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Internet Delivered Treatment for symptoms of Depression in the community

Submission date 19/06/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[X] Protocol
Registration date 16/07/2013	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 01/09/2020	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data

Plain English summary of protocol

Background and study aims

In Ireland the prevalence of depression has been reported to be 15.1% (8.9% from urban areas and 6.2% from rural areas). Worldwide, a large percentage of affected individuals do not have a medical diagnosis and do not seek treatment. Depression can be treated and Cognitive Behavior Therapy (CBT) is a recommended treatment option. Many in Ireland with depression find it difficult to access CBT. This is due to several factors, including personal barriers such as stigma and costs. However, in Ireland the shortage of trained professionals alongside the underdevelopment of services makes it difficult to access treatments. One type of low-intensity intervention that has been developed and has shown effectiveness are tailored treatment programs for specific disorders using the internet, both with and without the guidance of a clinician. Some initial research has been conducted in Ireland and large-scale studies are now needed. The objective of the current study is to introduce and evaluate the effectiveness of an internet-delivered low-intensity treatment for depression in an Irish adult community.

Who can participate?

Subjects aged 18-65 years with symptoms of depression can participate. All participants will be recruited from community users of the charity Aware in Ireland. Aware is a charity that aims to create a society where those with depression or related mood disorders and their families are understood and supported, are free from stigma and have access to a broad range of support options.

What does the study involve?

Students will be randomly allocated to one of the two groups:

1. Active treatment group: a computerized cognitive behavior program for the treatment of depression. The programme consists of seven sessions. Users will be supported in their use of the programme.

2. Waiting list control group: the participants in this group will receive computerized cognitive behavior program eight weeks after the active treatment group.

All participants will receive the same treatment.

What are the possible benefits and risks of participating?

There may be improvements in depression symptoms and health status.

Where is the study run from?
We will aim to recruit a sample of 100 participants. All participants will be recruited from community users of the charity Aware in Ireland.

When is the study starting and how long is it expected to run for?
We hope to begin recruitment in October 2013 and thereafter the trial will run until April 2014. The first eight weeks will be with an active treatment group and a waiting list control. Thereafter the waiting list control participants will begin treatment.

Who is funding the study?
SilverCloud Health Ltd and Aware Charity, Ireland.

Who is the main contact?
Dr Derek Richards,
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Internet-delivered treatment: Its potential as a low-intensity community intervention for adults with symptoms of depression: protocol for a randomized controlled trial

Acronym
IDTD

Study objectives
Depression is a high prevalence disorder, displaying high rates of lifetime incidence, early age onset, high chronicity, and role impairment. In Ireland prevalence of depression has been

reported to be 15.1%, with a difference in reported rates for urban (8.9%) and rural areas (6.2%). Worldwide, a large percentage of affected individuals have no medical diagnosis nor seek treatment. Depression can be treated and Cognitive Behavior Therapy (CBT) has established itself as an option for the treatment of depression. Many in Ireland with depression find it difficult to access evidence-based CBT, this is due to several factors, some of which are personal barriers such as stigma and costs. However, in Ireland systematic factors including the shortage of trained professionals alongside the relative underdevelopment of services makes it difficult to access treatments.

Similar to what has occurred in the UK with the development of a stepped-care model that includes both low- and high-intensity interventions needs to take root in Ireland. Collaborative and stepped-care has been approved as best practice by the National Institute for Clinical Excellence. One type of low-intensity interventions that has been developed and has demonstrated effectiveness are tailored treatment programs for specific disorders using the internet, both clinican-guided and stand-alone. While some preliminary research has come from Ireland what is now needed are some large scale studies on efficacy and effectiveness. Thus the objective of the current study is to implement and evaluate the potential of an internet-delivered low intensity treatment for depression in an Irish adult community sample.

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Psychology, Trinity College Dublin - approval pending

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
internet intervention for symptoms of depression in the community

1. An active treatment group
Mind Balance is a seven-module online CBT-based intervention for depression, delivered on a Web 2.0 platform using media-rich interactive content. The structure and content of the programme modules follow evidence-based principles of a traditional CBT programme, incorporating ideas from Mindfulness. Each module is structured in an identical way and incorporates introductory quizzes, videos, informational content, interactive activities, as well as homework suggestions and summaries. In addition, personal stories and accounts from other clients are incorporated into the presentation of the material.

The active condition consists of 7 modules of computerised Cognitive Behavioural Therapy (cCBT), over 8 weeks, with support providing weekly feedback on progress and exercises. The intervention teaches the principles of CBT and also different cognitive and behavioral strategies that participants can learn to help manage their depression.

2. A waiting list control.
Participants in the waiting-list control group receive no treatment for the duration of the first 8 weeks. At week 8 waiting-list participants will complete the primary and secondary outcome measures (BDI-II, Sociodemographic & History, GAD-7, WHOQOL, and CEQ) and will be given access to the program for 8 weeks with support from a trained volunteer at Aware.
The study seeks to observe and evaluate the effect of the treatment on changes in depressive symptoms in participants. Data will be collected at baseline and at the end of treatment, week 8 and at follow-up, week 12 (3-months) and week 24 (6-months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Beck Depression Inventory (BDI-II) measured at baseline and at the end of treatment, week 8 and at follow-up, week 12 (3-months) and week 24 (6-months).

Key secondary outcome(s))
1. General Anxiety Disorder 7 (GAD-7)
2. Work and Social Adjustment Scale (WSAS)
3. Credibility and Expectancy for treatment (CEQ)
4. Helpful Aspects of Therapy Form (HAT)
5. Satisfaction with Treatment (SAT)
6. Reasons for dropout

All above outcomes measured at baseline and at the end of treatment, week 8 and at follow-up, week 12 (3-months) and week 24 (6-months).

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. At least 18 years of age, either sex
2. Mild to Moderate depressive symptoms (BDI-II 14-29 range)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Total final enrolment

188

Key exclusion criteria

1. Suicidal intent/ideation: score >2 on BDI-II question 9
2. Currently in CBT treatment for depression
3. Psychotic illness
4. Alcohol or drug misuse
5. On medication for less than 1 month
6. Previous diagnosis of an organic mental health disorder
7. Depression preceding or coinciding a diagnosed medical condition

Date of first enrolment

01/10/2013

Date of final enrolment

01/04/2014

Locations

Countries of recruitment

Ireland

Study participating centre
Trinity College Dublin
Dublin
Ireland
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Sponsor information

Organisation

University of Dublin (Ireland)

ROR

https://ror.org/05m7pjf47

Funder(s)

Funder type

Industry

Funder Name
SilverCloud Health Ltd. (Ireland)

Funder Name
Aware Charity (Ireland)

Results and Publications

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	01/12/2015		Yes	No
Results article	results	01/08/2019	05/08/2019	Yes	No
Results article	results	21/10/2015	01/09/2020	Yes	No
Protocol article	protocol	21/05/2014		Yes	No