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GOLD Book Carer decision support for carers of people with dementia

Submission date
18/07/2011

Registration date
10/08/2011

Last Edited
24/01/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims
The majority of at-home care for people with dementia is given by family members but numerous studies have shown that dementia carers experience high levels of burden, which results in poor health outcomes and quality of life for them, and earlier institutionalisation for the person with dementia. Poor health outcomes include an increased risk of psychological illnesses such as depression and anxiety and an overall increased risk of illness and death. Interventions that address carer burden are therefore essential. This study aims to help carers of people with dementia by increasing their knowledge about the trajectory of dementia, improving their participation in decision-making about community services, reducing any feelings of conflict and anxiety they may have about making care decisions, and increasing the early use of community services. We aim to do this by providing carers with the GOLD Book decision aid (GBDA).

Who can participate?
Primary carers of people with dementia living in the community, aged 18 or over.

What does the study involve?
Carers are randomly allocated to either the intervention group (who receive the GBDA in the mail) or to the control group (who receive the GBDA at the end of data collection). Participants are interviewed at the beginning, middle and end of this three-month study about their role as a carer for a person with dementia. The interviews take about 45 minutes to complete. We assess the carers' health and stress levels, knowledge of dementia, service needs and whether they are satisfied, and how they are making decisions about care and services. At the end of the study some participants are also asked some specific questions about the book.

What are the possible benefits and risks of participating?
All participants in the study will receive a copy of the book (GBDA) that can help them think through service and support decisions. The study has no particular risks for participants, but the interview may evoke uncomfortable feelings. Assistance will be provided by the project staff to any participants who experience emotional discomfort as a result of the study.

Where is the study run from?
University of Tasmania (Australia)

When is the study starting and how long is it expected to run for?
February 2010 to February 2011

Who is funding the project?
Wicking Dementia Research and Education Centre of the Menzies Research Institute, University of Tasmania (Australia)

Who is the main contact?
Dr Christine Stirling
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Carer decision support: pilot evaluation of the GOLD Book decision aid for carers of people with dementia - a randomised controlled trial

Study objectives
The hypothesis to be tested is that a decision aid will lower primary dementia carers burden by improving their ability to make community service decisions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tasmania Health & Medical Human Research Ethics Committee, 26/03/2010, ref: H0010985

Study design
Randomised parallel wait-listed control study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stress and decisional conflict in carers of people with dementia

Interventions
The GOLD Book decision aid will be given to the intervention group, with control group receiving normal service support. Control group partiicpants will receive the GOLD Book decision aid after the 3 months follow-up data collection.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The Modified Carergiver Strain Index (MCSI) is a 13 item measure used to measure carer stress. The outcomes of the intervention will be assessed by comparisons between control and intervention groups at baseline (Time 1) and three months post intervention (Time 3), with the intervention given one week after baseline data is collected. Surveys will be delivered through face to face and phone interview.

Key secondary outcome(s))
1. Carer decisional state will be ascertained using the Decisional Conflict Scale (O'Connor 1993 /2005), a 16 item survey that yields a 5 scale measure of decisional uncertainty, and the Control Preferences Scale (Degner et al. 1997), which measures treatment decision making using 5 response statements.
2. Knowledge of dementia using a researcher generated knowledge survey
3. The outcomes of the intervention will be assessed by comparisons between control and intervention groups at baseline (Time 1) and three months post intervention (Time 3), with the intervention given one week after baseline data is collected. Surveys will be delivered through face to face and phone interview.

Completion date
01/02/2011

Eligibility

Key inclusion criteria

1. Primary carers of people with dementia living in the community
2. Aged 18+. self-identified as primary carers for a person with dementia
3. Able to read and speak English
4. These carers will be informal in the sense that they will be family members or friends and will not be undertaking care in a paid capacity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Children and/or young people (ie. <18 years)
2. People with an intellectual or mental impairment
3. Women who are pregnant
4. People highly dependent on medical care

Date of first enrolment
01/02/2010

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Australia

Study participating centre
University of Tasmania
Hobart
Australia
7000

Sponsor information

Organisation
Wicking Dementia Research and Education Centre, University of Tasmania

ROR
https://ror.org/01nfmeh72

Funder(s)

Funder type
Research organisation

Funder Name
Wicking Dementia Research and Education Centre (Australia) - Menzies Research Institute

Funder Name
University of Tasmania (Australia)

Alternative Name(s)
UTAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Results and Publications

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	19/03/2012	24/01/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes