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Effectiveness of a Minimal Intervention Strategy for patients with common mental disorders on sick leave: a pragmatic randomized controlled trial in General Practice

Submission date
17/01/2005

Recruitment status
No longer recruiting

Registration date
19/04/2005

Overall study status
Completed

Last Edited
15/04/2010

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.emgo.nl/research_prog/common/researchprojects_37.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4200.0003

Study information

Scientific Title

Acronym
MISS

Study objectives
The objective of this study is to assess the effectiveness of the minimal intervention package (MISS) for distressed patients in general practice.

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
Common mental disorders and sick leave

Interventions
This study is a pragmatic randomized controlled trial in general practice. Forty GPs will be randomized to the intervention group or the usual care group. The GPs in the intervention group will receive training in the implementation of the MISS intervention. This intervention package has been developed to assist the GPs in dealing with distressed patients. Within the limits of three 10-minute consultations, the GP should be able to:
1. Detect significant depression and anxiety, and to deal with it specifically

2. Educate the patient about distress and the best ways to cope with the situation
3. Advise the patient to see an occupational physician
4. Evaluate any progress four weeks later, and refer the patient to a psychological professional if no progress has been made

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Duration of occupational disability

Secondary outcome measures
Social functioning/quality of life, application for disability benefit after one year of sick leave (WAO), unemployment, psychological symptoms, and utilization of medical services. The outcomes will be assessed after 2, 6 and 12 months of follow-up.

Overall study start date
01/09/2003

Completion date
31/01/2005

Eligibility

Key inclusion criteria
Patients (20-60 years old) who visited their GP, having distress complaints, paid work and sick leave no longer than three months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
415

Key exclusion criteria
Severe psychiatric disorders (mania or psychosis), patients who were terminally ill or who couldn't speak Dutch properly.

Date of first enrolment
01/09/2003

Date of final enrolment
31/01/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
van der Boechorststraat 7
Amsterdam
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1081 BT

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
Laan van Nieuw Oost Indië 334
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Sponsor type
Research organisation

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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?
Results article	results	04/05/2006		Yes	No
Results article	results	01/06/2007		Yes	No
Results article	results	01/02/2010		Yes	No