

Psychosocial support for patients suffering from dementia and their care giving partners

Submission date 23/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/12/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

Dementia is a broad category of brain diseases that cause a long-term gradual decrease in the ability to think and remember. As there is currently no cure, interventions to help patients and caregivers to handle daily life with dementia are gaining importance. This study tests an intervention in a population of community dwelling older adults suffering from dementia who are cared for by a partner or family member. The aim of the intervention is to strengthen their personal and shared skills to better cope with the daily hassles that occur due to dementia.

Who can participate?

Community-dwelling patients with mild to moderate dementia and their partner/family caregiver who lives with them.

What does the study involve?

Participants are randomly allocated into two groups. One group receives nine sessions of a psychosocial support program. The other group receives a standard dementia consultation.

What are the possible benefits and risks of participating?

The intervention should lead to preservation or an increase of the patients' and caregivers' quality of life, and delay nursing home placement. There are no risks for the patients.

Where is the study run from?

Charité - Universitätsmedizin Berlin, Germany.

Who is funding the study?

Federal German Ministry of Education and Research.

When is study starting and how long is it expected to run for?

January 2011 to December 2013.

Who is the main contact?

Dr Michael Rapp

Study website

<http://dyadem.charite.de>

Contact information

Type(s)

Scientific

Contact name

Dr Michael Rapp

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

Fostering autonomy through a combined training and support program in patient/care giver DYAds in mild to moderate DEMentia (DYADEM): a randomized controlled trial

Acronym

DYADEM

Study hypothesis

Dementia describes a group of symptoms affecting intellectual and social abilities severely enough to interfere with daily functioning. Among other causes of dementia, Alzheimer's disease is the most common cause. Although dementia is far more common in the geriatric population, it can occur before the age of 60.

Since there is no curative medical treatment available today, non-pharmacological interventions to enable patients and caregivers to handle daily life with dementia are gaining importance, especially in view of demographic changes.

Hypotheses:

1. A specific psychosocial intervention in a dyad (patient with dementia and their affiliated) is more effective in maintaining quality of life than treatment as usual (TAU)-dementia consulting.
2. A combined intervention targeting patient/caregiver dyads is able to delay nursing home placement in this population
3. How do external and internal resources moderate the association between the burden of being sick and autonomy / self-contentment in dyads?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Charité Medical University, Berlin [Charité Universitätsmedizin, Berlin Ethikkommission] (Germany), 05/10/2011, ref: EA1/215/11

Study design

Interventional randomised controlled multi-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

<http://dyadem.charite.de> [German]

Condition

Dementia

Interventions

Intervention group: 9 sessions including socio and psychotherapeutic modules

Control group: treatment as usual dementia consulting, information sheet

Treatment group gets 9 weekly/ two-weekly sessions (1 to 2 hours) during approximately 12 weeks.

Session 1: couple specific psychosocial anamnesis

Session 2: social therapy I (information about support, social network, activities)

Session 3: psychotherapy I (stress, dyadic coping)

Session 4: socio-therapeutic consolidation via telephone

Session 5: psychotherapy II (communication training)

Session 6: social therapy II (daily routine coping strategies)

Session 7: psychotherapy III (problem solving)
Session 8: socio-therapeutic consolidation via telephone
Session 9: post-processing

Control group receives treatment as usual plus information sheets and contact details of support providers; duration: approximately 1 hour.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Combined standardized score of Quality of Life:

1. WHO-QoL (caregiver)
2. QOL-AD (dementia patient)

Secondary outcome measures

1. Autonomy:
 - 1.1. Activities of Daily Living (ADL)/ instrumental Activities of Daily Living (iADL)
 - 1.2. Older Adults Overprotection Scale (OPSA)
 - 1.3. Sense of Competence Questionnaire (SCQ)
2. Time to nursing home placement

Overall study start date

01/02/2012

Overall study end date

31/12/2013

Eligibility

Participant inclusion criteria

1. Community dwelling, diagnosed patients with mild to moderate dementia and their partner/ family caregiver
2. Are living together in one domestic home in Berlin, Germany
3. Are willing to participate together with their partner in the intervention

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Overall recruitment of N = 240 dyads (120 dyads in each group)

Participant exclusion criteria

1. Modified-Modified Schober Test (MMST) <15
2. Patient or partner/ family caregiver suffers from other specific psychiatric diseases (mental and behavioural disorders due to psychoactive substance use [ICD-10 F10-29])

Recruitment start date

01/02/2012

Recruitment end date

31/12/2013

Locations**Countries of recruitment**

Germany

Study participating centre

Charité - Universitätsmedizin Berlin

Berlin

Germany

10115

Sponsor information**Organisation**

Federal German Ministry of Education and Research [Bundesministerium für Bildung und Forschung (BMBF)] (Germany)

Sponsor details

Heinemannstr. 2

Bonn

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53175

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Sponsor type

Government

Website

<http://www.bmbf.de>

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration