

Champions for health: a web-based acceptance and commitment therapy (ACT) intervention to enhance emotional wellbeing and encourage engagement with lifestyle behavioral changes

Submission date 24/01/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/04/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Globally prevalence rates of common mental disorder (CMD) such as anxiety and depression are high. In the UK estimated population incidence rates are between 4-10%. The individual and economic cost is significant. In the UK, the estimated costs of mental health problems are £70-100 billion each year and account for 4.5% of GDP. Thus prevention and early intervention make economic sense.

In contrast, positive mental health and wellbeing are associated with benefits across health, social and economic domains. WHO report the following benefits: improved overall functioning, better lifestyle choices, greater educational attainment, higher income and higher productivity. Positive wellbeing has been proposed as a protective factor which may contribute to positive physical health and associated reductions in mortality. For example, one study found positive wellbeing to be associated with reductions in cardiovascular mortality in a healthy population. Thus interventions focused on improving physical health and wellbeing could promote positive aspects of health and lead to numerous health benefits at a population level.

Barriers to access

Patient and public access to psychological treatments to treat CMDs is often limited by long waiting lists, inadequate numbers of trained professionals able to meet the high demand for face-to-face therapies and social stigma attached to mental health in general. The experience of social stigma causes many not to initiate or continue effective treatment. Web-based interventions do not require users to identify themselves, the anonymity afforded through these platforms may encourage higher rates of personal disclosure and thus could be therapeutically beneficial.

Web-based context

As a result internet and web-based interventions provide a cost-effective means by which to deliver health promotion and wellbeing interventions.

Study aim

Thus the current study aims to conduct a cluster randomized control trial (RCT) to evaluate the impact of an acceptance and commitment therapy (ACT) based emotional wellbeing intervention on; lifestyle behaviour change; adherence and engagement with lifestyle behaviour change modules and emotional wellbeing.

Who can participate?

Members of staff at recruited organizations who are able to access the website

What does the study involve?

This evaluation will be achieved by inviting staff at selected organizations to take part in a 12-week staff health challenge. Participants will be able to take part by signing up to a website called Champions for Health. They will have the opportunity to choose a health challenge to take part in that is suited to their health needs and will be randomized to receive access to the emotional wellbeing intervention or not.

What are the possible benefits and risks of participating?

It is anticipated that participation in the study could bring benefits at individual level in regards to improved physical health through the adoption of positive lifestyle behaviour change. In addition to this it is anticipated that positive benefits will be seen to those randomised to receive the wellbeing intervention who engage with it for the 12 week duration. There are no anticipated risks to participants who consent to take part in this study.

Where is the study run from?

Swansea University (UK)

When is the study starting and how long is it expected to run for?

September 2019 to September 2020

Who is funding the study?

Health and Care Research Wales (UK)

Who is the main contact?

Mrs Menna Brown, menna.brown@swansea.ac.uk

Study website

<https://activateyourwellbeing.swansea.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

Mrs Menna Brown

ORCID ID

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

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

HCRW: SCS-14-11

Study information

Scientific Title

Champions for health: a randomized controlled trial of a web-delivered acceptance and commitment therapy (ACT) intervention to enhance subjective wellbeing and encourage engagement with lifestyle behavioral changes.

Study objectives

The use of an ACT-based, web-based intervention designed to promote emotional wellbeing will positively impact on health outcomes and engagement with lifestyle health behaviour change modules

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 02/09/2019, Swansea University Medical School research ethics committee (Swansea University Medical School, Singleton Park, Swansea, SA2 8PP; d.gonzalez@swansea.ac.uk; +44 (0)1792 295384), ref: 2019-0056
2. Approved 06/01/2017, Swansea Bay University Health Board, Research and Development Joint Study Review Committee (JSRC) (One Talbot Gateway, Baglan Energy Park, Port Talbot, SA12 7BR; Sandra.Husbands@wales.nhs.uk; +44 01639 683334)

Study design

A cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Internet/virtual

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 and lifestyle behaviour change

Interventions

Participants are required to register on the study website, provide consent and complete a study registration form with baseline health and wellbeing questionnaires. They will then be automatically allocated to either the control or intervention arms based on the information they provide about their employing organization and site location within the organization.

Participants are randomized at a cluster level, with each different site within the SBUHB health board (at which participants are employed) randomly allocated to either the intervention or the control arm. The researcher is blinded to this allocation. The website programmer used a randomly generated sequence to pre-program the website to allocate participants accordingly.

The intervention arm receives an emotional wellbeing intervention based on acceptance and commitment therapy (ACT). The intervention is available to participants via the Champions for Health website for 12 weeks and has been designed to be accessed on a weekly basis. However, participants will have access to all 12 weeks immediately and are free to navigate the resources as they wish. Each week contains an ACT skill to learn, practice exercises and an interactive motivational goal-setting tool.

The control arm participants have no access to the wellbeing intervention.

Both control and intervention participants will have access to five lifestyle behavior change modules via a health promotion website. The baseline health and wellbeing questionnaires are repeated for all participants at 12 weeks.

Intervention Type

Behavioural

Primary outcome measure

Emotional wellbeing measured by the Warwick-Edinburgh mental wellbeing scale (WEMWBS) and the patient health questionnaire for depression and anxiety (PHQ4) at baseline and 12 weeks

Secondary outcome measures

Psychological inflexibility and experiential avoidance measured by the Acceptance and Action Questionnaire-Revised (AAQ-II) at baseline and 12 weeks

Overall study start date

01/09/2019

Completion date

22/05/2020

Eligibility

Key inclusion criteria

1. Member of staff at recruited organizations
2. Ability to read and write in English
3. Consent to participation

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

Total: 800, Clusters: 4

Total final enrolment

175

Key exclusion criteria

Unable to access intervention due to lack of device or internet access

Date of first enrolment

17/02/2020

Date of final enrolment

28/02/2020

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Swansea University

Singleton Park Campus

Data Science Building
Floor 3
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation

Swansea University

Sponsor details

Singleton Park Campus
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+44 (0)1792 205678
reis@swansea.ac.uk

Sponsor type

University/education

Website

<https://www.swansea.ac.uk>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Health and Care Research Wales

Alternative Name(s)

Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 21/12/2021:

Dissemination via PhD thesis

Previous publication and dissemination plan:

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Menna Brown via email on menna.brown@swansea.ac.uk. The raw data collected in the study without identifying data will include, pre and post wellbeing scores (where completed), enrolment to modules and engagement with modules. This data will be available until completion of the PhD project it is linked to (which is anticipated in July 2021). It will be made available in an Excel spreadsheet. Consent from participants will be obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Intervention design	30/11/2020	04/04/2023	Yes	No