/07/2023	Yes	No