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Comparing the effectiveness of two types of internet-delivered therapy for adolescent depression – the ERiCA study

Submission date
12/08/2019

Recruitment status
No longer recruiting

Registration date
13/08/2019

Overall study status
Completed

Last Edited
22/06/2023

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
There is a great need for treatments for depression in teenagers that can be implemented in the early stages of depression and can be completed quickly. Internet-based treatments do not require people to wait for treatment and are not as expensive as face-to-face therapy. Internet-delivered cognitive behavioural therapy (I-CBT) has been shown to results in an improvement in symptoms in over half of patients. CBT involves changing how people think about depression and how they behave in response to depression. An alternative treatment is internet-based psychodynamic therapy (I-PDT), which helps people to be more aware of their emotions. The research team has previously developed an I-PDT programme and tested whether it is possible to deliver it and its initial effectiveness in a small study with promising results. This study aims to compare the effectiveness of I-PDT against I-CBT, which has been previously shown to help, in teenagers with depression.

Who can participate?
Adolescents aged 15-19 years with mild to moderate depression.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive I-PDT and the other group will receive I-CBT. Treatment will start immediately for both groups. Both treatments involve 8 therapist-supported internet-based self-help modules delivered over 10 weeks, with added therapist chat sessions. The participants will rate their depression, anxiety and emotions using questionnaires before the start of treatment, during the treatment and after the treatment has been completed.

What are the possible benefits and risks of participating?
For both treatments, the expected benefit is reduction of depression symptoms. In addition, internet-based treatments can reach depressed teenagers who might not have access to standard psychological treatments, for example because they live far from healthcare services or are reluctant to seek face-to-face treatment within standard healthcare services. Psychological treatments are based on the fact that participants share very personal information

and there is a risk that some participants might feel threatened or upset by being asked to think about or discuss difficult feelings. The project will also use established strategies to manage other types of risks, for example, participants who turn out to have more serious medical, psychological or social problems than was apparent at the start.

Where is the study run from?
Department of Psychology, Stockholm University (Sweden), in collaboration with the Department of Behavioural Sciences and Learning, Linköping University (Sweden).

When is the study starting and how long is it expected to run for?
August 2018 to January 2022

Who is funding the study?
The Kavli Trust (Norway) and the Department of Psychology, Stockholm University (Sweden)

Who is the main contact?
Björn Philips, bjorn.philips@psychology.su.se

Study website
https://erica.nu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
32/18

Study information

Scientific Title
Early internet-based interventions for children and adolescents (ERiCA): I-PDT versus I-CBT for depressed adolescents – a randomized controlled non-inferiority trial

Acronym
ERiCA

Study objectives
Internet-delivered psychodynamic therapy (I-PDT) is non-inferior to Internet-delivered cognitive behavioural therapy (I-CBT) in reducing depressive symptoms in adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/08/2019, Swedish Ethical Board Review Authority (Swedish Ethical Review Authority, Box 2110, SE-750 02 Uppsala, Sweden; +46 (0)10 4750800; registrator@etikprovning.se), ref. 2019-03023

Study design
Interventional randomised controlled trial, parallel-group non-inferiority design.

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Major depressive disorder in adolescents

Interventions
Immediately following inclusion, participants will be randomised to one of two arms with 1:1 ratio: I-PDT or I-CBT. An independent researcher, not involved in the study, will conduct the randomisation procedure by means of a computerised random number service.

Interventions: Both interventions consist of 8 therapist-supported self-help modules delivered over 10 weeks on a secure online platform. Modules consist of texts, videos, and assignments that participants send to their therapist to receive feedback within a few days. In addition, participants will receive 30 min of weekly therapist support over chat text.

Target intervention: Internet-delivered psychodynamic treatment (I-PDT) has the aim 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.

Control intervention: A previously evaluated Internet-delivered cognitive behavioural therapy (I-CBT) programme for adolescent depression. Treatment targets behavioural and cognitive factors documented to reduce symptoms of depression and anxiety, including psycho-education, behavioural activation, cognitive restructuring, affect regulation, anxiety management, and relapse prevention.

