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

Submission date 01/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2011	**Overall study status** Completed	
Last Edited 05/02/2018	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/09/2011

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

Age group
Senior

Sex
Both

Target number of participants
Planned sample size: 600

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
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Sponsor information

Organisation
German Federal Ministry of Education and Research (Germany)

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Sponsor type
Government

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	12/12/2012		Yes	No
Results article	results	23/01/2018		Yes	No