

Developing precision computerised cognitive behavioural therapy (cCBT) for adolescent depression: a pilot and feasibility protocol for the SPARX-UK trial

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Abstract

Background:

A serious game (SPARX), developed in New Zealand and incorporating cognitive behavioural therapy (CBT) principles, has been shown to help reduce symptoms of depression and anxiety in adolescents with mild to moderate depression. However, SPARX has never been trialled in the United Kingdom (UK) and there have been issues relating to low engagement when it has been used in a real-world context.

Aims:

To conduct the first pilot and feasibility randomised controlled trial (RCT) in England to explore the use of SPARX in child and adolescent mental health services (CAMHS) and school-based Mental Health Support Teams (MHSTs). The trial will explore whether SPARX supported by an e-coach (assistant psychologists) improves adherence and engagement compared with self-directed use. The trial results will be used to inform optimal mode of delivery (SPARX supported vs. SPARX self-directed), calculate an appropriate sample size for a full RCT, and to decide which setting (CAMHS vs. MHSTs).

Methods:

A total of 120 adolescents (11-19 years) will be recruited for this three-arm study. Adolescents recruited from CAMHS and MHSTs across England will be randomised to receive either SPARX with human support (from an e-coach), SPARX self-directed or a waitlist control group. Assessments will be conducted online at baseline, week 4, and 8-10-weeks post-randomisation. The assessments will include measures which capture demographic, depression (Patient Health Questionnaire modified for adolescents [PHQ-A]) and anxiety (Revised Child Anxiety and Depression Scale [RCADS]) symptomatology, and health-related quality of life data (EQ-5D-Y and proxy version). Analyses will be primarily descriptive. Qualitative interviews will be undertaken with a proportion of the participants and clinical staff as part of a process evaluation, the qualitative data gathered will be thematically analysed. Finally, feasibility data will be collected on recruitment details, overall study uptake and engagement with SPARX, participant retention, and youth-reported acceptability of the intervention.

Discussion:

The findings will inform the design of a future definitive RCT of SPARX in the UK. If shown to be effective, an online serious game utilising CBT principles ultimately has the potential to improve the provision of care within the UK's health services.

Trial registration:

ISRCTN: ISRCTN15124804. Registered on 16 January 2023, <https://www.isrctn.com/ISRCTN15124804>.

Key messages regarding feasibility

What uncertainties exist regarding the feasibility?

The feasibility of using an online serious game intervention (SPARX) for adolescents with mild to moderate depression is currently unknown in the United Kingdom (UK). Furthermore, the viability of utilising this intervention in different settings and whether there is an added benefit of limited human support on engagement rates is unknown and, in particular, the impact on recruitment rates, retention rates, study completion rates, acceptability of the intervention, and scalability to power a subsequent RCT.

Background

Adolescent depression

Depression among adolescents and young people has become a pressing public health issue with global prevalence rates showing that elevated self-reported depressive symptoms for adolescents was 34% and the prevalence for major depressive disorder and dysthymia was 8% and 4%, respectively [1] with increased rates reported as a result of the COVID-19 pandemic [2]. Depression has serious adverse effects on social, academic, and family functioning [3] with early onset depression being associated with higher rates of suicide attempts and suicide compared to individuals with no psychiatric disorders [4,5]. Notably, suicide is the fourth leading cause of death in young people globally [6]. The overall impact of untreated depression can be devastating for a young person and their family as well as costly to society. Early onset mental health problems are estimated to cost United Kingdom (UK) society £70-100 billion per year [7]. Therefore, it is imperative that adolescents are given timely treatment for their symptoms, not only for their mental health and outcomes but also to benefit the socioeconomic welfare of society more generally.

Barriers to treatment

There are effective interventions available for adolescent depression with current National Institute for Health and Care Excellence (NICE) guidelines recommending cognitive behavioural therapy (CBT) as a first-line treatment for adolescents with depression [8]. Despite the growing prevalence of adolescent depression, access to evidence-based treatment such as CBT is low amongst all demographics [9] with only 25% of adolescents in the UK receiving appropriate treatments [10]. Studies have also noted considerable barriers for adolescents accessing care [11]. Due to their affinity with technology, promising developments that may benefit some adolescents are online or digital health interventions (DHIs). One approach that has been shown to be effective for adolescents with depression is computerised CBT (cCBT), with randomised controlled trials (RCTs) and meta-analyses demonstrating their efficacy [12,13]. As a result, cCBT is recommended by NICE as part of a stepped-care model for the management of adolescents with mild to moderate depression [14]. With progress in digitised technology and programming algorithms, cCBT has become more interactive and aesthetically attractive to young people, particularly with the advent of 'serious games' [15]. The idea behind 'serious games' (and gamification more generally) is for there to be a primary purpose other than pure entertainment (e.g., learning and

behaviour change) [16]. The hope is that serious games (or adding gaming elements to an intervention) will make cCBT more engaging and user friendly whilst addressing important issues.

