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Effectiveness of early intervention among employees at high risk for long-term sickness absence

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/05/2009	Signs and Symptoms	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr N W H Jansen

Contact details
Department of Epidemiology
Maastricht University
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2384
Nicole.Jansen@epid.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR214

Study information

Scientific Title

Study objectives
What is the effectiveness of early preventive intervention among employees at high risk for long-term sickness absence?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised single blind active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Sickness absence

Interventions
The effectiveness of early intervention among employees at high risk for sickness absence will be determined by means of a randomised controlled trial, with an initial total follow-up period of 12 months.

The study will be based on a sample of 10,000 employees of ABN AMRO in the Netherlands. Selection of this sample will be based on the initial letter of the employees surname. To ensure smooth enrolment in the trial, the study population will be divided in five batches. Employees at high risk for long-term sickness absence will be identified by the screening questionnaire Balansmeter. The study involves employees whose high risk for long-term sickness absence can be prompted by either somatic conditions or mental health complaints, or both.

Employees will be asked to provide informed consent and those scoring above the cutoff point of the Balansmeter will be randomised over the experimental group and the control condition.

Employees in the experimental group will receive early treatment. Early treatment involves an interview by the occupational physician, which may be followed either by further guidance by the occupational physician or by external referral/guidance. External referral may include psychotherapy, cognitive behavioural therapy or social work.

The control group receives care as usual, as provided by the occupational physician, if the employee asks for help. In case of sickness absence the control group will receive socio-medical counselling in accordance with the practice guidelines of the NVAB. Outcomes will be evaluated at 6 and 12 months after randomisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sickness absence. All information regarding sickness absence will be gathered through record linkage on an individual level with the company register on sickness absence. Sickness absence measures include absence frequency, time to onset of first absence spell, and sickness absence duration. Sickness absence will be assessed during the complete follow-up period of 12 months.

Secondary outcome measures
Assessed at baseline and during follow-up by means of questionnaires:
1. (Mental) health status, capturing amongst others need for recovery from work, prolonged fatigue, and psychological distress
2. Working conditions, such as for example social support from supervisor and colleagues, psychological job demands, decision latitude and working hours
3. Medical consumption

Follow-up measurements will take place at 6 and 12 months after randomisation.

Overall study start date
01/01/2003

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Employees at high risk for future long-term sickness absence as identified by a validated screening questionnaire called "Balansmeter".

Participant type(s)
Patient

Age group

Not Specified

Sex
Not Specified

Target number of participants
327

Key exclusion criteria
1. Employees on sick leave
2. Pregnant employees
3. Treatment/guidance by occupational physician

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Epidemiology
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (UM) (Netherlands)

Sponsor details
Department of Epidemiology
P.O. Box 616
Maastricht
Netherlands
6200 MD
-
Nicole.Jansen@epid.unimaas.nl

Sponsor type

University/education

Website
http://www.unimaas.nl/default.asp?taal=en

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Industry

Funder Name
ABN AMRO (Netherlands) - Arbo Services

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