ISRCTN65120704 https://doi.org/10.1186/ISRCTN65120704

Suicide prevention through internet and media based mental health promotion

Submission date
29/11/2012

Recruitment status
No longer recruiting

Registration date
05/03/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Suicide is the third leading cause of death among people aged below 25 worldwide, and approximately 63,000 Europeans commit suicide each year in the 27 EU member states. The aim of this study is to develop a website (intervention website), specifically targeted at young people, which contains material that promotes good mental health, and to investigate if it has a positive effect on their mental health.

Who can participate?
2100 school pupils from 7 EU countries, aged 14-16 from randomly chosen public schools within the 7 countries are selected and asked to participate in the study. If and only if the school agrees to participate, the individual pupils are asked if they want to participate in the study.

What does the study involve?
The participating schools with their pupils are divided into groups on a random basis. One group of schools/pupils will then have access to the intervention website (treatment arm) and the other group will not (control arm). The questionnaire is answered in the participating schools during school hours. These questions are related to depression, anxiety, stress, alcohol/drug use and suicidal behaviors/ thoughts. The pupils will answer the questionnaire three times with two months in between each time, and answers are compared between those pupils who have had access to the website and those who have not.
As it is voluntary for the pupils to visit the website, a second aim of the study is to try two different techniques of promoting pupils use of the website, in order to find the most effective way of encouraging young people to use this kind of mental health promoting material. To do this, the (pupils in the-) schools that will have access to the website are divided into two sub-groups. One group will be informed about the website by a peer (young and youthful person, similar to the pupils themselves) and the other one by a professional (an older, more formal, professional person who is more different to the pupils but who is a lot of knowledge on the subject). This way it is possible to investigate which type of person is more effective in promoting mental health material to young people.

What are the possible benefits and risks of participating?
The questions that will be asked participants are very personal ones, and some participants

might have strong emotional reactions (e.g. feeling anxiety or stressed) when asked questions about e.g. past suicide attempts. What could be beneficial is that some participants will have access to the intervention website, which contains educational material, self-help advice, the possibility to chat with a mental health professional and more. However, participants will not be aware of which group they belong to, so website access cannot be guaranteed. For this reason, all participants will get a leaflet which contains contact information to various health care institutions, to which one can turn if having questions or being in distress.

Where is the study run from?
The study is carried out in 7 EU countries by the following institutions: Estonia (Estonian-Swedish Mental Health and Suicidology Institute), Hungary (Vadaskert Foundation Child & Adolescent Psychiatric Hospital & Clinic), Italy (University of Molise), Spain (Hospital Del Mar), United Kingdom (Anglia Ruskin University), Lithuania (Vilnius University) and Sweden (Karolinska Institutet).

When is the study starting and how long is it expected to run for?
The study started in December 2012 and will run till June 2013.

Who is funding the study?
European Commission and co-funded by the 7 participating centers.

Who is the main contact?
Dr Vladimir Carli
vladimir.carli@ki.se

Study website
http://www.supreme-project.org

Contact information

Type(s)
Scientific

Contact name
Dr Vladimir Carli

Contact details
National Centre for Suicide Research and Prevention of Mental Ill-health) (NASP)
Karolinska Institutet
Stockholm
Sweden
171 77
+46 707 533 524
vladimir.carli@ki.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Research project funded by the European Agency for Health and Consumers (EAHC). Grant Agreement: 2009 12 19

Study information

Scientific Title
Suicide prevention through internet and media based mental health promotion: a randomized single-blind minimal treatment-controlled parallel multi-centre study