The evidence for SPARX

One serious game in cCBT format is called SPARX (Smart, Positive, Active, Realistic, X-factor thoughts). Originally developed in New Zealand [17], where SPARX is publicly available, it uses CBT principles and techniques to help address symptoms of depression (and anxiety) in adolescents with mild to moderate depression. SPARX is designed as a self-help intervention where the user navigates their own way through a virtual universe, developing CBT skills as they progress. This involves participants undertaking a series of challenges to restore the balance in a fantasy world dominated by GNATs (Gloomy Negative Automatic Thoughts). The first RCT using SPARX was a non-inferiority trial in New Zealand where SPARX was compared with treatment as usual (TAU) amongst adolescents seeking help for their depression [17]. Per protocol analyses showed that SPARX was not inferior to TAU (face to face therapy) with a post intervention mean reduction on the primary outcome measure (Children's Depression Rating Scale-Revised) of 10.32 for SPARX compared to 7.59 for TAU. Improvements were maintained at 3-month follow-up. It was also reported to be acceptable and safe.

Subsequent trials of SPARX have been conducted on adolescents with depression in New Zealand. For instance, Fleming et al. [18] conducted a pragmatic RCT and found there were significantly greater reductions in depression and anxiety symptoms from baseline to week 5 for the SPARX group compared with a wait-list control, with gains being maintained at 10-week follow-up amongst young people excluded from mainstream schools. Lucassen et al. [19] found a significant decrease in depression and anxiety symptoms in sexual minority (e.g., lesbian, gay and bisexual) adolescents using the rainbow version of SPARX from pre to post intervention, which were maintained at follow-up. Most sexual minority participants said they would recommend the adapted version of SPARX to a friend (80%) and thought it would appeal to other young people (85%). Finally, a stepwise cohort study design by Fleming et al. [21] used an adapted resilience version of SPARX, but the sample was too small ($n=19$) to evaluate the intervention as planned.

Three trials using SPARX have been completed outside of New Zealand to date. One RCT used SPARX as a depression prevention tool, and was conducted in the Netherlands [20]. This showed no difference between SPARX and other conditions including group-based CBT offered in-person (and most notably a monitoring control) and, similarly, a small cluster RCT conducted in Ireland found no significant effects compared with a no intervention control [21]. The most recent trial was a depression prevention study carried out in Australia [22]. This cluster RCT found that participants in the adapted resilience version of SPARX condition showed significantly reduced depression symptoms on the Major Depression Inventory relative to the control group at post-intervention ($d=0.29$) and 6 months post-baseline ($d=0.21$) but not at 18 months post-baseline ($d=0.33$).

Taken together, the evidence for SPARX is limited and primarily restricted to studies undertaken in Australasia. Evaluations conducted elsewhere have not found clear benefits of SPARX compared to no treatment controls [20,21]. Therefore, we cannot assume that the evidence for SPARX internationally has been established. Digital interventions are context dependent and positive findings in one nation may not translate to other countries [23]. Thus, there is a need to evaluate SPARX outside of its region of origin and the present study is the first UK trial to do this.

The issue of engagement with DHIs

Whilst DHIs for adolescents such as SPARX have shown encouraging outcomes, there have been several issues relating to low engagement, which in the context of health services refers to a lack of uptake and poor adherence (i.e., continued use) related to an intervention. For example, a study evaluating a self-directed internet-based mental health intervention (MoodGYM) in senior high schools found that only 8.5% (45/527) of participants logged on to use MoodGYM, with very few proceeding beyond the first part of the programme [24]. Moreover, a systematic review of cCBT found that just 56% of participants completed all of their therapy sessions [25]. The importance of engagement with DHIs cannot be overstated, as research suggests that greater adherence and engagement is generally associated with more positive clinical outcomes [26–28].

Several studies have found that engagement and adherence to an intervention may relate to certain characteristics to do with the intervention, the user, or the condition targeted. For example, reasons for poor engagement in online therapy have included participants finding the intervention too demanding and being unable to find time to complete tasks [29], preferring face-to-face therapy with a human therapist [30], and experiencing problems with their computer or poor internet access [31]. One study evaluating youth engagement with an app for depression found participating in a monitored session significantly improved adherence. In addition, other predictors of greater adherence were sex (being female), living in a rural area and lower pre-test anxiety [35].

For mental health apps in particular, reasons identified for low engagement include poor usability (i.e., difficult to use or unenjoyable content), lack of user-centric design (i.e., not meeting the needs of the user), concerns about privacy and trust, and the unhelpfulness of apps in emergencies [32]. Creating and maintaining interest for adolescents is of key importance when designing DHIs. Indeed, Ritterband et al. [33] argued the need for three main components (or what are often termed “essential ingredients”) to provide a more immersive and engaging environment: (i) Multimedia (e.g., audio, visual, and image components); (ii) Interactivity; and (iii) Personalisation. Although these components were not specified for any age group in particular, adolescents tend to prefer audio, visual and interactive programs to keep them engaged [34]. In terms of personalisation, Ritterband et al.’s [33] suggestion is consistent with the literature in that several reviews demonstrate that tailoring leads to improved engagement and better outcomes in attitude, behavioural intention, and behaviour change [35], although there is a lack of evidence regarding the optimal form of personalised support in terms of DHIs [36].