Intervention Type
Behavioural

Primary outcome measure
1. Depressive symptoms measured using the Quick Inventory of Depressive Symptomatology in Adolescents (QIDS; Bernstein et al., 2010) via internet-delivered self-rating forms pre-treatment, weekly during treatment and post-treatment (within 2 weeks of end of treatment). Differences in efficacy between conditions will be investigated by growth curve analysis using data from all measurement points. The non-inferiority margin is defined as Cohen's d=.30. If the non-inferiority hypothesis is falsified, analysis of superiority will follow.

Secondary outcome measures
1. Anxiety symptoms measured pre- and post-treatment (within 2 weeks of end of treatment) using the Generalised Anxiety Disorder 7- item scale (GAD-7; Kroenke et al., 2010)
2. Anxiety symptoms measured using the GAD-7 scale at 1, 6, and 12 months post-treatment
3. Depression symptoms measured using QIDS at 1, 6, and 12 months post-treatment
4. Emotion regulation and self-compassion measured pre- and post-treatment (within 2 weeks of end of treatment) through the Emotion Regulation Skills Questionnaire (ERSQ; Grant, Salsman & Berking, 2018) and Self-Compassion Scale short-form (SCS-SF; Raes, Pommier, Neff & Van Gucht, 2011)
5. Cost-effectiveness of treatments evaluated with the Trimbos and Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P; Bouwmans et al, 2013), pre-treatment and at 12-month follow-up. In line with recommendations for assessing cost-effectiveness in treatments of adolescents (Goorden, van der Schee, Hendriks, & Hakkaart van Roijen, 2016), only the sections of TIC-P regarding health care use will be administered.
5. Possible moderators for outcome will be analysed using the following measures pre-treatment, weekly during treatment and post-treatment (within 2 weeks of end of treatment): Experience in Close Relationships – Relationships Structure (ECR-RS; Feddern, Donbaek & Elklit, 2014); Operationalized Psychodynamic Diagnosis-Structure Questionnaire Short-form (OPD-SQS; Ehrenthal, Dinger, Schauenburg, Horsch, Dahlbender & Gierk, 2015), single item expectancy measure (adapted from Moras & Jones 1992 in Connolly Gibbons et al., 2003) and The Personality Inventory for DSM Short Form (PID-5; Krueger, Derringer, Markon, Watson & Skodol, 2013); SCS-SF (Raes, Pommier, Neff, & Van Gucht, 2011)
6. Possible mediators (and moderators) for outcome will be analysed using the following

measures: Emotion Regulation Skills Questionnaire 9 (ERSQ-9; Grant, Salsman & Berking, 2018), Short Alliance Inventory (SAI; Falkenström et al., 2015). Both will be measured pre-treatment, weekly during treatment and post-treatment (within 2 weeks of end of treatment).

Overall study start date
10/08/2018

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Adolescents aged 15-19 years
2. Suffering from major depressive disorder as primary diagnosis according to DSM-5 as established through 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
Mixed

Sex
Both

Target number of participants
270 (135 + 135)

Total final enrolment
272

Key exclusion criteria
1. Risk of suicidality and/or previous suicide attempts
2. Partaking in other psychological treatment
3. Psychotropic medication not stable for at least 1 month
4. Primary diagnoses other than MDD
5. Current fulfilment of any of the following diagnoses: any psychotic disorder, bipolar I/II disorder, antisocial personality disorder, or autism-spectrum disorder
6. Comorbid drug or alcohol abuse

Date of first enrolment
19/08/2019

Date of final enrolment
07/10/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Psychology, Stockholm University
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Sponsor information

Organisation
Stockholm University

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Sponsor type
University/education

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ROR
https://ror.org/05f0yaq80

Funder(s)

Funder type
Charity

Funder Name
Kavlifondet (Kavli Trust)

Results and Publications

Publication and dissemination plan
The primary outcome paper will present outcome data in a journal with open access publication. 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 user representatives from Suicide Zero. Since Norwegian and British researchers are included in the research group, we are prepared for a rapid dissemination of treatments and study results to Norway and UK following the present RCT.

Intention to publish date
15/06/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not publicly available due to the sensitive nature of the data collected from adolescents about mental health but will be available upon reasonable request. Access is given to the full protocol by this publication. The dataset will be available upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/06/2020	22/10/2020	Yes	No
Results article		05/07/2022	11/07/2022	Yes	No
Results article	secondary outcomes	11/05/2023	15/05/2023	Yes	No
Results article	The interplay between alliance and emotion regulation as predictors of outcome in Internet-based treatments for adolescent depression	11/05/2023	22/06/2023	Yes	No