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Randomised controlled trial of the effectiveness of Big White Wall compared to other online support

Submission date
03/10/2016

Recruitment status
No longer recruiting

Registration date
01/11/2016

Overall study status
Completed

Last Edited
26/04/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression and anxiety are common mental health problems and are the second and seventh leading causes of years lived with disability in the world among all health problems respectively. These mental health problems are so common that it is necessary to find a broader means of supporting sufferers, as many do not receive adequate treatment. The internet has proved to be an effective way of helping people to access treatment that may not have been able to do so previously. Big White Wall (BWW) is a digitial service which helps support people suffering from common mental health problems, using peer support. It is an anomymous service which allows users to interact with and support one another, without needing to reveal who they are. The aim of this study is to investigate the effectiveness of BWW in helping to improve mental wellbeing in people with symptoms of depression and anxiety.

Who can participate?
People aged 16 years and over who have symptoms of depression and anxiety.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive six months free access to the Big White Wall (BWW) website. Participants are able to access any part of the BWW site (apart from the option of personalised therapy or counselling sessions that are currently available on BWW for certain users with NHS prescriptions) and interact with other users within the boundaries of the site's House Rules. Those in the second group are directed to the Moodzone area of the NHS Choices website where they are able to access information about depression and anxiety. The website contains reading material and suggestions about maintaining mental health as well as providing ways to test themselves for depression and anxiety. At the start of the study and then after 3, 6, 12 and 26 weeks, participants in both groups complete a range of questionnaires to measure their mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from receiving information and support from the web-based services. There are no notable risks involved with participating.

Where is the study run from?
The study is run from the Institute of Mental Health and takes place online (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Catherine Kaylor-Hughes
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02902159

Secondary identifying numbers
32184

Study information

Scientific Title

Randomised controlled trial of an established direct to public peer support and e-therapy programme (Big White Wall) versus information to aid self-management of depression and anxiety

Acronym
REBOOT Notts

Study objectives
The aim of this study is to:
1. Investigate the impact on wellbeing of an online peer support site (Big White Wall) that provides 24 hour supported self-management compared to online information alone (NHS Moodzone), for people with symptoms of depression and anxiety
2. Explore who and how many people might wish to utilise such a service and include those that are socially isolated and hard to reach

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 07/06/2016, ref: 16/EM/0204

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention

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
Specialty: Mental Health, Primary sub-specialty: Depression; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

Interventions
Participants will be randomised to one of two groups. Randomisation will be made via a computer generated pseudo-random code using random permuted blocks of varying size by a system embedded within the website. No stratification or minimisation is required. The outcome will be single-blind with the research team responsible for the collection, cleaning and analysis of the data remaining blind to arm allocation until data collection has been completed.

Arm 1: Big White Wall
Participants will receive six months free access to the Big White Wall website. They will create a user profile using a pseudonym which will be linked to the trial ID that they are assigned within the study website. Participants will be able to access any part of the BWW site (apart from the option of personalised therapy or counselling sessions that are currently available on BWW for certain users with NHS prescriptions) and interact with other users within the boundaries of the site's House Rules. A record of their logins, time on site, interactions and page categories will be recorded by BWW on behalf of the study team.

Arm 2: Moodzone
Participants will be directed to the Moodzone area of the NHS Choices website where they will be able to access all of the available material on Mental Health including depression and anxiety for six months. The site contains reading material and suggestions about maintaining mental health and provides measures of depression and anxiety for visitors to use.

Participation in the study will be for six months, receiving electronic follow up invitations at 3, 6, 12 and 26 weeks after randomization which are to be completed on the website through their user login. Participants may also be asked to take part in a short interview by phone or face to face to talk about their experiences of services and/or the study within three months of the end their participation

Intervention Type
Other

Primary outcome measure
Change in self-rated well-being at 6 weeks after baseline using the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) at baseline, 3, 6, 12 and 26 weeks.

Secondary outcome measures
1. Maintenance of well-being is measured using the WEMWBS at baseline, 3, 6, 12 and 26 weeks
2. Anxiety is measured using the 7-Item Generalised Anxiety Disorder Scale (GAD-7) at baseline, 3, 6, 12 and 26 weeks
3. Levels of depression are measured using the 9-Item Personal Health Questionnaire (PHQ9-9) at baseline, 3, 6, 12 and 26 weeks
4. Health Related Quality of Life is measured using the 12-item medical outcomes study short form health survey version 2.0 (SF-12v2) at baseline, 3, 6, 12 and 26 weeks
5. Social support is measured using the Medical Outcomes Study 8-Item Social Support Survey at baseline, 3, 6, 12 and 26 weeks
6. Social function is measured using the 8-item Work and Social Adjustment Scale (WSAS) at baseline, 3, 6, 12 and 26 weeks

Overall study start date
01/01/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria

1. Aged 16 years and over
2. Live in the County of Nottinghamshire, including Nottingham City
3. Scores between 10-20 on the Personal Health Questionnaire (PHQ9); added 24/04/2018: and /or 10+ on GAD7
4. Access to internet through a PC or smartphone (Windows, iOS, Android)
5. Able and willing to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2200; UK Sample Size: 2200

Total final enrolment
397

Key exclusion criteria
1. Scores 20 or more on the PHQ-9 (severe depression)
2. Scores 2 or 3 on PHQ-9 item "thoughts that you would be better off dead or of hurting yourself in some way"
3. Participant does not feel that they are sufficiently proficient in the use of the English language

Date of first enrolment
19/09/2016

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Mental Health
Triumph Road

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Sponsor information

Organisation
University of Nottingham

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. The protocol will be written up and sent to an appropriate peer-reviewed scientific journal
2. Demographic assessments will be explored and presented to inform engagement as well as a source of interest for commissioners, service providers and service users
3. The initial findings will be synthesised in the summary reports of the programme of research and disseminated to regional partners
4. Qualitative findings analysed and written up. Dissemination through presentations at conferences and appropriate peer-reviewed scientific journals
5. Primary and secondary outcomes measures will be written up and disseminated through local, regional and national research and practice networks, by means of conference presentations, publications and email. Health economics analysis of the data will alsobe completed and disseminated.
6. The results will be publicised through the CLAHRC-EM Communications department as well as publication in peer reviewed journals, local, national and international scientific conferences
7. There will be an end of study event to which participants, commissioners, health and community groups involved in the study engagement will be invited. The presentation will take the form of an interactive workshop where the participants can consider and discuss the implications of the findings including the next steps that might be taken to improve care for patients.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/12/2017		Yes	No
Preprint results	results		19/02/2021	No	No
Results article		23/04/2021	26/04/2021	Yes	No
HRA research summary			28/06/2023	No	No