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

Submission date Recruitment status Prospectively registered 27/05/2005 No longer recruiting [X] Protocol Statistical analysis plan Registration date Overall study status 10/06/2005 Completed [X] Results [] Individual participant data Last Edited Condition category Mental and Behavioural Disorders 05/08/2015

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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)

ROR

https://ror.org/04pz7b180

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

Alternative Name(s)

Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

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?
Results article	results	15/09/2009		Yes	No
Results article	results	01/01/2011		Yes	No
Results article	results	01/11/2015		Yes	No

<u>Protocol a</u>	<u>rticle</u>	protocol	05/10/2005		Yes	No
Study web	<u>osite</u>	Study website	11/11/2025	11/11/2025	No	Yes