

Trial Description

Title

OUTDOOR ACTIVE - Development of a community-based outdoor physical activity promotion program in older adults 65+

Trial Acronym

OUTDOOR ACTIVE

URL of the trial

<https://www.uni-bremen.de/de/buten-aktiv.html>

Brief Summary in Lay Language

Physical activity is an important prerequisite for healthy aging. Yet, only a small proportion of older adults move sufficiently. With rising age, engagement in physical activity is declining.

OUTDOOR ACTIVE focuses on physical fitness and activity of the Bremen population between 65 and 75 years. The aim is to test an approach to increase outdoor physical activity in this population group within selected sub-districts of Bremen. The project includes the local population and actors, with whom ideas and measures to encourage outdoor physical activity are jointly developed and implemented. The effect is measured in two large-scale health examinations by means of a before-after comparison and compared with the population of sub-districts where such a program was not implemented.

Brief Summary in Scientific Language

Physical activity is an important prerequisite for healthy aging. Still, only a small proportion of older adults move sufficiently. In addition to the general health benefits of physical activity, outdoor physical activity has beneficial effects on vitamin D levels and mental and emotional well-being through exposure to sensory impressions (Boyes 2013, Thompson et al., 2011). Thus, the positive influence of the environment in EEG recordings could be demonstrated (Aspinall et al., 2013). In addition, it has been shown that older adults who are physically active outdoors show higher levels of activity overall than those who only practice indoor sports (Kerr et al., 2012).

In general, the success of physical activity programs is heterogeneous (Ashworth et al., 2009, Richards et al., 2013), depending, amongst others, on the nature of the intervention and the existence of a methodological approach to intervention development (Cleland et al 2013). Community-based participatory approaches (CBPRs) offer great potential for interventions, especially if they follow an ecosystemic approach as they strongly involve the community (Haggis et al., 2013). CBPR have been used successfully in occupational health promotion (Sorensen & Barbeau 2006) and are useful in reducing health inequalities (Salimi et al., 2012). However, there is very little experience with CBPR in the development of community-based physical activity programs in older adults.

A cluster randomized trial (CRT) will be carried out in which eight sub-districts of Bremen (four intervention parts, four parts of the control area) will be involved.

The districts are determined by simple random sampling. Initially, a population-based survey (t0) is carried out in the intervention and control parts. This includes measurements of physical activity (accelerometer) and fitness (Senior Fitness Test (Rikli, 2013), see attachment), a short physical examination (blood pressure, short anthropometry) and a self-administered questionnaire on individual and exogenous determinants of physical activity.

A physical activity program will be developed in the intervention parts with actors in the community and with public participation. The program will be developed using a CBPR approach, the PRECEDE-PROCEED model (PPM, Green & Kreuter 2005).

Each development step is communicated and discussed in the community and tested for its feasibility. The intervention material is being developed as part of an ecological model (Cunningham et al., 2004). Subsequently, the implementation of the program is implemented. Sustainability of the program will be promoted by, for example, integrating sports clubs.

For the formal CRT evaluation, a follow-up survey (t1) will be carried out in intervention and controls to examine longitudinal changes and to be able to analyze an effect on the outcome parameters.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015117**
- Date of Registration in DRKS: **2018/07/17**
- 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.: **2018-06 , Ethikkommission der Universität Bremen, Bibliothekstrasse 1, 28359 Bremen**

Secondary IDs

Health condition or Problem studied

- ICD10: **Z72.8 - Other problems related to lifestyle**
- Free text: **Lack of physical activity**

Interventions/Observational Groups

- Arm 1: **In randomly sampled sub-districts of the city of Bremen, a community-based program to promote outdoor physical activity will be developed and implemented in a participatory fashion; observation unit are the inhabitants of the sub-district (cluster-randomised trial)**
- Arm 2: **Inhabitants of randomly selected sub-districts of the city of Bremen without intervention (control sub-districts)**

Characteristics

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

Primary Outcome

Physical activity (accelerometer measurements: Vector magnitude of 3-dimensional counts); measurement times at the beginning and end of the intervention phase; observation period 1 year

Secondary Outcome

Senior Fitness Test (6 exercises measuring endurance, strength, balance, flexibility); measurement times at the beginning and end of the intervention phase; observation period 1 year

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Universität, Bremen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/07/23**
- Target Sample Size: **808**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

Adults aged 65 to 75 years (born 01.09.1943-01.09.1953) with primary residence in the randomly selected sub-district of Bremen.

Exclusion criteria

Persons not able to give consent.

Addresses

■ Primary Sponsor

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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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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

DRKS-ID: **DRKS00015117**

Date of Registration in DRKS: **2018/07/17**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Trial Publications, Results and other documents

- Paper **Bammann K, Drell C, Lübs LL, Stalling I. Cluster-randomised trial on participatory community-based outdoor physical activity promotion programs in adults aged 65-75 years in Germany: protocol of the OUTDOOR ACTIVE intervention trial.**

* *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.*