

# Effects of structuring doctor-patient-communication in primary care of patients with multimorbidity (MultiCare AGENDA)

<b>Submission date</b> 01/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/02/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
01ET1006A-K

## Study information

**Scientific Title**

Effects of structuring doctor-patient-communication in primary care of patients with multimorbidity (MultiCare AGENDA): a multi-center, parallel group, cluster-randomized controlled trial

## **Acronym**

MultiCare AGENDA

## **Study objectives**

We assume that the number of pharmaceutical agents taken by the patient can be reduced in the intervention group. We will compare the change in medication intake between baseline and follow-up in the intervention and control group. We expect that the mean difference between the changes in both groups will be at least 1.5 drugs less in the intervention group. A minimum difference of 0.5 drugs between both groups is defined as clinically relevant.

In order to include a measure that reflects the subjectivity of the patient we will also measure the health related quality of life. It is assumed that a reduction of medications used will not impair quality of life. We will compare the change in health related quality of life as measured by EuroQoL EQ-5D, UK value set between baseline and follow-up in the intervention and control group. We expect that the mean change in the intervention group will not be statistically significantly inferior to the mean change in the control group.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of the Medical Association of Hamburg approved on 1st July 2011, approval no. PV3788

## **Study design**

Multi-center parallel group cluster-randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Multimorbidity

## **Interventions**

The intervention consists of three special consultations by GPs for patients with multimorbidity.

The consultations comprise of:

1. Performing a narrative doctor-patient-dialogue aimed at carving out treatment targets and priorities of the patient
2. Performing a narrative patient-centred medication review, and
3. Performing a narrative doctor-patient-dialogue reflecting the attainment of treatment targets and priorities of the patient. Before the GPs in the intervention arm start with the respective consultations they will be trained by members of the study team.

Control arm: Care as usual

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Number of pharmaceutical agents taken by the patient
  2. Health related quality of life as measured by the EuroQoL EQ-5D, UK value set
- Measured at baseline and post intervention (12 months)

## **Key secondary outcome(s)**

1. GPs knowledge of the medication taken by patient
  2. Patient satisfaction with GP services as measured by the EUROPEP questionnaire
  3. Patient empowerment as measured by the Health Care Empowerment Questionnaire
  4. Health care utilization (e.g. contacts with GP and specialists, hospital admissions)
- Measured at baseline and post intervention (12 months)

## **Completion date**

31/08/2013

# **Eligibility**

## **Key inclusion criteria**

1. Age 65-85 years at time of recruitment
2. At least one contact with the GP within the most recent quarter (3 months period)

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Senior

## **Sex**

All

## **Key exclusion criteria**

1. Poorly known patients to the general practitioner (GP) because of accidental consultation
2. Patients that are treated by the GP for less than 12 months
3. Patients with less than 3 diagnoses out of a list of 42 groups of chronic diseases and syndromes
4. Insufficient ability to consent (e.g. dementia)
5. Insufficient ability to participate in studies (e.g. severe psychic illness)
6. Severe illness probably fatal within 3 months according to the GP
7. Residence in a nursing home

- 8. Deafness
- 9. Insufficient ability to speak and read German
- 10. Participation in other scientific trials

**Date of first enrolment**

01/09/2011

**Date of final enrolment**

31/08/2013

## Locations

**Countries of recruitment**

Germany

**Study participating centre**

University Medical Center Hamburg-Eppendorf

Hamburg

Germany

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## Sponsor information

**Organisation**

German Federal Ministry of Education and Research (Germany)

**ROR**

<https://ror.org/04pz7b180>

## Funder(s)

**Funder type**

Government

**Funder Name**

German Federal Ministry of Education and Research (Germany) (Funding no. 01ET1006A-K)

## Results and Publications

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	23/01/2018		Yes	No
<a href="#">Protocol article</a>	protocol	12/12/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes