

Dempower: Living Life and Doing Things Together couple-management guide

Submission date 16/10/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/11/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dementia is a group of symptoms that relate to the decline to the functioning of the brain. This can lead to memory loss, difficulty carrying out daily activities, thinking and other symptoms. This project is one of eight work programmes within the Neighbourhoods and Dementia study developed in response to the former Prime Minister's Challenge on Dementia (DH, 2012) and is led by a team in Sweden. The key focus of the study is to develop a 'Living life and doing things together' couple-management guide for couples where one partner has a diagnosis of dementia and to assess the acceptability of the guide. Researchers in Sweden have looked at what had been done before and have analysed interview data to identify common issues raised by couples. Discussions with couples in England identified a need to make the guide more user friendly, i.e. using visual material rather than just written material. This study adapting the guide into an app form and aims to determine how much support couples need to engage with this app and whether they make use of it in their day-to-day lives. If there is support for the app, a future study will assess whether it is superior to 'usual care'.

Who can participate?

Couples who have a partner/spouse with a diagnosis of dementia.

What does the study involve?

Couples recruited in the study are offered a Samsung tablet. Researchers support and train them to use the tablet and the app. Couples are encouraged to complete two sections of the app per week. On an average each section takes between 20-30 minutes. Couples may choose to navigate through the app in any order and may choose to engage with only parts of the app if they wish. Couples are asked to complete a set of questionnaires before they start working with the app and after they have completed the app. A researcher supports the person with dementia to complete these questionnaires and offer support to the caring partner if required. The app has four themes and several sections under each of these themes. On completing each theme couples will be asked to answer a theme specific questionnaire together.

What are the possible benefits and risks of participating?

Participants may benefit from having access to an extensively compiled resource in the form of an app and some useful tips on managing everyday life. Couples receive dedicated support to

learn how to use the tablet and the app. The app involves videos, suggestion for games, music, outdoor activities and preloaded games on the tablet. It provides couples the opportunity to try and engage with games, watch videos and actively engage in activities together. Couples can keep the tablet for their use after the end of the study and all that they have uploaded onto the tablet during their participation. The app and the questionnaires are not expected to cause any direct harm. If at any point participants experience psychological or emotional discomfort whilst using the app or answering questions then the researcher will allow time to rest or stop the study altogether. Participants may find using the tablet or the app difficult, to deal with this concern couples will be offered a lot of support and training. Participants might find answering self-administered questionnaires burdensome, if this happens they are encouraged to talk to the researcher and the researcher offers support either in person or over the telephone.

Where is the study run from?

This study is being run by the University of Manchester and it recruits participants from dementia /memory cafés and takes place in participants homes.

When is the study starting and how long is it expected to run for?
December 2014 to March 2019

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
Dr Reena Lasrado
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Study website
<http://www.neighbourhoodsanddementia.org/>

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35387

Study information

Scientific Title

Dempower: Living Life and Doing Things Together couple-management guide for couples living at home in which one partner has dementia - a feasibility study

Study objectives

The aim of the study is to investigate the feasibility and acceptability of a couple-management guide delivered in the form of an app called 'DemPower' among couples living together at home where one partner has dementia and to determine whether a full integrated clinical and economic RCT (randomised clinical trial) could be conducted.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. North West - Greater Manchester South Research Ethics Committee, 18/09/2017, ref: 17/NW/0431
2. Regional Ethical Review Board Linköping Sweden, 04/08/2017, ref: Dnr: 2017 2017/281-31

Study design

Non-randomised; Interventional; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Physical, Management of Care

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

See additional files

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

The study uses a prospective, non-randomised feasibility design to investigate the level of uptake of DemPower among couples where one partner has a diagnosis of dementia. A set of outcome measures and evaluation questionnaire will be used for data collection. The methodology facilitates an assessment of study processes to explore the criteria for a full trial.

The intervention DemPower is a couple-management guide delivered in the form of an electronic application on android tablets. The 'Living Life and Doing Things Together' project, one of eight work programmes within the Neighbourhoods and Dementia study (<http://www.neighbourhoodsanddementia.org/work-programme-6/>) developed the guide and is currently converting the guide into DemPower app. The app is aimed at enhancing wellbeing and couple relationship where one partner has a diagnosis of dementia.

