RESEARCH PROTOCOL

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

Protocol version: 2

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2. INTRODUCTION

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 interactive digital application, originally developed in Indonesia with MRC funding (IMPeTUs MR/R012741/1), to improve mental health literacy and self-management skills, for use in the UK with young people aged 12-14. We have also co-designed an additional third book designed specifically for young people in the UK.

The IMPeTUs intervention includes an immersive story line digital game in which young people play as two characters facing mental health challenges. Their decisions affect the direction of the game and eventual outcomes. This application will allow for UK specific intervention content to be developed and for associated materials to be co-produced with young people, parents, professionals and other stakeholders.

In the current study, we will test whether it is feasible to deliver and evaluate our intervention in education and community settings in the UK. We will randomly allocate 20 young people to receive our intervention and 20 to not receive it and then follow them up 3-months later. We will explore how many young people want to take part in our study (recruitment and retention), how much they use our intervention and what sort of follow-up data they are willing to provide. We will speak to facilitators (n=4-6), young people (n=10) and professionals (n=6-10) about their experiences of receiving and delivering our intervention and parents/guardians (n=6-10) about their child's experiences with the intervention. We will use these findings to collaboratively design a larger study to explore the costs and impacts of our intervention.

We have appointed a PPI advisory panel and implementation reference group to oversee our project and will work with young people and those with experience of mental health difficulties in the delivery of study activities. We will use different ways (e.g. leaflets, social-media, journal articles, animations/podcasts) to tell young people, families, professionals and communities about our work.

3. BACKGROUND

Mental health problems are a major global public health issue. Common mental health problems such as anxiety and depression, account for 13% of the global burden of disease and affect

approximately 10–20% of children and young people (CYP) worldwide [1]. Population studies show that the prevalence of depression rises sharply after puberty, and 50-70% of depressed CYP have a recurrent episode within five years [2]. CYP onset is associated with depression in adulthood, poorer physical health and functioning across the lifespan, and increased suicide risk [3].

Approximately half of all mental health disorders begin by the age of 14 [4]. The impact of mental ill health is significant across the life course contributing to poorer social and physical health outcomes, premature mortality, and economic burden [3]. In England, one in eight children (13%) aged 5-19 have a mental disorder [5]. Further, the percentage of young people with a probable mental health disorder has increased by approximately 6% between 2017-2020, likely an impact of COVID-19 [6].

Rates of under-recognition and under-treatment of depression are higher in CYP than in adults, resulting in poorer clinical and social outcomes [7]. Seventy percent of young people experiencing mental health difficulties in high income countries do not receive evidence-based treatment at an appropriate age [8]. In the UK, mental ill health is the largest cause of disability contributing up to 22.8% of the total burden, a greater health burden than other major health diseases [9]. The cost of mental ill health is estimated to be in excess of £16 billion for depression and anxiety alone. This economic burden is also rising exponentially. Pre-pandemic analyses projected the total societal costs of depression to reach US$ 16.0 trillion by 2030, a cost comparable to that of cardiovascular disease [10]. Emerging data suggest an additional post-pandemic increase in burden and treatment need among young people [6].

Improving the mental health of children and young people is a national and international imperative [11-12]. It is also a national research priority, with the James Lind Alliance setting 10 specific priority areas for mental health in children and young people including a focus on mental resilience and identifying what self-help and self-management resources work [13].

COVID-19 has significantly impacted on the mental health of children and young people. There are a myriad of government/policy, third sector/VCSE and academic reports published signaling the concern for mental health and well-being among adults and young people [14-16]. While the focus on transforming services to meet the needs of young people with poor mental health has been a policy imperative in the UK since 2015 [17], the pandemic has highlighted and exacerbated the gap between the needs of young people and the solutions on offer. The current pandemic presents an opportunity to develop preventative solutions which are cost-effective in the short- and longer term. Such solutions have the potential to support young people today to become healthier future generations of adults [18-20].

Mental health literacy (MHL) is defined as ‘knowledge and beliefs about mental disorders which aid their recognition, management or prevention.’ It includes i) the ability to recognise disorders; ii) awareness of the types of professional help and treatments available, iii) knowledge of effective self-help strategies; iv) knowledge and skills to give ‘first-aid’ and support to others; and v) knowledge of how to promote mental wellbeing and prevent mental health disorders [21]. In adults, low levels of mental health literacy have been found to be associated with higher rates of

mortality [22]. Systematic reviews examining the effectiveness of mental health literacy interventions for adolescents demonstrate their potential value as health promotion and prevention tools [23-24].

