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A network-based care management intervention for patients with type II diabetes and multiple comorbidities (GEDIMAplus)

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
25/02/2014

Overall study status
Completed

Last Edited
13/06/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The increasing occurrence of multiple, co-occurring long-term disease conditions places a burden for modern health systems. Methods to manage patient care (care management interventions) in Germany have been evaluated with promising results. However, further studies are necessary to explore the full potential of care management interventions for the improvement of outpatient diabetes care. The aim of this study is to find out how well a GP surgery net-based, IT-supported care management intervention with integrated telephone monitoring works for patients with type II diabetes and multiple co-occurring long-term conditions.

Who can participate?
Patients with type II diabetes and at least two severe long-term conditions, who are enrolled in the Disease-Management-Program Diabetes mellitus type 2 (DMP Diabetes) can participate in the study.

What does the study involve?
Patients will be randomly allocated to case management (PTC) or usual care (TAU). Both PTC and TAU receive usual care. Patients allocated to PTC receive an 18-month care management intervention given by a trained health care assistant as an add-on to usual care. This complex care management intervention consists of the two main elements: assessments including home visits and regular telephone-monitoring.

What are the possible benefits and risks of participating?
All participants and informal care givers help to improve the care given for patients with diabetes and multiple co-occurring conditions in the future. In addition patients in the PTC will potentially benefit by an improved diabetes-related self-care behaviour. There arent any risks expected for patients and informal care givers taking part in this study.

Where is the study run from?
The study is run by Genossenschaft Gesundheitsprojekt Mannheim e.G. (GGM), Germany from 30 primary care practices (PCP).

When is the study starting and how long is it expected to run for?
The study starts in February 2014 and is expected to run for 18 months.

Who is funding the study?
The Federal Ministry for Education and Research (BMBF), Germany.

Who is the main contact?
Dr Dominik Ose, MPH
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01KQ1003B

Study information

Scientific Title
A multi-center, individual-level randomized, 18-month, parallel-group superiority trial to compare the efficacy of a complex primary care practice network-based care management intervention versus usual care in the improvement of self-care behavior among patients with type II diabetes and multiple comorbidities (GEDIMAplus)

Study objectives

To assess the efficacy of a primary care practice net-based, IT-supported care management intervention with integrated telephone monitoring for patients with diabetes type II and multiple co-occurring chronic conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical University of Heidelberg Ethics Committee, Germany, 02/12/2013, Ref.: S-590/2013

Study design
Prospective 18-month multi-center investigator-blinded two-armed open label individual-level randomized parallel-group superiority trial (RCT)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Diabetes mellitus type 2 and mulitple co-occuring chronic conditions.

Interventions
Participants are randomized to two groups:
1. Intervention:
The 18-month care management intervention (GEDIMAplus) is delivered by a trained health care assistant as add-on to usual care and consists of 2 main elements: 3 home visits including structured assessment of medical and social needs and 24 structured telephone monitoring contacts. All elements are IT-supported using a care manager-software as intervention platform. In addition goal setting between primary care physicians and patient based on the results of the assessment will take place.
2. Control: usual care in the scope of the statutory health care system (DMP Diabetes).

Care for other diseases (chronic or acute) besides diabetes is managed by PCP physicians individually based on personal experience, guidelines and/or patients preferences.

Data collection: baseline (T0), primary endpoint after 9 months (T1), follow-up after 18 months (T2)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in diabetes related selfcare behavior using a German version of the revised Summary of diabetes self-care activities measure (SDSCA-G) after 9 months.

Secondary outcome measures
1. Change in SDSCA-G at T2
2. Mean change in each of the five dimension of self-care captured by the SDSCA-G
3. Mean change in physician-reported glycosylated hemoglobin A1 (HbA1c %) at T1/T2
4. The cumulative incidence of physician-reported (severe) symptomatic hypoglycemia at T1/T2
5. Mean change in patient-reported health related quality of life (HRQL) at T1/T2
6. Mean change in patient-reported self-efficacy to cope with chronic conditions
7. Differences in service utilization
8. Costs of health care provision and financial burden of informal care between intervention and control group

Overall study start date
01/02/2014

Completion date
31/07/2015

Eligibility

Key inclusion criteria
Primary care practices (PCPs):
PCP physicians must fulfill the following criteria: Specialized in General Practice, Internal Medicine or Practical Physician (praktischer Arzt) and function as Primary care physician (Hausarzt) according to German regulations. Both single and group practices (Gemeinschaftspraxen) are eligible to participate.

Patients:
To be eligible for participation in the study, patients have to be:
1. Aged 18 years or above
2. Diagnosed with type 2 diabetes mellitus (ICD 10: E11-E14)
3. Enrolled in the DMP Diabetes, and diagnosed with at least two severe chronic comorbidities (schwerwiegende chronische Erkrankung) according to the definition enshrined in § 62 SGB V.
Additionally, written informed consent is a prerequisite for participation in the study.

Patients caregiving family member:
A caregiving family member is defined as the family member who (from the patients perspective) spends the largest amount of time with informal care (e.g. spouse, partner, father, mother, son, daughter, others) and lives in the same household.

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 592 patients (291 per arm) will be recruited in 30 PCPs.

Total final enrolment
495

Key exclusion criteria
PCPs and patients caregiving family members:
PCPs and patients caregiving family members who do not fulfill the inclusion criteria will be excluded.

Patients:
1. Patients who do not fulfill the inclusion criteria will be excluded. Additional exclusion criteria are patients with: Severe acute psychiatric disorders, e.g. schizophrenia, schizotypal and delusional disorders (ICD 10: F20-F29), dementia (ICD 10: F00-F03), mental and behavioral disorders due to psychoactive substance use (ICD 10: F11-F16; F18; F19) (except for alcohol (ICD 10: F10) and tobacco use (ICD 10: F17)), malignant neoplasms (ICD 10: C00-C97) and/or current chemotherapy or radiotherapy, transplanted organ and tissue status (ICD 10: Z94), care involving dialysis (ICD 10: Z49), insurmountable language and communication problems, emergency cases.

Date of first enrolment
01/02/2014

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Germany

Study participating centre
Voßstr. 2, Geb. 37
Heidelberg
Germany
69115

Sponsor information

Organisation
Federal Ministry for Education and Research (BMBF) (Germany)

Sponsor details
Hannoversche Straße 28-30
Berlin
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10115

Sponsor type
Government

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Federal Ministry for Education and Research (BMBF), Germany, in the scope of the project 'Gesundheitsregion der Zukunft'

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	21/06/2014		Yes	No

Results article	results	12/06/2019	13/06/2019	Yes	No