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Internet-delivered interventions for people with depression and anxiety in IAPT services

Submission date
16/05/2017

Recruitment status
No longer recruiting

Registration date
06/06/2017

Overall study status
Completed

Last Edited
14/08/2024

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
Depression and anxiety are common mental health problems. There are effective treatments for depression and anxiety and one of these is talking therapies using a technique called cognitive behavioural therapy (CBT). CBT is a type of therapy that helps people to change the way they think and behave. In recent years internet-delivered CBT has emerged as an alternative to face-to-face psychological services, and it has proven to be successful in treating people with depression and anxiety. SilverCloud is an innovative online behavioral health and wellness e-therapy delivery platform. It enables healthcare organisations to deliver a broad range of highly engaging and interactive online behavioral and long-term illness content, programs and support to their clients and patients. SilverCloud is proven to improve clinical/patient outcomes, dramatically reduce the cost of behavioral health delivery/support, increase scalability/reach and increase access. The aim of this study is to evaluate the effectiveness and cost-effectiveness of this program in improving the symptoms of depression and anxiety disorders.

Who can participate?
Adults who are suffering from depression or anxiety.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive immediate treatment with internet-delivered CBT for either depression or anxiety. Those in the second group receive the treatment after an eight week wait. At the start of the study and then after three, six, nine and twelve months, participants in both groups complete a range of questionnaires to assess their mental wellbeing, to find out if they have benefited from the treatment.

What are the possible benefits and risks of participating?
Participants may benefit from receiving the treatment, which could help improve their symptoms. There are no notable risks involved with participating.

Where is the study run from?
Talking Therapies IAPT (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2018

Who is funding the study?
SilverCloud Health (Ireland)

Who is the main contact?
Dr Derek Richards

Contact information

Type(s)
Scientific

Contact name
Dr Derek Richards

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SilverCloud Health
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Additional identifiers

Protocol serial number
214669

Study information

Scientific Title
Digital IAPT: The effectiveness & cost-effectiveness of internet-delivered interventions for depression and anxiety disorders in the Improving Access to Psychological Therapies programme

Acronym
D-IAPT

Study objectives
The aim of this study is to evaluate the effectiveness and cost-effectiveness of internet-delivered interventions for symptoms of depression and anxiety disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NHS North-West Haydock Research Committee, 16/05/2017, ref: 17/NW/0311

Study design
Single-blind parallel-group randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression and anxiety disorders

Interventions
Post diagnostic assessment participants will be randomised to either the immediate treatment (depression or anxiety) or a waiting list control group using random permuted blocks using block sizes of 9 and including stratification within a 2:1 ratio between treatment groups – depression and anxiety - and the waiting list control group.

Immediate treatment group: Participants will be assigned to either the Space from Deopression or the Space from Anxiety interventions and they will be encouraged to use the intervention over 8 weeks and they will receive up to 6 online reviews from their clinician supporter over that time. Data will be collected at baseline, continuously at each session, at 8 weeks and at 3, 6, 9 and 12 months follow-up.

Space from Depression
The online intervention 'Space from Depression' is a seven-module online CBT-based intervention for depression, delivered on a Web 2.0 platform using media-rich interactive content. Programme content is delivered in a non-linear fashion. Each module takes roughly 1 hour to complete and it is recommended one module be completed per week. The structure and content of the programme modules follow evidence-based CBT principles. The treatment is comprised of established cognitive and behavioural components including self-monitoring, self-control desensitization, gradual stimulus control, thought recording, behavioural activation, cognitive restructuring, relaxation training and challenging core beliefs. Each module is structured to incorporate introductory quizzes, videos, informational content, interactive activities, as well as homework suggestions and summaries. In addition, personal stories and accounts from other users are incorporated into the presentation of the material. The intervention follows NICE guidelines for the treatment of depression and the intervention has been tested and proved efficacious (National Institute for Clinical Excellence, 2009; National Institute for Health and Clinical Excellence, 2006; D. Richards, Timulak, et al., 2015)

Space from Anxiety
Space from Anxiety is an eight-module online CBT-based intervention for Anxiety. The structure and content of the program modules follow established evidence-based principles of CBT for the treatment Anxiety. The treatment comprises cognitive, emotional, and behavioral components that include self-monitoring, relaxation training, cognitive restructuring, and worry outcome monitoring. The treatment is delivered on a Web 2.0 platform using media-rich interactive content. The getting started module for the core Anxiety programme introduces the user to the cycle of anxiety and the emotional, cognitive and behavioural aspects of anxiety. The goal of the intervention is to help people with anxiety as a primary disorder manages their

thoughts, emotions and behaviours to help them alleviate their symptoms. The intervention follows NICE guidelines for the treatment of anxiety and the intervention has been tested and proved efficacious (National Institute for Clinical Excellence, 2009; National Institute for Health and Clinical Excellence, 2006; D. Richards, Timulak, et al., 2015).