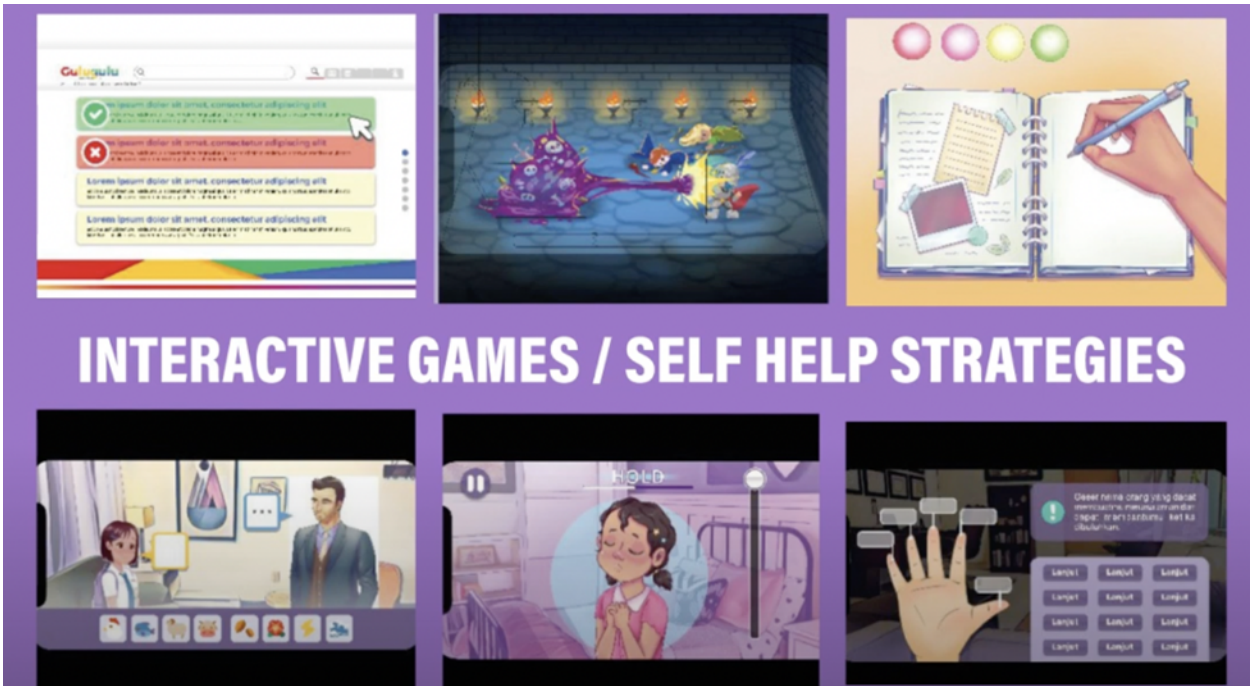
Inadequate mental health literacy in adolescents significantly increases the risk of developing moderate-severe depression [25]. Encouragingly, adolescents demonstrate a strong preference for peer and family support over professional support, suggesting that universal mental health literacy programs may have benefits for both primary and secondary disease prevention [26]. School-based psycho-educational interventions are effective in reducing stigma, promoting young peoples' mental health knowledge, and increasing mental health literacy but require but rely on educational engagement, leadership and delivery support at a local level [27]. There is a dearth of co-produced and self-directed digital mental health literacy interventions for young people in the UK.

Overview of the technology: Stepped care prevention and treatment approaches, where psychological interventions are delivered in different steps according to need, are considered an optimal solution to reduce the burden on health systems [28]. Our solution is a mental health prevention intervention designed to reduce the burden on health systems through better self-management of mental health and timely intervention through improved recognition and effective help-seeking.

We have co-adapted and extended an interactive resource, originally developed in Indonesia with MRC funding (IMPeTUs MR/R012741/1), for use in school and community health settings in the UK. We have co-produced training materials for facilitators, educational materials for parents, and implementation resources.

