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A fully automated and web-based intervention for stress management

Submission date	Recruitment status	[ ] Prospectively registered
30/08/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Background and study aims:
Stress is very common and related to death and many different health conditions such as increased risk for coronary heart diseases, depression, and anxiety. Prolonged stress often causes symptoms such as fatigue, migraine, worries, lower back pain, pain in arms and shoulders that can have a negative effect on individuals and society (e.g. increased work absenteeism). Stress management methods are known to reduce levels of stress and, as a result improve psychological and physical health. Personal counselling has a limited capacity to provide stress management, but easily accessible stress management methods may be more effective for larger numbers of people.
The aim of this project is to test the effects of a web-based stress management system ('NewMe Stresse Mindre').

Who can participate?
Anyone over 18 years old, who was invited via social media, and was able to provide a valid e-mail address.

What does the study involve?
The participants were randomly allocated to two groups. One group received the web-based system and the other group received no treatment. The web-based system consisted of 13 sessions in total and lasts for about a month. In addition, participants had to fill in web-based questionnaires at 1, 2, and 6 months after starting the study. The participants in the no treatment group were given access to the web-based system after the final data was collected.

What are the possible benefits and risks of participating?
Participants may have experienced decreases in their stress levels and learned techniques and exercises that they can apply as preventive efforts or during stressful life events any time later. There were no associated or expected risks of participating.

Where is the study run from?
University of Oslo in collaboration with Changetech AS.

When is study starting and how long is it expected to run for?
The study started in mid 2011 and data collection was ended in late 2011

Who is funding the study?
Research Council of Norway

Who is the main contact?
Mr Filip Drozd
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A fully automated and web-based intervention for stress management: a randomized controlled trial

Study objectives
1. The web-based stress management intervention is more effective in reducing levels of stress than the waitlist control group.
2. The effect of the stress management intervention is mediated through mindfulness and decisional procrastination.
3. The effects on levels of stress are not moderated by age, gender or educational levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwegian Social Science Data Services, 13 May 2011, ref: 26816

Study design
A two-armed randomized controlled trial where the experimental group receives the web-based stress management program and the control group receives no treatment (i.e. a waitlist).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Participants from the normal population with a perceived need for stress management

Interventions
NewMe Stresse Mindre ('NewMe Less Stress') is a fully automated and web-based intervention. It consists of 13 sessions and lasts for about one month. There are three sessions per week. So every Monday, Wednesday, and Friday, users receive an email with a link to that particular sessions content. Each session is structured in two sections. The first section is psychoeducational and addresses a specific topic related to stress (e.g. procrastination or worries). The second section has different psychological techniques and exercises for dealing with stress. These techniques and exercises are related to the specific topic presented in the psychoeducational section. Furthermore, home assignments are given to do in-between sessions. NewMe Stresse Mindre takes on an ecclectic approach to stress management and applies information, techniques and exercises previously documented to be effective for stress reduction. This includes information, techniques and exercises from positive psychology, metacognitive therapy, and mindfulness-based cognitive-behavioural therapy. The control group (i.e. waitlist) did not receive any other treatment. They were, however, told that they would be given access to NewMe Stresse Mindre once the final data were collected approx. 6 months after study inclusion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All patients were surveyed at baseline, 1, 2, and 6 months post-intervention enrollment: Depression Anxiety Stress-Stress sub-scale (DASS-S; Lovibond & Lovibond, 1995)

Secondary outcome measures
1. Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003)
2. Melbourne Decision Making Questionnaire-Procrastination sub-scale (MDMQ-P; Mann, Burnett, Radford, & Ford, 1997).

Overall study start date
01/05/2011

Completion date
01/05/2016

Eligibility

Key inclusion criteria
All participants had to provide a valid e-mail address and be >= 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
It was estimated that we needed approx. 235 participants in total

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
Norway

Study participating centre
Sletta 16
Askim
Norway
1807

Sponsor information

Organisation
Research Council of Norway (Norway)

Sponsor details
P. O. Box 2700
St. Hanshaugen
Oslo
Norway
0131

Sponsor type
Research council

Website
http://www.forskningsradet.no/

ROR
https://ror.org/00epmv149

Funder(s)

Funder type
Research council

Funder Name
Research Council of Norway ref: 187979 (Norway)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/04/2013		Yes	No