Internet-assisted therapy for adults with depressive symptoms: a study for the effectiveness of interpersonal therapy (IPT) compared to cognitive behaviour therapy (CBT)

Submission date 10/10/2008	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 27/10/2008	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 10/07/2014	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Internet-assisted therapy for adults with depressive symptoms: a randomised controlled trial for the effectiveness of interpersonal therapy (IPT) compared to cognitive behaviour therapy (CBT)

Study objectives

1. To determine whether an internet-delivered module of interpersonal therapy (IPT) is as effective as a cognitive behaviour therapy (CBT) module in reducing symptoms of depression and anxiety

1.1. To determine which if any psychological variables mediate the effects on these outcomes, or predict adherence to the IPT intervention

1.2. To determine which if any psychological variables moderate the effects on these outcomes, or predict adherence to the IPT intervention

2. To determine whether the internet-delivered module of IPT is rated as feasible, acceptable and satisfactory as the CBT module

3. To determine whether the IPT and CBT modules produce comparable effects to the MoodGYM intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee (HREC), Australian National University (ANU) Canberra, 14/09 /2008, ref: 2008/269

Study design Single-centre interventional automated online randomised controlled trial

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Depressive and anxiety disorders

Interventions

The conditions used in the study are:

Cognitive behaviour therapy (CBT):

The Internet-assisted CBT intervention was developed by the Centre for Mental Health Research (CMHR), Australian National University (ANU). This intervention is based on the principles of CBT. It was developed by the e-hub team and consists of three major sections each of which contains 10 or so exercises or sets of messages. The programme will be offered over 4 weeks. Each week an automated email will be used to remind participants of the availability of their new module.

Interpersonal psychotherapy (IPT):

IPT is a time-limited psychotherapy developed by Klerman et al. (1984) focusing on the onset of depression associated with interpersonal stress. IPT seeks to identify and link interpersonal stressors or conflicts to mood symptoms and to improve interpersonal functioning to reduce depressive symptoms. It has shown to be effective in reducing depressive symptoms among adults. The internet-assisted form of IPT, developed by the CMHR, ANU, consists of four modules. The material will be delivered over four weeks.

Standard CBT (MoodGYM) - control condition:

Participants in this condition will receive the standard online CBT package as delivered over 4 weeks by MoodGYM.

Follow-up: 6 months after end of intervention

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. Symptoms of depression and anxiety as measured by the Goldberg Anxiety and Depression Questionnaires (0 'no depression/anxiety' - 9 'depression/anxiety') four times during the course (1 per week)

2. Symptoms of depression as measured by the Center for Epidemiologic Studies Depression Scale (CES-D) (0 'no depressive symptoms' - 60 'severe depressive symptoms') measured at pretest (baseline), post-test (after intervention) and follow-up (6 months)

Secondary outcome measures

1. Mental Health Literacy (to be developed by CMHR)

2. Stigma, as measured with the Depression Stigma Scale (DSS) - Personal: 9 items, 1 (high level of stigma) to 35 (low level of stigma)

3. Satisfaction with the intervention as measured with the Client Satisfaction Questionnaire (CSQ-8): score 1 (not satisfied) to 32 (very satisfied)

4. Dysfunctional thinking as measured with the Dysfunctional Attitudes Scale-Short Form (DAS-SF) (18 items, 1: low dysfunctional thinking to 126 high level of dysfunctional thinking)

5. Drop-out, measured by the drop-out survey developed by CMHR

6. Worrying, measured with the 7-item Generalised Anxiety Disorder Scale (GAD-7) (0 'no anxiety' - 21 'high level of anxiety')

7. Eurohisqol (8 item) to measure quality of life (1: poor quality of life - 40: high quality of life)

8. Days out of role to measure disability (0 days: no disability; 30 days: severe disability)

9. Mastery to measure perceived control, 7 items (1: low internal control; 28 high internal control)

10. Adherence to the intervention measured by sessions completed

All scales will be measured at pre-test (baseline), post-test (after intervention) and follow-up (6 months), except for the drop out survey (only when people drop out) and CSQ (only post-test).

Overall study start date

01/11/2008

Completion date

01/11/2009

Eligibility

Key inclusion criteria

All individuals (both males and females) will be included in the trial unless they are currently under 18 years of age or are currently receiving treatment for depression by a mental health specialist. Both people with and without depressive symptoms can participate in this trial, as the intervention aims to prevent depression as well as to treat the condition.

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 300 (data recruitment closed since December 2011)

Key exclusion criteria

Individuals younger than 18 years or currently under treatment for depression by a mental health specialist

Date of first enrolment 01/11/2008

Date of final enrolment 01/11/2009

Locations

Countries of recruitment Australia **Study participating centre Centre for Mental Health Research** Canberra Australia ACT 0200

Sponsor information

Organisation Centre for Mental Health Research (CMHR) - The Australian National University (ANU) (Australia)

Sponsor details Building 63 Eggleston Road Canberra Australia 0200 ACT

Sponsor type University/education

Website http://cmhr.anu.edu.au

ROR https://ror.org/019wvm592

Funder(s)

Funder type University/education

Funder Name Centre for Mental Health Research (CMHR) - The Australian National University (ANU) (Australia)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

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?
<u>Results article</u>	results	13/05/2013		Yes	Νο