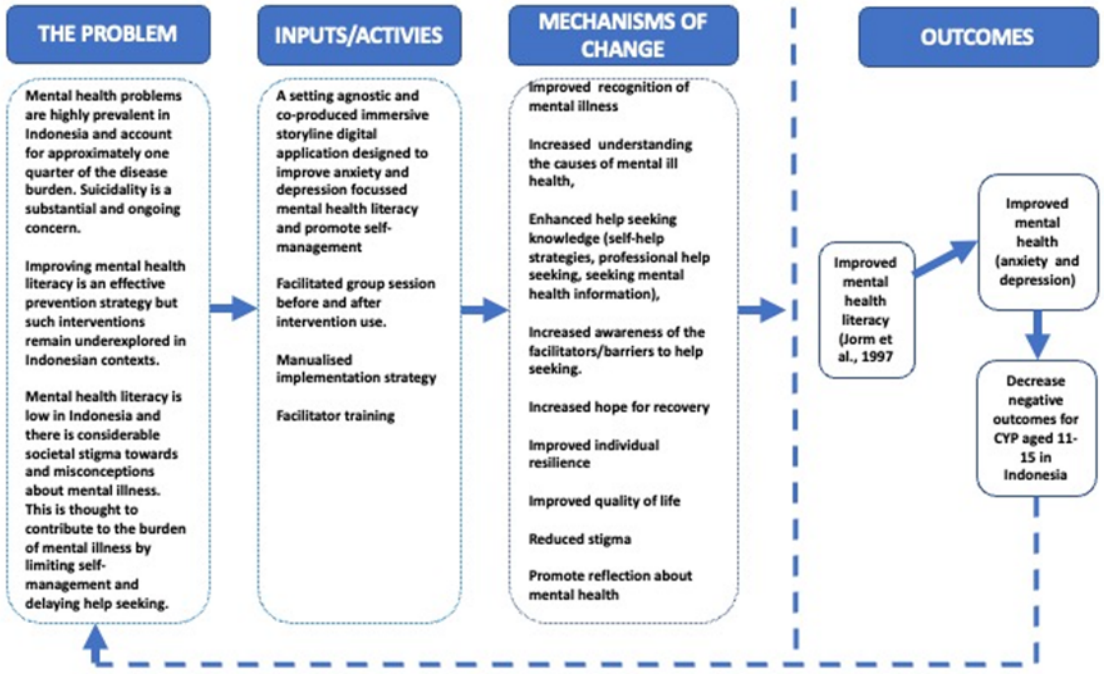
The IMPeTUs intervention includes an immersive story line digital game for CYP in which children play as a character facing mental health challenges [28]. Their decisions affect the direction of the game and outcomes. The storyline format is interspersed with interactive games and activities to promote engagement and support the development of self-help strategies. CYP also participate in facilitated group discussions before and after playing the game to enable discussions about the issues raised in the game. Our preparator work has allowed for the existing intervention content to be adapted for use in the UK and for additional material to be co-produced with CYP, parents, professionals and other stakeholders. This includes an additional intervention book, a training toolkit and evidence-based implementation strategy to optimise use in the UK.

Figure 1: Screenshots of interactive elements of the intervention



Proof of concept for our candidate intervention comes from Patient and Public Involvement (PPI) feedback in the co-design and initial testing (n=8) and evidence from 9 ongoing case study evaluations (n=90 CYP) which suggests our intervention is accessible, acceptable, and implementable to CYP. A theory of change underpinning the current intervention can be found in Figure 1.

Figure 1: Theory of change



We have co-adapted this intervention for use with UK adolescents and will co-produce a protocol for definitive evaluation of our intervention. This will include a randomised control trial and mixed method process evaluation to evaluate the clinical and cost effectiveness of our intervention in line with MRC guidelines for the evaluation of complex interventions.

Value proposition - Benefits to patients and the healthcare system: Our co-adapted intervention is evidence based, co-produced and developmentally appropriate. These features of intervention development maximise the likelihood of implementation effectiveness amongst UK adolescents aged 12-14. This age range was chosen as a direct result of PPI activities undertaken as part of the development of this grant. This age range corresponds to key stage 3 in the UK educational system, is pre-exam curriculum stage and is also relevant in terms of mental illness prevention as the peak period of onset is in the mid to late teens.

Conceptual frameworks identify health literacy as a critical mediator of health and functional outcomes [30]. Systematic reviews and effectiveness studies demonstrate that mental health promotion interventions, when implemented effectively, can have lasting, positive effects on health [31,32]. Longitudinal, population-based cohorts (N= 7857) have demonstrated a relationship between lower mental health literacy and higher mortality rates in older adults [22] and identified mental health literacy as a significant predictor of psychological and pharmacological treatment engagement [33]. Reductions in morbidity and mortality will be mediated by individual, social and system-level variables, especially those that increase health behaviour and/or health service engagement.

MHL skills have consistently been shown to be associated with improved health outcomes and social determinants of health. The available evidence suggests improved recognition and knowledge about mental illness and appropriate help can improve help seeking in children and young people. This is important given studies show that as little as one third of adolescents seek appropriate treatment for mental health problems; timely and appropriate help seeking in early adolescence is critical given its association with reduced likelihood of mental disorder in later older adolescence and later life [34]. Further, poorer MHL has been associated with increasing mental illness among adolescents [35].

Adolescents express preference for peer and family/community support rather than professionally led services which indicates that our intervention may have considerable benefit for improving MHL [26]. There is good evidence to indicate components of effective digitally delivered interventions include active ingredients such as tailoring to specific populations, evidence-based content, video illustration, quizzes and other interactive features [36]. The design of the current MHL intervention is based on these components of effective engagement and digital implementation.

The project will produce freely available evidence-based guidance to maximise widespread adoption, implementation and reach for communities. This will include guidance on the universal and culturally specific features of the MHL intervention to support co-adaption of the intervention for other high-income and low-income communities according to local population needs. We will work with local health and care partners to make resources available via existing networks, including training and best practice knowledge hubs to encourage wide roll-out of the programme deliverables.

The focus of our MHL intervention is prevention, building community capacity, reducing health inequalities and better mental health. These align with Public Health England strategy priorities (2020-2025) [37]; therefore we will be well placed to submit an application to NIHR Public Health Research funding streams. The current application will assure funders that we have developed an optimal strategy for implementation and definitive evaluation to embed and sustain the intervention.

