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Randomized controlled trial of psychiatric consultation embedded in continuing education to company physicians for employees with sick leave absence through psychiatric disorders

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
27/10/2010

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
N/A

Study information

Scientific Title

Acronym
BACO Trial

Study objectives
In a randomized controlled study comparing psychiatric consultation with care as usual by the company physician, patients will improve in the intervention group in terms of duration of sick leave, general functioning and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from local ethics committee (METiGG [Kamer Zuid]), date of approval: November 16, 2005 (ref: 5127).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Psychiatric, mental disorders/illness, depressive disorders, anxiety disorders

Interventions
Company physicians are randomised over 2 conditions:
1. The intervention group
2. Care-as-usual group
All company physicians in both conditions receive continuing education and follow a training programme targeted at diagnosis and treatment of depressive disorder and anxiety disorder. In the intervention group patients of company physicians receive psychiatric consultation as

well, resulting in an individually tailored diagnosis and treatment advice.
These psychiatric consultations are embedded in the continuing education to company physicians.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Reduction of symptoms as measured with the PHQ and quality of life as measured with the SF-20.

Secondary outcome measures
Number of complaints, general functioning, fatigue, duration of sick leave.

Overall study start date
03/10/2005

Completion date
01/05/2008

Eligibility

Key inclusion criteria
Employees with absence from work for a period of at least 6 weeks and no plan for resumption of work within 12 weeks, and a positive screen on either the PHQ or the Whiteley Index.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
Insufficient command of Dutch language, negative outcome of PHQ screen, dementia, psychotic symptoms or suicide risk, or the expectation of the company physician of a work related conflict.

Date of first enrolment
03/10/2005

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Trimbos-instituut
Utrecht
Netherlands
3500 AS

Sponsor information

Organisation
Trimbos-instituut Netherlands Institute of Mental Health and Addiction

Sponsor details
Da Costakade 45 Postbus 725
Utrecht
Netherlands
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+31 (0)30 2971100
info@trimbos.nl

Sponsor type
Not defined

Website
http://www.trimbos.nl

ROR
https://ror.org/02amggm23

Funder(s)

Funder type
Charity

Funder Name
ArboUnie, ArboNed, STECR Alladin Program

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	27/02/2007		Yes	No
Results article	results	07/09/2010		Yes	No