Trial Description

Title

BewARe - Analysis of load requirements

Trial Acronym

BAB

URL of the trial

https://www.beware-projekt.de/

Brief Summary in Lay Language

The object of the explorative observational study is the acquisition of vital parameters of seniors in rehabilitation heart sports in phase III.

The planned study is part of the BMBF-funded project "BewARe - Sensor-supported movement training for seniors in an intelligent augmented reality system" as part of the BMBF Programme "Interactive systems in virtual and real spaces - Innovative technologies for a healthy life".

Brief Summary in Scientific Language

- Determination of framework data during cardiac sports by seniors (minimum age 60 years old) with cardiovascular diseases

- Determination of the subjective perception of the adequate stress intensity by the participants and leaders of the cardiac sports group

Organizational Data

- DRKS-ID: **DRKS00016864**
- Date of Registration in DRKS: **2019/04/01**
- 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.: **EA/259/18 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1229-5347**

Health condition or Problem studied

- ICD10: **I10.9 - [generalization I10: Essential (primary) hypertension]**
- ICD10: **I99 - Other and unspecified disorders of circulatory system**

Interventions/Observational Groups

- Arm 1: **Before the start of the study, participants will be informed of the objectives and purposes of the observational study by an information event. Participants who have agreed to participate in this study will be checked for inclusion and exclusion criteria. On the test day, participants receive questionnaires with an integrated Borg scale. Validated assessments and objective measurements of vital parameters are carried out. In addition, the training unit is documented by the study personnel.**

  With the heart sport group leaders an assessment is carried out by means of a questionnaire with integrated Borg scale to evaluate the load of the participants.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Analysis of the subjective perception of the adequate stress intensity by the participants:

- Questionnaire for the acquisition of framework data such as age, gender, height, weight as well as medical history and the duration of participation in rehabilitation heart sport groups

- Heart rate measurement by means of a Wearable watch, which is worn on the wrist and records the pulse over the entire training period

- Blood pressure measurement using a conventional digital blood pressure monitor

- Questionnaire on self-assessment, which contains standardized assessments such as the Borg scale and scale for recording perceived physical condition (WKV-20)

- Further questions refer to the pulse, the exercises or the evaluation of the heart sport group leader.

- Questionnaire for the stress assessment of the participants, which contains standardized assessments such as the Borg scale filled by the heart sport group leader

Secondary Outcome

Comparison of subjective perception and objective measurement data of the participants during the rehabilitation heart sport group

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Herzsportgruppe am Sport-Gesundheitspark Berlin e.V. im Evangelischen Geriatriezentrum Berlin (EGZB), Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/04/04**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Participant:

- ≥ 60 years
- Participant of phase III cardiac rehabilitation
- Diagnosed cardiovascular disease
- Informed about the study
- signed consent from the participant

Phase III cardiac rehabilitation group Leader:
- currently active as cardiac rehabilitation group leader
- at least 3 years professional experience

Exclusion criteria

Participant:

- Participant of Phase I+II cardiac rehabilitation
- resting blood pressure over 200/110 mmHg
- Exclusion of the participant from the training unit by the attending physician of the cardiac sport group
- Presence of legal support

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): **[---]***

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.*