User engagement appears to be crucial in successfully implementing digital interventions and for positive outcomes. Reduced adherence means patients do not benefit from the full effects of the treatment, which impacts on recovery and in turn leads to increased healthcare costs [37]. Behaviour change mechanisms within interventions are unlikely to have any effect if participants are only briefly exposed to them [38]. Moreover, much of the literature to date has been on factors affecting engagement and adherence for adult populations and there is a paucity of studies in youth populations. More research needs to be conducted in this area, as factors that may affect adult populations may not necessarily relate to a youth population. As developers of DHIs need to understand what the essential components are to better engage users, more studies need to carry out rigorous evaluations to precisely determine these factors. We will address this in our work by trialling a novel supported and personalised version of SPARX to evaluate whether there is an added benefit of human support on adherence and engagement rates.

Aims

This pilot and feasibility RCT aims to evaluate SPARX for adolescents with mild to moderate depression in England to inform the development of a future definitive RCT.

Objectives

The feasibility objectives of the trial are to examine the use of SPARX in particular settings (Child and Adolescent Mental Health Services [CAMHS] and school-based Mental Health Support Teams [MHST]) and whether supported SPARX has an added benefit on adherence and engagement. Feasibility of the intervention will be determined by the proportion of participants completing at least four modules of SPARX. More than 80% completion would be considered feasible, whereas below 40% will be considered not to be feasible. For the likely outcome of completion rates falling between these limits, detailed analysis of trial data, including process evaluation qualitative interviews, will be used to inform the approaches that may improve adherence rates in subsequent trials. Value added by the supported SPARX intervention will be considered in terms of how much greater, if at all, the adherence rates are. The pilot objective is to estimate the variance of change in the primary outcome measure (Patient Health Questionnaire modified for adolescents [PHQ-A] [39]) to calculate an appropriate sample size for the full definitive trial.

Methods

Trial design

This trial is a single blind, three-arm, pilot and feasibility randomised controlled trial, with an embedded process evaluation. The study settings are CAMHS and MHSTs. CAMHS are National Health Service (NHS) centres that assess and treat young people with emotional, behavioural, or mental health difficulties and MHSTs are a recent government initiative designed to support young people with mental

health issues in education settings. All CAMHS and MHSTs will be recruited from England. CAMHS and MHSTs will recruit 120 participants (aged 11-19 years) in total as the unit of randomisation. Participants will be followed up at weeks 4 and 8-10 after baseline.

Our protocol follows the Consolidated Standards of Reporting Trials (CONSORT) extension for randomised pilot and feasibility trials [40] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [41]. Please see Additional file 1 for our SPIRIT checklist.

Recruitment procedure

Across all sites (Patient Identification Centres [PICs] and research site), the procedure will be as follows: the initial approach will be from a member of the patient's usual care team (i.e., CAMHS/ MHST clinician/practitioner) and information about the trial will be given to potential participants. All individuals conducting initial patient identification at sites will be given the inclusion/exclusion criteria for the study. The usual care team will provide the adolescent and their parent/guardian a participant information sheet. The parent/guardian participant information sheet will have a QR code and website link to an online consent to contact form specifying their preferred mode of contact (e.g., telephone or Microsoft Teams). Parents/guardians who provide consent to contact will be contacted by a member of the research team who will explain the study process and ascertain initial screening eligibility over the phone/Microsoft Teams to determine the presence of any obvious exclusion criteria. The consent will be done via videoconferencing to provide some assurance of identity. It is a requirement that parents are consented to the trial as they will be completing the Development and Well-Being Assessment (DAWBA) [42] and other measures. However, there will be a dual process for participation, with under 16-year-olds providing child assent along with their parent/guardian providing written consent. Over 16-year-olds can provide their own written consent.

Members of the clinical care team, or clinical research study officers at study sites, will be asked to record the numbers of patients approached (and to record the reason for non-participation). For those who consent to contact, parents'/patient's contact details will be provided to the research team. Reasons for non-participation will be recorded (where given) for CONSORT purposes.

Screening

After the research team receive the consent to contact form and contact details, they will arrange a telephone/videoconferencing screening appointment with the parent or adolescent (if they are 16 years or over). This screening approach has shown to be effective in previous trials of similar interventions [43,44]. At this point the following details will be recorded: contact details, age of depression onset and brief clinical history, previous contact with health care services, previous/current medications or therapy for depression, access to internet/PC/Mac/laptop/smartphone, other diagnoses, and inclusion/exclusion criteria. The researcher will outline the time commitment involved in the trial at this stage. Adolescents meeting any exclusion criteria or not meeting all inclusion criteria at this time point will not be invited to the baseline assessment. If the adolescent is not eligible for the study or does not

wish to attend a baseline appointment, the researcher will record the reason for non-participation. Reasons for not attending baseline assessment will be recorded for CONSORT reporting.

Baseline and consent appointment

Families who meet the initial eligibility screening criteria and who are willing to attend a Microsoft Teams baseline appointment will be asked to complete a DAWBA [42] assessment online prior to the baseline appointment.

