

Digital support for young people with their mood and wellbeing

Submission date 23/03/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 29/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/12/2023	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

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
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Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

257222

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

13 years

Upper age limit

19 years

Sex

All

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

United Kingdom

Scotland

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

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Government

Funder Name

Health and Care Research Wales

Alternative Name(s)

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

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

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

Results and Publications

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 article		05/06/2023	06/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol (preprint)		21/11/2022	29/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes