

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**

19/04/2005

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

15/04/2010

**Condition category**

Mental and Behavioural Disorders

☐ 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](http://www.emgo.nl/research_prog/common/researchprojects_37.asp)

## Contact information

**Type(s)**

Scientific

**Contact name**

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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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## **Sponsor information**

**Organisation**

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

**Sponsor details**

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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?
<a href="#">Results article</a>	results	04/05/2006		Yes	No
<a href="#">Results article</a>	results	01/06/2007		Yes	No
<a href="#">Results article</a>	results	01/02/2010		Yes	No