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Evaluation of internet-based cognitive-behavioral therapy blended with sessions for depression in young adults

Submission date
18/07/2022

Recruitment status
No longer recruiting

Registration date
25/07/2022

Overall study status
Completed

Last Edited
25/07/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Unipolar depressive disorders are one of the leading causes of disability-adjusted life years among adolescents and young adults worldwide. Early age of depression onset is a risk factor for recurrent depression, is associated with poor academic achievement and impaired quality of life, and predicts worsened mental and physical illness.

Cognitive behavioral therapy (CBT) is an empirically supported behavioral intervention for depression. Adaptions of in-person CBT protocols into Internet-based formats (ICBT) can realize intervention to more individuals in need. ICBT programs that include therapist support are shown to be more effective than self-guided programs and demonstrate effects similar to those found with in-person treatment. To include strong therapist support in ICBT, and moreover, to conduct sessions using video telehealth can be consistent with young adults' communication preferences. Treatment that combines both internet-based self-guided material and live therapist sessions is referred to as 'blended treatment'.

The primary aims of this study are to test the efficacy of blended CBT treatment for young adults with major depressive disorder recruited nationally.

Who can participate?
Young adults aged 18-19 yearsold with depression.

What does the study involve?
Participants will be allocated randomly to one of two groups, with an equal chance of being in either group (like tossing a coin). One group will receive 10 weeks of blended CBT and the other will receive 10 weeks of self-guided ICBT for a major depressive episode (MDE). For participants receiving blended CBT, treatment will include 8 self-help modules, and up to 10 individual therapist sessions using telehealth. Participants allocated to the comparative self-guided ICBT will be provided the 8 self-help modules without therapist sessions. To assess the treatment

effects and maintenance of treatment gains, participants will be asked to complete questionnaires before treatment, during treatment, at post-treatment (10 weeks) as well as follow-up questionnaires at 6 months, and 12 months.

What are the possible benefits and risks of participating?
For both treatments, the expected benefit is a reduction of depression symptoms. Based on the existing literature for internet-based treatment approaches funded in cognitive behavior therapy, we do not expect participants to suffer any serious physical injury, financial, social, or legal harm from partaking in the present study, beyond what may be ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Where is the study run from?
Pennsylvania State University (USA)

When is the study starting and how long is it expected to run for?
From January 2022 to August 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Michelle G. Newman, mgn1@psu.edu

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
Nil known

Study information

Scientific Title
Internet-based cognitive behavioral therapy blended with sessions versus self-guided internet-based cognitive behavioral therapy for depression in young adults: a randomized controlled trial

Study objectives
Internet-based CBT blended with sessions is superior to self-guided ICBT in reducing depression symptoms in young adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2022, the Institutional Review Board, Human Research Protection Program Pennsylvania State University (The 330 Building, Suite 205, University Park, PA 16802, US; +1 (814) 863-8699; IRB-orp@psu.edu), ref: 00018688

Study design
Interventional randomized controlled trial

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Major depressive disorder in young adults

Interventions
Eligible subjects will be randomly assigned to 10 weeks of blended CBT for a major depressive episode (MDE) or to 10 weeks of self-guided CBT. A random number generator will be used to assign the participants (1:1 ratio).

Both interventions include 8 online self-help modules that teach behavioral and cognitive strategies that participants can learn to reduce and help manage depression and comorbid anxiety. The modules span psycho-education, behavioral activation, cognitive restructuring, emotion regulation, anxiety management, and relapse prevention.

Experimental treatment:
The experimental condition consists of Blended CBT. For 10 consecutive weeks, participants will complete the 8 self-help modules combined with up to 10 individual therapist sessions delivered via video telehealth technology. In addition to sessions, therapists will provide feedback on progress and skills practice assignments.

Active comparator:
The active comparator condition consists of self-guided ICBT. For 10 consecutive weeks, participants will complete 8 self-help modules.

