ISRCTN66386086 https://doi.org/10.1186/ISRCTN66386086

Case Management for the treatment of patients with Major Depression in General Practices

Submission date
27/05/2005

Recruitment status
No longer recruiting

Registration date
10/06/2005

Overall study status
Completed

Last Edited
05/08/2015

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.prompt-projekt.de

Contact information

Type(s)
Scientific

Contact name
Dr Jochen Gensichen

Contact details
Theodor-Stern-Kai 7
Frankfurt a.M.
Germany
D - 60590
+49 (0)69 6301 83882
gensichen@allgemeinmedizin.uni-frankfurt.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01Gk0302

Study information

Scientific Title
Case Management for the treatment of patients with Major Depression in General Practices

Acronym
PRoMPT (PRimary care Monitoring for depressive Patients Trial)

Study objectives
General practices based Case Management for patients with major depression reaches - compared to a treatment without case management - an improvement of the patients outcome (depression).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major Depression

Interventions
Case Management including systematic telephone monitoring by the General Practice Team versus usual care

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Major Depression: Status of depression in patient health questionnaire (PHQ-D, Löwe 2001)

Secondary outcome measures
1. Adherence of patient to therapy (self-report by patient)
2. Quality of life (QoL) (SF 36, Bullinger 1987)
3. Costs

Overall study start date
01/05/2005

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Diagnosis Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM IV) "Major Depression" as per Patient Health Questionnaire Depression (PHQ-D) screening
2. Anti-depressive therapy
3. Medical care by a family doctor
4. Age 18-80
5. Capability to voluntary, informed participation in research (written confirmation)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
68 GP clinics including 10 patients each, N = 680

Key exclusion criteria
1. Patients who cannot answer questionnaires independently
2. Patients who are terminally ill or could not speak German properly

Date of first enrolment
01/05/2005

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Germany

Study participating centre
Theodor-Stern-Kai 7
Frankfurt a.M.
Germany
D - 60590

Sponsor information

Organisation
Federal Ministry of Education and Research (BMBF) / German Aerospace Center (DLR) (Germany)

Sponsor details
Heinemannstr. 2
Bonn
Germany
D - 53227
+49 (0)228 3821 225
magret.knull@dlr.de

Sponsor type
Government

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	05/10/2005		Yes	No
Results article	results	15/09/2009		Yes	No
Results article	results	01/01/2011		Yes	No
Results article	results	01/11/2015		Yes	No