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Problem-solving in caregiver counseling

Submission date	Recruitment status	[_] Prospectively registered
30/12/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/03/2017	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is based on results of a previous study with family caregivers (ISRCTN86289718 - http://www.isrctn.com/ISRCTN86289718). The aim of this study is to train caregiver counselors in structured problem-solving (PS) and to evaluate its effectiveness in routine settings.

Who can participate?
Caregiver counselors, and family caregivers (age >18) who are assigned to one of the participating counselors and experience significant burden (physical and mental health, loneliness).

What does the study involve?
Counselors are randomly allocated to the training group or the waiting list group.
Counselors allocated to the training group receive training in problem solving (PS). It focuses on using PS for caregiver issues or problems, to master possible challenging interactions with the caregiver during counseling, and to overcome work-related difficulties. The training is delivered in a workshop (two days and one follow-up day) plus bi-weekly individual supervision by a psychotherapist over six months. Caregiver counselors are evaluated before and after training, and six months later. The counselors of the waiting list group counsel or give advice to caregivers according to standard home care counseling.
Caregivers receive regular counseling by one of the participating counselors with or without advanced PS training. Caregivers' depressive symptoms and further outcomes like caregiver self-efficacy, leisure time satisfaction and negative problem-orientation are assessed after enrolment, and after three and six months. A random sample of participating caregivers is interviewed in addition to the assessments.

What are the possible benefits and risks of participating?
We hope there is a positive impact on both sides: the caregivers who receive better help by the trained counselors, and the trained counselors who can improve their qualification. All participating counselors will eventually receive the advanced training. We do not expect any risks for counselors and caregivers taking part in this study.

Where is the study run from?
1. Clinic for Geriatric Rehabilitation, Robert-Bosch-Hospital (Germany)
2. Department of Clinical Psychology and Psychotherapy of the University of Tübingen (Germany)

When is the study starting and how long is it expected to run for?
Training and evaluation are running from November 2013 to October 2016

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Pilot projects for further development of the statutory German nursing care insurance according to § 8 Abs. 3 SGB XI (Modellvorhaben zur Weiterentwicklung der Pflegeversicherung gem. § 8 Abs.3 SGB XI)

Study information

Scientific Title
Problem-solving in caregiver counseling: a cluster randomized implementation study

Acronym
PLiP (ProblemLösen in der Pflegeberatung)

Study objectives
An advanced training in problem-solving for caregiver counselors has a positive impact on family caregivers who experience burden and depressive symptoms compared to usual counseling according to the German social legislation 7a SGB XI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the University of Tuebingen, Germany, 17/10/2013, ref.: 508/2013BO2

Study design
An implementation study with a prospective cluster randomized, wait-list controlled design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depressive symptoms of informal family caregivers

Interventions
The counselors randomized to the training condition receive a specific training over six months. The counselor training is based on problem-solving (PS) for caregiver counselors according to the six principles of the problem-solving model developed by D'Zurilla and colleagues (D'Zurilla & Goldfried, 1971; D'Zurilla, Nezu, & Maydeu-Olivares, 2004; D'Zurilla & Nezu, 2006): (a) optimism and orientation, (b) problem definition and facts, (c) goal setting, (d) generation of alternatives, (e) decision making, and (f) implementation and verification. The training in PS comprises the following three dimensions: (1) facilitating caregiver PS with the structured PS approach, a card-sorting task that was developed to identify problems unique to each caregiver, and tailored written information, (2) using PS to master difficult or challenging interactions with the caregiver, (3) using PS for own work-related difficulties as an aspect of mental hygiene.

The training is delivered in an initial two-day workshop, a follow-up day after 4 months, and individual bi-weekly telephone supervision contacts over six months after the initial workshop to facilitate the implementation of the PS principles and the card-sorting task in daily counseling practice. During the evaluation period (over a further 6 months) after the training period the counselors have four additional contacts with their supervisor.

The trainers and supervisors are cognitive behavioral therapists and clinical psychologists with specific experience in PS training with caregivers.

The counselors of the control condition (waiting-list control group) counsel or give advice to caregivers according to the statutory home care counseling (7a SGB XI).

