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Telephone-based behaviour-therapeutic intervention to reduce family caregiver burden in chronic stroke (Telefongestützte verhaltenstherapeutische Intervention zur entlastung Pflegender angehöriger von Schlaganfall-betroffenen)

Submission date 05/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/06/2007	**Overall study status** Completed	
Last Edited 11/07/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
328/2006V

Study information

Scientific Title
Telephone-based behaviour-therapeutic intervention to reduce family caregiver burden in chronic stroke (Telefongestützte verhaltenstherapeutische Intervention zur entlastung Pflegender angehöriger von Schlaganfall-betroffenen)

Acronym
TIPS

Study objectives
A telephone-based behaviour-therapeutic intervention for family caregivers in chronic stroke can reduce their subjective caregiver burden and depressive symptoms. It does not raise total costs of formal and informal care or indirect costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of the University of Tuebingen (Germany) (www.uni-tuebingen.de), gave a positive vote for the study on the 25th October 2006 (ref: 328/2006V).

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Burden of family caregivers of chronic stroke survivors

Interventions
Intervention group:
Telephone-based problem solving training over 12 months. It comprises two home visits (after randomisation and month three) and regular telephone contacts with decreasing frequency over 12 months:
1. Month one: weekly
2. Months two to three: biweekly
3. Months 4 to 12: monthly, plus up to four additional optional contacts

The problem solving procedure is structured into the following six steps using different cognitive-behavioural techniques like cognitive restructuring and communication skill training according to a fixed intervention manual:
1. Problem definition and facts
2. Optimism and orientation
3. Goal setting
4. Generation of alternatives
5. Decision making
6. Implementation and verification

For initial problem orientation a card sorting procedure with 40 cards is used. The intervention is delivered by a psychologist.

Intervention and control group:
All participants receive a monthly information letter by post on care-giving or stroke related issues (i.e., caregiver rights, nutrition, relaxation techniques) over one year.

Interventions and assessments are delivered by different teams; the assessment team is blinded to the different groups by the study centre. Because communicating of their status by the participants a complete blinding is probably not possible.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Subjective caregiver burden (Sense of Competence Questionnaire [SCQ])
2. Caregiver depression (the Centre for Epidemiological Studies Depression scale [CES-D])
3. Total costs of formal and informal care
4. Indirect costs

Measured at:
T0 (Agreement) primary and secondary outcomes
T1 (3 ½ months after T0) primary and secondary outcomes
T2 (12 months after T0) primary and secondary outcomes
T3 (24 months after T0) and T4 (36 months after T0) institutionalisation rates

Secondary outcome measures

1. Ability of social problem solving
2. Social activities
3. Social support
4. Subjective physical symptoms
5. Burden of behavioural symptoms
6. Subjective health related quality of life
7. Qualitative analysis of caregiver burden with description of main problem areas with the card set
8. Institutionalisation rates of care recipients over a prolonged observational period

Measured at:
T0 (Agreement) primary and secondary outcomes
T1 (3 ½ months after T0) primary and secondary outcomes
T2 (12 months after T0) primary and secondary outcomes
T3 (24 months after T0) and T4 (36 months after T0) institutionalisation rates

Overall study start date
01/03/2007

Completion date
31/10/2010

Eligibility

Key inclusion criteria
Care recipient:
1. 60 years or older at the time moment of index stroke* (loss of neurological function due to an ischaemic or haemorrhagic intracranial vascular event)
2. Formal need of care or help for at least 1.5 hours a day (10.5 hours per week) (this time criteria corresponds to the criteria for receiving benefits from the statutory German nursing insurance), or
3. Need of care in form of supervision or for care recipients with cognitive impairment for at least 1.5 hours a day (10.5 hours per week) (these people are currently not adequately considered by the statutory German nursing insurance, but might be in the future)

Caregiver:
1. Age: 18 years and older
2. Family member, who has cared for the stroke survivor for at least six months
3. Time spent with care of stroke survivor (including nursing care, supervision and contact) at least 1.5 hours per day or 10.5 hours per week. There can be additional support with care (e.g. professional community nurses)
4. Significant caregiver burden assessed with six screening questions
5. Living in the region of Stuttgart (maximum of one hour with public transport from the study centre)
6. Availability of a telephone extension
7. At enrolment, plan to remain in area for the duration of the intervention
8. Ability to communicate over the telephone

* In the case of recurring strokes the index stroke is defined as the last stroke that increases the demand of care in a significant way

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
104 participants after 12 months

Total final enrolment
122

Key exclusion criteria
Care recipient:
1. Planned nursing home placement within the next six months
2. Unstable or progressive severe disease
3. Terminal status based on a prognosis of less than six months

Caregiver:
1. Duration of caregiving for the stroke survivor more than five years after index stroke
2. Mental disease like schizophrenia, alcohol addiction or cognitive impairment (rapid dementia screening test less than nine points)
3. Severe and unstable or progressive diseases like cancer
4. Not able to understand and speak German language
5. Temporary increased caregiver burden because of an acute illness (greater than repetition of the screening after such an episode of increased burden)
6. Involved in another clinical trial of interventions for caregivers (non-drug study)

Date of first enrolment
01/03/2007

Date of final enrolment
31/10/2010

Locations

Countries of recruitment
Germany

Study participating centre

Abteilung für Klinische Psychologie und Entwicklungspsychologie
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Sponsor information

Organisation
Robert Bosch Hospital (Robert-Bosch-Krankenhaus) (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.rbk.de/01.html

ROR
https://ror.org/034nkkr84

Funder(s)

Funder type
Government

Funder Name
Central Associations of the Statutory Health Insurances (Spitzenverbaende der Pflegekassen), represented by the Federation of Salaried Employees Health Insurance Funds (Verband der Angestellten-Krankenkasse e.V.) (Germany)

Funder Name

Added 20/07/09: Central National Association of the Statutory Health Insurance Funds (GKV-Spitzenverband) (Germany) since 01/07/2008

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014	11/07/2019	Yes	No