Waiting list control group: Those in the waiting list group will be given access to the programme after an 8 week waiting period post randomisation. This group will receive assessments at baseline, and before they begin treatment after the 8 week waiting period.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression is assessed using the Patient Health Questionnaire-9 (PHQ-9) at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
2. Anxiety is assessed using the Generalized Anxiety Disorder-7 (GAD-7) at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up

Key secondary outcome(s))
1. Diagnosis of depression or anxiety for research purposes will be established using the M.I.N.I. International Neuropsychiatric Interview 7.0 (MINI) at baseline and 3 months follow-up
2. Work and social adjustment is assessed using the Work and Social Adjustment (WASA)at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
3. Social Anxiety is assessed using the Social Phobia Inventory (SPIN)at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
4. Health Anxiety is assessed using the Short Health Anxiety Inventory (HAI) at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
5. Panic is assessed using the Panic Disorder Severity Scale-Self Report (PDSS-SR)at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
6. GAD symptoms are assessed using the Penn State Worry Questionnaire (PSWQ) at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
7. Quality of life for users of mental health services is assessed using the Recovering Quality of Life scale (ReQoL)at baseline, throughout treatment, at 8 weeks and at 3, 6, 9 and 12 months follow-up
8. Client service usage is assessed using the Client Service Receipt Inventory (CSRI)at baseline, throughout treatment, at 8 weeks and at 6, 9 and 12 months follow-up
9. Emotion regulation is assessed using the Emotion Regulation Questionnaire (ERQ) at baseline and at 8 weeks
10. Rumination is assessed using the Positive Beliefs about Depressive Rumination Scale – adapted (PBRS-A) version at baseline and 8 weeks
11. Therapeutic Expectancy is assessed using the Expectancy and Credibility Questionnaire (ECQ) for the treatment group at baseline, 4 and 8 weeks
12. Therapeutic Alliance for patients is assessed using the Scale to Assess Therapeutic Relationships – Patient Version (STAR-P) throughout treatment
13. Therapeutic Alliance for clinicians is assessed using the Scale to Assess Therapeutic Relationships – Clinician Version (STAR-C) each time they review a patient and using semi-structured interview with clinicians.
14. CBT Skills is assessed using the Frequency of Actions and Thoughts Scale (FATS) at 3, 6, 9 and 12 months follow-up
15. Therapist behaviours are assessed by clinicians using the therapist behaviours checklist throughout treatment

Completion date
01/08/2019

Eligibility

Key inclusion criteria
1. A score of ≥ 9 on PHQ-9 and/ or a score of ≥ 8 on GAD-7
2. 18 years of age
3. Suitable for an internet-delivered intervention (iCBT)
4. Users of the Berkshire NHS Trust IAPT Talking Therapies Step 2 services

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
361

Key exclusion criteria
1. Suicidal intent/ideation
2. Psychotic illness
3. Currently in psychological treatment for depression and/or anxiety
4. Alcohol or drug misuse
5. Previous diagnosis of an organic mental health disorder

Date of first enrolment
28/06/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Talking Therapies IAPT
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Sponsor information

Organisation
SilverCloud Health

ROR
https://ror.org/05319p535

Funder(s)

Funder type
Other

Funder Name
SilverCloud Health

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Derek Richards.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	01/09/2020	Yes	No
Results article	nested longitudinal qualitative results	28/05/2021	14/07/2021	Yes	No
Results	secondary analysis	18/01	14/07		

article		/2021	/2021	Yes	No
Results article	Cost-Effectiveness	01/06/2022	01/07/2022	Yes	No
Results article	Durability of treatment effects	25/04/2022	01/07/2022	Yes	No
Results article	The relationship between posttherapeutic Cognitive Behavior Therapy skills usage and follow-up outcomes of internet-delivered Cognitive Behavior Therapy	21/06/2022	01/07/2022	Yes	No
Protocol article	protocol	02/03/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	assessment of psychometric measures	09/04/2021	14/07/2021	Yes	No
Other publications	secondary analysis	12/07/2023	14/08/2024	Yes	No
Preprint results	non-peer-reviewed dropout results	01/08/2021	14/07/2021	No	No