

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	<input type="checkbox"/> Prospectively registered
Registration date 19/12/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 27/10/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C.M. Feltz-Cornelis, van der

Contact details
Trimbos-instituut
Department of Diagnosis and Treatment
P.O. Box 725
Utrecht
Netherlands
3500 AS
cfeltz@trimbos.nl

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

3500 AS

+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