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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

Registration date
28/09/2018

Overall study status
Completed

Last Edited
23/03/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Two-arm randomised controlled trial

Study type(s)
Quality of life

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

Key secondary outcome(s)
Depression and anxiety symptomatology, measured using the Hospital Anxiety Depression Scale at baseline, 3 months, 6 months and 12 months

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
29 Years

Sex
All

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
Insitutionen för Medicin och Hälsa
Linköping
Sweden
58183

Sponsor information

Organisation
Linköping University

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

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?
	results				

Results article		20/03/2020	23/03/2020	Yes	No
Protocol article	protocol	15/08/2019	19/08/2019	Yes	No