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Evaluation of "Demenz anders sehen (Demas)", an Internet-based video conferencing support group for family caregivers of persons with dementia

Submission date 12/08/2013	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/09/2013	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/05/2020	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Domestic care for a relative with dementia is often associated with symptoms of depression and high levels of stress. To assist family caregivers of people with dementia, we developed an internet-based video conferencing support group programme. It is called "Demenz anders sehen (Demas)" (A different perspective on dementia). The goal of our study is to find out how well this programme works. If found to be effective, this could be practised on a broader scale.

Who can participate?
Our study aims at family caregivers of persons with dementia in Germany.

What does the study involve?
The programme consists of ten weekly sessions of about 90 minutes. Each group (4-7 members plus facilitator) meets in the video-chatroom of Demas. Information on the disease itself, how to improve the well-being of the affected person, how to improve communication with the affected person and information on stress management is given throughout the ten sessions. Moreover, participants can exchange their experiences with each other and receive advice from the trained facilitator.
Participants are randomly assigned to two study groups: members of the intervention group can start into the program right away, while members of the waiting list group have to wait for three months before they can enter the programme.

What are the possible benefits and risks of participating?
The goal of the programme is to provide its participants with new knowledge on dementia care, to support them emotionally and thus help them cope with the caring situation more effectively. Possible benefits include a higher care-related efficiency, increased well-being and lower levels of stress and depression. Risks of participating mainly relate to the possible frustration of being allocated to the waiting list group. Frustration can also occur as a result of (perceived) technical problems in the chat-room.

Where is the study run from?
The study is fully internet based. It runs on the website www.demenz-anders-sehen.de, which is managed by the Berlin-based Delphi Ltd, Germany.

When is the study starting and how long is it expected to run for?
The study starts in August 2013 and is expected to run for 18 months.

Who is funding the study?
The study is funded by the National Association of Statutory Health Insurance Funds in Germany (GKV-Spitzenverband).

Who is the main contact?
Dr Peter Tossmann, tossmann@delphi-gesellschaft.de
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Study website
https://www.demenz-anders-sehen.de

Contact information

Type(s)
Scientific

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

Evaluation of "Demenz anders sehen (Demas)", an Internet-based video conferencing support group for family caregivers of persons with dementia - an online randomised controlled trial

Acronym
Demas

Study objectives
Three months after randomisation and compared to a no-intervention wait list, participants of "Demas" will have a significantly lower subjective burden of caregiving and significant lower depression scores. Moreover, their caregiving related self efficacy will be significantly higher than in the wait list three months after randomisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics committee of the Magdeburg Stendal University of Applied Sciences on 29 July 2013 (ref: AZ 4973-34)

Study design
Randomized 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
Patient information can be downloaded from https://www.demenz-anders-sehen.de/studieninfos [German language]

Health condition(s) or problem(s) studied
Family caregivers of persons with dementia

Interventions
After consenting to the study conditions, participants are asked to fill out the baseline questionnaire. Afterwards and provided the eligibility criteria are met participants who dont have a webcam or headset get this equipment free of charge by mail. To test the equipment, to introduce the participants to the video chat and to explain the next steps in the study, a staff member calls the participant and meets him/her in the video chat. After the equipment has successfully been tested in the video chat each participant is allowed for randomization. Randomization is done blockwise with sets of approx. 10 to 12 participants.

There are two study groups:
1. Members of the intervention group can start into the program with the next scheduled intervention session. The intervention is group-based and consists of ten weekly sessions of about 90 minutes facilitated by Rehabilitation Psychologists (B.Sc.). Each group (4-7 members plus facilitator) meets in the video-chatroom of Demas.
2. Members of the wait list can commence using the program after three months.

Follow-up surveys are conducted 3, 6 and 12 months after randomization. Just like the baseline measurement these surveys are conducted via online-questionnaire.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Subjective burden of caregiving according to the "Berliner Inventar zur Angehörigenbelastung Demenz" (BIZA-D, Zank, Schacke & Leipold, 2006; [Berlin Inventory of Caregiver burden - Dementia])
2. Satisfaction with one's own performance as a caregiver according to The Sense of Competence Questionnaire (SCQ German version, Pfeiffer et al, in preperation)

The outcomes are measured at baseline and 3, 6 and 12 months after randomization.

Secondary outcome measures
1. Depression according to PHQ-9 (German version; Löwe, Spitzer, Zipfel, & Herzog, 2002)
2. General Self Efficacy according to Allgemeine Selbstwirksamkeit Kurzskala (Beierlein et al., 2012)

The outcomes are measured at baseline and 3, 6 and 12 months after randomization.

Overall study start date
26/08/2013

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. According to the family caregiver, the care recipient has been diagnosed with dementia.
2. The family caregiver provides care for at least 90 minutes per day.
3. There are no plans to admit the care recipient to a nursing home in the next six months.
4. The family caregiver himself / herself does not suffer from psychiatric disorders such as alcohol use disorder, schizophrenia, dissociative disorder, bipolar disorder, dementia.
5. The family caregiver has basic computer skills and has a computer with broadband internet connection.
6. The family caregiver (male and female caregivers) is at least 18 years old.

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
136

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
26/08/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Germany

Study participating centre
Delphi - Gesellschaft für Forschung, Beratung und Projektentwicklung mbH
Berlin
Germany
14057

Sponsor information

Organisation
The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) (Germany)

Sponsor details
Forschungsstelle Pflegeversicherung
Reinhardtstr. 30
Berlin
Germany
10117

Sponsor type
Not defined

Website
http://www.gkv-spitzenverband.de/

ROR
https://ror.org/03psr2094

Funder(s)

Funder type
Industry

Funder Name
The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) (Germany) - funding development of the intervention and the study.

Results and Publications

Publication and dissemination plan
2016 results in https://www.gkv-spitzenverband.de/media/dokumente/pflegeversicherung/forschung/projekte_unterseiten/demas/2016_11_29_Demas_Endbericht_Jun2016.pdf (added 29/05/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration