

Does the inclusion of an emotional wellbeing intervention into an existing, web-based, health promotion programme improve public sector staffs ability to improve their health behaviours? Protocol for a feasibility study

Submission date 12/01/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/08/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Positive mental health and wellbeing are a priority both in the UK and globally, evidenced by an increase in policy documents focused on population wellbeing. For example, mental health is a Welsh Government (WG) priority area. 'Our Healthy Future' and 'Together for Mental Health', Wales's mental health strategy, states promoting better mental wellbeing as a key strategic objective. There is limited research exploring the role of emotional wellbeing programmes on physical health behaviour change programmes and health outcomes. This study represents one of the first to explicitly explore the additional benefit of an emotional wellbeing program on physical health behaviour change programs which aim to improve individual's health outcomes. The aim of this study is to assess the acceptability to participants of including an emotional wellbeing module within the champions for health programme.

Who can participate?

Staff at Abertawe Bro Morgannwg University Health Board.

What does the study involve?

The study involves taking part in a web-based, work place health promotion programme designed to support public sector staff in Wales to improve their lifestyle and health behaviours. Participants are randomly allocated to either one of four groups. Those in the first group receive access to the five physical health promotion modules only. Those in the second group receive access to an additional emotional wellbeing module. Those in the third group receive the same as the second group plus access to a selection of films where people talk about their personal experiences with mental health. Those in the fourth group receive the same as the second group plus a social comparison message. The health promotion programme is available to use free of cost for a period of 12 weeks. At the start of the study and again after 12 weeks, participants in both groups complete a number of questionnaires to assess their mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from participation through improved health and emotional wellbeing and free access to the web-based programme. There are no known notable risks for participants wishing to take part.

Where is the study run from?
Abertawe Bro Morgannwg University Health Board (UK)

When is the study starting and how long is it expected to run for?
February 2017 to May 2019

Who is funding the study?
Health Care Research Wales (UK)

Who is the main contact?
Mrs Menna Brown
Menna.brown@swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Menna Brown

ORCID ID
<http://orcid.org/0000-0003-1427-1648>

Contact details
Swansea University
Medical School
Singleton campus
ILS2
Swansea
United Kingdom
SA2 8PP
+44 1792 606312
menna.brown@swansea.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HCRW: SCS-14-11

Study information

Scientific Title

Champions for Health: a web-based wellbeing intervention to support physical health behaviour change: Protocol for a feasibility study

Study objectives

The inclusion of an emotional wellbeing intervention within the champions programme will improve users (randomised to intervention arm) level of engagement with the physical health behaviour change modules and the platform overall.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. College of the Human and Health Sciences & College of Medicine Research Ethics Committee, Swansea University, 11/01/2017
2. ABMU Health Board Joint Study Review Committee (JSRC), 06/01/2017

Study design

Feasibility randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Emotional wellbeing

Interventions

Randomisation procedure:

Participants are randomly allocated to a study arm after they complete the online registration process. A random sequence generator has been programmed into the registration process to ensure automated allocation to trial arms. The researchers are not involved in this allocation process and do not know who has been allocated to which study arm until the data is exported from the database at the end of the 12 weeks.

Current study arms as of 24/01/2019:

Study arm 1: Control

Those allocated to this study arm have access to the following five physical health modules (treatment): weight optimisation, physical activity, alcohol reduction, smoking cessation and five a day. Each module consists of information and advice on how to make healthy lifestyle changes (the resources were developed by public health wales). Participants have access to a personal user dashboard where they can record and monitor their progress over the trial duration. The modules are described as health challenges and participants can select as many modules as they want to, to take part in. The aim of each module is to provide healthy lifestyle information to the participants on how to make positive lifestyle improvements in their chosen health topic. Participants are encouraged to log onto the website weekly or as often as they wish to record their health behaviours. For example if a participant has selected the 'five a day' module, the user dashboard asks participants to record which fruits and vegetables they have consumed each day. This information is then displayed visually for them to track and monitor their progress.

Study arm 2: Intervention

In addition to the above, those allocated to one of the three intervention arms will also receive access to an emotional wellbeing intervention. The intervention consists of a structured, 12 week module. Participants are advised to use one per week but can navigate through at their own pace. This intervention (treatment) is based on Acceptance and Commitment Therapy (ACT), it covers the six core components of ACT over the 12 weekly modules and includes activities to try out and PDF resources to download for continued use. Participants can submit data each week to encourage engagement and continued use. They can track their engagement in the user dashboard.

Study arm 3: Intervention

Study arm 2 plus access to a selection of films where people talk about their personal experiences with mental health, produced and made available by PocketMedic.

Study arm 4: Intervention

Study arm 2 plus a social comparison message

Previous study arms:

Study arm 1: Control

Those allocated to this study arm have access to the following five physical health modules (treatment): weight optimisation, physical activity, alcohol reduction, smoking cessation and five a day. Each module consists of information and advice on how to make healthy lifestyle changes (the resources were developed by public health wales). Participants have access to a personal user dashboard where they can record and monitor their progress over the duration of the 12 week trial. The modules are described as health challenges and participants are asked to select up to two modules to take part in.

The aim of each module is to provide healthy lifestyle information to the participants on how to make positive lifestyle improvements in their chosen health topic. Participants are encouraged to log onto the website weekly or as often as they wish to record their health behaviours. For example if a participant has selected the 'five a day' module, the user dashboard asks participants to record which fruits and vegetables they have consumed each day. This information is then displayed visually for them to track and monitor their progress over the 12 weeks.

Study arm 2: Intervention

In addition to the above, those allocated to the intervention arm also receive access to an emotional wellbeing intervention. The intervention consists of 12 weekly modules which will be released once per week in sequential order once the prior week has been opened. This intervention (treatment) is based on Acceptance and Commitment Therapy (ACT), it covers the

six core components of ACT over the 12 weekly modules and includes activities to try out and PDF resources to download for continued use. Participants can record their mood over the 12 week period in the user dashboard alongside the physical health modules to view and monitor changes and progress over time. Accompanying this intervention is the five ways to wellbeing textual information (provided by Public Health Wales) and information on sleep and relaxation.

At the start of the study and again after 12 weeks, participants in both groups complete a number of questionnaires to assess their mental wellbeing.

Intervention Type

Behavioural

Primary outcome measure

Emotional wellbeing, measured using the wellbeing score on the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 12 weeks

Secondary outcome measures

1. Health and wellbeing, measured using the Patient Health Questionnaire for Depression and Anxiety (PHQ-4) at baseline and 12 weeks
2. Psychological flexibility, measured using the Acceptance and Action Questionnaire—Revised (AAQ-II) at baseline and 12 weeks

Overall study start date

04/01/2015

Completion date

31/05/2019

Eligibility

Key inclusion criteria

1. Member of staff at selected health board
2. Aged 18 or above
3. Internet access
4. Ability to read written English
5. Ability to consent

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100 in total, 25 in each arm

Total final enrolment

121

Key exclusion criteria

1. Not a member of staff at selected health board
2. Not aged 18 or above
3. No Internet access
4. Inability to read written English
5. Inability to consent

Date of first enrolment

28/01/2019

Date of final enrolment

26/04/2019

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Abertawe Bro Morgannwg University Health Board

One Talbot Gateway

Baglan Energy Park

Seaway Parade

Port Talbot

United Kingdom

SA12 7BR

Sponsor information

Organisation

Swansea University

Sponsor details

Swansea University

Singleton park

Swansea

Wales

United Kingdom

SA2 8PP
+44 1792 606060
reis@swansea.ac.uk

Sponsor type
University/education

ROR
<https://ror.org/053fq8t95>

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Results and Publications

Publication and dissemination plan
Publication in a high-impact peer reviewed journal.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Menna Brown (Menna.brown@swansea.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/08/2020	10/06/2020	Yes	No