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The PsyWell study: promoting Psychological Wellbeing using an internet-based training programme

Submission date 19/04/2010	**Recruitment status** No longer recruiting
Registration date 27/05/2010	**Overall study status** Completed
Last Edited 11/01/2013	**Condition category** Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.warwick.ac.uk/go/psywell

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
The PsyWell study: A randomised controlled trial of an internet-based cognitive behaviour therapy based training programme to improve psychological wellbeing

Acronym
PSYWELL

Study objectives
A self-delivered online CBT-based training programme can promote mental wellbeing in the general population

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Black Country NHS Research Ethics Committee (NRES) approved in March 2010 (ref: 10 /H1202/21)

Study design
Randomised controlled trial with two arms: intervention and waiting-list control

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental wellbeing

Interventions
Intervention group receive access to MoodGYM. MoodGYM is a 5 week program comprising of 5 interactive modules, a series of quizzes and 29 exercises. The modules provide training in techniques of cognitive therapy (cognitive restructuring), behavioural methods for overcoming dysfunctional thinking, relaxation, problem solving, assertiveness and self-esteem training, and strategies for coping with relationship break-up. The quizzes include a series of anxiety and

depression scales (that permit the user to track the change in their symptoms across modules) and a range of other measures (such as quizzes which assist the user to understand their particular profile of thinking patterns or to identify their preferred and actual pleasant events profile). Feedback on the quizzes is based on normative data collected from large scale epidemiological surveys. Users can consult their workbook containing completed exercises at any time. At the end of each module, the user can, if they wish, print out a summary of their session, including the level of their depressive and anxiety symptoms, their scores on other tasks, their goals and achievements. This summary is written in a format that is intended to be taken to the persons health practitioner should this be deemed appropriate by the user. The user is provided with a personalised certificate of completion at the end of the five modules. Participants in the intervention arm will receive weekly email reminders to log into the trial portal where they can access the intervention.

Comparison group is a waiting list control who will receive access to MoodGYM after 3 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mental wellbeing, comparing changes from baseline to follow-up at 6 weeks and 3 months. This will be measured using the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).

Additional information added as of 08/12/2010:
Updated prior to final outcome measures being measured in the trial to give additional information on ISRCTN, as advised by our steering group. No changes made to original plans, just further information for the purposes of providing full information and clarity.

The primary outcome will be changes from baseline on the WEMWBS mental wellbeing scale, comparing the repeated measures (6 weeks, and 12 weeks) between the two groups. We will use mixed-model repeated-measures ANOVA with measurement occasion as a within-groups factor and intervention as a between-groups factor. We will compare changes from baseline in each group at 6-weeks post-test, and 12 week follow-up. We will use the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).

Co-variates are: age, sex, educational level, employment status, ethnic group, baseline marital status, baseline general health, baseline smoking status, baseline mental health scores, baseline physical activity, baseline alcohol use, baseline drug use, previous mental health service use, previous internet use and experience, previous experience of CBT, previous experience of internet-based CBT.

Secondary outcome measures
The following measured at 6 weeks and 3 months:
1. Depression (CES-D)
2. Anxiety (GAD-7)
3. Quality of life (EQ5D)
4. Physical activity (self-report)
5. Health service use (self-report)

Additional information added as of 08/12/2010:
Updated prior to final outcome measures being measured in the trial to give additional information on ISRCTN, as advised by our steering group. No changes made to original plans, just further information for the purposes of providing full information and clarity.

Secondary outcomes will be changes from baseline for depression scores, anxiety scores, quality of life measurement, and for physical activity, and for health service use, measured at baseline and 12 weeks. We are measuring these using the CES-D (depression), GAD-7 (anxiety), EQ5D (quality of life), the single-item measure of physical activity, and self-report of health service use of number of attendances in primary care, secondary care outpatients, and secondary care inpatient stays. We will also compare self-rated general health.

Co-variates are: age, sex, educational level, employment status, ethnic group, baseline marital status, baseline general health, baseline smoking status, baseline mental health scores, baseline physical activity, baseline alcohol use, baseline drug use, previous mental health service use, previous internet use and experience, previous experience of CBT, previous experience of internet-based CBT.

We will also undertake the following pre-specified sub-group analyses, comparing primary and secondary outcome measures for the following subgroups:
1. Age groups: we have an a priori hypothesis that MoodGYM may be of more benefit to a young age group as it was originally developed for this group. We will therefore undertake a subgroup analysis for the age group aged 25 and younger (and compare with the group aged over 25).
2. Gender: male and female. There is some research to suggest gender differences in mental wellbeing and in response to psychological intervention. We will therefore undertake a subgroup analysis by gender (male and female subgroups).
3. Educational level: as this is an information based intervention it is possible that those with a higher level of education and literacy may do better. We will therefore analyse subgroups by educational level. We will analyse two subgroups:
3.1. Those with a degree level qualification or higher
3.2. Those without
4. Previous psychiatric history: we will compare those who have previously received treatment for a mental health problem to those without this history.
5. Previous experience of cognitive behavioural therapy: we will compare those with previous experience of cognitive behavioural therapy to those without.
6. Depression: we will compare those who are indicated to have depression at baseline (using CES-D), to those who do not.
7. Anxiety: we will compare those who are indicated to have anxiety at baseline (using GAD-7) to those who do not.

Overall study start date
01/06/2010

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Adults aged 18 or over
2. Located in England

3. Able to read and write English
4. Have access to the internet in order to use the intervention
5. Have an email address where they can be contacted
6. Give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2040

Key exclusion criteria
1. Aged under 18
2. Located outside England
3. Unable to read and write English
4. Unable to access the intervention
5. No email address provided
6. Email address has already been registered as a trial participant
7. No consent given

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Sciences Research Institute
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
University House
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/services/rss/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Department of Health/NHS Choices (UK)

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?
Results article	results	31/12/2012		Yes	No