

How can we promote positive mental health among young adults in Sweden? An evaluation of a new mobile phone-based intervention

Submission date 10/09/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/03/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mental health problems have increased among young adults in Sweden the recent years. In 2016, half of women and a third of men between the ages 16-29 reported that they frequently experienced worry, stress, anxiety or sleeping problems. An innovative mobile phone-based program aims to enhance well-being among young adults. This study aims to investigate the effect of the new mobile phone-based program on mental health outcomes among young adults, and to investigate potential mediators (positive emotions, thoughts and behaviors).

Who can participate?

Students (healthy volunteers) over 18 years of age

What does the study involve?

Participants are randomly allocated to either an intervention (mobile-phone based program) or control group. The intervention aims to increase users' positive mental health through automatic text messages that are sent to users throughout the program with on average one text message a day. The program runs for 10 weeks. The effect of the program on primarily well-being but also depression and anxiety symptoms is measured at the start of the study and at 3-6- and 12 months follow-up.

What are the possible benefits and risks of participating?

Possible benefits could be an increase in wellbeing if the intervention turns out to be effective. No significant risks are foreseen. The study aims to recruit healthy volunteers and the intervention is preventative aiming to promote mental health. Participants signing up to the study hoping to gain access to the intervention but allocated to the control group could experience negative emotions. The invitation text therefore gives details about the study design to inform participants at an early stage that they may not be given access to the intervention.

Where is the study run from?

It is run by a research group based at Linköping University but universities throughout Sweden will be invited to take part.

When is the study starting and how long is it expected to run for?
October 2018 to April 2020

Who is funding the study?
Linköping University (Sweden)

Who is the main contact?
Dr Kristin Thomas

Contact information

Type(s)
Public

Contact name
Dr Kristin Thomas

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Dnr 2018/5-31

Study information

Scientific Title
How can we promote positive mental health among young adults in Sweden? An evaluation of a new mobile phone-based intervention

Study objectives
The intervention group will increase their positive mental health significantly more compared to the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The regional ethical review board, Linköping University, 17/04/2018, ref: 2018/5-31

Study design

Two-arm randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Positive mental health

Interventions

Participants will be randomized to either the intervention or control group. Each participant will be allocated a number 1 or 2 with equal probabilities using Java's built-in random number generator (`java.util.Random`). Randomization is thus fully computerized, does not use any strata or blocks, and is not possible to subvert, because this and all subsequent study processes are fully automated.

Intervention group

The intervention is a mobile phone based intervention that aims to increase participants' positive mental health. The text messages include text and/or links to pictures, interactive exercises and further reading. Text messages are automatically sent to users throughout the program with on average 1 text message a day. The program runs for ten weeks with a new theme being introduced each week. These themes have been shown to be important for our positive mental health and include e.g. practicing gratitude or identifying personal strengths.

Control group

The control group will be given contact details of their local Student health services and Primary care center in a text message after randomization. The Student health services in Sweden are responsible for mental health promotion among university students.

Intervention Type

Other

Primary outcome measure

Positive mental health, measured using the Mental health Continuum-Short Form at baseline, 3 months, 6 months and 12 months

Secondary outcome measures

Depression and anxiety symptomatology, measured using the Hospital Anxiety Depression Scale at baseline, 3 months, 6 months and 12 months

Overall study start date

01/10/2018

Completion date

01/04/2020

Eligibility**Key inclusion criteria**

1. University students between the ages of 18-29 years of age
2. Able to read and understand Swedish
3. Own a mobile phone

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

29 Years

Sex

Both

Target number of participants

A total of 503 participants

Total final enrolment

654

Key exclusion criteria

1. High score on the Mental Health Continuum – Short Form defined as a self-rated score above 70 (maximum score 84)
2. Mild depressive or anxiety symptomatology defined as a score of 10 and above on either subscale on the Hospital Anxiety Depression Scale

Date of first enrolment

01/10/2018

Date of final enrolment

01/04/2019

Locations

Countries of recruitment

Sweden

Study participating centre

Linköping University

Institutionen för Medicin och Hälsa

Linköping

Sweden

58183

Sponsor information

Organisation

Linköping University

Sponsor details

Faculty of Medicine and Health Sciences

Department of Medical and Health Sciences

Linköping

Sweden

58183

Sponsor type

University/education

Website

www.liu.se

ROR

<https://ror.org/05ynxx418>

Funder(s)

Funder type

University/education

Funder Name

Linköpings Universitet

Alternative Name(s)

Linköping University, Linköping University, LiU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Publication and dissemination plan

Additional documents (study protocol including statistical analysis plan) will be available but not yet published. Planned publication of the results in a high-impact peer reviewed journal during the first quarter of 2020.

Intention to publish date

01/03/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the General Data Protection Regulation and recommendations from our regional Ethical Committee.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/08/2019	19/08/2019	Yes	No
Results article	results	20/03/2020	23/03/2020	Yes	No