Adolescents and one of their parents/guardians will be invited to attend a remote baseline appointment via Microsoft Teams. At this appointment, the details collected over the telephone/videoconferencing for the patients will be checked. The researcher will go through the consent process with the adolescent and their parent/guardian, and they will be consented into the trial. During this assessment, the researcher will send a live link to participants on Microsoft Teams where the participant will have an opportunity to read the information sheet again and have a consent form to complete. The researcher will complete a paper or online version of an intellectual disability screening measure (Child and Adolescent Intellectual Disability Screening Questionnaire [CAIDS-Q]) [45] and the PHQ-A with adolescents to confirm eligibility. The researcher will then complete paper or online versions of all baseline measures with eligible participants. The participant will be given their study ID at the point of randomisation when they are enrolled into the study. A log will be kept matching screening IDs with study IDs. Randomisation will occur via REDCap at or just after the baseline appointment, prior to starting the trial.

Ethical approval

The SPARX-UK trial obtained ethical approval from the South West - Cornwall & Plymouth Research Ethics Committee on 15 December 2022 (Ethics Ref: 22/SW/0149) and has been registered with ISRCTN, trial number 15124804.

A schematic diagram of the trial design is shown in Fig. 1.

Study participants and sample size rationale

Participants in this trial are the adolescents and it is also a requirement that one of their parents/guardians are consented to the trial. One of the aims of this study is to estimate the variance of the primary outcome measure (change in PHQ-A) so that a sample size can be computed for a subsequent trial of intervention efficacy. There are multiple methods suggested for sample sizes in pilot studies, but here the numbers are aimed at overall smallest sample size (pilot plus subsequent trial), for which 40 per arm is reasonable [46].

Study population

Study participants will be adolescents aged 11 to 19 years with mild to moderate levels of depression.

Eligibility criteria

Inclusion criteria

Adolescents will be eligible for the study if:

- They are aged 11 to 19 years on the date of consent (researcher confirms with parent at screening) referred to CAMHS or MHST
- Presented at CAMHS/MHST for treatment with symptoms indicative of mild to moderate depressive disorder
- Able to provide written consent or, if under age 16, written parental consent and written/verbal child assent (confirmed at baseline)
- Has access to a computer with internet access or smartphone or device to use SPARX and must be able to install and log in (confirmed at baseline)
- They and their parent can read and write in English (confirmed at baseline)

Exclusion criteria

Adolescents will not be able to enter the study if ANY of the following apply:

- Clinical concerns that depression is too severe to benefit from SPARX and self-harm/suicidal risk is too high
- Intellectual disability or physical limitations precluding the use of SPARX (confirmed at baseline via CAIDS-Q)
- Had (in past three months) or currently having treatment with CBT/interpersonal therapy (confirmed at baseline)
- Has another major mental health disorder (e.g., psychosis, eating disorder) where the primary focus was not depression as confirmed by a clinician or DAWBA
- Safeguarding concerns that are not currently being managed (i.e., the young person is the subject of a safeguarding investigation) as confirmed by a clinician

Trial setting

This is a single-centre trial that will be run online across England. Our main research site is Oxford Health NHS Foundation Trust with approximately four PICs covering several regions of England. Adolescents will be followed up at weeks 4 and 8-10 weeks after baseline.

SPARX intervention

SPARX is a DHI for young people with mild to moderate depression and was designed as a stand-alone self-help intervention that can be accessed online. SPARX was created to address the gap in adolescent depression treatment options, and it uses CBT techniques to address symptoms of depression. SPARX uses elements of fantasy gaming to engage the user in experiential learning with a Guide acting as a 'virtual therapist' to explain how to use the skills learnt in the gaming environment into 'real life'.

At the beginning and end of each module, the user interacts, in the first person, with a character called the 'Guide', who provides psychoeducation, gauges mood, and sets and monitors real-life challenges, equivalent to homework. The user is then transported to the 'game world' to undertake interactive challenges. Upon successfully completing each module, the user returns to the Guide who puts the skills learnt in the game world into a 'real life' context and sets a 'challenge' (i.e., CBT homework task) to facilitate skill generalisation. SPARX uses evidence-based CBT skills that focus on six 'gems of power' specifically: "Relax" (relaxation training); "Do it" (e.g., behavioural activation); "Sort it" (e.g., social skills training); "Spot it" (recognising or naming cognitive distortions); "Solve it" (problem solving); and "Swap it" (e.g., cognitive restructuring).

There are 7 modules (or levels) in total and each one lasts approximately 30 minutes. A breakdown of the core content of each module is outlined in Table 1.

After consulting with various stakeholders, the version of SPARX being used for this trial will retain the voice actors from the original New Zealand version. However, there will be differences from previous studies and the version available to the New Zealand public, including:

- No in-app measures or associated feedback.
- The added ability to replay previously completed modules.
- Localisation of specific guidance (e.g., signposting to UK-based support services).

Human support

Participants randomised to receive supported SPARX will receive personalised guidance from an e-coach throughout their use of the intervention. The e-coach will provide limited contacts (less than 15 minutes per module) according to the e-coach manual, as well as adherence reminders in case a module is not completed within 7 days. The feedback to be provided has the primary purpose of supporting, encouraging and, motivating participants, as well as promoting adherence to the intervention. In the supported arm, e-coaches will provide personalisation options to participants. This will include a choice of 1 or 2 modules being released per week and the contact modality (e.g., Teams/phone/email). E-coaches will also be able to access basic SPARX usage data for the participant(s) they are supporting throughout the trial. The e-coaches are Psychology Assistants, who are graduates in Psychology and all work within CAMHS. They will be supervised by a Professor of Psychology with extensive clinical expertise working with adolescents (PS) and a researcher with a clinical background and extensive

knowledge of SPARX (ML). The use of support within SPARX has never been explored in any previous trials.