4. STUDY OBJECTIVES

Aim: To evaluate the feasibility/acceptability of an RCT to assess the clinical and cost effectiveness of our co-adapted intervention.

Objectives:

- To train 4-6 facilitators to deliver our co-adapted intervention.
- To recruit 40 young people (four groups of ten, across four sites) to participate in a trial to evaluate the feasibility of a cluster-randomised controlled trial to determine the clinical and cost-effectiveness of our intervention by quantifying participant recruitment, retention and 3-month follow up rates.
- To determine intervention acceptability and identify from multiple stakeholder perspectives the barriers and facilitators to implementation.

- To examine the applicability (content-validity) and acceptability (full and partial completion rates, sensitivity to change) of proposed trial outcome measures and the need for additional CYP prioritised outcomes.
- To collect outcome data to inform parameters for a fully-powered trial, including the identification and standard deviation of the proposed outcomes measure needed to estimate trial sample size.
- To co-produce with stakeholders a protocol for definitive evaluation of our intervention.

5. STUDY DESIGN AND PROTOCOL

The MRC recommends feasibility testing to ensure new interventions can be implemented prior to undertaking definitive evaluations through fully powered randomised controlled trials [44].

Design: A multi-site, cluster-randomised feasibility trial with nested process evaluation.

Target population: 40 CYP aged 12-14, attending school and community settings (study sites) in Greater Manchester. This age range was chosen following PPI consultation as it corresponds to key stage 3 in the UK educational system, is pre-exam curriculum stage and is relevant in terms of mental illness prevention as the peak period of onset is in the mid to late teens. Parents/guardians (n=6-10), professionals (n=6-10) and facilitators (n=4-6) will also participate alongside CYP participants in the nested process evaluation.

Participants must have capacity to consent (checked at each assessment point) and be able to read and write in English to engage with study materials. Translation of materials is not possible in the current study but will be prioritised in a future study should our intervention show promise. CYP participants need to have access to a smartphone/tablet to use the intervention.

Setting: Education and community settings in Greater Manchester.

Sample size: Our feasibility trial will not formally test intervention effect so a formal power calculation is not appropriate. Instead, sample size has been selected to allow us to assess key feasibility outcomes (recruitment, retention, intervention uptake) and to allow sufficient replications of the study protocol to highlight barriers to completion in the main trial. The sample size will also allow us to estimate differences in means for intervention outcomes to within 0.25 standard deviations.

Recruitment: Four sites (schools/ community venues) will be recruited to the study. All eligible CYP in participating sites will be invited to take part. Educational professionals and community leaders (facilitators) will issue study information to potential participants and obtain CYP assent and parental consent and contact information and collect CYP baseline measures. Direct invitations and information sheets will be available at participating sites so that interested participants can enquire about the study directly.

Randomisation: In this study, 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 have been recruited at that cluster, to prevent allocation bias. The allocation

sequence will not be revealed to the other study investigators. Outcome data will predominantly be self-report.

Intervention: Our intervention combines an interactive individual game in conjunction with pre-post facilitated group discussions. Our candidate intervention will be co-adapted in phase 1 and additional content and materials co-produced with a range of stakeholders including CYP, parents, professionals and community members.

Group-delivery is a low-cost delivery model which can derive additional benefits through peer-to-peer support. Systematic review and meta-analysis [49-50] suggests that engaging students in activities such as games, simulations and group work is more effective than relying solely on didactic methods. We will align the structure of our intervention with current evidence [51-53] supporting the effectiveness of short-term programmes for mental health education and mental health first-aid. Frequency, duration and content of the intervention will be recorded by facilitators and reviewed in phase 2 facilitator and CYP interviews to explore whether treatment was delivered as intended.

Minimum levels of intervention require engagement in each of the chapters of the intervention for a minimum of 1 h each and participation in a facilitated group session before and after the intervention (minimum 5-6 hours in total).

The intervention will provide a range of techniques to improve mental health literacy and promote self-management, e.g. cognitive reframing, distraction and/or the substitution of more adaptive behaviours. Intervention content will be standardised via a manual. Intervention facilitators health and community workers will be trained by a multidisciplinary team, comprising co-applicants Lovell, Dubicka and a PPI representative.

Fidelity: Frequency, amount and content of the intervention will be recorded by the facilitators and reviewed in CYP interviews to explore whether treatment is delivered as intended.

Comparator: Our comparator is assessment only. We will ascertain the range and variability in usual care. The frequency, amount and type of health services accessed by intervention and control arm participants will also be recorded. The control group will be offered access to the intervention at study end.

Feasibility outcomes: The primary outcomes are feasibility outcomes. We will assess CYP recruitment and retention rates, intervention uptake and engagement rates, and the variability and potential floor/ceiling effects in our proposed patient outcome measures. CYP outcomes will be measured as baseline (prior to randomisation), post-intervention (or at approximately 6 weeks post-randomisation for control group participants) and 3-month follow-up.

