

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Dr Peter Tossmann

Contact details

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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 preparation)

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