The project is evaluated on two different levels: impact of the caregiver counseling 1) on the informal caregivers (main endpoint, telephone interviews), and 2) on the caregiver counselor (paper-and-pencil interviews).

Evaluation:
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Randomisation:
Ulm University - Institute of Epidemiology and Medical Biometry

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Informal caregiver:
Depressive symptoms (Centre for Epidemiological Studies Depression scale; Radloff, 1977).
Measured at T0 (after enrollment) , T1 (3 months after T0), T2 (6 months after T0)

Key secondary outcome(s))
Informal caregiver:
1. Caregiver burden (Sense of Competence Questionnaire; Vernooij-Dassen,1993) - Short version (Pendergrass et al., submitted).
2. Subjective physical complaints (Giessen Subjective Complaints List [Gießener Beschwerdebogen]; Brähler, Hinz & Scheer, 2008) - Subscale: Pains in Limbs (updated 21/07 /2015; was previously Exhaustion).
3. Negative problem orientation (Social Problem Solving Inventory - Revised; D'Zurilla, Nezu, & Maydeu-Olivares, 2002; Graf, 2003) - Subscale: Negative Problem Orientation.
4. Leisure time satisfaction (Leisure Time Satisfaction Questionnaire, Stevens et al., 2004).

Additional assessments:
1. Health service use (3 months retrospective)
2. Care-related quality of life (CarerQol; Brouwer, et al., 2006)
3. Semi-structured interviews with a random sample of caregivers

All caregiver domains (except the interviews) are measured at:
T0 (after enrollment)
T1 (3 months after T0)
T2 (6 months after T0)

Caregiver counselor:
1. Session management self-efficacy (Counselor Activity Self-Efficacy Scales; Lent et al., 2003) - Subscale: Session Management Self-Efficacy.
2. Difficult client behaviors self-efficacy (Counseling Self-Estimate Inventory; Larson et al., 1992) - Subscale: Difficult Client Behaviors.

Additional assessments:
1. Burnout (Maslach Burnout Inventory; Büssing et al., 1992) - Subscales: Emotional Exhaustion, Depersonalization, and Personal Accomplishment.
2. Self-Care (Program to promote psychosocial health resources; Kaluza, 2011) - Subscale: Self-Care Questionnaire.

3. Evaluation questionnaire by the informal caregiver.
4. Workload (Trier Inventory of Chronic Stress; Schulz, Schlotz & Becker 2004) - Subscale: Workload.
Counselors assigned to the intervention group are evaluated at T0 (enrollment, previous to the training), 6 months after T0 (after the training), 12 months after T0 (after the caregiver evaluation period).

Counselors assigned to the waiting list are evaluated at T0 (enrollment), 6 months after T0 (after the caregiver evaluation period; previous to the training), 12 months after T0 (after the training).

Completion date
31/10/2016

Eligibility

Key inclusion criteria
Caregiver counselors:
1. Providing caregiver counseling according to 7a SGB XI
2. Are qualified according to the recommendations of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)
3. Agreed to participate in the advanced training 'Family caregiver counseling is problem-solving' and the evaluation.

Informal caregivers:
1. Significant subjective caregiver burden assessed with three screening questions (decreased mental and physical health, feelings of loneliness, subjective caregiver burden)
2. Comprehensive counseling or case management is necessary (at least one personal counseling session and at least one telephone-based or personal follow-up contact)
3. Having the primary responsibility for someone who cannot fully take care of himself or herself according to the criteria of the German statutory nursing insurance
4. Is the main contact person for the caregiver counselor
5. 18 years and older
6. Consented to participate in the evaluation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Caregiver counselors:
1. Incomplete participation in the advanced training course 'Family caregiver counseling is problem-solving' (non-participation in the 2-day main training course or/and less than 50% of the 13 bi-weekly supervision telephone contacts)

Informal caregivers:
1. Professional paid responsibility for care recipient
2. Not able to speak and read German

Date of first enrolment
15/11/2013

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
Germany

Study participating centre
Robert-Bosch-Hospital (Robert-Bosch-Krankenhaus)
Auerbachstraße 110
Stuttgart
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Sponsor information

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

ROR
https://ror.org/03psr2094

Funder(s)

Funder type
Industry

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

Results and Publications

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?
Protocol article	protocol	06/03/2017		Yes	No