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The iChill Project: can generalised anxiety disorder be prevented and treated using e-health interventions?

Submission date	Recruitment status
26/10/2009	No longer recruiting
Registration date	**Overall study status**
04/01/2010	Completed
Last Edited	**Condition category**
02/10/2014	Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

NHMRC Project Grant 525419

Study information

Scientific Title
The effectiveness of online therapy for the prevention and treatment of generalised anxiety disorder: a multicentre randomised controlled trial

Acronym
The iChill Project

Study objectives
This study will evaluate the effectiveness of online therapy (utilising ecouch) for the prevention and treatment of generalised anxiety disorder (GAD), and the conditions under which online therapy of this sort is most efficacious.

There are two separate studies within this one trial registration. The prevention trial will involve participants who score at a subclinical yet elevated level for GAD, whereas the treatment trial will use participants for whom a diagnosis of GAD has been confirmed.

Within the prevention arm participants will be randomly assigned to one of five conditions. These will be:
1. Ecouch therapy
2. Ecouch therapy plus weekly telephone support
3. Ecouch therapy plus weekly email support
4. An attention-matched control condition (entailing participants answering general questions and reading through online health-related information)
5. The attention-matched control condition plus weekly telephone support

It is hypothesised that, within the prevention arm:
1. Ecouch online therapy, compared with the control condition, will reduce symptoms of anxiety, prevent the development of GAD, reduce worry, and depression, improve mental health literacy, enhance help seeking and improve other secondary outcomes
2. The addition of support for participants undergoing ecouch therapy, either in the form of automated emails or telephone calls, will have a greater impact on participants' anxiety levels than ecouch alone
3. Provision of ecouch therapy plus weekly telephone support will have greater effect than weekly telephone support simply in the context of the control condition
4. There will be no significant difference found in intervention effect between ecouch plus weekly telephone support and ecouch plus weekly email support - in other words, the medium whereby weekly support is provided should have no effect
5. A relationship will be found between participant adherence/ drop-out and response to intervention, and participant characteristics, symptoms of depression, formal treatment contacts, education level attained, experience in the use of web applications, and perceived need for treatment

Within the treatment arm of the study, participants will be randomly assigned to one of three conditions. These will be:
1. Ecouch

2. Provision of selective serotonin reuptake inhibitor (SSRI) medication (sertraline)
3. The attention control used in prevention arm. All conditions will also involve four face-to-face clinician monitoring sessions.

It is hypothesised that:
1. The web-based intervention (ecouch) and the antidepressant intervention (sertraline), compared with the attention control condition will reduce anxiety symptoms, reduce the number of GAD diagnoses, reduce worry and depression, improve mental health literacy and improve other secondary outcomes
2. The web-based intervention (ecouch) will not produce significantly poorer outcomes than those observed in the antidepressant (sertraline) condition

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Australian National University Human Research Ethics Committee, 09/12/2008, ref: 2008/548
2. University of Sydney Ethics Board, 04/11/2009, ref: 12091

Study design
Multicentre 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
Generalised anxiety disorder

Interventions
The intervention of interest to this study is ecouch for GAD. This is a 10-week, online, multimedia application that comprises of:
1. Psycho-education containing information on:
1.1. The definition of worry
1.2. Distinction from stress
1.3. Differentiation of worry, fear and anxiety
1.4. Description of anxious thinking
1.5. Differentiation of GAD from PD, specific phobia and SAD, adjustment disorder and PTSD
1.6. Description of risk factors for GAD

1.7. The problem of comorbidity
1.8. Consequences of anxiety
1.9. Treatments for anxiety, including medical, psychological and lifestyle treatments
2. Cognitive behaviour therapy (CBT) targeting worry-related thoughts and beliefs and dealing with the purpose and meaning of worry, the act of worrying (detection, attentional practice, worry practice) and the content of worry
3. Relaxation exercises covering both meditation and progressive muscle relaxation (PMR)
4. Physical activity intervention - using walking - tailored to participants' individual motivation levels (based on the stages of change model), and level of fitness

Participants allocated to the SSRI medication condition within the treatment arm of the study will receive sertraline. Sertraline will be administered for 10 weeks as a tablet by mouth on a fixed-flexible schedule. Treatment will be initiated at a daily dose of 25 mg for one week. If participants display good tolerability, dosage will be increased to 50 mg/day for the next four weeks. Dosage may be increased to 100 mg/day after this time if participants experience an insufficient clinical response but good tolerability. Participants who respond to drug therapy will be offered the opportunity to continue taking sertraline during the 12-month follow-up. Treatment response will be defined as a score of 1 (very much improved) or 2 (much improved) on the Clinical Global Impression-Improvement Scale (CGI). Pill counts will be used to document adherence.

