Trial Description

Title
Preference-based interventions to promote sustained physical activity

Trial Acronym
PROMOTE II

URL of the trial
http://www.aequipa.de/teilprojekte/promote.html

Brief Summary in Lay Language
The main aim of the PROMOTE II-project is to adapt, develop, implement and evaluate various types of interventions for the initiation and maintenance of physical activity in older adults. Study participants will receive either a paper-pencil or simplified web-based physical activity intervention that initially inactive participants with little affinity to technology find easy to interact with. To evaluate the effectiveness of different types of interventions on physical, psychological, and cognitive parameters, physical activity and psychological variables will be assessed at baseline and follow-up. Cardiovascular fitness, as well as motor and cognitive function, will be assessed in a subsample to explore possible changes in a pooled sample of participants of the preceding and current study.

Brief Summary in Scientific Language
PROMOTE II addresses knowledge gained during the preceding study PROMOTE I, the scientific research goals of which were: to develop and test individually tailored eHealth-interventions for the promotion of a physically active lifestyle in persons 60 years of age and above in a randomized controlled field trial, to examine intervention effects on physical, psychological and cognitive indicators for healthy ageing, and to analyze the acceptance of the interventions among participants.
Based on the gained knowledge and participants’ feedback in the preceding study, PROMOTE II aims:
a) to adapt the web-based interventions further to improve usability and develop a simplified print intervention that initially inactive participants with little affinity to technology find easy to interact with.
b) to investigate implementation, feasibility, and use of two interventions (web-based vs. simplified print), as well as changes in PA, among older adults (aged 60 years and above) in a randomized trial with a cross-over design over the course of nine months.
c) to explore associations of changes in PA with possible changes in physical fitness and cognitive capacity in a pooled sample of participants of both phases of PROMOTE.

Participants will first be randomized to either (a) a web-based intervention, or (b) a simplified print intervention. 30% of those in group (a) will receive a PA tracker in addition to access to the website. All intervention arms will be offered weekly.
group sessions over the course of ten weeks. After three months, all study arms will be informed about both interventions. Participants will be given the choice to remain in their study arm or to cross over to the other study arm. With that, a crossover design with potential intervention designs web-web, print-print (matched) or web-print and print-web will be generated.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: DRKS00016073
- 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.: 635, Ethik-Kommission der Ärztekammer Bremen

Secondary IDs

Health condition or Problem studied

- Free text: Physical inactivity

Interventions/Observational Groups

- Arm 1: Intervention group 1: Paper-pencil intervention with subjective physical activity monitoring
- Arm 2: Intervention group 2: Web-based intervention with subjective physical activity monitoring
- Arm 3: Intervention group 3: Web-based intervention with subjective and objective physical activity monitoring (subgroup of intervention group 2)

Characteristics
Primary Outcome

The primary outcome is the change in physical activity. It is assessed at baseline, at 3 and 9 months via triaxial accelerometers (worn over the course of 7 days).

Secondary Outcome

Further, functional, cognitive and mental health and other relevant parameters that are associated with physical activity will be assessed. These include physical fitness (gait speed via 4-meter-walk-test; handgrip via dynamometer; cardiovascular fitness via 2-minute-step-test) and cognitive fitness (via Mini Mental Status Test – short version), quality of life (EuroQol-5D-3L), well-being (Satisfaction with Life Scale), self-efficacy and intention (based on the Health Action Process Approach Model), body satisfaction (Physical Self-Description Questionnaire), depressive symptoms (Center for Epidemiological Studies Depression Scale), and fear of falling (Elderly Fall Screening Test). Outcomes are assessed at baseline, 3 and 9 months.

Countries of recruitment

DE Germany

Locations of Recruitment

other 14 Ortsteile in den Gebieten Bremen Ost und Bremen Nord:-
Burgdamm (Ortsteil) - Lesum (Ortsteil) - St Magnus (Ortsteil) -
Vegasack (Ortsteil) - Schönebeck (Ortsteil) - Aumund-
Hammersbeck (Ortsteil) - Rönnebeck (Ortsteil) - Radio Bremen
(Ortsteil) - Riensberg (Ortsteil) - Gartenstadt Vahr (Ortsteil) -
Neue Vahr Südwest (Ortsteil) - Oberneuland (Ortsteil) -
Ellener Feld (Ortsteil) - Blockdiek (Ortsteil)
Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 60 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

- Informed consent for study participation
- Device with internet access in household available
- Independent living
- Basics skills in German language
- Study participants can independently visit assessments
- Study participant can walk independently (without walking aid)

Exclusion Criteria

- Permanent fulfillment of target criterion regarding physical activity: regularly physically active for more than a year, i.e. 150 minutes moderate endurance training per week, strength training of main muscle groups twice a week and balance training twice a week
- Participation in PROMOTE I
- Planned vacation during intervention period which is longer than two weeks
- Medically prohibited to be physically active
- Cognitive deficits (Mini-Mental-Score ≤27)
- Implanted devices, e.g. pacemaker, brain pacemaker or implanted hearing aid
- Severe visual impairments
- Permanent impairments due to a stroke or a transient ischemic attack (TIA)
- Permanent impairments due to a brain surgery
- Neurological diseases like Alzheimer dementia, Parkinson, Multiple Sclerosis
- Impairments due to an acute spine injury
- Fractures/surgeries in the last six months which limits participation (if no medical clearance is present)
- Severe diseases of the cardiovascular system (e.g., cardiac arrhythmia, arterial occlusive disease, heart failure, pacemaker, hypertension) (if no medical clearance is present)
- Severe diseases of respiratory system (e.g., COPD, severe asthma) (if no medical clearance is present)
- Severe limitations due to arthritis or osteoarthritis in the legs (if no medical clearance is present)
- Severe osteoporosis (if no medical clearance is present)
- Diabetes diagnosis less than six months ago (if no medical clearance is present)
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 complete, follow-up complete
- Study Closing (LPLV): 2020/01/31

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.