Clinical outcomes: The primary clinical outcome measure will be a version of the mental health literacy scale, the Knowledge and Attitudes to Mental Health Scale (KAMHS). Additional measures will include the short version of the Mood and Feeling Questionnaire (MFQ), the World Health Organisation Five Well-Being Index (WHO-5), the Revised Children's Anxiety and Depression Scale (RCADS), the Family Cohesion and Satisfaction with Communication sub-scales of the Family Adaptability and Cohesion Evaluation Scale (FACESIV), and the SF-36

quality of life questionnaire. We will assess the feasibility of these different outcome measures as part of our feasibility trial.

At baseline, CYP demographics and psychiatric history will be recorded.

Analysis: As this is a feasibility trial, analysis will be mostly descriptive.

We will identify the number of study referrals, consents to research contact, and calculate cumulative and monthly recruitment rates. We will examine referral and recruitment rates between different sites (e.g. education and community settings) and recruitment routes (e.g. professional or self-referral).

The proportions of target sample size achieved, of participants who start and engage in the intervention, and the proportion retained in the study and providing outcome data will be calculated. Descriptive statistics will assess the completeness and variability of participant and cost outcome measures at each point.

We will undertake exploratory comparisons of intervention outcomes on an intention-to-treat basis, recognising that these analyses will be underpowered. These will focus on plausible ranges for effect sizes as indicated by 95% confidence intervals, and will be analysed with adjustment for the corresponding baseline measure of the outcome, in order to improve precision. We will attempt to control for clustering in this analysis by including a random intercept in a mixed model, although the small sample size may prove prohibitive. If this analysis can not be realised, we will adjust for site as a fixed effect. We will also present an adjusted mean difference (95% CI) based on ANCOVA (adjusted for corresponding baseline value of the outcome, with no adjustment for site).

Feasibility success criteria: See success criteria outlined below:

Progression criterion: Willingness of participants to be randomised

- Red: Recruit < 60% of required sample.
- Amber: Recruit 60-80% of required sample.
- Green: Recruitment > 80%.

Progression criterion: Retention in intervention arm

Participants will be considered retained in the intervention arm if they are available for assessment at 3 month follow-up.

- Red: Retain < 60% of participants in the intervention arm at 3-month follow-up
- Amber: Retain 60-80% of participants in the intervention arm at 3-month follow-up
- Green: Retain > 80% of participants in the intervention arm at 3-month follow-up.

Progression criteria: Uptake of intervention

Participants will be considered to have suitably engaged with the intervention if they take part in each of the chapters of the intervention for a minimum of 1 h each and participate in a facilitated group session before and after the intervention (minimum 5-6 hours in total).

- Red: Engage <60% of participants at the requisite level described above.
- Amber: Engage 60-80% of participants at the requisite level described above.
- Green: Engage >80% of participants at the requisite level described above.

Process Evaluation: We will use the MRC process evaluation model [44] to explore the delivery and reach of our intervention and understand barriers/enablers to roll-out.

Qualitative interviews 1-2 months post-intervention will explore the acceptability of trial procedures and the feasibility of our intervention with CYP, parents/guardians, professionals and facilitators. Interview schedules will be informed by the Theoretical Framework of Intervention Acceptability (TFA) [55] and the Consolidated Framework for Implementation Research (CFIR) [56].

Purposeful maximum variation techniques will be used to sample trained intervention facilitators (n=4-6), parents/guardians (n=6-10), CYP (n=10) and relevant professionals (n=6-10). Maximum variation sampling will ensure participants of different ages, genders, baseline scores and outcome are included.

Interviews will be digitally recorded, transcribed verbatim and analysed using Framework Analysis, with coding undertaken blind to trial outcomes. Analysis will encompass inductive and deductive coding informed by NPT and CFIR.

We will host a one-day workshop with our PPI advisory panel, to synthesise learning and revise our preliminary theory of change and use this to guide intervention refinement and optimise referral and evaluation protocols.

Patient and public involvement: We have consulted project partners and engaged 8 young people in a group discussion to inform the development of our application. CYP felt strongly that the age range for our intervention should be reduced from 11-16 in our original expression of interest to 12-14 in the current application as they felt it would not be possible to produce an intervention which was developmentally appropriate and sufficiently engaging for all CYP aged 11-16. Participatory discussion also confirmed that many young people have little or no contact with health services and may not be regularly attending education institutes. Optimal recruitment strategies for phase 2 will be collaboratively derived with attendees at phase 1 workshops. We also embedded multiple engagement strategies (social media, community advertising, online resources) to generate interest in our study and maximise study deliverables in line with CYP feedback. Our proposed PPI advisory group chair led the design and delivery of our 3-minute video pitch.

We will draw on our experience to develop patient and public involvement (PPI) informed by NIHR Involve guidelines including:

- a track record of PPI in mental health research;
- an award-winning profile for innovative co-production;
- established links with community networks including underserved groups in Greater Manchester.