The attention control/placebo conditions of the trial will consist of participants reading health-related information in weekly modules on topics including environmental health, nutrition, a healthy heart, energise yourself and your family, medicines in your home, temperature extremes, oral health, blood pressure and cholesterol, calcium and back pain. In order to maintain the face validity of the control materials, there will also be questions at the start of each module that link the content with anxiety.

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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sertraline

Primary outcome measure
GAD-7, a 7 item self-report scale measuring symptoms of GAD. In addition, for the Treatment trial any reductions in GAD diagnoses will be assessed using the Anxiety Disorders Interview Schedule-IV (ADIS-IV) (a clinician administered interview) which will be administered at assessment, post-intervention and 12 months post-intervention.

Secondary outcome measures
1. Fewer cases of GAD at six months post-intervention, as measured by a second administration of the MINI
2. Reduction in worry, measured by the Penn State Worry Questionnaire
3. Anxiety sensitivity, as measured by ASI
4. Reduction in depression symptoms assessed by the CES-D and PHQ-Depression
5. Alcohol use measured by AUDIT, disability, measured by the 'Days Out of Role' questions from the US National Comorbidity Survey and number of hours worked per day
6. Improvements in health knowledge using formats previously developed for depression and adapted for anxiety (Anxiety Literacy [A-Lit])
7. Help-seeking using scales measuring actions taken to overcome anxiety adapted from parallel depression versions of these, perceived need for treatment assessed by the following item: "Was there ever a time in the last 12 months when you felt that you might need to see a health professional because of problems with your emotions or nerves?"
8. Adherence measured by survey return rates and website usage
9. Preferences for treatment type and expectations of the trial will be assessed using previously developed formats, and levels of psychological distress using the K10

Further outcome measures to be included in the assessments may also be potential risk factors and mediators of the effectiveness of the intervention. Personal and perceived stigma toward those with GAD will be assessed by a new scale currently under development - the Generalised Anxiety Stigma Scale, while participants' ability to identify mental illness will use measures using prototypes, and perceptions of personal health will be rated using a self-perceived emotional health item, symptoms of social phobia will be assessed using the Social Phobia Inventory and a new social phobia screener that is in development, whilst symptoms of panic will be measured using PHQ Panic and a new panic disorder screener that is in development. Availability of social support will be assessed using MOS Social Support, preferences for treatment type and expectations of the trial will be assessed using previously developed formats. Predictors including smoking, medication use, perceived helpfulness of sources, childhood adversity, physical health and life events will use scales developed for a previous study.

In addition, for the Treatment trial worry will be measured by the Anxious Thoughts Inventory, somatic symptoms associated with worry will be measured by the Worry and Anxiety Questionnaire - Somatic Subscale, the impact of worry on participants' lives will be measured by the Life Interference Scale, and global social, occupational and psychological functioning will be assessed by the Global Assessment of Functioning scale. These scales will be administered at baseline, post-intervention, 6 months post-intervention, and 12 months post-intervention.

Overall study start date
31/01/2010

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Aged 18 - 30 years, either sex
2. Access to the internet
3. Score 5 or higher for GAD (as assessed through GAD-7 scale)
4. Consent to participate

5. Provide active email address and phone number
6. Sufficient English language literacy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Prevention arm: 600 (5 conditions x 120); treatment arm: 120 (3 conditions x 40)

Key exclusion criteria
1. For prevention arm: meet criteria for GAD on MINI (if criteria are met, retained for treatment arm)
2. Current or previous diagnoses of psychosis, schizophrenia or bipolar disorder
3. Prevention arm: meet criteria for social phobia, panic disorder, or PTSD on MINI; treatment arm: primary diagnosis of social phobia, panic disorder, PTSD, OCD, major depression or substance dependence on ADIS-IV
4. At risk of suicide/self-harm
5. Currently on psychiatric medications
6. Currently undergoing CBT or seeing a psychologist/psychiatrist

Additional criteria for treatment arm:
7. Clinical diagnosis of GAD on ADIS-IV
8. Taking monoamine oxidase inhibitors (MAOIs) (+/- 14 days before or after treatment); concomitant pimozide
9. Treatment with sertraline in the past three months for a period of two or more weeks
10. Planning to become pregnant/pregnant/breastfeeding

Date of first enrolment
31/01/2010

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Australia

Study participating centre

Centre for Mental Health Research
Canberra
Australia
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Sponsor information

Organisation
Centre for Mental Health Research (CMHR) (Australia)

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Sponsor type
University/education

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ROR
https://ror.org/019wvm592

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (NHMRC) (Australia):

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
1. Grant to the Centre for Mental Health Research (ref: 525419)

Funder Name
2. Fellowship to Helen Christensen (ref: 525411)

Funder Name
3. Fellowship to Kathy Griffiths (ref: 525413)

Funder Name
4. Capacity Building Grant supporting Philip Batterham (ref: 418020)

Funder Name
Brain & Mind Research Institute Foundation (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?
Protocol article	protocol	30/04/2010		Yes	No
Results article	results	02/09/2014		Yes	No