Statistical analysis plan for IMPeTUs UK: A cluster-randomised controlled feasibility trial for a digital mental health literacy intervention for young people aged 12-14 in the United Kingdom.

Version 1.0

Trial registration: XXXXXXX

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Introduction

Background and rationale

Approximately half of all mental health disorders begin by the age of 14. 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. In England, one in eight children (13%) aged 5-19 have a mental disorder. 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.

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. Systematic reviews examining the effectiveness of mental health literacy interventions for adolescents demonstrate their potential value as health promotion and prevention tools.

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 children and young people (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 preparatory 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.

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.

Study methods

Trial design

A two-arm, cluster randomised controlled feasibility trial with 1:1 allocation. All individuals at a study site will be recruited before the site is randomised to the intervention or control arm, to ensure allocation concealment.

Randomisation

Sites will be randomly allocated (cluster-randomisation) to one of the two arms with 1:1 allocation using block randomisation (block size of 4).

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. 40 CYP will be recruited, with 10 at each of 4 sites. The sample size will also allow us to estimate differences in means for intervention outcomes to within 0.25 standard deviations.

Confidence and Significance

As a feasibility study, the aim is not to test for a treatment effect. We will present 95% confidence intervals for comparisons of outcomes between groups, focussing on the range of plausible effect sizes that are compatible with the study data.

Estimand, compliance and protocol violation

As a feasibility study, the primary aim is not to estimate a treatment effect. There will be exploratory analyses of clinical outcome measures however. These will be conducted with the intention of estimating the effect of being allocated to the intervention, regardless of compliance or protocol violation (historically referred to as "intention to treat", recently referred to as the "policy estimand").

Interim analysis

There will be no interim analyses.

Missing data

Missing covariate data

The only measures to be adjusted for in the analysis of clinical outcomes are site (as a random effect) and the baseline value of the outcome variable. Site will be complete, and we anticipate that baseline outcome values will be complete or nearly complete. We would use mean imputation in the event that a baseline outcome value was missing, which is a valid approach in the context of a randomised trial.

Missing outcome data

Feasibility outcomes are defined regardless of compliance or loss to follow-up, and so no missing data strategy is required. Analysis of clinical outcomes will be conducting assuming that missing data are missing at random given adjustment for site and baseline value of the outcome.

Study population

Screening data

No formal analysis of factors associated with participation are planned.

Eligibility

The proportion of eligible participants from those screened, and reasons for ineligibility, will be tabulated. Note given the liberal inclusion criteria in the present study, the number of persons screened who are ineligible is anticipated ot be low.

Recruitment and Attrition

The numbers screened, eligible, consenting, participating and contributing outcome data will be presented in the form of a CONSORT flow diagram.

Baseline Characteristics

Baseline characteristics, including participant demographics and baseline values of the clinical outcome measures will be summarised overall and by randomised group.

Analysis

Feasibility outcomes

Feasibility outcomes are CYP recruitment and retention rates, intervention uptake and engagement rates. These will be assessed by calculating 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. Feasibility success criteria are defined as follows.

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.

Clinical outcomes

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 linear mixed model, although the small sample size may prove prohibitive. If this analysis cannot 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). No transformations of the clinical outcomes are planned prior to analysis. We will use the feasibility study to learn about any distributions of the outcome measures in this setting.

Subgroup analyses

None.

Sensitivity analyses

None planned.

Additional analyses

None planned.

Safety data

Serious adverse events will be analysed descriptively, with frequencies presented by treatment group.

Software

Analysis will be conducted in R.