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Is internet-delivered therapy more effective than internet-delivered brief support in reducing depressive symptoms in adolescents?

Submission date
20/12/2018

Recruitment status
No longer recruiting

Registration date
25/01/2019

Overall study status
Completed

Last Edited
28/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
The need of development of early, short and focused interventions for depressed adolescents is urgent. Internet-based interventions are designed to increase access to psychological treatments and cost-effectiveness. Empirical support is already established for Internet-based cognitive behavioural therapy (I-CBT) with response rate of about 60 %. In the present study, the aim is to test the feasibility and efficacy of a recently developed internet-based treatment for depressed adolescents – internet-delivered psychodynamic therapy (I-PDT).

Who can participate?
Adolescents aged 15-18 years with mild to moderate depression will be included.

What does the study involve?
The study is a randomized controlled trial for 72 participants, in which half of the participants will begin treatment immediately after inclusion and the other half will receive a brief supportive contact until they receive the treatment 10 weeks after inclusion. The interventions consist of 8 therapist-supported self-help modules delivered over 8 weeks with added chat sessions. Primary outcome will be severity of depressive symptoms. Secondary outcomes will be anxiety symptoms and psychiatric diagnoses. The aim of I-PDT is to decrease emotional avoidance and increase awareness and experience of emotions. Participants are encouraged to gradually approach previously warded off feelings. They will also be taught how to link their emotions to their symptoms. Another treatment goal is to acquire a greater capacity for anxiety regulation.

What are the possible benefits and risks of participating?
The expected benefit of the treatment is that it will reduce depressive symptoms among the participants. Internet-based treatments bear the possibility to reach depressed adolescents who do not have access to adequate psychological treatment, for example due to geographical reasons, or are reluctant to seek face-to-face treatment within the health care system. Psychological treatments are based on the fact that participants share very personal information and there is a risk that some participants might experience this as a threat to their integrity. The

project will use established strategies to manage other types of risks, for example that some participants turns out having more serious medical, psychological or social problems than was discovered at inclusion.

Where is the study run from?
Department of Psychology, Stockholm University, Sweden.

When is the study starting and how long is it expected to run for?
This trial is a pilot study that will start in 3 January, 2019, and run until 30 June, 2019. The pilot study is the first part of a larger project and the next step will be a large non-inferiority randomized controlled trial investigating comparative effects between I-PDT and an already established internet based treatment (I-CBT) for adolescents.

Who is funding the study?
The project has received funding from the Kavli Trust for the years 2019-2023.

Who is the main contact?
Main contact is principal investigator Björn Philips, Associative Professor, at the Department of Psychology, Stockholm University, Sweden.

Study website
https://erica.nu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018/2268-31/5

Study information

Scientific Title
ERiCA I-PDT for depressed adolescents – a pilot randomized controlled trial

Acronym
ERiCA

Study objectives
Internet-delivered psychodynamic therapy (I-PDT) is more effective than symptom monitoring and brief support via internet with regard to reducing depressive symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Board in Stockholm, 13/12/2018, ref. 2018/2268-31/5.

Study design
Interventional, randomized controlled trial, pilot study

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 below to request a participant information sheet

Health condition(s) or problem(s) studied
Mild to moderate depression in adolescents

Interventions
Directly after inclusion, participants will be randomized to one of two arms with 1:1 ratio: intervention or control condition. An independent researcher, not involved in the study, will conduct the randomisation procedure by means of a computerised random number service.

Intervention: Internet-delivered psychodynamic treatment (I-PDT) that consists of 8 therapist-supported self-help modules delivered over 8 weeks in a secure online platform. Modules consist of texts followed by assignments which they send to their therapist and receive feedback within a few days, complemented with 30 minutes chat support weekly. The aim of I-PDT is to decrease emotional avoidance and increase awareness and experience of emotions.

Participants are encouraged to gradually approach previously warded off feelings. They will also be taught how to link their emotions to their symptoms. Another treatment goal is to acquire a greater capacity for anxiety regulation. Treatment duration is 8 weeks and measurements are made prior to treatment, weekly during treatment, and at termination.

Control condition: Brief supportive contact over internet over 8 weeks, with monitoring of symptoms and well-being as well as exchange of short messages between participant and therapist. Duration is 8 weeks and measurements are made prior to the supportive contact, weekly during the supportive contact, and at termination. After 10 weeks, participants in the control condition will be offered the I-PDT-program with email-support. New measurements will be made weekly during the treatment and at termination.

Intervention Type
Behavioural

Primary outcome measure
1. Depressive symptoms will be measured using the Quick Inventory of Depressive Symptomatology in Adolescents (Bernstein et al., 2010) via internet delivered self-rating forms pre-treatment, weekly during treatment and post-treatment.
1.1. In order to fully explore trajectories of change and possible moderating and mediating factors over time, a parallel process latent growth curve strategy will be employed.
2. Differences in efficacy between conditions will be investigated by modelling interaction effects of group and time.

Secondary outcome measures
1. Anxiety symptoms will be measured weekly using the Generalised Anxiety Disorder 7- item scale (GAD-7; Kroenke et al., 2010).
2. The severity of depression symptoms will be measured pre- and post-treatment using the Montgomery Åsberg Depression Rating Scale (Svanborg & Åsberg, 1994).

Overall study start date
01/11/2018

Completion date
20/10/2019

Eligibility

Key inclusion criteria
1. Adolescents 15-18 years of age
2. Suffering from mild to moderate symptoms of depression according to a diagnostic interview (MINI 7.0).
3. Have access to a computer/smartphone/tablet with internet connection
4. Able to read, write and speak Swedish without the aid of an interpreter.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
72

Total final enrolment
76

Key exclusion criteria
1. Risk of suicidality and/or earlier suicide attempts,
2. Partaking in other psychological treatment,
3. Psychotropic medication not stable since at least three months,
4. Other primary diagnoses in need of other treatment
5. Current fulfillment of any of the following diagnoses: any psychotic disorder, bipolar I/II disorder, antisocial personality disorder, and autism-spectrum disorder.
6. Comorbid drug or alcohol abuse.

Date of first enrolment
03/01/2019

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Psychology, Stockholm University
Department of Psychology, Stockholm University
Stockholm
Sweden
SE-106 91

Sponsor information

Organisation
Department of Psychology, Stockholm University

Sponsor details

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Sponsor type
University/education

Website
https://www.psychology.su.se/

ROR
https://ror.org/05f0yaq80

Funder(s)

Funder type
Charity

Funder Name
Kavli Trust

Results and Publications

Publication and dissemination plan
The primary outcome paper will present outcome data in a journal with open access publication, with preliminary time-point for publication in October 2019. Data that break the blind will not be presented prior to the release of mainline results. No outcome data will be published or presented before data collection is completed. The results will also be disseminated in popular science form through different media, partly with help of the user representatives from Suicide Zero.

Intention to publish date
15/10/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	30/03/2020	01/04/2020	Yes	No
Results article	results	14/07/2020	10/08/2020	Yes	No
Results article	findings from interviews	06/12/2022	08/12/2022	Yes	No
Results article	Sudden gains and large intersession improvements	17/08/2020	28/02/2024	Yes	No