

A randomised controlled trial of the feasibility and effectiveness of Internet-based interventions for depression in a telephone counselling setting

Submission date 10/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2012	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

The aim of this research is to evaluate the effectiveness of Internet-based tools (MoodGYM [<http://www.moodgym.anu.edu.au>] and BluePages [<http://www.bluepages.anu.edu.au>]) in the treatment of depression and anxiety among callers to a large, national telephone counselling centre. This project will use a randomised controlled trial to assess 1) whether self-administered online cognitive behaviour therapy and psychoeducation are effective in reducing symptoms of depression and anxiety and 2) whether regular contact from a telephone counsellor optimises the effectiveness of these programs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Australian National University Human Ethics Committee. Date of approval: 14/03/2007 (ref: 2007/12)

Study design

Stratified, multi-centre, randomised controlled trial. 2 x 2 factorial design.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

Depression and anxiety

Interventions

The participants will be randomly allocated to the following four arms:

Arm 1: MoodGYM, an evidence based depression prevention website based on cognitive behavioural therapy, and BluePages, a website providing evidenced based information on depression.

Arm 2: MoodGYM and BluePages plus weekly telephone contact from a support person.

Arm 3: Attention control condition, in which participants receive weekly telephone contact from a support person to discuss factors associated with depression.

Arm 4: "Treatment as usual" control condition, in which participants access telephone counselling as usual.

Duration of interventions: 6 weeks

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The following will be assessed at pre-intervention, post-intervention, and 6 and 12 months post-intervention:

1. Depression, as measured by the Centre for Epidemiological Studies Depression Scale
2. Anxiety, as measured by the Depression Anxiety and Stress Scales

Secondary outcome measures

The following will be assessed at pre-intervention, post-intervention, and 6 and 12 months post-intervention:

1. Dysfunctional thoughts (Automatic Thoughts Questionnaire)
2. Personal stigma, assessed by a scale developed by the researchers of this study
3. Beliefs about the Internet, assessed by the items developed by the researchers of this study
4. Mental health literacy, assessed by the items developed by the researchers of this study
5. Help-seeking, assessed by the items developed by the researchers of this study
6. Depression literacy, assessed by the items developed by the researchers of this study
7. Cognitive behaviour therapy literacy, assessed by the items developed by the researchers of this study
8. Alcohol use, measured by the Alcohol Use Disorders Identification Test
9. Quality of life, assessed by the European Health Interview Survey 8 (EUROHIS-8)
10. Suicidal ideation, assessed using four items from the 28-item General Health Questionnaire (GHQ-28)

Overall study start date

01/07/2007

Completion date

31/12/2008

Eligibility

Key inclusion criteria

Callers to a national telephone counselling service who:

1. Are aged 18 years or older, both men and women
2. Consent to participate
3. Are English-speaking
4. Have access to the Internet at least once a week
5. Obtain a score of 22 or above on the Kessler Psychological Distress Scale (K-10)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

Key exclusion criteria

Individuals who:

1. Report a history of schizophrenia, psychosis or bipolar disorder
2. Are currently receiving cognitive behavioural therapy
3. Have a reading impairment

Date of first enrolment

01/07/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Australia

Study participating centre

Centre for Mental Health Research

Canberra, ACT

Australia

0200

Sponsor information

Organisation

The Australian National University (Australia)

Sponsor details

Centre for Mental Health Research
Building 63
Eggleston Road
Canberra, ACT
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Sponsor type

University/education

Website

<http://www.anu.edu.au>

ROR

<https://ror.org/019wvm592>

Funder(s)**Funder type**

Government

Funder Name

Australian Research Council, Linkage Grant (ref: LP0667970)

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?
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Other publications	evaluation of recruitment challenges	01/12/2010	Yes	No
Other publications	effectiveness of internet-based interventions	01/12/2011	Yes	No
Results article	secondary outcomes results	27/06/2012	Yes	No