Trial Description

Title

Prevention by lay-assisted Outdoor-Walking in the Elderly at Risk (The POWER Study): a randomized controlled trial

Trial Acronym

POWER

URL of the trial

[---]*

Brief Summary in Lay Language

In a randomized, controlled interventional superiority-trial, 345 individuals ≥65 years of age recruited from nursing homes, community nursing services and general practice surgeries will be randomized into two groups. The intervention group will participate in a lay-helper assisted physical activation intervention for 6 months. An assigned lay-helper will visit them three times a week to go for an outdoor walk of 30 to 50 minutes or equivalent indoor activity. Participants and lay-helpers will keep an activity diary together, noting the date, time, duration and type of each activation exercise (outdoor, indoor). Persons in the control group are invited to two lectures covering topics related to health at old age to keep them motivated over the course of the study.

Brief Summary in Scientific Language

This will be a randomized controlled interventional study to test the effectiveness of a layperson assisted walking intervention in a community and nursing home setting. Recruitment will take place in primary care practices, home care nursing services and nursing homes. Individuals eligible for participation will be identified by the collaborating partners. Primary care practitioners will be instructed to consecutively recruit patients fulfilling inclusion and exclusion criteria. Home care nursing services and nursing homes will be instructed to screen their existing patients for eligibility and then consecutively recruit each incoming patient until the recruitment goal is met. Individuals in the intervention group will participate in a layperson assisted physical activation intervention for 6 months. They will be visited by an assigned layperson three times a week to go for an outdoor walk of up to 30-50 minutes. The duration can be adjusted to individual need or tolerability. In case of bad weather, the activity can take place indoors and will be a combination of walking and balance exercises.
Persons in the control group will be invited to two lectures covering topics related to health at old age to keep them motivated over the course of the study. The events will be easy to understand and entertaining to fit the cognitive capacity of the target population.

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

[---]*

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015188**
- Date of Registration in DRKS: **2018/08/31**
- 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.: **208/17 , Ethik-Kommission des Fachbereichs Medizin der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- Free text: **physical activity**
- Free text: **Quality of Life**

Interventions/Observational Groups

- Arm 1: **30-50 minutes of accompanied physical activation 3 times a week for 6 months: outdoor walking or supplementary indoors activity carried out by trained lay-helpers**
- Arm 2: **Two events with topics related to health at old age**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

- Who is blinded: **assessor, data analyst**
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Physical function measured by the Short Physical Performance Battery (SPPB)

Secondary Outcome

SPPB-Score at the end of the follow up extension study;
Quality of life operationalized by the EQ-5D-5L;
Fear of falling measured by the Falls Efficacy Scale (FES-I);
Clock-drawing-test;
Physical activity level;
Number and duration of lay-assisted intervention activities participated in (according to activity diary)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Marburg**
- other **Altenheime, Witten, Marburg**
- other **Ambulante Pflegedienste, Marburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/12/11**

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- Target Sample Size: **220**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

over 65 with reduced mobility and low social support

Exclusion criteria

Individuals meeting one or more of the following criteria will be excluded from the study:
Not giving informed consent;
Mini-mental status test (MMST) score at baseline < 18;
Insufficient physical function (Short Physical Performance Battery Score at baseline ≤2 in nursing homes and ≤3 in community setting);
Excellent physical function (SPPB-Score ≥10);
Permanently bedridden;
Can only be mobilized in a wheelchair;
Regular physical activity at least equivalent to the intervention (>150 minutes/week);
Severe diseases with a life expectancy of less than 6 months;
Other foreseeable inability to take part in the intervention for 6 months;
Known alcohol or drug addiction or active psychosis during the last 12 months;
Also, otherwise eligible individuals will be excluded, if another person from the same household (e.g. marriage partner or partner / sibling if living together) is already participating in the study.

Addresses

- **Primary Sponsor**

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Philipps-Universität Marburg
Mr. Prof. Dr. med. Norbert Donner-Banzhoff
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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.)**

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  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

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.*