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

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

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

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Contact details

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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

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