Acronym
SUPREME

Study objectives
1. Compared to only the minimal intervention (minimal intervention contact information leaflet), the web-based mental health promotion intervention in this trial will lead to a decrease in indicators of mental health problems, increase knowledge regarding mental health and related treatment institutions, self-help strategies for preventing mental ill-health, as well as improve attitudes towards individuals suffering from mental health problems.
2. Success-rates in the referral of participants to the intervention website will be different for referral by "peers" vs. "professionals". In this hypothesis, while other variables are held constant, "peers" are defined as young (18-24 years) and youthful (with regards to demeanor and appearance) investigators from the research group, as opposed to "professionals" who are older (40+) and more formal in demeanor and appearance (also from the research group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Ethical Review Board in Stockholm, Council at Karolinska Institutet, department 3 (Regionala etikprövningsnämnden i Stockholm, Kansli vid Karolinska institutet, avdelning 3), 20 /06/2012, Reference number: 2012/413-31/3, Protocol number: 2012/3:6
2. Faculty (of Health, Social Care & Education) Research Ethics Panel, UK, 10/10/2012, Reference number: 11/086
3. Clinical Research Ethics Committee Parc de Salut MAR (Comité Ético de Investigación Clínica Parc de Salut MAR), 21/10/2012, Reference number: 2012/4621/I
4. Scientific and Medical Research Council Sekretariat Research Ethics Committee (ETT TUKEB) [Egészségügyi Tudományos Tanács Titkárság Tudományos es Kutatásetikai Bizottság (ETT TUKEB)], Hungary, 20/04/2012, Reference number: 12869/2012/EKU (227/PI/12)
5. Tattinna Medical Research Ethics Committee (TMEK) [Tattinna Meditsiiniuuringute Eetikakomitee (TMEK)], 17/05/2012, Decision number: 2747, Application number: 1175, Protocol number: 162
6. Comitato Bioetico Di Ateneo, Università Degli Studi Del Molise, Italy, 10/03/2011, Reference /Protocol number: 7377-II/5 del 10.3.2011
7. Vilnius Regional Committee for Bioethics, Faculty of Medicine of Vilnius University, 06/11 /2012, Reference number: 158200-11-544-155, Protocol number: 8,3

Study design

Randomized single-blind minimal treatment-controlled parallel multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Suicidality, major risk factors, suicide prevention

Interventions
Arm 1 (Intervention/treatment condition) - Intervention website promotion by peer & minimal intervention: At baseline, the participants are given a detailed description of the intervention website, its components and modules, and instructions how to access it. It is explained that it is optional for participants to visit the website, and that no school hours are allocated for this activity. This website promotion is executed by two peers from the research center. At post and follow-up evaluation, participants are briefly reminded about the website and encouraged to visit it. Each of the 3 interventions occurs on a single occasion, approximately 1 hour long. The minimal treatment comprises a leaflet with contact information to - and a description of - 5 different health care institutions to which participants can turn. The minimal intervention leaflet is distributed to participants only at baseline.

Arm 2 (intervention/treatment condition) - Intervention website promotion by professional & minimal intervention: At baseline, the participants are given a detailed description of the intervention website, its components and modules, and instructions how to access it. It is explained that it is optional for participants to visit the website, and that no school hours are allocated for this activity. This website promotion is executed by two professionals from the research center. At post and follow-up evaluation, participants are briefly reminded about the website and encouraged to visit it. Each of the 3 interventions occurs on a single occasion, approximately 1 hour long. The minimal treatment comprises a leaflet with contact information to - and a description of - 5 different health care institutions to which participants can turn (same as arm 1). The minimal intervention leaflet is distributed to participants only at baseline.

Arm 3 (comparator/control condition) - Minimal intervention: At baseline, participants are told briefly about the website but informed that they cannot access it yet. No detailed description of the website is given, nor is it promoted. The baseline session is held by any two persons from the research group (the control group fall outside the testing of hypothesis. The control participants only receive the minimal treatment, which comprises a leaflet with contact information to - and a description of - 5 different health care institutions to which participants can turn (same as arm 1 and 2). No minimal intervention is given at post evaluation. At the follow-up evaluation (end of

study), participants are given a detailed description of the website and how to access it (the same description as arm 1 and 2 are given at baseline). Each of the 3 interventions occurs on a single occasion, approximately 1 hour long.

Further description of intervention/treatment conditions (Arm 1 & 2)

About Peers and Professionals
The difference between peers and professionals lies in their apparent similarity with the participants, and the main purpose of having two different kinds of website promoters is to investigate hypothesis 2.

Intervention website
Participants in arm 1 and 2 get access to the intervention website (are able to create user accounts if they choose to) 24/7 at baseline and throughout the whole study (4 month total duration). The website contains information articles about depression, anxiety, worry, stress, bullying, violent behavior, sexual abuse, substance misuse/addiction, food/nutrition, health complication related to over eating/under eating and unhealthy internet use. The articles describe the condition, self-help strategies and give contact information to health care institutions and support groups. The website also contains 5 user-interactive modules:
1. Discussion forum: users can discuss mental health topics.
2. Idea box: users can post their ideas of how mental health can be promoted in their community and receive comments on their ideas from the moderator.
3. Reasons for living: users post their reasons for why life is worth living.
4. Chat: Users can book an appointment to have a text based chat session with a mental health professional or researcher from the center.
5. Self-assessment: users can fill out an online questionnaire and receive comments on their answers to assess their own mental health.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hypothesis one, regarding the efficacy of the intervention: Primary data will be collected using a questionnaire which is administered to participants at baseline evaluation (day 0), post evaluation (month 2) and follow-up evaluation (month 4). Post and follow-up measures occur after the participants have been exposed to the intervention website (arm 1, 2) or the minimal intervention contact leaflet (arm 3). The questions are sometimes administered on ordinary paper and sometimes as an electronic online questionnaire.

