

Effectiveness of acceptance and commitment therapy for students with psychological distress

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| Submission date 19/09/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 11/12/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 11/12/2012 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims:

Many students suffer from psychological distress and most of them do not seek help. The objective of the study was to investigate the effects of the group course, called "Getting more out of your life" for college students with psychological distress. The secondary objective of the study is to evaluate the effectiveness of this course on positive mental health, mindfulness, and psychological flexibility.

Who can participate?

Students with mild to moderate anxiety and/or depression symptoms, male or female aged over 17 years.

What does the study involve?

The participants were randomly allocated to one of the following groups:

1. Experimental condition: the group course "Getting more out of your life". The course is provided by universities and a mental health institution.
2. Control condition: The participants are on a waiting list for three months. After the waiting period they receive the same group course as the experimental condition.

What are the possible benefits and risks of participating?

Participants may benefit by an improvement in their mental health. We do not expect many risks associated with participation and no side effects. Participants are allowed to seek for help elsewhere and they can stop all times with the study and/or group course.

Where is the study run from?

University of Twente (Lead Centre)
Saxion University Deventer
Saxion University Enschede
University Zeeland
Indigo Nijmegen

When is study starting and how long is it expected to run for?

The study is started in September 2011 and ended in November 2012. Participants were recruited for one month.

Who is funding the study?

Fund NutsOhra, The Netherlands

Who is the main contact?

Dr. Martine Fledderus

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness of acceptance and commitment therapy for students with psychological distress: evaluation in a randomized controlled trial

Study objectives

It is hypothesised that the group-course based on acceptance and commitment therapy for students shows superior effects in reducing depressive symptoms, anxiety symptoms and in increasing psychological flexibility, mindfulness and positive mental health compared to a waiting list.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dutch Medical-Ethical Review Board for Mental Health Care Institutes (METIGG), 10 May 2011, ref: 11.122

Study design

A randomized controlled multi-centre trial with a waiting list as a control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Depression, anxiety

Interventions

The intervention is called Getting more out of your life and is based on ACT and augmented with mindfulness exercises. The intervention consists of four three-hour group-sessions. The first three sessions are weekly and there are two weeks between the third and last session, in total the intervention lasts for five weeks. The intervention is provided by clinical therapists with ample experience in ACT and mindfulness.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Depression (Center of Epidemiological Studies Depression Scale) is assessed at baseline, five weeks after baseline, 3 months after baseline and, 9 months after baseline (only experimental group), and 12 months after baseline (only control group).

Secondary outcome measures

1. Anxiety (Hospital Anxiety and Depression Scale-Anxiety subscale), psychological flexibility (AAQ-II)

2. Mindfulness (FFMQ-SF)

3. Positive mental health (Mental Health Continuum- Short Form) are assessed at baseline, five weeks after baseline, 3 months after baseline and, 9 months after baseline (only experimental group), and 12 months after baseline (only control group).

Overall study start date

01/09/2011

Completion date

01/11/2012

Eligibility

Key inclusion criteria

The participants are students from the university with psychological distress (> 10 on the CES-D and > 3 on the HADS-A).

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80

Key exclusion criteria

1. The presence of a mood disorder according to the Mini International Neuropsychiatric Interview (MINI)-PLUS. People with severe mood disorder are referred to the general practitioner
2. The presence of mild to high suicide risk according to the MINI-Plus
3. No psychological distress (< 10 on the CES-D or < 3 on the HADS-A)
4. Started three months ago with medication for psychological distress
5. Receiving an treatment for psychological distress
6. Trouble with the Dutch language (reading or learning difficulties)

Date of first enrolment

01/09/2011

Date of final enrolment

01/11/2012

Locations

Countries of recruitment

Netherlands

Study participating centre
University of Twente
Enschede
Netherlands
7522 NB

Sponsor information

Organisation

Fund NutsOhra (Netherlands)

Sponsor details

Amstelplein 6
Amsterdam
Netherlands
1096 BC
info@fondsnutsohra.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.fondsnutsohra.nl/>

ROR

<https://ror.org/04ev7sy32>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Fund NutsOhra (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