Our strategy is underpinned by the standards set out in the UK Standards for Public Involvement in Research framework (https://sites.google.com/nihr.ac.uk/pi-standards/standards).

We will establish a PPI advisory panel comprising key stakeholders e.g. CYP, carers, health and education policy leads and professionals, VCSE representatives. Based on prior experience, 2 sub-panels will be established: one for young people and one for adults (n=5-6/each). Sub-panels will meet quarterly. To facilitate communication, a member of the young person's panel will attend adult meetings.

Advisory panel members will receive an induction, supplemented throughout the project with support from the research team, and peer-support through PPI meetings/ad hoc arrangements. All PPI representatives will be linked with local support networks and training and development opportunities.

Optimising inclusivity and diversity requires acknowledgement of the under-representation of ethnic minorities, women and other minority groups. We have adopted an integrated participatory approach to ensure diversity in study design, participation and partnership working. We will work directly with CEI collaborators and advisory groups to identify and overcome barriers that may restrict engagement and participation in research by different groups. Our core team, specialist collaborators and project partners have access to a wide range of CYP/family networks and Third Sector organisations working directly with underserved groups. Two members of our CEI advisory group will be elected to act as Equality and Diversity champions.

We will identify service-user researchers to contribute to qualitative and quantitative research, and lead meetings on intervention development and intervention co-adaptation. Research training and mentorship will be provided to CYP (e.g. qualitative research). Brooks, Lovell, Bee have led NIHR and MRC programmes developing and delivering research education for MH service-users and carers. The course is cited as good practice and included in the NICE shared learning database. It has been adapted and implemented amongst CYP PPI contributors in the UK.

6. STUDY PARTICIPANTS

Inclusion criteria:

CYP- Aged 12-14 years attending school and community settings (study sites) in Greater Manchester. Young people will also need access to a smartphone/ tablet to use the intervention.

Professionals/facilitators- Those working with CYP taking part in the evaluation of the intervention

Parents/guardians- Those whose children are taking part in the evaluation of the intervention

Exclusion criteria:

Those unable to give informed consent/assent.

Recruitment:

Facilitators will identify eligible CYP participants and issue direct invitations to these participants to be part of the trial. The direct invitation will either inform the CYP to contact the facilitator (a staff member of the study site) for further information (for an information pack) about the study or

already include an information pack about the study. The information pack will include a contact details form, and information sheets and assent/consent forms for both CYP and their parent/guardian for completion.

In the two study sites of the intervention arm, facilitators will identify professionals who work directly or indirectly with the CYP taking part in the evaluations of the intervention, and issue direct invitations to these individuals to be part of the interview/focus group discussion. Parents/guardians of the CYP in the intervention arm will also be sent direct invitations to be part of the interview/focus group discussion. Again, potential participants will then be issued with consent forms, information sheets and contact details forms.

Participants who withdraw consent:

Participants can leave the study at any time for any reason if they wish to do so without any consequences. If a participant wishes to withdraw from the intervention, we will ask whether they would be happy for us to continue to collect outcome data from them, again making it clear that there will be no negative consequences should they decline. As the statistical analysis is planned according to intention to treat principle, participants that discontinue the intervention but still provide outcome data will be included in the analysis in the group that they were allocated to.

7. DELIVERABLES

Our proposal builds on strong partnerships between the University of Manchester and Arsa Kids Game Designers. We will adopt an inclusive, proactive approach to dissemination with high stakeholder participation.

By study end, we will have built strong relationships with study partners and enhanced research capacity amongst PPI contributors. We will have explored the barriers and enablers to the implementation and uptake of our co-produced intervention and public, professional and policy levels. We will have co-produced an acceptable and developmentally appropriate digital intervention to support mental health literacy and promote self-management amongst young people aged 12-14 in the UK along with associated training and educational materials and implementation and sustainability resources.

We will have co-refined an evidence-based theory of change model to strengthen and underpin the future evaluation and use of our intervention in the UK and established new collaborative partnerships with professional and lay communities. We will have worked in partnership to initiate the implementation of our evidence-based intervention in diverse local settings. We will have evaluated the implementation, uptake and acceptability of our intervention and examined the feasibility of future evaluation. We will have increased the capacity of educational and community workers to deliver our intervention and refined training materials and educational materials for parents.

At programme end, we will have co-produced a digital application to promote mental health literacy and self-management for young people aged 12-14 along with manualised protocols to support high quality definitive evaluation of our intervention. We will have explored the acceptability of our intervention and ascertained the feasibility of its evaluation and co-developed

a strategy to optimise its scalability and sustainability. We will have strengthened mental health advocacy in study sites through PPI capacity building and developed strong networks to take this intervention forward.

8. DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Trial participant data will be captured using questionnaires on paper forms issued by facilitators at study sites. These paper forms will be stored at the study site in a locked cabinet. Researchers will liaise with facilitators to collect paper forms as soon as practically possible, within four working days of data collection. Paper forms will be transferred to a locked cabinet at the University of Manchester campus site.