The questionnaire consists of 5 different types of questions/scales, and the questionnaires used in post and follow-up evaluation also includes a 6th part with follow-up questions on the intervention.

1. Background questions/demographic variables: Specific items for measurement of life and family situation, socioeconomic status (SES), help-seeking behavior.
2. Internet use: Specific items for the measurement of the participants internet use; frequency and intensity of daily internet use, as well as descriptive information of the most common internet activities is gathered.

3. The Depression, Anxiety and Stress scale-42 (DASS-42) (Lovibond & Lovibond, 1995) is a 42 item scale used for the measurement of (clinical) depression, anxiety and stress
4. Paykel's suicide ladder (Paykel et al. 1972) is a 5 item scale used for the measurement of the suicide risk. Suicide-risk behaviors and suicidal ideation is measured.
5. Risk behaviors: Specific items on mental health related risk behaviors are measured. Items relate to alcohol and drug use, tobacco use, bullying and decision making (Gächter et al. 2007).
6. Post and follow-up questions relate to the intervention website and the minimal intervention contact leaflet: If it was used by the participant, and if so, how helpful it was perceived.

The second type of outcome data is intervention website user statistics. General website statistics are collected using programs such as Google Analytics. These variables include frequency and duration of website use and time spent using different modules, both for individual users and on an aggregate level. All statistical analyses will be performed on datasets using randomly generated participant ID's and questionnaire and web-based data. While the identity of website users is not tracked, study participants log in to the website using their randomly assigned participant ID, which allows questionnaire data to be connected to website statistics.

Secondary outcome measures
Data is collected from the users interactions on the intervention website. These include chat, forum and blog entries made by users.

Overall study start date
01/12/2012

Completion date
01/06/2013

Eligibility

Key inclusion criteria
In this multicenter study, each center (i.e. country) selects a catchment area to create a pool of schools. The catchment area can be defined by its geographical location and/or demographical and/or political variables (e.g. a municipality, city, etc.) and which of these variables should be applied is decided by the individual center. First, a list of all schools within that area is obtained, and the following inclusion criteria is then applied, in order to create a pool of schools which are eligible for study recruitment:
1. The school authority agrees to participate
2. The school is public
3. The school contains at least 100 pupils within the age range of 14-16
4. The school has more than two teachers for pupils aged 15
5. No more than 70% of the pupils are of either sex (within those school class/es where pupils will be recruited)
6. Informed consent from pupils (and parents when applicable) is obtained

Remaining is a list eligible schools. This list is then randomized so that the schools appear in a random contact order and they are then contacted accordingly and asked to participate in the study. If the first school declines the request (school participation is voluntary), the second school on the list is contacted, and so forth. When the target sample size is (estimated to be) reached, an information session is
organized in the respective schools where pupils (14-16 years old) and their teachers are

informed about the study and asked to participate. All participants are thus registered pupils of the selected schools.

Only pupils who voluntarily agree to participate by supplying written consent are included. No further participant inclusion or exclusion criteria are used.

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Total target number of participants: 2100 minimum

Total final enrolment
2286

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Estonia

Hungary

Italy

Lithuania

Spain

Sweden

United Kingdom

Study participating centre

National Centre for Suicide Research and Prevention of Mental Ill-health) (NASP)
Stockholm
Sweden
171 77

Sponsor information

Organisation
Karolinska Institute (Sweden)

Sponsor details
Swedish National Centre for Suicide Research and Prevention of Mental Ill-health (NASP)
Stockholm
Sweden
171 77
+46 852 487 026
nasp@ki.se

Sponsor type
Research organisation

Website
http://ki.se/nasp

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Health Programme of the Executive Agency for Health and Consumers (EAHC) (Grant Agreement: 2009 12 19)

Funder Name
The Swedish National Prevention of Suicide and Mental Ill-Health (NASP), at Karolinska Institutet (Sweden)

Funder Name
Estonian-Swedish Mental Health and Suicidology Institute (ERSI) (Estonia)

Funder Name
Vadaskert Foundation Child & Adolescent Psychiatric Hospital & Clinic (VAGLE) (Hungary)

Funder Name
University of Molise (UNIMOL) (Italy)

Funder Name
Vilnius University (VU) (Lithuania)

Funder Name
Hospital Del Mar, Barcelona (PsMAR) (Spain)

Funder Name
Anglia Ruskin University (ANGLIA) (UK)

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	13/07/2016	17/12/2020	Yes	No
Results article	results	05/04/2018	17/12/2020	Yes	No