



**PLEASE NOTE:** This trial has been registered retrospectively.

## Trial Description

### Title

**Wearable health technologies for older, chronically ill patients**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

[---]\*

### Brief Summary in Scientific Language

**In an aging society an increasing number of people is no longer able to cope with their disease due to multimorbidity and cognitive impairments. These physical and psychological impairments often result in a loss of quality of life. In 2009 in Germany, 60% of women and 53% of men older than 65 years were facing at least on chronic disease. In total, there are more than 80% of people older than 65 years in western European Countries who suffer from a chronic condition. Many of them are in need of help on a daily basis to deal with their disease. One variant of wearable health technologies (WHT) to support health promotion behavior are so called fitness trackers, which are body worn sensors. With their aid, patient data can be documented and analyzed to provide feedback about their current health status. Reliable data about psycho-social factors influencing the usage of WHT and subjective experiences of patients are largely missing. This prospective study consists of a qualitative information collection on patients' perspectives and expectations with respect to WHT in advanced age. The observations gained through this first part of the project will be used to define the design of an intervention step to address efficacy and tolerability of a wearable tool in the aged as far as well-being and disease-relevant basic vital parameters are concerned.**

## Organizational Data

- DRKS-ID: **DRKS00009740**
- Date of Registration in DRKS: **2016/02/12**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **15-350** , **Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **I00-I99 - Diseases of the circulatory system**
- ICD10: **E11 - Non-insulin-dependent diabetes mellitus**

## Interventions/Observational Groups

- Arm 1: **People with Diabetes Type II and cardiovascular disease, their relatives and treating physicians are queried once with the aid of a semi-structured questionnaire concerning their perspectives and expectations with respect to wearable health technologies. Additionally they are questioned about sociodemographic data.**

## 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

**Qualitative survey of the study participants concerning their perspectives and expectations with respect to wearable health technologies.**

### Secondary Outcome

none

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- University Medical Center **Klinik II für Innere Medizin, Köln**
- University Medical Center **Herzzentrum, Köln**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/23**
- Target Sample Size: **12**
- 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

**People older than 65 years with Diabetes Type II and cardiovascular disease are questioned. They should live independently at home. At the moment of the interview they should not be hospitalized. Their relatives and treating physician are also queried. Participation must be voluntarily. Study participants must be fluent in German language.**

### Exclusion criteria

**At least one inclusion criteria is not the case.**



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## Addresses

### ■ Primary Sponsor

**Fortschrittskolleg Wohlbefinden bis ins hohe Alter**

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### ■ Contact for Scientific Queries

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### ■ Contact for Public Queries

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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: [---]\*

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/04/30**

## Trial Publications, Results and other documents

- Paper **Wearables zur Unterstützung des Selbstmanagements von älteren Menschen mit chronischen Erkrankungen**

\* 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.