Better Days - A psychological online intervention for overall mood and depressive symptoms

Submission date	Recruitment status	Prospectively registered		
21/01/2013	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/02/2013	Completed	[X] Results		
Last Edited 14/03/2018	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

The World Health Organization defines mental health as a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her own community. This definition implies that mental health is not merely the absence of mental illness, but it also requires the presence of well-being. It is suggested that mental health is a range which consists of complete and incomplete mental health. Those who have complete mental health are said to be flourishing, they experience positive emotions and appear to function well both psychologically and socially. Those who have incomplete mental health are said to be languishing, their life is characterized by low social, emotional and psychological well-being and could be described as empty and stagnating. There are at least two reasons why mental health professionals should be equally concerned about languishing, as about the presence of depression. First, languishing is equally prevalent as major depression, and second, languishing has been found to be associated with equal levels of psychosocial impairment as depression. The worst outcomes were observed in individuals who were languishing and had a co morbid episode of depression. Thus, the aim of this project is to test the effects of an easy-access and scalable web-based positive psychotherapy intervention designed to increase overall mood and reduce symptoms of depression among healthy and normal functioning adults.

Who can participate?

Anyone over 18 years old, who was invited via social media, and was able to provide a valid email address.

What does the study involve?

Participants were randomly allocated to two groups. One group received the web-based intervention and the other group received no treatment (i.e. control group). The web-based intervention consisted of 13 sessions in total which last for about one month. Participants had to fill in web-based questionnaires at 1, 2, and 6 months after study onset and those in the control group were given access to the web-based intervention after the final data collection was completed.

What are the possible benefits and risks of participating? Participants may learn how to increase their subjective well-being and acquire helpful psychological tools that they can use in times of distress or in times when they do feel good, but would like to increase their wellness even further, any time later. There are no associated or expected risks of participating, however, participants may experience increases in overall mood and reductions in depressive symptoms.

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

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

Who is funding the study? Research Council of Norway

Who is the main contact? Filip Drozd filip.drozd@r-bup.no

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Better Days - A randomized controlled trial of an online positive psychotherapy intervention for overall mood and depressive symptoms

Study objectives

1a. The web-based online intervention - 'Better Days' - increases overall mood among participants in the experiment group over time, as compared to participants in the control group.
1b. The web-based online intervention - 'Better Days' - decreases depressive symptoms for participants in the experiment group over time, as compared to the control group.

2a. The treatment effect of 'Better Days' is tested for moderation effects of gender, age, and education on overall mood.

2b. The treatment effect of 'Better Days' is tested for moderation effects of gender, age, and education on depressive symptoms.

3a. The treatment effect of the 'Better Days' intervention on overall mood is mediated via optimism over time.

3b. The treatment effect of the 'Better Days' intervention on symptoms of depression is mediated via optimism over time.

Ethics approval required

Old ethics approval format

Ethics approval(s) Norwegian Social Science Data Services, 02/05/2011, ref: 26812/3/LT

Study design

Two-armed randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Internet/virtual

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied Normal population / mood and depressive symptoms

Interventions

Experimental group receives the web-based positive psychology program and the control group receives no treatment (i.e. a waitlist).

Better Days 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. 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 wellbeing such as engaging in pleasant activities or acts of kindness. The second section provides participants with specific psychological techniques and exercises for increasing well-being or reducing depressive symptoms such as engaging in acts of kindness or utilizing one's character strengths. 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. Better Days applies information, techniques and exercises previously documented to be effective for increasing subjective well-being or reducing symptoms of depression.

The control group (i.e. waitlist) did not receive any other treatment. They were, however, told that they would be given access to Better Days once the final data were collected approx. 6 months after study inclusion.

Intervention Type

Behavioural

Primary outcome measure

- 1. Positive & Negative Affect Schedule (PANAS; Watson, Clarke & Tellegen, 1988)
- 2. Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977)

All participants were measured on primary outcomes on baseline, 1, 2, and 6 months postintervention enrollment.

Secondary outcome measures

1. Life Orientation Test-Revised (Scheier, Carver & Bridges, 1994)

2. Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003)

All participants were measured on secondary outcomes on baseline, 1, 2, and 6 months postintervention enrollment.

Overall study start date

01/05/2011

Completion date

01/05/2016

Eligibility

Key inclusion criteria

- 1. Participants from the normal population aged 18+, either sex
- 2. Participants providing a valid e-mail address

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants It was estimated that we needed about 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 Changetech Gaustadalleen 21

Oslo Science Park Oslo Norway NO-0349

Sponsor information

Organisation Research Council of Norway (Norway)

Sponsor details

PO 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 Norges Forskningsråd

Alternative Name(s) Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type Government organisation

Funding Body Subtype National government

Location Norway

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Filip Drozd (filip.drozd@r-bup.no). Data are anonymized and stored for purposes of reproducibility/replicability, systematic reviews and meta-analyses, or similar, until 31/12/2021. Aggregate results will be provided by corresponding author upon request.

IPD sharing plan summary

Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/09/2014		Yes	No