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

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

Plain English summary of protocol

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
Charité - Universitätsmedizin Berlin
Geriatric Psychiatry Center
Psychiatric University Hospital St. Hedwig
Department of Psychiatry, Campus Mitte
Grosse Hamburger Str. 5-11
Berlin
Germany
10115

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 objectives
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]

Health condition(s) or problem(s) studied
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

Completion date
31/12/2013

Eligibility

Key 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)

Key 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])

Date of first enrolment
01/02/2012

Date of final enrolment
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
Germany
53175
-
information@bmbf.bund.de

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