Outcomes

Primary outcome measures

Feasibility measures: This includes adherence to intervention, numbers approached/numbers consented and randomised, errors in randomisation, drop-out rates at each time point, outcome measure completion rates, instances of unblinding, protocol deviations, and qualitative information on acceptability and feasibility. This data will be collected throughout the trial by researchers and used to inform the feasibility of conducting a future RCT.

Pilot outcome: The variance of the change in *Patient Health Questionnaire modified for adolescents (PHQ-A)* [39] from baseline. PHQ-A is adapted from the PHQ-9 and modified for adolescents. It is a 9-item measure with each measure rated on a 4-point scale that assesses the severity of depressive disorders and episodes) in children and adolescents. The measure is completed by the adolescent. Each item asks the adolescent to rate the severity of their depression symptoms during the past two weeks. The total score can range from 0 to 27, with higher scores indicating greater severity of depression. There are four additional items which relate to difficulties performing everyday tasks, suicidal thoughts and attempts however these are not scored. The questionnaire has established validity and reliability [39]. A 5-point change is viewed as clinically significant [47]. The PHQ-A was chosen as the primary outcome measure, as this was the preferred option of our Patient and Public Involvement (PPI) group over other commonly used measures of depression.

Secondary outcome measures

Revised Child Anxiety and Depression Scale (RCADS) [48]: The RCADS is a 47 item self-report questionnaire that measures symptoms of depression and anxiety in children and adolescents. The RCADS consists of six subscales helpful in screening children and adolescents for high prevalence disorders, including: separation anxiety disorder, social phobia, generalised anxiety disorder, panic disorder, obsessive compulsive disorder (OCD), and major depressive disorder. A Total Anxiety Scale score (sum of the 5 anxiety subscales) and a Total Internalizing Scale score (sum of all 6 subscales) are derived, with higher scores indicating increased symptom severity. The RCADS has demonstrated good structural validity, reliability, and convergent and discriminant validity [48]. The RCADS is a widely used instrument within CAMHS and MHSTs.

EQ-5D-Y and EQ-5D-Y (Proxy version) [49,50]: The child-friendly EQ-5D version (EQ-5D-Y) was introduced by the EuroQol Group in 2009 as a more comprehensible instrument suitable for children and adolescents and is based on the EQ-5D-3L. The EQ-5D-Y comprises the following five dimensions: mobility, looking after myself, doing usual activities, having pain or discomfort, and feeling worried, sad, or unhappy. Each

dimension has 3 levels: no problems, some problems, and a lot of problems. The adolescent is asked to indicate his/her health state by selecting the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the adolescent's health state. The EQ VAS records the adolescent's self-rated health on a vertical visual analogue scale where the endpoints are labelled "The best health you can imagine" and "The worst health you can imagine". The EQ-5D-Y (Proxy version) asks the caregiver (the proxy) is to rate the child's/adolescent's health-related quality of life in their (the proxy's) opinion. Both measures have established validity and reliability [49,50] and will be used in this study to measure health related quality of life.

Clinical Global Impressions Scale (CGI)-Severity/ Improvement [51]: The CGI provides an overall clinician-determined summary measure that considers all available information, including a knowledge of the patient's history, psychosocial circumstances, symptoms, behaviour, and the impact of the symptoms on the patient's ability to function. The CGI comprises two companion one-item measures evaluating the following: (a) severity of psychopathology from 1 to 7 and (b) change from the initiation of intervention on a similar seven-point scale. The CGI-S asks one question: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?" which is rated on a seven-point scale (from 1=normal, not at all ill to 7=among the most extremely ill patients). The CGI-I consists of one item: "Compared to the patient's condition at admission to the project this patient's condition is..." and is rated from 1=very much improved since the initiation of intervention to 7=very much worse since the initiation of intervention. The questionnaire has established validity and reliability and is widely used in clinical research [52].

Concomitant interventions: To assess what other treatments/interventions the adolescent is accessing during the study period; parents will be asked to complete a short questionnaire, which asks about current diagnoses and treatments/interventions/medication in progress. This will be completed at baseline as part of the demographic questionnaire completed with the researcher, and then again at 8–10-week follow-up with the researcher via telephone/ Microsoft Teams.

Usage data: Indices such as number of modules completed, time spent using SPARX, number of logins, and time spent with e-coaches (if in supported arm) will be recorded throughout the trial and will be used to measure adherence and engagement as part of the process evaluation.

Adverse events

Adverse events/side effects will be recorded by the PHQ-A and on a modified version of the side effects scale developed by Hill and Taylor [53]. The scale consists of 17 short items relating to common side effects (such as headaches, anxiety, sleep, and low mood). The participant is asked to respond on a 5-point scale ranging from "not at all" to "all the time" to describe the presence of each item. The adverse events/side effects scale will be completed at baseline (to ascertain presence of these symptoms prior to the intervention), mid-intervention and 8–10-week follow-up.

