

# Effectiveness and working mechanisms of e-health modules focusing on worry and self-esteem for anxiety symptoms in undergraduates

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Primary objective: To map the effectiveness and working mechanisms of e-health modules on worrying and self-esteem in reducing subclinical anxiety symptoms among students

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON51300

### Source

ToetsingOnline

### Brief title

Effectiveness of e-health modules for anxiety

### Condition

- Anxiety disorders and symptoms

### Synonym

Generalized anxiety disorder; anxiety symptoms

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit van Tilburg

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Anxiety, E-health, Self-esteem, Worry

## Outcome measures

### Primary outcome

- Anxiety: State Trait Anxiety Inventory (STAI - trait)
- Worry: Penn State Worry Questionnaire (PSWQ)

### Secondary outcome

- Self-esteem: Rosenberg Self-Esteem Scale (RSES)
- Metacognitions: Metacognitions Questionnaire (MCQ)
- Psychological well-being: Mental Health Continuum - Short Form (MHC-SF)
- Positive emotions: Modified Differential Emotions Scale (mDES)
- Depressive symptoms: Beck Depression Inventory (BDI)
- Exposure tendency: Self-reported Engagement in Exposure exercises

Questionnaire (SEEQ)

- Avoidance: Fear Questionnaire (FQ)

## Study description

### Background summary

The current research focuses on the effectiveness of e-health interventions to reduce anxiety among students and increase their well-being. Student life is a turbulent time, in which young adults are expected to become increasingly independent, while the challenges increase. Students therefore regularly suffer from fears, whereby complaints such as worrying and doubts about their own ability occur regularly. E-health interventions can offer a good opportunity to combat such complaints. It is known from the literature on generalized anxiety disorder that fears can be 'treated' through interventions aimed at worrying and self-image. Both ways seem to be effective. However, most e-health interventions for healthy subjects are somewhat general, in order to be able to

treat the largest possible target group. This may miss an opportunity to respond to specific mechanisms that play a role in anxiety symptoms (i.e., meta-cognitions and self-esteem).

In addition, even less is known about the effective mechanisms of e-health interventions, and - more generally - of psychotherapy. Most e-health studies focus on treatment effectiveness and have too few measurement moments to determine to what extent different e-health interventions work in different ways. More knowledge about the effective mechanisms of e-health interventions can help us to understand how e-health interventions work, so that they can be improved in the future and more targeted recommendations can be made for individuals ('personalized medicine').

## **Study objective**

Primary objective: To map the effectiveness and working mechanisms of e-health modules on worrying and self-esteem in reducing subclinical anxiety symptoms among students

## **Study design**

Randomized controlled trial (RCT). Tilburg University students with increased anxiety symptoms are randomly assigned to one of three conditions: a self-esteem e-health module, a worrying e-health module or a control waiting list, in which no intervention is offered.

## **Intervention**

Participants who are assigned to an intervention follow either an online worry module (<https://mirro.nl/module/piekeren/>) or an online self-image module (<https://mirro.nl/module/zelfbeeld/>). Both modules take 4 weeks to complete.

## **Study burden and risks**

The modules may have beneficial effects for participants, because participants can complete an e-health module free of charge that is intended to reduce complaints and improve well-being, but this is not certain. The modules are already offered online and are freely accessible to everyone. The modules have been developed by New Health Collective/Mirro in collaboration with psychologists. For this reason, we expect that the modules will not have any adverse effects on the participants. The only possible burden we foresee is that the modules could be confronting for some participants. However, participation is voluntary and participants may withdraw from the study at any time.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

### **Inclusion criteria**

- Adults (18 years or older)
- Students of Tilburg University
- GAD-7 score of 5 or higher (generalized anxiety disorder diagnosis is permitted)

### **Exclusion criteria**

- Presence of severe psychopathology (other than generalized anxiety disorder) or addiction
- Simultaneous psychological care or (e-)treatment
- A medical condition that affects psychological well-being
- High suicide risk (acute planning or severe suicidal ideation)

- Acute grief
- Medication use is allowed, but must have been stable in the past 3 months and must (probably) remain stable in the next 3 months

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	03-01-2022
Enrollment:	225
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	16-02-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL79374.028.21