The DemPower is structured under four primary themes and several sections within each theme. The themes and corresponding sections are introduced using storyboard techniques with a voiceover. Video clips of couples where one partner has dementia, sharing their experiences demonstrating particular situations follow storyboard illustrations. The app also makes suggestions for activities under each section. Examples of some suggested activities include: games (stored on the device), links to useful information, taking pictures; writing reflections, discussing emotions, needs and required changes to their home and their approach to daily life.

On completion of baseline assessments, the tablets with preloaded DemPower app will be handed over to couples. The participants are followed up on a monthly basis over a telephone call and home visits are arranged as per participants' requirements. They are encouraged to engage with a minimum of two sections per week. They have the option to engage with a selection of sections or with the entire guide and in any order. Participants are expected to complete the guide within a period of three months from the date of device hand over.

Intervention Type

Other

Primary outcome measure

Feasibility is measured through a set of evaluation questionnaires designed by the study team. Participants are encouraged to complete theme specific questionnaires at the end of each theme as they progress with the app. Researchers will administer the overall app evaluation questionnaire at end point, the end of three months from the intervention handover date or at the time that participants declare as completed.

Secondary outcome measures

1. Quality of life is assessed using 'Quality of Life in Alzheimer's disease' (QoL-AD) tool in both partners at baseline and endpoint
2. Carers related quality of life is assessed using 'Care quality of life' (CAREQOL) tool at baseline and endpoint
3. Self efficacy is assessed using 'General Self efficacy scale' (GSE) in both partners at baseline and endpoint
4. Interconnectedness is assessed using 'the inclusion of other in self scale' (IOS) in both partners at baseline and endpoint

5. Mutuality is assessed using 'mutuality scale' (MS) in both partners at baseline and endpoint
6. Health status is assessed using EQ5D-5L in both partners and DEMQOL in partner with dementia at baseline and endpoint
7. Health and social care service use is assessed using service use questionnaire in both partners at baseline and endpoint
8. Usability is measured using Systems Usability Scale at endpoint

Overall study start date

01/12/2014

Completion date

29/03/2019

Eligibility

Key inclusion criteria

1. Couples who have a partner/spouse with a diagnosis of dementia
2. Couples who live together in ordinary housing (not residential care)
3. Both partners understand and speak English (in the UK) or Swedish (in Sweden)
4. Couples in a long term relationship for two years or more

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 50

Total final enrolment

44

Key exclusion criteria

1. One or both partners are blind
2. Any partner who has become completely immobile or bed bound
3. Both partners have a diagnosis of dementia
4. Couples where one or both partners lack capacity or may have fluctuating capacity

Date of first enrolment

31/10/2017

Date of final enrolment

01/10/2018

Locations

Countries of recruitment

England

Sweden

United Kingdom

Study participating centre**Open Doors Dementia Café**

Roe Green Cricket Club Pavilion

Greenleach Lane

Worsely

United Kingdom

M28 2QW

Study participating centre**EDUCATE**

The Meadows

Owens Farm Drive

Stockport

United Kingdom

SK2 5EQ

Study participating centre**County Council of Östergötland [Region Östergötland]**

Linköping

Sweden

SE-581 91

Study participating centre**City of Linköping [Linköpings kommun]**

Linköping

Sweden

SE- 581 8

Study participating centre**Municipality of Norrköping [Norrköpings kommun]**

Norrköping

Sweden

SE-601 81

Sponsor information

Organisation

The University of Manchester

Sponsor details

Research Practice Governance
Faculty of Biology, Medicine & Health
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United Kingdom
M13 9PT

Sponsor type

University/education

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

Economic and Social Research Council

Alternative Name(s)

ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The following two papers were accepted for publication on 25/09/2017 in the journal called - 'Dementia, The International Journal of Social Research and Practice'

1. A review of couple-centred interventions in dementia: exploring the what and why – part A
2. An extended review of couple-centred interventions in dementia: exploring the what and why – part B

The Study team will submit the following protocol paper to the 'JMIR Research Protocols' and a paper on co-production to 'Qualitative Health Research' by 30/10/2017.

1. DemPower: designing and implementing a home-based couple-management guide where one partner has dementia – protocol development
2. Co-production in dementia: identifying higher order themes for a self-management guide aimed at couples where one partner has a diagnosis of dementia

The results from the feasibility study will be published in a high-impact peer reviewed journal some time during early 2019. A link to the protocol will be provided as soon as it is accepted for publication.

Intention to publish date

30/04/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	31/08/2017	24/10/2017	No	Yes
Protocol article	protocol	10/08/2018		Yes	No
Results article		16/11/2021	17/11/2021	Yes	No
HRA research summary			26/07/2023	No	No