

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

<b>Submission date</b> 19/04/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/01/2013	<b>Condition category</b> 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

## Study website

<http://www.warwick.ac.uk/go/psywell>

## Contact information

### Type(s)

Scientific

### Contact name

Dr John Powell

### Contact details

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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-variables 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

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Kirby Corner Road  
Coventry  
England  
United Kingdom  
CV4 8UW

## 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?
<a href="#">Results article</a>	results	31/12/2012		Yes	No