Screening measures

Development and Wellbeing Assessment (DAWBA) [42]: The DAWBA is a package of interviews and questionnaires completed by parents designed to generate ICD-10 and DSM-IV / DSM-5 psychiatric diagnoses for children and young people. The DAWBA computer algorithm estimates the probability of having a psychiatric disorder in bands of <.1%, .5%, 3%, 15%, 50% and >70% based on large community-based population studies [42], the top two levels have been shown to reliably indicate presence of a clinician-rated diagnosis and can be used as an alternative to clinician-rated diagnoses in research studies [54]. The DAWBA has established validity and reliability [42]. The parent reported DAWBA starts with a Strengths and Difficulties Questionnaire (SDQ) [55]. If the participant is later enrolled in the trial, this will be used as their baseline SDQ. DAWBAs that score people as being likely to have any conditions will be second reviewed by the Chief Investigator (and medical expert) to ascertain that they should be excluded from the trial. It must be noted that the DAWBA is not being used in this trial to diagnose depression but to establish possible comorbid disorders and determine study eligibility (i.e., whether to exclude potential participants from the study).

Child and Adolescent Intellectual Disability Screening Questionnaire (CAIDS-Q) [45]: The CAIDS-Q is being utilised to determine the presence of intellectual disability at baseline. The questionnaire contains seven-items (two on literacy, one on telling the time, one on friendships, two on previous contact with specialist services and current educational support and one on tying laces). They are answered in a Yes/No format by someone who knows the person well and some items can be tested directly with the adolescent (depending on age/communication). A total score is calculated which is converted to a percentage score. A cut-off (by age group) indicates if the child is likely to have an intellectual disability or not. The questionnaire has established validity and reliability [56].

Process Evaluation

The process evaluation will follow the Medical Research Council's (MRC) guidelines for evaluating complex interventions [57]. It will explore the components suggested in MRC guidelines, namely reach, dose, fidelity of implementation of intervention and make recommendations for adaptations for the future RCT. It will also examine the contextual factors and potential mechanisms underlying participant behaviour change and probe for any unexpected consequences.

Interviews will be conducted with adolescents (target $n \geq 30$) and parents of adolescents ($n \geq 30$) after they have completed their 8–10-week follow-up. Purposive sampling will be used so that a diverse range of views on the intervention are voiced. Interviews with e-coaches supporting the intervention (target $n \geq 3$) and clinicians recruiting to the study ($n \geq 5$) will be conducted during trial delivery. Online feedback from participants will also be analysed together with usage indices recorded as part of the online system such as total time spent with e-coach, number of modules completed and number of logins. A brief online questionnaire will be given to participants who drop out of the trial early to gain a more holistic overview of engagement with SPARX. A full process evaluation protocol will be published.

Table 2 outlines the completion time points for each outcome measure and who completes them.

Table 2. Baseline and outcome measures

Months post-randomisation	0	0	1	2
Time Point	Telephone/videoconference screening	Baseline	Mid-intervention (4wk)	Primary End point (8-10wk)
Consent		R (P+A)		
Randomisation		R		
PHQ-A		R (A/P)	A/P	R (A/P)
CAIDS-Q		R (A/P)		
RCADS		R (A/P)		R (A/P)
Screening for eligibility	R (P)	R		
SDQ & DAWBA (Conducted post telephone/ videoconference screen & prior to baseline)	P			
CGI-S/I		R (A/P)		R (A/P)
EQ-5D-Y		R (A)		R (A)
EQ-5D-Y (Proxy version)		R (P)		R (P)
Demographics		R (A/P)		
Concomitant interventions		R (A/P) *		R (A/P)
Adverse events		R (A/P)	A/P	R (A/P)
Interview (Process Evaluation)				R

Note: P = parent; A = adolescent; R = researcher; PHQ-A = Patient Health Questionnaire modified for adolescents; CAIDS-Q = Child and Adolescent Intellectual Disability Screening Questionnaire; RCADS = Revised Child Anxiety and Depression Scale; SDQ = Strengths and Difficulties Questionnaire; DAWBA = Development and Wellbeing Assessment; CGI-S/I = Clinical Global Impressions Severity/ Improvement.

*Taken as part of demographic questionnaire at baseline

Safeguarding and participant care

No significant risks to physical safety are anticipated; however, changes in depressive symptoms may occur in adolescents during the trial and cause psychological harm. Although a formal data monitoring committee is not required due to the minimal physical risks associated with the intervention, we will have an independent scientific advisory board throughout the trial. To ensure participant safety, adverse events will be recorded through completion of the PHQ-A completed by the adolescent at baseline, 4 weeks, and 8-10 weeks. An adverse event will be recorded where there is clinically meaningful deterioration from baseline on the PHQ-A. On the PHQ-A, a ≥ 5 point increase (i.e. moving one severity category) is regarded as clinically meaningful and thus an adverse event will be recorded when this occurs or where there is an increase of one, or more, points from baseline to follow-up (4 weeks and/or 8-10 weeks) on item number 9 or a positive response (i.e. 'Yes') on any of the two additional suicide items from baseline to follow-up.

