Trial Description

**Title**

Proactive patient-centred treatment planning with chronically sick older patients

**Trial Acronym**

PrefCheck

**URL of the trial**

http://www.mh-hannover.de/17923.html

**Brief Summary in Lay Language**

Older patients have multiple chronic diseases and turn to their GPs (general practitioners) to receive holistic care for their health problems. As it does not make sense, to treat all health conditions simultaneously, a prioritisation is necessary. The aim of this study is to test an innovative and patient-centred treatment planning approach for older patients with multiple diseases in general practice. To begin with, a geriatric assessment (STEP) will be performed to receive an overview of all relevant health problems. Subsequently the GP and his patient exchange their views on the importance of each health problem and incorporate priority problems into a treatment plan. This procedure shall prevent overloaded treatments and reduce these to an acceptable volume. The exchange of health and treatment priorities could be offered as a programme in addition to the normal consultation.

**Brief Summary in Scientific Language**

Background. The aim of the study is to develop and test a consultation guide (PrefCheck) for general practitioners (GPs) based on geriatric assessment results. It shall facilitate priority setting and treatment planning based on partnership with older patients with multiple chronic diseases.

Methods and aims. The mixed-method-study has three complementary parts: In a first part health and treatment priorities of 32 patients and their 8 GPs are determined and explored on the basis of assessment results. These findings lead to the development of the consultation guide, which is subsequently tested in a cluster-randomized controlled intervention study with 40 GPs and 320 patients. Every patient receives the STEP-assessment with a resulting problem list. On the basis of this list, the doctor and patient independently determine, which health problem is of priority. Subsequently it is tested whether the PrefCheck consultation guide results in an improved number of shared health and treatment priorities between patients and their doctors. The study concludes with an evaluation study that determines acceptance and feasibility in focus groups.

Conclusions. The consultation guide shall strengthen the position of older patients
in the doctor-patient-relationship, increase the level of information on both sides and contribute to a shared and holistic treatment planning.

Organizational Data

- DRKS-ID: DRKS00000792
- Date of Registration in DRKS: 2011/04/06
- 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.: 5069, Ethikkommission der Medizinischen Hochschule Hannover

Secondary IDs

Health condition or Problem studied

- Free text: Health and everyday life problems as assessed by the STEP-assessment
- Free text: other volunteered health problems

Interventions/Observational Groups

- Arm 1: Intervention group (160 patients and 20 doctors) using the consultation guide "Prefcheck" for the health and treatment planning procedure.
- Arm 2: Control group (160 patients and 20 doctors), with no consultation guide that helps prioritizing problems. Doctor and patient only use the assessment results.

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: Double or multiple blind
- Who is blinded: [---]*
- Control: Other
- Purpose: Supportive care
Study Type: **Interventional**

Study Type Non-Interventional: [--]*

Allocation: **Randomized controlled trial**

Blinding: **Double or multiple blind**

Who is blinded: [--]*

Control: **Other**

Purpose: **Supportive care**

- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [--]*

**Primary Outcome**

Agreement (Cohen's Kappa) of the importance ratings for the health problems between each patient and his doctor. The importance ratings for the health problems per patient is determined two weeks after the doctor-patient-consultation. A significant difference of the Kappas between intervention- and control patients will be ascertained with a t-test. Additionally, in a multilevel regression modell the influence of group affiliation (intervention or control) on the agreement of the importance ratings will be tested.

**Secondary Outcome**

The secondary outcomes relate to the patients. Questions are administered two days and two weeks after the doctor-patient consultation. A sum score will be calculated for the responses related to each outcome: satisfaction with visit to doctor (ZAP-subscale) and satisfaction with doctor's information, shared decision making (readiness and experienced), doctor-patient-relationship, empowerment (questions composed of API, Man-Song-Hing and own). Significance tests will determine differences between intervention- and control group.

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

**Recruitment**
Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 70 Years
- Maximum Age: 120 Years

Additional Inclusion Criteria

having been to the GP's office

Exclusion criteria

nursing status II, III, dementia, no ability to understand or speak German, legal incapacity, no telephone

Addresses

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(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): 2010/07/05

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.