

A pilot research project into the use of online resources for low mood and anxiety in the voluntary sector

Submission date 24/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/07/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Rebeca Martinez

Contact details

Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

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r.martinez@clinmed.gla.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FM05006

Study information

Scientific Title

A pilot research project into the use of online resources for low mood and anxiety in the voluntary sector

Study objectives

Anxiety and stress are common and cause difficulties in everyday life. It has been estimated that around one in two people who experience these problems choose to seek help on their own or through the voluntary services.

The National Phobics Society already works to relieve and support those living with anxiety disorders by providing information, support and understanding via an extensive range of services, including one-to-one email and telephone support services. Many people have overlapping difficulties of low mood and anxiety. The offer of support through the voluntary sector offers a very attractive option for people who wish to seek help for their difficulties but may find it difficult to do so through mainstream health services.

"Living Life to the Full" is a free, web-based life skills site (supported by the Scottish Executive Health Department) aimed at low mood and anxiety, which is based on the Cognitive Behaviour Therapy model. The written version of these materials on which this website is based on, have proven to be very effective in the treatment of low mood in a primary care population (effect size: 1.27, CSO CZH 461).

The aim of this study is to pilot and evaluate the use of Living Life to the Full, which can be accessed free of charge from a persons' home or local library with the support of the voluntary sector agency: National Phobics Society (NPS) - the UK's predominant anxiety charity. The recruitment for this study is from the voluntary sector, and does not involve any recruitment within the NHS. The aim is to recruit people with anxiety or anxiety and low mood who contact the National Phobics Society (NPS). The form of support will be offered by email support by trained NPS volunteers.

Hypotheses:

1. Take-up, retention and drop-out in the two arms
2. The relative effect size of the interventions
3. The acceptability of the approach to participants and self-help support workers
4. Effect that the severity of symptoms has on people's use and benefit from the use of the active intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Glasgow (UK) Ethics Committee, 05/09/2007, ref: FM05006

Study design

Randomised controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied

Depression, anxiety

Interventions

This is a pilot randomised controlled trial comparing an online life skills package, Living Life To The Full (LLTFF) which is based on the Cognitive Behaviour Therapy model, delivered with brief email support (at least one email per week), compared with matched email support in the other arm of the study. The support will be within the time frame specified for brief interventions (i.e. approximately 60 minutes in total delivered over 6 weeks - the time used per participant will be recorded and the reasons for using more time will be explored), for people experiencing significant symptoms of anxiety and/or low mood.

Intervention Type

Behavioural

Primary outcome measure

1. Beck Anxiety Inventory (BAI) score at 4 months
2. Beck Depression Inventory (BDI-II) score at 4 months

Secondary outcome measures

1. Work And Social Adjustment Scale (WASAS)
2. Single item satisfaction scale
3. Four-items assessing mental health literacy

All outcomes will be measured at 6 weeks and 4 months.

Overall study start date

01/10/2007

Completion date

01/05/2008

Eligibility**Key inclusion criteria**

1. Aged 16 and above
2. Living in the UK

3. Currently experiencing significant anxiety and or low mood as indicated by a nine-item Patient Health Questionnaire (PHQ-9) score above 10 or a seven-item PHQ (PHQ-7) score above 10
4. Have online access and an active email address
5. Wish to work in this way to address their difficulties

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. No access to broadband internet, soundcard and speakers either at home or the local library
2. Cannot read/understand the written and audio content
3. Active suicidal intent (as defined by a score of 2 or more on the suicide item questionnaire)

Date of first enrolment

01/10/2007

Date of final enrolment

01/05/2008

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

Gartnavel Royal Hospital

Glasgow

United Kingdom

G12 0XH

Sponsor information**Organisation**

Glasgow Institute of Psychosocial Interventions (GIPSI) (UK)

Sponsor details

Gartnavel Royal Hospital
The Academic Centre
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH
-
chris.williams@clinmed.gla.ac.uk

Sponsor type

Research organisation

ROR

<https://ror.org/00vtgdb53>

Funder(s)**Funder type**

Research organisation

Funder Name

Glasgow Institute of Psychosocial Interventions (GIPSI) (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