Adverse events will also be recorded through the Hill and Taylor [53] side effects scale completed at baseline, 4 weeks, and 8-10 weeks by the parent/guardian. A score on any item that is equal-to-or-greater-than 2 ("about half the time") and greater than their baseline score is recorded as an adverse event. The Chief Investigator, who is a medical expert, will be alerted if any of these occur. Any related or unexpected serious adverse events will be reported to the Research Ethics Committee.

Patient and public involvement

The initial study grant was reviewed and received feedback from a panel of young people with lived experience of accessing services for depression/mental health conditions. Since January 2022 a group of Patient and Public Involvement (PPI) members has met regularly to advise and guide the research. The group comprises one parent and three young people with lived experience relevant to the study. PPI has shaped the design of the trial and its dissemination in the following ways:

- Reviewing and selecting outcome measures, including choosing our primary outcome measure (PHQ-A).
- Co-development of study materials including participant information sheets, the parent manual, and instructions on downloading SPARX.
- Involvement in discussions regarding trial and recruitment processes.
- Completing the intervention and providing feedback on content and all modules.
- Attending ongoing meetings to provide PPI perspective and assist with troubleshooting (e.g., recruitment and retention).
- Guiding interview topics and shaping questions for the process evaluation interview schedules.
- Providing feedback on signposting services and the design for accessing signposting within the intervention.

The PPI group mainly contributes remotely to enable involvement from members who are not geographically close, and all members are paid for their time in line with National Institute for Health and Care Research (NIHR) involvement guidelines. Their advice and input will be sought throughout the trial

including participation in facilitating and analysis of the interviews with young people and parents, co-creating lay summaries, and other dissemination materials including involvement in conference presentations and as co-authors on publications.

Statistical methods

Quantitative analyses

Summary statistics will be presented for this trial using Microsoft Excel. No interim analyses are planned. Summary statistics, proportions and standard deviations will be given to estimate the change in PHQ-A, variance, and recruitment rates (per month) in different settings and whether there is compliance (defined as the percentage completing 4 levels or more of SPARX). The primary pilot outcome is the variance in change in the primary outcome measure (PHQ-A). A full analysis plan will be made available before unblinding of data and anything that is not planned will be considered data dependent and considered speculative [58].

Qualitative analyses

Qualitative interviews with adolescent participants receiving the online intervention and their parent will capture general feedback on their experiences of taking part in the trial as well as satisfaction and acceptability of the intervention as part of the process evaluation. We will explore, with both participants receiving the intervention and intervention supporters (i.e., the e-coaches), their experiences of receiving and supporting the intervention online, mechanisms of impact, barriers, and facilitators to taking part in the intervention and in their continued involvement. Referring clinicians and e-coaches will also be interviewed to gain their experiences of being involved in the trial.

All interviews will be audio-recorded and transcribed by a University of Nottingham approved external transcription company. Transcripts will be anonymised before analysis. Interviews will be analysed using reflexive thematic analysis [59] and, more broadly, themes will be organised using the framework method [60]. All analysis will be conducted using NVivo 12. Coding and organisation of codes will be cross-checked within the research team to ensure validity.

Discussion

This study is the first of its kind to investigate an online serious gaming intervention called SPARX for adolescents with mild to moderate depression in the UK. By offering a remote intervention to adolescents with depression in England we hope to offer an alternative intervention based on CBT principles for adolescents that can become mainstream and thus improving provision of care within the health service. Given the complexities and barriers with which adolescents with depression can present and face, including not being able to access treatment or avoiding face-to-face interventions due to stigma, online interventions are an especially important treatment pathway to consider going forward. With cCBT

recommended in NICE guidelines for the treatment of adolescents with mild to moderate depression, this trial is especially important. Should the SPARX-UK trial prove effective, it will pave the way for a new and accessible type of intervention for adolescents across the UK. Furthermore, by refining our recruitment process, data collection procedures, and running of the intervention itself, from this trial, we aim to prepare for a much larger subsequent RCT in which we will compare outcomes between our SPARX intervention (either supported or self-directed) with care as usual.

Abbreviations

CAIDS-Q: Child and Adolescent Intellectual Disability Screening Questionnaire

CAMHS: Child and Adolescent Mental Health Services

cCBT: Computerised Cognitive Behavioural Therapy

CGI-S/I: Clinical Global Impressions-Severity/Improvement scale

DAWBA: Development and Wellbeing Assessment

DHI: Digital Health Intervention

GNATs: Gloomy Negative Automatic Thoughts

MHST: Mental Health Support Team

NICE: National Institute for Health and Care Excellence

NHS: National Health Service

PHQ-A: Patient Health Questionnaire modified for adolescents

PIC: Patient Identification Centre

PPI: Patient and Public Involvement

RCADS: Revised Child Anxiety and Depression Scale

RCT: Randomised Controlled Trial

SPARX: Smart, Positive, Active, Realistic, X-factor thoughts

TAU: Treatment as Usual

Declarations

Ethics approval and consent to participate

The SPARX-UK trial obtained ethical approval from the South West - Cornwall & Plymouth Research Ethics Committee on 15 December 2022 (Ethics Ref: 22/SW/0149).

Consent for publication

Not applicable

Availability of data and materials

Not applicable, the manuscript does not contain any data.