Quantitative data will be entered from paper copies to Excel in tabular format (with one row per research participant). This data will be anonymised as participants will be referred to using a study ID number in the Excel dataset. The data will be subject to data validation by the trial statistician. The database will be set up during the recruitment phase of the trial, and will be stored on centrally-hosted, resilient and backed-up storage space, in line with Research Council UK Research Data Management guidelines. This storage space will only be accessible to study investigators and researchers.

Qualitative data from interviews/focus group discussions will be recorded using an encrypted digital recorder. If the interview/focus group is conducted via Zoom, Zoom software will be used to record audio. These recordings will be uploaded to secure university servers at the first possible opportunity and deleted from data capture devices.

We will use direct quotations from participants in study dissemination activities. Transcripts will be anonymised once transcribed and all identifiable information removed. Any quotes that are used will not identify participants in any way.

Personal data - written and audio recordings of consent will contain participant names. Manual consent forms will be stored securely in a locked filing cabinet in a locked office in the University of Manchester and will only be accessible to the study team. Audio recordings of informed consent will be stored on secure university servers which are backed up regularly and will only be accessible to the study team. We will need to collect and temporarily store email addresses and phone numbers in order to arrange/conduct interviews. Participants who opt in to obtain a summary of the results of the study will also provide their email addresses. These will be stored in a database securely on UoM servers and securely deleted once summaries have been sent out.

Interviews will be transcribed by an external transcription company (First Class Secretarial) with existing relationships (e.g. confidentiality agreement) with UoM. Audio-files will be sent via secure file transfer provided by the company. Manual consent forms and hard copies of study data will be stored securely in a locked filing cabinet in a locked office in the University of Manchester and will only be accessible to the study team.

Audio-recordings of informed consent and audio recordings of interviews also constitute personal data and will be stored on secure university servers which are backed up regularly and will only be accessible to the study team. Quantitative data will be entered into SPSS for analysis and stored securely on UoM servers.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the EU General Data Protection Regulation 2016 and Data Protection Act 2018.

Transcripts will be anonymised upon receipt from the transcription company with participants being allocated a non-identifiable pseudonym. Consent/assent forms will be stored securely and separately within a locked office at the University of Manchester and will not be linked to pseudonyms.

Both hard copy and audio-recordings of informed consent will be securely destroyed 5 years after study end. Audio files will be destroyed immediately upon receipt of transcript. The University of Manchester policy on storage of anonymised research data is 5 years after the last publication of the study or for 10 years, whichever is greater. Participant contact details will be destroyed immediately at study end, unless the participant wants a summary of the results. Summaries of results will be sent out within one year of study end and then contact details will be destroyed.

Study data and material may be looked at by individuals from the University of Manchester, or from other regulatory authorities, for monitoring and auditing purposes, and this may well include access to personal information.

The data will be only analysed by the study team at the University of Manchester or remotely using secure access to anonymised datasets.

Anonymised electronic data will be stored securely on University of Manchester servers which are backed up regularly and will only be accessible to the study team for 5 years after the last publication of the study or for 10 years, whichever is greater. It will then be securely deleted in line with guidance from IT at UoM.

9. STATISTICAL CONSIDERATIONS

Sample size and description of the statistical analysis are described in Section 6. A Statistical Analysis Plan document will be authored by the trial statistician during the recruitment phase of the trial.

10. DATA MONITORING AND QUALITY ASSURANCE

We have embedded clear line management structures and lines of accountability in our study to minimise risks to research delivery and financial administration. Research and financial governance will be led from the University of Manchester, drawing on professional finance services and established infrastructure and regulatory systems.

Chief Investigator Brooks has substantial experience of leading NIHR and UKRI funded mental health grants, including the development and pilot testing of mental health literacy interventions.

Brooks will be responsible for overall leadership and will be accountable to the project funders. A full-time programme researcher (Helen Brierley) will coordinate day-to-day operations, accountable to the CI. Ardisasmita will lead on digital product development.

The programme management group (PMG) will consist of all applicants (Lovell, Bee, Brooks, Wilkinson), collaborators (Dubika), the programme researcher (Brierley) and software developer (Ardisasmita), who will meet bi-monthly to discuss progress. A PPI advisory panel (n=8-10) will meet quarterly; a named chair (DC) with lived experience of childhood depression has been identified.

An Implementation Reference Group (IRG) will be convened (comprising 8-10 health, educational and third sector leads and the PPI Chair), who will meet quarterly to advise on product implementation and optimise sustainability.

A data monitoring committee will not be convened for this trial, owing to the short study duration.

11. ETHICAL CONSIDERATIONS

Approvals:

We will involve 40 CYP participants in our feasibility trial. To ensure that our intervention is acceptable, feasible and meets the needs of its end-users, it is imperative that these activities seek input from a range of stakeholders, including children and young people, teachers, family members, and relevant professionals. Ensuring the rights and welfare of all those who volunteer to participate in our programme is a fundamental principle of ethical research. Approval will be obtained from the University of Manchester’s Research Ethics Committee.

