

# Participatory ergonomics for mental health disorders, a randomised controlled trial and cost-effectiveness evaluation

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/05/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

NTR473

# Study information

## Scientific Title

## Study objectives

Is participatory ergonomics for workers with common mental disorders more (cost-)effective on return-to-work than usual clinical medical care?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added as of 23/08/2007: The Medical Ethics Committee of the VU University Medical Center (Amsterdam, The Netherlands) has approved the study protocol.

## Study design

Randomised open label active controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Other

## Participant information sheet

## Health condition(s) or problem(s) studied

Mental disorders

## Interventions

A project group consisting of experts in the field of mental disorders will develop a protocol for workplace adaptations based on methods used in participatory ergonomics (PE).

Work(place) adaptations, will be applied by a trained occupational nurse. A group of stakeholders (sick listed worker, the worker's supervisor, and potential other stakeholders) in the return-to-work (RTW) process will be formed and guided by the occupational nurse. The protocol is directed to achieve consensus among stakeholders regarding feasible work(place) adaptations to facilitate RTW.

Patients will be randomised to PE or usual clinical care ( $n = 2 \times 72$ ). A process analysis will be included.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Sickleave duration until full return-to-work

**Secondary outcome measures**

1. Psychological complaints
2. Functional status
3. Coping
4. Direct and indirect costs

**Overall study start date**

15/09/2005

**Completion date**

15/09/2009

**Eligibility****Key inclusion criteria**

1. Sicklisted due to distress problems due to overwork (completely or partially)
2. Between 18 and 65 years of age

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

160

**Key exclusion criteria**

1. Duration of sick leave longer than 3 months
2. Juridical conflict at work
3. No ability to complete questionnaires written in the Dutch language

**Date of first enrolment**

15/09/2005

**Date of final enrolment**

15/09/2009

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

VU University Medical Center

Amsterdam

Netherlands

1081 BT

## **Sponsor information**

**Organisation**

TNO Quality of Life (Work & Employment) (Netherlands)

**Sponsor details**

P.O. Box 718

Hoofddorp

Netherlands

2130 AS

**Sponsor type**

Research organisation

**ROR**

<https://ror.org/01bnjb948>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Expert Reintegration Studies Centre (STECR) (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="#">Protocol article</a>	protocol	14/01/2008		Yes	No
<a href="#">Results article</a>	results	01/09/2010		Yes	No
<a href="#">Results article</a>	results	01/09/2010		Yes	No