Competing interests

The intellectual property for SPARX is held by UniServices at the University of Auckland. Any proceeds from licensing or selling SPARX outside of New Zealand will be shared in part with UniServices and Sally Merry, Karolina Stasiak, Mathijs Lucassen and two other co-developers (not involved in the current study). Kapil Sayal was an Expert Panel Member for the NICE Depression in Children and Young People Guideline Update Committee (CG28).

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Authors' contributions

CH wrote the grant application and acquired funding for the study. CH and PS conceived the study design. SM, KS, ML, and others designed the intervention. KK wrote the paper. CLH, CB, SD, CG, ML, SM, KapS, KirS, KS, CRT, ET, PS, CH critically reviewed the manuscript. The content of the manuscript has not been published or submitted for publication elsewhere. All authors have approved the final manuscript for submission.

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Table

Table 1 is available in the Supplementary Files section.

Figures

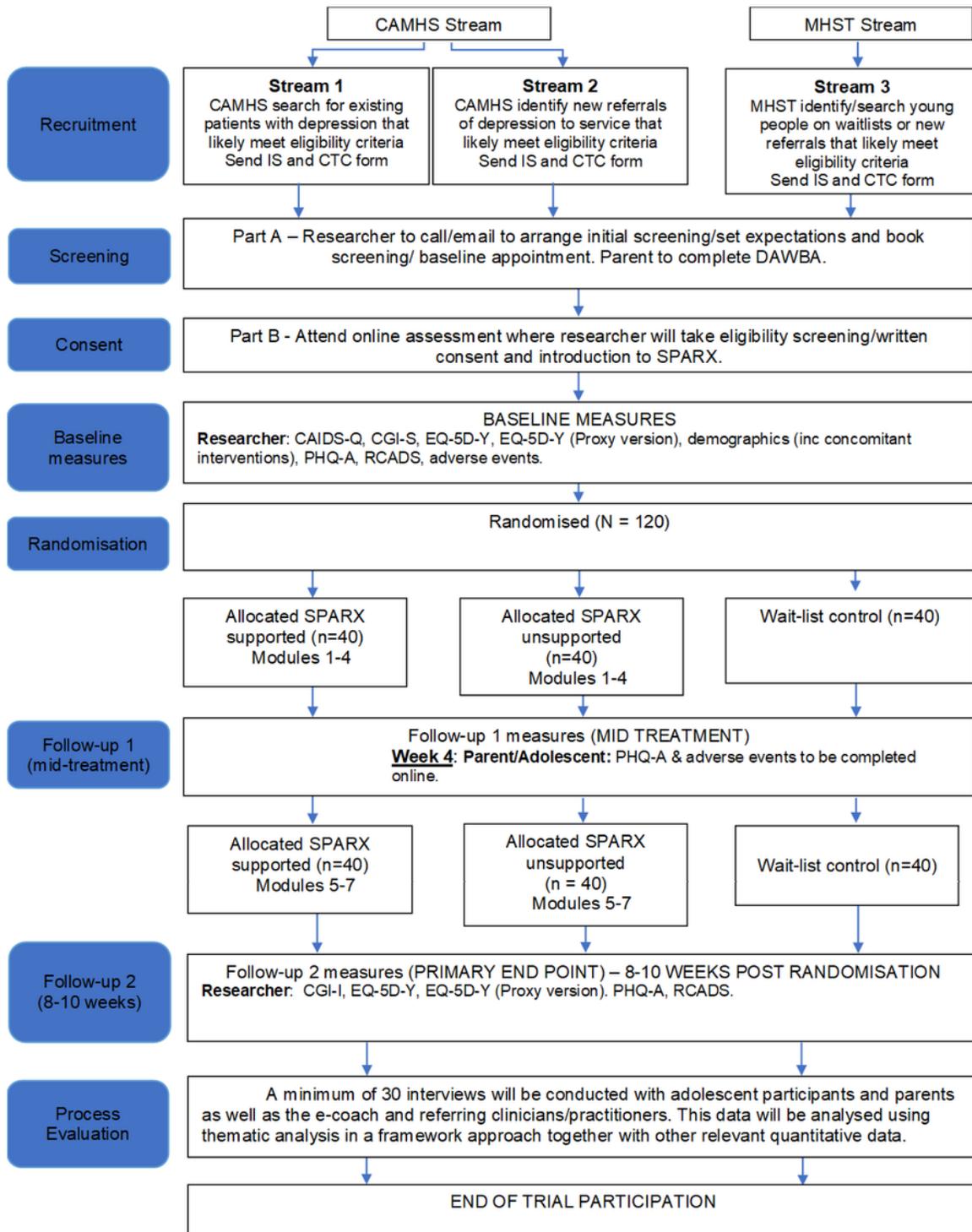


Figure 1

Schematic diagram of trial design

Note: CAMHS = Child and Adolescent Mental Health Services; MHST = Mental Health Support Teams; IS = Information Sheet; CTC = Consent to Contact; DAWBA = Development and Wellbeing Assessment; CAIDS-Q = Child and Adolescent Intellectual Disability Screening Questionnaire; CGI-S/I = Clinical Global

Impressions Severity/Improvement; PHQ-A = Patient Health Questionnaire modified for adolescents;
RCADS = Revised Child Anxiety and Depression Scale.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table1.docx](#)
- [SPIRITFillablechecklist15Aug2013.doc](#)