ISRCTN11928453 https://doi.org/10.1186/ISRCTN11928453

# Effectiveness of acceptance and commitment therapy for students with psychological distress

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 19/09/2012 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 11/12/2012 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 11/12/2012 | Mental and Behavioural Disorders | [ ] 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
m.fledderus@utwente.nl

# Contact information

### Type(s)
Scientific

### Contact name
Dr Martine Fledderus

### Contact details
University of Twente
Drienerlolaan 5
Enschede
Netherlands
7522 NB
+31 534896098
m.fledderus@utwente.nl

# Additional identifiers

# 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

### Primary study design

Interventional

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

### Study type(s)
Treatment

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

### Key secondary outcome(s)
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 basline, five weeks after baseline, 3 months after baseline and, 9 months after baseline (only experimental group), and 12 months after baseline (only control group).

### 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

### Healthy volunteers allowed

No

### Age group
Adult

### Sex
All

### 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 refered 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)

### ROR
https://ror.org/04ev7sy32

## Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Fund NutsOhra (Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration