

# Internet-based preventive intervention for depression and anxiety: Role of support?

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21118

### Source

NTR

### Brief title

N/A

### Health condition

internet-interventions; preventive; depression; anxiety; support.  
Dutch: internetinterventies; preventief; depressie; angst; begeleiding.

## Sponsors and support

**Primary sponsor:** VU University (Vrije Universiteit)

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

Symptoms of depression and anxiety

## Secondary outcome

- Diagnosis of depression and/or anxiety
- Drop-out from the intervention
- Quality of life
- Economic costs
- Working alliance
- Client satisfaction
- Problem-solving skills.

## Study description

### Background summary

There is no doubt that self-help through the Internet is an effective preventive intervention. It is not clear, however, whether it is necessary to offer these interventions with professional support or without.

Furthermore, if professional support is necessary, it is not clear which level of support is needed. The differences between these types of web-based self-help have not been examined well, although this is very important from the point-of-view of implementation. A system without coaching is much more easy to implement than a system with coaching, which needs an infrastructure of coaches, professional training, and an institute which functions as employer for the coaches. In the current project, we directly compare web-based self-help with different levels of coaching and without a coach. We recruit a total of 500 subjects with mild to moderate depression and/or anxiety and assign them at random to one of five conditions:

(1) Web-based problem solving through the Internet (self-examination therapy) without coach;

(2) The same as 1, but with the possibility to ask help from a coach on the initiative of the respondent;

(3) The same as 1, but with weekly contacts with a coach;

(4) Weekly contacts with a coach, but no web-based intervention;

(5) Information only (through the Internet).

As intervention we use the existing website Allesondercontrole, based on the principles of brief problem-solving. An earlier trial showed that it is effective in reducing depression and anxiety. We examine the effects after the intervention, after 3 months, and after 12 months.

## Study objective

- Internet interventions without coach are less effective than those with a coach
- The expected smaller outcomes weigh up to the advantages of a much simpler infrastructure, in clinical and economic outcomes

## Study design

Measures are taken at baseline (pre-test), directly after the intervention (post-test, 5 weeks after baseline) 3 months later, and 12 months later.

## Intervention

1. Brief internet-based problem-solving on the Internet ('self-examination' treatment) without coaching (but with automated emails at regular times).
2. The same as in 1, but with the possibility for the subject to approach a coach on his or her own initiative (by email).
3. The same as in 1, but with a coach who will actively approach the subject at regular times (once per week, by email)
4. No Internet intervention, but a coach will approach the subject weekly (by telephone) to discuss problems and give general support (non-specific intervention).
5. Only information on depression and anxiety (on the Internet).

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. 18 years or older
2. Having symptoms of depression and/or anxiety (as defined by scoring above the cut-off of 16 on the CES-D and/or 8 on the HADS)
3. Having access to a computer with a fast internet connection
4. Being prepared to participate in the study

### Exclusion criteria

- 1 Which are not too severe (1 standard deviation above the population mean on the CES-D, cut-off <39 and/or HADS cut-off <15)
2. Having suicidal intentions
3. Currently under treatment by a mental health specialist

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	07-01-2009
Enrollment:	500
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	24-06-2008
Application type:	First submission

## 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
NTR-new	NL1306
NTR-old	NTR1355
Other	: WC2007-066
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

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N/A