Onderzoek naar drie online zelfhulptrainingen voor slapen, stress en piekeren als aanpak van depressiepreventie.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22160

Source
NTR

Health condition

Sleep, stress, worry, depression, anxiety, well-being.

Sponsors and support

Primary sponsor: Trimbos Institute (Netherlands Institute of Mental Health and Addiction).
Source(s) of monetary or material Support: This research is funded by the Ministry of Health, Welfare and Sport.

Intervention

Outcome measures

Primary outcome

The primary outcome is:

- Depression (Inventory of Depressive Symptomatology, time points: baseline, 3 months, 6

months)

Secondary outcome

- Depression (Inventory of Depressive Symptomatology, time points: baseline, 3 months, 6 months)

- Anxiety (Generalized Anxiety Disorder Scale, time points: baseline, 3 months, 6 months)

- Well-being (Warwick-Edinburgh Mental Well-being Scale, time points: baseline, 3 months, 6 months)

- Cost-effectiveness (Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness, shortened version, time points: baseline, 3 months, 6 months)
- Sleep (Jenkins Sleep Evaluation Questionnaire, time points: baseline, 3 months and 6 months);

- Stress (Perceived stress scale, time points: baseline, 3 months, 6 months); or

- Worry (Penn State Worry Questionnaire, time points: baseline, 3 months, 6 months).

Study description

Background summary

The primary aim of this study is to determine the effectiveness of three online self-help interventions aimed at respectively sleep, stress and worry, in terms of 1) decreases in sleep, stress and worry, 2) decreases in depressive and anxiety symptoms, and 3) increases in well-being. A secondary aim is to identify subgroups which benefit most from the interventions (e.g. males or females). Furthermore, an economic evaluation will be conducted to examine the cost-effectiveness of the three self-help interventions.

The design of the study is a randomised controlled trial with one experimental condition and one waitlist control condition. The study population consists of adults (18 years and older) who experience sleeping problems, stress or worrying and have mild to moderate depression levels. Assessments take place at baseline, 3 months after baseline and 6 months after baseline.

Study objective

1. Subjects who participate in the self-help intervention for sleep will experience a reduction in sleeping problems.

2. Subjects who participate in the self-help intervention for stress will experience a reduction

in stress.

3. Subjects who participate in the self-help intervention for worry will experience a reduction in worrying.

4. Subjects who participate in any of the three self-help interventions will experience a decrease in depressive symptoms.

5. Subjects who participate in any of the three self-help interventions will experience a decrease in anxiety symptoms.

6. Subjects who participate in any of the three self-help interventions will experience an increase in well-being.

Study design

1. At baseline

2. Three months after baseline

3. Six months after baseline

Intervention

Participants are randomised into:

1. Experimental condition

2. Waitlist control condition (with full access to usual care)

Participants in the experimental condition have direct access to the online self-help intervention of their choice (better sleep, less stress or less worry), whereas participants in the control condition gain access to the intervention of their choice after 3 months.

Participants are offered three online self-help-interventions aimed at sleep, stress and worry. For the purposes of the study, subjects can only participate in one of the three interventions.

The theoretical expectation is that a reduction in sleeping problems, stress or worrying will reduce the risk of developing a depressive disorder.

Participants can follow the intervention independently from their homes, on a computer, tablet or iPad. Each intervention consists of information (psycho-education) and exercises. The method is based on principles from cognitive behavioral therapy, mindfulness and positive psychology.

'Sleep better' (in Dutch: 'Beter slapen') is aimed at people who experience difficulties with sleeping, such as sleeping too often, waking up too early or difficulty falling asleep. Participants learn how to manage factors which negatively influence their sleep, as well as how they can positively influence their sleep as to prevent or reduce insomnia. This intervention consists of 19 exercises divided over 4 themes:

- Sleeping habits: 5 exercises to gain insight into sleeping habits

- Relaxation: 5 exercises to learn how to relax

- Less worrying: 5 exercises to reduce worrying

- Thinking differently (about sleep): 5 exerices to learn recognizing unhelpful thoughts and transforming these into helpful thoughts

'Less stress' (in Dutch: 'Minder stress') is aimed at people who experience excessive levels of stress. This intervention consists of 15 exercises divided over 3 themes:

- Thinking differently: 5 exerices to learn recognizing unhelpful thoughts and transforming these into helpful thoughts

- Relaxation: 5 exercises to learn how to relax

- Recharge your energy: 6 exercises to recharge your energy

'Less worry' (in Dutch: 'Minder piekeren') is aimed at individuals who worry frequently or excessively. This intervention consists of 18 exercises divided over 4 themes:

- Positive thinking: 4 exercises to learn how to think more positively

- Relaxation: 5 exercises to learn how to relax

- Less worrying: 5 exercises to reduce worrying

- Thinking differently: 5 exerices to learn recognizing unhelpful thoughts and transforming these into helpful thoughts

Duration of the intervention:

Each participant decides for oneself how frequently one uses the intervention and which exercises one does and which not. Nonetheless, participants are recommended to spend 2 to 3 hours per week over a period of at least 4 weeks. Each participant has one year long access to the chosen intervention.

Contacts

Public
Universiteit Twente | Centre for eHealth and Wellbeing Research |
Faculteit der Gedragswetenschappen | Vakgroep Psychologie, Gezondheid en Technologie |
Marion Spijkerman
Drienerlolaan 5 (Cubicus, kamer C140)
Enschede 7500 AE
The Netherlands
053 - 489 6545
Scientific
Universiteit Twente | Centre for eHealth and Wellbeing Research |
Faculteit der Gedragswetenschappen | Vakgroep Psychologie, Gezondheid en Technologie |
Marion Spijkerman
Drienerlolaan 5 (Cubicus, kamer C140)
Enschede 7500 AE
The Netherlands
053 - 489 6545

Eligibility criteria

Inclusion criteria

1. 18 years and older;

2. experiences problems with sleep, stress or worry (subjective experience);

3. experiences mild to moderate depressive symptoms as determined with the Inventory of Depressive Symptomatology (IDS-SR, score 14-38);

4. has access to a computer with a solid Internet connection (the intervention and the questionnaires are offered online);

5. has an e-mail address;

6. has sufficient computer skills;

7. has sufficient Dutch language skills.

Exclusion criteria

1. experiences severe depressive symptoms as determined with the IDS-SR (score > 38);

2. has suicidal thoughts and/or plans as measured with item 18 from the IDS-SR;

3. experiences no depressive symptoms as determined with the IDS-SR (score < 14).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-06-2014
Enrollment:	292
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-05-2014

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	NL4479
NTR-old	NTR4612
Other	Medical Research Ethics Committee (METC) of the University Medical Center Utrecht : 14-119/D

Study results

Summary results
The researchers will publish about the effectiveness as well as the cost-effectiveness of the online self-help interventions for sleep, stress and worry.