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

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
23/05/2011

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 x 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?
Protocol article	protocol	14/01/2008		Yes	No
Results article	results	01/09/2010		Yes	No
Results article	results	01/09/2010		Yes	No