Risks:

The key ethical issues for the programme include principles of confidentiality, participant anonymity and informed consent/assent to participate in research. We will follow guidelines developed by the International Ethical Research Involving Children (ERIC) project. Parental consent for CYP participation will be collected along with assent from the CYP who wish to be involved in our study where necessary. Age-appropriate written consent and assent forms will be developed in collaboration with our PPI advisory group. We will also develop parental and child-friendly versions of our participant information sheets (PIS). Those designed for CYP will provide information in simple and engaging terms to promote and enhance understanding between study participants and researchers. It will be made clear to all participants that participation is voluntary and that they can withdraw from the study at any time, without any detrimental impact.

Training will be provided to researchers working on the study in relation to ethical guidelines and they will be provided with a detailed protocol approved by the relevant ethical committees and our PPI advisory group. The project will satisfy all NIHR and University of Manchester's (UoM's) requirements and guidelines on data management, sharing, security and ethics, including the UoM's Research Data Management policy, which is part of UoM's framework for good research practice.

12. ADVERSE EVENT RECORDING

The IMPETUS adverse event procedure for reporting serious and non-serious adverse events will be followed by all research staff and facilitators. This procedure includes the timeframes for reporting, the appropriate contacts for reporting and their contact details. The completed adverse event forms will be kept in the Trial Master File.

13. STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

14. FUNDING

This study is funded by the National Institute of Health Research (NIHR) – i4i Connect 5 & Children and Young People's Mental Health scheme (Ref: NIHR20382)

15. PUBLICATION POLICY

Dissemination: We will co-develop with our advisory panel, leaflets, video/podcasts and a social-media strategy, to engage professionals and patients in our research, raise awareness of mental health literacy and self-management, stimulate the demand for our intervention and disseminate our learning.

Local, national and international dissemination will occur via CYP, professional and research-orientated conferences. We will publish in high-impact journals, with our PPI contributors and researcher contributing as lead and co-authors. If our findings suggest a full trial is feasible, we will work with our PPI panel to develop the full trial protocol.

We will ensure that our communications are clear and concise and take account of the needs and preferences of different groups. Our most successful engagement and dissemination mechanisms have been inclusive and proactive with high stakeholder participation. In the UK we have co-produced theatre productions, animations and podcasts with patients and families to raise public and professional awareness of our work.

16. INTELLECTUAL PROPERTY

A core deliverable from our programme will be an interactive, evidence-based digital application to enhance mental health literacy in young people in the UK. In addition to the publications in peer-reviewed journals, we will work closely with voluntary agencies to disseminate our learning and include our intervention into existing and future programmes.

The research materials and methodology proposed in this application build on previous academic and clinical work conducted by the applicants. Development of our PPI research methods course was funded by the NIHR who are willing for this work to be utilised and disseminated. New knowledge generated by the research team will be synthesised and used to underpin the development of a new mental health literacy intervention and accompanying implementation

guidance, training materials and educational resources. We have discussed with the University of Manchester's Intellectual Property Centre (UMIP) how best to capture, manage and utilise IP. The programme's applicants, in collaboration with UMIP will be responsible for the recognition and capture of new IP and its subsequent dissemination and adoption. To maximise impact and reach, we will make all our training and intervention resources freely available to UK schools, health services and third-sector equivalents participating in research. A patent search did not reveal anything that would restrict our freedom to operate. There is no background IP to be used that is owned by anybody other than the applicants and study partners. To the best of our knowledge, our deliverables are novel and represent new resources of relevance to UK health, education and voluntary sectors.

The current IMPeTUS intervention is currently used for research purposes only and it will always be free to use in this capacity with appropriate licensing approval. We have an agreement with Arsa Kids with regards to future licensing agreements for ongoing research. The main application will always be free of charge for users. However, future strategies for commercialisation to be considered in the current application are 1) payment to unlock additional content, 2) payment to customise central avatars, 3) use of advertisements inside the game with the option to remove these with payment. An optimal sustainability strategy will be developed during the current 12-month study.

Sustainability is a key focus of our proposed study as detailed by the implementation focus throughout phases 1 and 2. From the outset we will examine the barriers and enablers to the use of our intervention from the perspective of multiple relevant stakeholders. Data collection and analysis will be underpinned by theories of implementation science to maximise the systematic uptake of research findings into routine practice and support the future uptake and evaluation of our proposed intervention. The intervention will be hosted by Arsa Kids and maintained by in-house game designers to ensure sustainability in the long-term.

Community engagement, capacity building, and cooperation between users, commissioners, and local stakeholders are built into the implementation of our intervention and are integrated into a whole system approach that ensures its long-term sustainability. IMPetUS includes facilitated aspects that can be delivered through existing local services or voluntary and community organisations.

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