Trial Description

Title

Training and recreation days for tandems from people in need of care and their relatives

Trial Acronym

TANDEM

URL of the trial

https://pflege-tandem-svlfg.de/

Brief Summary in Lay Language

The project objective is the development, testing and evaluation of a one-week prevention programme for caring relatives, in which the persons in need of care also participate. The programme is implemented by the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) in cooperation with the Rehabilitation and Prevention Centre Bad Bocklet and the AZURIT Care Centre Bad Bocklet. The main aim is to promote the well-being of the caring relatives. In order to achieve this, care-related burdens are to be reduced and protective factors built up.

Brief Summary in Scientific Language

1. background and objective
Caring relatives are a vulnerable target group with increasing importance for nursing care in Germany. At the same time, relief and support for caring relatives are considered to be loss-making. The Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) offers caring relatives a regular inpatient training and recovery week throughout Germany. Studies have shown that this can increase the well-being of caregivers. However, the person in need of care is not yet present, so that some caring relatives cannot or do not want to participate. Therefore, the existing concept is to be expanded and tested for these persons. The primary goal is to promote the well-being of the caring relatives.

2. intervention
The intervention is financed by law and is composed as follows:
a) one-week prevention programme "care tandem",
b) care of the person in need of care during the "care tandem" and
c) individual counselling.

3. recruitment
Participants (n=130 intervention group) are recruited via public relations work and personal contact with the SVLFG (in particular nursing counselling, care administration, prevention service). Participation in the study is subject to informed consent.

4. design
The evaluation is designed as a controlled interrupted time series. The allocation

to the groups is not randomized. The data are collected by means of questionnaires.
Arm 1: Panel intervention group
The intervention group gets questionnaires at six points in time (baseline: 6, 3 and 0 months before; follow-up: 3, 6 and 9 months after). The primary goal is well-being. Secondary targets are subjective health, care tasks, personal limitations, acceptance of the care situation, support and health behaviour.
Arm 2: Panel control group
The panel control group receives no specific intervention and gets questionnaires at four points in time (0, 3, 6 and 9 months). The targets correspond to those of the intervention group.

4. statistics
The development of the target values before is compared with the development after. With methods of panel regression all (also unobserved) time-stable heterogeneities are controlled, so that the before measurements of the intervention group compensate the missing randomization. Temporal trends are controlled by including the panel control group.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00016365**
- Date of Registration in DRKS: **2019/01/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **085/2018 , Ethikkommission der Deutschen Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

- Free text: **Well-being or depressivity of caring relatives**

Interventions/Observational Groups

- Arm 1: **a) One-week prevention programme "care tandem",
b) care of the person in need of care during the "care tandem" and
c) individual counselling.
ad a) "care tandem" is a one-week prevention programme in the setting of a rehabilitation clinic (rehabilitation and prevention centre Bad Bocklet). The programme includes a nursing course, opportunities to exchange experiences and health promotion units in the fields of exercise and relaxation. At the end an individual action plan for a health promotion activity is drawn up ("self-care project"). The programme contains both separate and common elements for the carers and those in need of care.
ad b) The persons in need of care are cared for in the hotel of the rehabilitation clinic, in the geriatric department of the rehabilitation clinic or in the neighbouring facility for short-term care (AZURIT nursing centre Bad Bocklet). A daily programme for the persons in need of care is guaranteed.
ad c) In the run-up to the "care tandem", the SVLFG provides home care counselling in order to draw up a care plan for the person in need of care. Following on from "care tandem", the SVLFG tele-centre makes telephone contacts at three points in time (3, 6 and 9 months) in order to offer support for the implementation of the "self-care project". If care-related questions need to be clarified, the SVLFG care counselling is involved.**
- Arm 2: **caring relatives without specific intervention**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**Baseline (6, 3 and 0 months - control group only 0 months) and follow-up (3, 6 and 9 months)
Well-being (World Health Organization 5-item Well-Being Index, WHO-5)**

Secondary Outcome

**Baseline (6, 3 and 0 months - control group only 0 months) and follow-up (3, 6 and 9 months)
subjective health (11 points NRS);**

care tasks, personal limitations, acceptance of the care situation, institutional support (Das Berliner Invententar zur Angehörigenbelastung - Demenz - Praxisversion, BIZA-D-PV);
health behaviour.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/01/15**
- Target Sample Size: **130**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Caring relatives (1) who look after a person in need of care in a domestic environment who is entitled to benefits from the agricultural care insurance or the agricultural accident insurance (need for care due to an accident at work);
(2) who are currently not in psychotherapeutic treatment;
(3) with consent to participate in the study.

Exclusion criteria

Caring relatives whose person in need of care shows dementia-related tendencies to run away or requires special medical care (germination, respiration) or is not transportable.

Addresses

■ **Primary Sponsor**

Institut für Qualitätssicherung in Prävention und Rehabilitation GmbH an der Deutschen Sporthochschule Köln
Eupener Str. 70
50933 Köln
Germany

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URL: **www.iqpr.de**

■ **Contact for Scientific Queries**

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- **Collaborator, Other Address**

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  URL: **www.rehazentrum-bb.de**

- **Collaborator, Other Address**

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  Ms.

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bayerisches Staatsministerium für Gesundheit und Pflege
  Haidenauplatz 1
  81667 München
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.stmgp.bayern.de**

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **Anderer**
- Reason, if Reason for Recruiting Stop "Other": **Due to the general conditions resulting from the Covid pandemic, the interventions had to be stopped indefinitely. A resumption is planned but not yet scheduled. There is a waiting list.**

- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **36**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **36**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*