

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

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

**ORCID ID**  
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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](http://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?
<a href="#">Protocol article</a>	protocol	15/08/2019	19/08/2019	Yes	No
<a href="#">Results article</a>	results	20/03/2020	23/03/2020	Yes	No