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Digital support for young people with their mood and wellbeing

Submission date
23/03/2022

Recruitment status
No longer recruiting

Registration date
29/04/2022

Overall study status
Completed

Last Edited
21/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression is common in young people, and most are not getting any help. Researchers have developed a digital programme, MoodHwb, with young people and families/carers to support their mood and well-being. The programme is a website and an app. It aims to engage and promote self-help, help-seeking, and social support. The study aims to further develop and test MoodHwb by looking at how young people use it and by getting feedback from young people, parents/carers and professionals who use it. If found to be effective, the programme could be made freely available and rolled out in health, education, youth and social services/charities.

Who can participate?
Adolescents aged 13 to 19 years old who have problems with their mood and wellbeing (e.g. feeling down or low in mood), their parents and carers, and professionals who work with young people.

What does the study involve?
Young people interested in the study will be asked to fill out a form on the study website. If eligible, they will be asked to complete consent forms and then questionnaires about their mood and wellbeing. Two-thirds of young people will have access to the online programme and a third will receive a digital information pack. A computer will decide which group they will go into. The young people with access to the programme will be able to use it as much they like, either on their own or with someone else. Two months later all participants will be asked to complete questionnaires again. Some of the young people and parents/carers who had access to the programme will be interviewed for their feedback on it. There will also be a group meeting for professionals to discuss the programme.

What are the possible benefits and risks of participating?
Participants may find it useful and interesting to take part in the study. Some might find it difficult to think about mental health problems when taking part in the project, and the researchers will try to avoid this as much as possible. They will arrange for meetings to be as convenient and comfortable as possible. The meetings will be focused on the programme, and not on the participants' personal experiences of mental health difficulties. If after taking part they feel the need for support, they can get in touch with the researchers at any time. The

researchers will discuss the problems with them and whether they need to talk to someone else, such as their family doctor.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
November 2018 to January 2024

Who is funding the study?
1. National Institute for Health Research (UK)
2. Health and Care Research Wales (UK)

Who is the main contact?
Dr Rhys Bevan Jones
bevanjonesr1@cardiff.ac.uk, YouthOnlineStudy@cardiff.ac.uk.

Study website
https://www.ncmh.info/help-with-research/digital-support-study/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
257222

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 257222, CPMS 49679

Study information

Scientific Title
Further development and feasibility trial of a digital programme for adolescent depression (MoodHwb)

Study objectives
The digital programme to support mood and well-being in young people, MoodHwb, and the trial methods are feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, Wales REC 3 (Health and Care Research Support Center, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920785735; Wales.REC3@wales.nhs.uk), ref: 21/WA/0205

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, School

Study type(s)
Treatment

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
Adolescent depression

Interventions
Participants will be assigned randomly 2:1 to use the digital programme, MoodHwb, or digital health information sheets (all will also continue with their usual treatment). The randomisation will be computerised and stratified related to site (Wales/Scotland sites). Two-thirds of the

participants will be from Wales and one-third from Scotland. The young people (and their families/carers) will complete questionnaires about their mood and behaviour at the start of the study and again after 2 months. Some will also be interviewed and there will be a focus group for professionals to discuss the programme and study.

Intervention Type
Other

Primary outcome measure
1. Feasibility and acceptability outcomes related to the digital programme, including:
1.1. Level of usage of programme, from Web usage, questionnaire and interview data, after 2 months
1.2. Views/acceptability of design and content of programme, from interview and focus group data, after 2 months
1.3. Technical and accessibility aspects, from Web usage, questionnaire and interview data, after 2 months
2. Feasibility and acceptability outcomes related to the trial methods, including:
2.1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 6 months - updated 29/03/2023: 9 months
2.2. Retention rate assessed using the number of participants who consent to participate who remain in the study at 2 months
2.3. Completeness of outcome measure questionnaire data at baseline and 2 months
2.4. Views/acceptability of the methods, particularly the remote approaches, from questionnaire data at baseline and 2 months, and interview data at 2 months

Secondary outcome measures
Core set of domains at baseline and 2-month follow-up including:
1. Depression literacy/knowledge measured using the Adolescent Depression Knowledge Questionnaire
2. Stigma measured using the Depression Stigma Scale
3. Self-efficacy measured using the General Self-Efficacy Scale
4. Help-seeking behaviour measured using the General Health-Seeking Questionnaire
5. Wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale
6. Depressive and anxiety symptoms measured using the Mood and Feelings Questionnaire; Revised Children’s Anxiety and Depression Scale-short version

Overall study start date
01/11/2018

Completion date
31/01/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/03/2023:
1. Adolescents aged 13-19 years
2. Experiencing depressive symptoms
3. Sufficient understanding of English
4. Access to the Internet and a valid email address

Previous inclusion criteria:
1. Adolescents aged 13-19 years
2. Experiencing depressive symptoms, where this is the primary mental health difficulty
3. Sufficient understanding of English
4. Access to the Internet and a valid email address

Participant type(s)
Patient

Age group
Mixed

Lower age limit
13 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
120 young people and their parents/guardians

Key exclusion criteria
Current exclusion criteria as of 29/03/2023:
1. Young people already receiving specialist treatment for depression (e.g. cognitive behavioural therapy (CBT) in secondary child and adolescent mental health services [CAMHS])
2. Presence of other mental health difficulties, where alternative support might be appropriate

Previous exclusion criteria:
1. Young people already receiving specialist treatment for depression (e.g. cognitive behavioural therapy (CBT) in secondary child and adolescent mental health services [CAMHS])
2. Presence of severe depressive symptoms
3. Presence of other severe mental health difficulties

Date of first enrolment
14/11/2022

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Scotland

United Kingdom

Wales

Study participating centre
Cardiff University
Park PLACE
Cardiff
United Kingdom
CF10 3AT

Study participating centre
University of Glasgow
University Avenue
Glasgow
United Kingdom
G12 8QQ

Sponsor information

Organisation
Cardiff University

Sponsor details
Research and Innovation Services
7th Floor
McKenzie House
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE
+44 (0)2920879273
resgov@cardiff.ac.uk

Sponsor type
University/education

Website
https://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

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

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
Planned publication of protocol and trial findings in high-impact peer-reviewed journals

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the PI at YouthOnlineStudy@cf.ac.uk, subject to review according to internal processes and appropriate data sharing agreements, at the Centre for Trials Research, Cardiff University and the University of Glasgow.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		21/11/2022	29/03/2023	No	No
Protocol article		05/06/2023	06/06/2023	Yes	No
HRA research summary			28/06/2023	No	No