Intervention Type
Behavioural

Primary outcome measure
Depressive symptoms measured using the Quick Inventory of Depressive Symptomatology in adolescents (QIDS-A17-SR) at baseline and 10 weeks (post-treatment)

Secondary outcome measures
1. Depressive symptoms measured using the QIDS-A17-SR at 6 and 12 months
2. Depressive symptoms measured using the Patient Health Questionnaire 9 (PHQ-9) at baseline, weekly during treatment, and post-treatment (10 weeks)
3. Depressive symptoms measured using the PHQ-9 at 6 and 12 months
4. Remission from DSM-5 depression diagnosis measured using clinical interview at post-treatment (10 weeks)
5. Anxiety symptoms measured using the Generalized Anxiety Disorder Q-IV (GAD-Q-IV) at baseline, during treatment, and post-treatment (10 weeks)
6. Anxiety symptoms measured using the GAD-Q-IV at 6 and 12 months
7. Clinical improvement measured by the Clinical global Impression Scale – Improvement (CGI-I) at post-treatment (10 weeks)
8. Loneliness measured using the UCLA Loneliness Scale-8 (ULS-8) at baseline, post-treatment, 6 months, and 12 months
9. Treatment satisfaction and acceptance of treatment measured using measures developed for the study post-treatment, and at 6 months
10. Mediators and moderators analyzed using the following:
10.1. The Behavioral activation for depression scale-Short (BADS-SF) at baseline, during treatment, and post-treatment
10.2. The Skills of Cognitive Therapy (SoCT) at baseline, during treatment, and post-treatment
10.3. Program usage (single question, rating 0-4) during treatment
10.4. Implementation of CBT skills learned in intervention using a measure developed for the study at post-treatment and 6 months
10.5. Credibility Expectancy Questionnaire (CEQ) during treatment
10.6. Working Alliance Inventory-Short (WAI-S) during treatment
10.7. Causes for pre-mature intervention termination at termination

Overall study start date
01/01/2020

Completion date
01/08/2025

Eligibility

Key inclusion criteria
1. Have access to a computer and/or mobile phone with an internet connection and data plan allowing 90 min spent on treatment per week
2. Fluent in the English language in terms of speaking, listening, reading, and writing
3. Aged 18-19 years
4. Presence of depressive symptoms as measured by a score ≥10 on the QIDS -17-SR
5. Fulfill DSM-5 Criteria for a major depressive episode
6. Depression is deemed the primary concern
7. Those currently taking antidepressants, central stimulants, and/or neuroleptics, will be accepted, if no change in dosage at least 6 weeks prior to study participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
300 (150 + 150) Sample size was determined based on attaining 80% power to identify small but clinically meaningful differences in primary and secondary outcomes. Based on power estimates derived from Monte Carlo simulation exercises (the gold standard for estimating power when determining sample sizes before or after conducting the study) (Abraham & Russell, 2008; Arnold, Hogan, Colford, & Hubbard, 2011), roughly 300 clinical participants (150 blended treatment and 150 self-guided ICBT) with full data. Power estimation for all analyses were specified with an effect size of .20 (i.e., for the primary treatment outcome, a treatment change of .20 in the blended treatment vs. self-guided ICBT condition).

Key exclusion criteria
1. Unable to consent, or actively confirm study participation
2. Ongoing/prior (CBT) treatment within the last 6 months
3. Significant suicidal ideation and/or history of previous suicide attempt
4. Judged to have problem/disorder that warrants more intensive in- person mental health and /or medical treatment (i.e., alcohol, substance use, and/or eating disorder, meets diagnostic criteria for psychotic disorders)
5. Judged to have other current severe problems require other actions at first hand

6. Lack of access to computer and/or mobile phone with an internet connection and sufficient data plan
7. Has ever been diagnosed with autism spectrum disorder and/or Attention Deficit Hyperactivity

Date of first enrolment
01/08/2022

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
United States of America

Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (through the PI and Co-PI’s professorship research contracts)

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals and presentations at peer-reviewed scientific conferences and seminars.

Intention to publish date
01/08/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are of sensitive nature, thus are not expected to be publicly available. Access will be provided upon reasonable request (from date of publication) from the study principal investigator Prof Newman (mgn1@psu.edu).

IPD sharing plan summary
Available on request