Trial Description

Title

Enhancing self-care adherence in heart failure patients by developing a manual containing well-defined and theory-based behaviour change interventions through the application of the COM-B behaviour model

Trial Acronym

ACHIEVE study (behAviour CHange IntErVentions on sElf-care)

URL of the trial

http://gepris.dfg.de/gepris/projekt/270822994

Brief Summary in Lay Language

International guidelines recommend self-care as an integral part of heart failure management. Despite evidence of self-care efficacy, patients with heart failure often do not follow the recommended self-care measures. However, self-care behaviour can be improved by appropriate behaviour-changing interventions. However, previous intervention studies have shown different results in improving self-care adherence. The reasons given are a lack of theoretical underpinning and an inadequate description of the intervention by descriptors, which prevents identification of the underlying mechanisms and the possibility of reproducability. The aim of this study is to develop a theory-based concept of behavioral intervention in the form of a manual containing the descriptors for the reproducability of interventions as described in the literature. The intervention manual is then to serve as a basis for the subsequent conduct of an exploratory study, the aim of which is to improve self-care adherence.

Brief Summary in Scientific Language

Although international guidelines recommend on-going self-care as part of routine heart failure management, and despite evidence supporting the positive outcomes related to self-care, patients are frequently unable to adhere. Heart failure self-care can be modified and enhanced through behaviour change interventions (BCIs). However, previous self-management interventions have shown limited success in improving adherence to self-care because they were neither theory-based nor well defined, which precludes the identification of underlying causal mechanisms as well as transparency and reproducibility of the intervention. Thus, we propose to develop an intervention manual that contains theory-based BCIs that are well-defined using eight descriptors proposed to describe BCIs in a standardised way. The manual will serve as a blueprint, which then can be applied with confidence in a subsequent exploratory trial that seeks to enhance patients' adherence to self-care. To manage the process of developing BCIs in a systematic fashion, our work programme consists of four stages. Behaviour change interventions will be based on both selected statements of findings that were derived by our research team from the recently completed qualitative meta-summary project (HE 7352/1-1) and findings from a quantitative meta-analysis published by Kessing et al. (2016). These two up-to-date comprehensive reviews synthesising qualitative and quantitative studies will be used to extract factors

(target behaviours) associated with self-care adherence / non-adherence (Stage 1). Patients' health behaviour associated with adherence to self-care will be reinforced; behaviour associated with non-adherence will be modified through instigating new desirable behaviour. Extracted behaviours associated with adherence/non-adherence will then be mapped onto the 'Capability, Opportunity, Motivation and Behaviour' (COM-B) model, thus capturing the underlying mechanisms that are involved (Stage 2). To develop approaches for change, the 'Taxonomy of Behaviour Change Techniques' will be used to allow effective mapping of the target behaviours onto established behaviour change techniques to either reinforce facilitating factors or to modify hindering ones (Stage 3). Suggested BCIs will then be translated into locally relevant interventions using the Normalisation Process Theory (NPT) in order to overcome the difficulties of implementing theoretically derived interventions into everyday practice. Applying NPT will assist in identifying factors that promote/inhibit the effective and sustained incorporation of interventions into routine clinical work. Finally, a consensus development method (Delphi technique) will be employed to fine-tune content and acceptability of the intervention manual (Stage 4) to increase the likelihood of successfully piloting and implementing future BCIs into the German health care system.

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

No

Description IPD sharing plan

According to the votum of the ethics committee, data from the interviews will not be forwarded to anyone outside the Institute of General Practice (ifam). However, anonymous data may be used in excerpts for publication or teaching purposes.

Organizational Data

- DRKS-ID: **DRKS00014855**
- Date of Registration in DRKS: **2018/07/04**
- 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.: **2018-30 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50 - Heart failure**

Interventions/Observational Groups

- Arm 1: **We propose to develop an intervention manual that contains theory-based behaviour change interventions (BCIs) that are well-defined using eight descriptors proposed to describe BCIs in a standardised way. The manual will serve as a blueprint, which then can be applied with confidence in a subsequent exploratory trial that seeks to enhance patients' adherence to self-care. To manage the process of developing BCIs in a systematic fashion, our work programme consists of four stages. Behaviour change interventions will be based on both selected statements of findings that were derived by our research team from the recently completed qualitative meta-summary project (HE 7352/1-1) and findings from a quantitative meta-analysis published by Kessing et al. (2016). These two up-to-date comprehensive reviews synthesising qualitative and quantitative studies will be used to extract factors (target behaviours) associated with self-care adherence / non-adherence (Stage 1). Patients' health behaviour associated with adherence to self-care will be reinforced; behaviour associated with non-adherence will be modified through instigating new desirable behaviour. Extracted behaviours associated with adherence/non-adherence will then be mapped onto the 'Capability, Opportunity, Motivation and Behaviour' (COM-B) model, thus capturing the underlying mechanisms that are involved (Stage 2). To develop approaches for change, the 'Taxonomy of Behaviour Change Techniques' will be used to allow effective mapping of the target behaviours onto established behaviour change techniques to either reinforce facilitating factors or to modify hindering ones (Stage 3). Suggested BCIs will then be translated into locally relevant interventions using the Normalisation Process Theory (NPT) in order to overcome the difficulties of implementing theoretically derived interventions into everyday practice. Applying NPT will assist in identifying factors that promote/inhibit the effective and sustained incorporation of interventions into routine clinical work. Finally, a consensus development method (Delphi technique) will be employed to fine-tune content and acceptability of the intervention manual (Stage 4) to increase the likelihood of successfully piloting and implementing future BCIs into the German health care system.**

Characteristics

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

Primary Outcome

At this point in time no information can be provided regarding the primary outcome since the content of the theory-based behaviour change intervention has to be developed first.

Secondary Outcome

not applicable

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **deutschlandweit / across Germany**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/02/27**
- Target Sample Size: **17**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Qualitative semi-structured interviews with approximately 15-17 key stakeholders, i.e. those targeted by the intervention or involved in its development or delivery, will be conducted using NPT (Normalisation Process Theory) to guide the interview questions.
Approximately 15-17 key stakeholders, i.e. those targeted by the intervention or involved in its development or delivery, will be recruited from across Germany at a later date (Stage 4). Interviews will be conducted in places that are convenient for the stakeholders according to their preferences.

Exclusion criteria

not applicable

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

- Paper **Published research protocol**

** 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.*