The wellbeing project: internet interventions to improve mental health and wellbeing

Submission date 08/04/2008	Recruitment status No longer recruiting	[X] Prospectively registered [X] Protocol	
Registration date 09/05/2008	Overall study status Completed	Statistical analysis plan	
Last Edited	Condition category	[X] ResultsIndividual participant data	
11/10/2016	Mental and Behavioural Disorders		

Plain English summary of protocol

Background and study aims

Depression is the primary cause of disability in Australia. As treatment many people prefer psychological and physical activity interventions and self-help modes of delivery. Support groups and internet support groups in particular are a popular form of self-help for depression. The aim of this study is to evaluate the effectiveness of an automated internet intervention and an internet support group for depression.

Who can participate?

People aged between 18 and 65 with evidence of psychological distress, determined through a screening questionnaire

What does the study involve?

The study involves two separate stages. First there is a survey of people aged between 18 and 65 to find out more about the emotional health of people living in the city as well as in rural areas. Then 500 people are chosen from among those who returned the survey and are willing to participate in the study. Participants are randomly allocated to one of four groups. The first group is given access to an automated internet intervention for depression consisting of depression information and an active self-help module. The second group is given access to an internet support group. The third group is given access to both of these interventions. The fourth group is given access to an internet intervention consisting of open-ended questions that probe health factors that might be related to depression (e.g. work habits and stress, nutrition). The study lasts 12 weeks and takes about half an hour of participants' time each week. At the end of the 12 weeks participants are asked to complete a follow-up survey about the issues covered by the study. Participants are then contacted 6 months after the study and then again after 12 months.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Australian National University (Australia) When is the study starting and how long is it expected to run for? May 2008 to March 2010

Who is funding the study? National Health and Medical Research Council (Australia)

Who is the main contact? Dr Kathy Griffiths Kathy.Griffiths@anu.edu.au

Contact information

Type(s)

Scientific

Contact name

Dr Kathy Griffiths

Contact details

Centre for Mental Health Research Australian National University Canberra Australia 0200 +61 (0)2 6125 9723 Kathy.Griffiths@anu.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Do internet support groups and internet interventions improve mental health and wellbeing?

Study objectives

Depression is the primary cause of disability in Australia. It has been argued that a substantial percentage of the disease burden associated with depression could be averted with the delivery of evidence-based treatments. However, to succeed, such a program would need to develop feasible methods for delivery and to consider consumer treatment preferences. Many consumers prefer psychological and physical activity interventions and self-help modes of delivery. Peer-to-peer mutual support groups, and internet support groups (ISGs) in particular

are a popular form of self help for depression. ISGs are highly accessible and consumers report they are helpful in reducing their depressive symptoms. However, the efficacy of ISGs has not been established. The current study seeks to evaluate the efficacy of an internet intervention for depression and an ISG both as independent interventions and in combination.

The study will evaluate the effect and relative effects of the D-couch (an automated internet intervention on depression) and Talking Point (an internet support group) interventions on depressive symptoms, social support, self-esteem, quality of life, depression literacy, stigma and help-seeking in people with depression.

The primary hypothesis is that:

D-couch and Talking Point will each be associated with a greater reduction in depression symptoms from baseline to post-intervention than the control.

Secondary hypotheses are that:

- 1. The magnitude of improvement in depression will be greater for:
- 1.1. The internet conditions combined (D-couch and Talking Point) than for either condition alone; and
- 1.2. D-couch compared to Talking Point
- 2. Talking Point participants will show a greater increase in perceived social support and self-esteem than non-Talking Point participants at post-test
- 3. D-couch and Talking Point will each be associated with improved quality of life, and decreased anxiety, disability and stigma. Both interventions will also be associated with improved depression literacy, but the effect will be greater for D-couch.
- 4. Both D-couch and Talking Point will be associated with an increase in empowerment but the effect of empowerment will be greater for Talking Point
- 5. Adherence will be greater among D-couch participants with access to Talking Point than for D-couch participants without access to the Internet support group

Ethics approval required

Old ethics approval format

Ethics approval(s)

Australian National University Human Research Ethics Committee, 15/12/2007, ref: 2007/2259

Study design

Randomised 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Depression

Interventions

This study involves two active interventions and an attention-matched placebo (control) described below:

1. Intervention group one:

D-couch: a multi-media internet application on depression comprising of a depression literacy module and an active self-help module. The depression literacy module contains information about the symptoms and types of depression and their diagnosis, sources of help, statistical information about the prevalence and disability burden associated with depression, depression risk factors, and evidence-based medical, psychological and lifestyle treatments for depression based on updated systematic reviews and clinical practice guidelines. The self help module comprises online versions of treatments amendable to delivery online and known to be effective in face-to-face therapy or as bibliotherapy. These include:

- 1.1. Cognitive behaviour therapy
- 1.2. Interpersonal therapy
- 1.3. Applied relaxation
- 1.4. Problem solving, and
- 1.5. Physical activity

2. Intervention group two:

Talking Point: an internet support group which uses a bulletin board format for discussions.

3. Control group:

HealthWatch: the control condition. An internet application comprising open ended questions that probe health factors that might be related to depression (e.g. work habits and stress, nutrition).

Participants receive one of the above conditions or a combination of D-couch and Talking Point. Each program is delivered over 12 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Depressive symptoms: Centre for Epidemiology Studies - Depression (CES-D) 20-item self-report measure of depression severity. Measured at baseline, post-intervention (3 months), 6-month follow-up and 12-month follow-up.

Secondary outcome measures

- 1. Anxiety symptoms: Penn State Worry Questionnaire (PSWQ)
- 2. Quality of life: EUROHIS-QOL 8-item index
- 3. Disability: 'Days Out of Role' questions adapted from US National Comorbidity Survey

- 4. Depression knowledge:
- 4.1. D-Lit 21-item measure of depression literacy
- 4.2. An additional measure of depression treatment knowledge
- 5. Perceived social support:
- 5.1. Medical Outcomes Study Social Support Survey (MOS)
- 5.2. UCLA Loneliness Scale
- 6. Stigma: Depression Stigma Scale
- 7. Help seeking: purpose developed items
- 8. Self esteem: Rosenberg Self-esteem Scale
- 9. Empowerment:
- 9.1. Empowerment scale: Power-powerlessness subscale
- 9.2. Participation in healthcare measure
- 10. Satisfaction and user-perceived benefits

Outcomes will be measured at baseline, post-intervention (3 months), 6-month follow-up and 12-month follow-up.

Overall study start date

12/05/2008

Completion date

30/03/2010

Eligibility

Key inclusion criteria

- 1. Aged 18 65 years, either sex
- 2. Evidence of psychological distress determined through screening questionnaire
- 3. Access to the internet at home
- 4. Willingness to participate in the trial

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

500

Key exclusion criteria

- 1. Current/prior participation in a project conducted by the Centre for Mental Health Research
- 2. Report that they are currently receiving treatment from a mental health professional or support group

Date of first enrolment

12/05/2008

Date of final enrolment

30/03/2010

Locations

Countries of recruitment

Australia

Study participating centre Australian National University

Canberra Australia 0200

Sponsor information

Organisation

Australian National University

Sponsor details

Centre for Mental Health Research Building 63 Canberra Australia 0200 +61 (0)2 6125 2741 cmhr@anu.edu.au

Sponsor type

Hospital/treatment centre

Website

http://www.anu.edu.au

ROR

https://ror.org/019wvm592

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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>Protocol article</u>	protocol	08/03/2010		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	08/01/2016		Yes	No