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Improving mental health literacy among children and young people aged 12-14 years in the United Kingdom

Submission date
23/06/2022

Recruitment status
No longer recruiting

Registration date
30/08/2022

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental health problems are estimated to affect 10-20% of children and adolescents worldwide. Research shows that the prevalence of depression rises sharply after puberty and that over half of depressed adolescents have a recurrent episode within five years. Mental health literacy can be defined as knowledge and beliefs about mental disorders which help people to prevent, recognise and manage problems. We know that low levels of mental health literacy significantly increase the risk of adolescents developing moderate to severe depression and that improving mental health literacy may be a useful way to reduce the future burden of depression amongst young people.

We have co-adapted with young people, parents, professionals and other stakeholders an existing digital application (the intervention), originally developed for young people aged 11-15 years in Indonesia to improve mental health literacy and self-management skills, for use in the UK with young people aged 12-14 years. We have also co-designed an additional third book for the application, designed specifically for young people in the UK.

The study aim is to determine the feasibility of delivering and evaluating the use of the digital application in education and community settings in the UK. We will explore how many young people want to take part in our study, how much they use the intervention and what sort of follow-up data they are willing to provide. We will also speak to young people about their experiences with the intervention. We will use these findings to collaboratively design a larger study to explore the costs and impacts of the intervention.

Who can participate?
Young people aged 12-14 years old, of all genders, attending educational and community settings and with access to a smartphone or tablet

What does the study involve?
The study will take place over a 3-month period at four study sites across Greater Manchester (two schools and two community venues). The sites will be initially approached through existing contacts of the study team. Ten young people aged 12-14 years will be recruited at each site.

To test the feasibility of the digital application, a cluster randomised control trial will be used. In this study, an equal number of clusters (two per arm) will be allocated to the intervention and control arms. The young people in the intervention arm will have access to the digital application and the young people in the control arm will not have access to the digital application. Following recruitment and the completion of demographic and baseline questionnaires at all sites, randomisation will then decide which of the two clusters (sites) have access to the intervention. This will be achieved by using a blocked randomisation list. The study statistician will produce the randomisation list. A cluster will not be allocated until the full set of 10 young people has been recruited at that cluster, to prevent allocation bias. The allocation sequence will not be revealed to the other study investigators.

The outcome data will predominantly be self-reported using quantitative questionnaires that measure mental health literacy and other mental health-related measures. At each site, all the young people will complete these questionnaires in a similar timeframe; at baseline, post-intervention (or about a month after baseline for the control group) and follow-up (at 3 months). At the intervention arm sites, we will collect qualitative data through semi-structured interviews /focus groups with young people. This will focus on the experiences of using the application.

What are the possible benefits and risks of participating?
The possible benefit is that the digital application could help young people learn about their mental health and develop self-management techniques, and the study will help improve the app for future use. The possible risk is that talking and thinking about mental health can be difficult for young people.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2022 to May 2023

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

Who is the main contact?
Dr Helen Brooks
helen.brooks@manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Helen Brooks

ORCID ID

https://orcid.org/0000-0002-2157-0200

Contact details
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)7837471975
helen.brooks@manchester.ac.uk

Type(s)
Scientific

Contact name
Dr Jack Wilkinson

ORCID ID
https://orcid.org/0000-0003-3513-4677

Contact details
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 3066000
jack.wilkinson@manchester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A cluster-randomised controlled feasibility trial for a digital mental health literacy intervention for young people aged 12-14 years in the United Kingdom

Acronym
IMPETUS

Study objectives
1. The IMPETUS app improves mental health literacy of young people aged 12-14 years
2. Rolling out the IMPETUS app to educational and community settings is feasible

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2022, University of Manchester Research Ethics Committee (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)161 306 6000; research.ethics@manchester.ac.uk), ref: 2022-14361-24300

Study design
Multi-centre interventional cluster-randomized feasibility trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Improvement of mental health literacy

Interventions
Forty children and young people aged 12-14 years will be recruited across four study sites (community and educational settings). Ten young people will be recruited per site (cluster).

The intervention arm is participants having access to a digital application, the 'IMPETUS app'. This is an immersive storyline digital game in which young people play as a character facing mental health challenges. Their decisions affect the direction of the game and eventual outcomes. The control arm is participants not having access to the 'IMPETUS app.'

An equal number of clusters (two per arm) will be allocated to the intervention and control arms. This will be achieved by using a blocked randomisation list. The study statistician will produce the randomisation list. A cluster will not be allocated until the full set of 10 participants has been recruited at that cluster, to prevent allocation bias. The allocation sequence will not be revealed to the other study investigators.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
IMPETUS application

Primary outcome(s)
1. Feasibility measured using children and young people recruitment and retention rates, intervention uptake and engagement rates, and the variability and potential floor/ceiling effects in our proposed patient outcome measures at baseline (prior to randomisation), post-intervention (or at approximately 6 weeks post-randomisation for control group participants) and 3-month follow-up.

2. Mental health literacy is measured using the Knowledge and Attitudes to Mental Health Scale (KAMHS) at baseline, post-intervention and 3-month follow-up

Key secondary outcome(s))
1. Core depressive symptoms measured using the short version of the Mood and Feeling Questionnaire (MFQ) at baseline, post-intervention and 3-month follow-up
2. Well-being measured using the World Health Organisation Five Well-Being Index (WHO-5) at baseline, post-intervention and 3-month follow-up
3. Levels of anxiety measured using the Revised Children's Anxiety and Depression Scale (RCADS) at baseline, post-intervention and 3-month follow-up
4. Family cohesion and adaptability measured using the Family Cohesion and Satisfaction with Communication sub-scales of the Family Adaptability and Cohesion Evaluation Scale (FACESIV) at baseline, post-intervention and 3-month follow-up
5. Health status measured using the SF-36 questionnaire at baseline, post-intervention and 3-month follow-up

Completion date
15/05/2023

Eligibility

Key inclusion criteria
1. Aged between 12 and 14 years old
2. Attending the study site
3. Access to a smartphone/tablet to use the application

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
14 years

Sex
All

Total final enrolment
19

Key exclusion criteria

1. Aged under 12 years old and over 14 years old
2. Not attending the study sites
3. No access to smartphone/tablet

Date of first enrolment
01/07/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the Mendeley repository (https://data.mendeley.com/). Anonymised quantitative study data from questionnaires will be stored and shared. This data will be available following publication of the study and stored in perpetuity, on the grounds that it may be used to reproduce the results of the study. This data will be accessible to anyone without restriction. Consent from participants will be obtained to share this data. Data will be anonymised and participant ID numbers will be used in the dataset.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/07/2025	05/08/2025	Yes	No
Participant information sheet	version 5	23/06/2022	18/07/2022	No	Yes
Protocol file	version 2	11/04/2022	18/07/2022	No	Yes
Statistical Analysis Plan	version 1.0	12/07/2022	18/07/2022	No	Yes