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# Computerised cognitive behavioural therapy for adolescent depression: a pilot and feasibility randomised controlled trial

**Submission date**
10/01/2023

**Recruitment status**
No longer recruiting

**Registration date**
16/01/2023

**Overall study status**
Completed

**Last Edited**
07/08/2025

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims

Adolescent depression is on the rise in the UK and so it's very important to find a good way of helping young people manage their symptoms. Currently, many young people with depression do not get the therapy they need because of long waiting lists within healthcare services. Young people who access computerised therapy may also not complete all the sessions or find it difficult to engage. In New Zealand, a team of researchers developed a way of supporting young people with depression by developing a computer game called SPARX. This involves the young person navigating their way through a virtual world as an avatar, meeting different characters, and learning various techniques to help manage their low mood symptoms. The researchers tested this online game in a large study where it appeared to work well and showed positive findings. SPARX has been tested in other countries where it also showed positive results. Now the game needs to be tested in the UK with people from different areas, different backgrounds, and different ages to make sure it is acceptable and useful to adolescents. Just because something worked well in a different country with different people, it doesn't mean the same would be true here. The research team are also looking to see if a supported version of SPARX is better at keeping young people engaged with the program rather than a self-directed version. To do this, a third of all adolescents will randomly be allocated to a waitlist group who will not have access to SPARX, a third to the original version of SPARX which is self-directed and a third to receive a supported and personalised version of SPARX in which an eCoach provides online human support alongside SPARX. A computer program allocates these groups randomly to ensure it is fair and to make sure the groups are the same to start with. None of the researchers or members of the care team will have any input into which group participants are placed in. The findings from this study will help us to further develop SPARX which will hopefully allow more young people to benefit from evidence-based interventions. This is a feasibility study (a practice run before doing a large-scale study). The study will help us find out more about how helpful young people with depression find additional support, and how it can be improved the support and SPARX going forward; if young people who have depression find this type of trial acceptable and whether they are willing to be randomly allocated to receive SPARX, or to be put on a waiting list; whether young people taking part can complete the questionnaires planned to be used, without difficulty; and, to estimate how many young people will be needed to recruit for

the larger trial. These changes can then be implemented before a larger study is started to ensure that the research meets the patient's needs.

Who can participate?
Families in England with a young person (aged between 11 and 19 years old) who experiences mild to moderate levels of depression. Both the young person and one parent/guardian will participate.

What does the study involve?
Once our research team receives consent to contact potentially eligible participants, one of the researchers will contact the person to arrange a suitable day and time to conduct an initial assessment by Microsoft Teams. Participants will be sent a link to complete the Development and Well-Being Assessment (DAWBA) questionnaire before attending a face-to-face Teams assessment. The DAWBA will ask for and collect information on the child's possible diagnoses. If the intervention is not suitable for the child from the information provided in the DAWBA form, the trialists will let them know. At the initial assessment on Teams, the researcher will go through various assessments and consent will also be taken at the beginning of the session. The assessments will include asking about the child's symptoms of depression and anxiety and whether the child has any learning difficulties. The assessor will also collect background information including recording the child's age, gender, ethnicity, and what other treatments, therapies, and medication the child is currently receiving. They will also ask for information about the parents' education and current employment, as well as the use of services over the last three months (such as the use of health services, voluntary services, and education services). If the child meets the study inclusion criteria they will be asked to complete more questionnaires online. It is expected that the whole Teams assessment will take approximately 1 hour.

The child will then be randomly allocated to one of the following groups:
1. Waitlist. The child will continue on the waitlist for CAMHS/MHST without getting access to SPARX. The parent and child will still be in the trial and will be asked to complete questionnaires after 4 weeks and again at 8-10 weeks.
2. SPARX only. The child will complete SPARX through their computer or mobile phone. SPARX consists of 7 online delivered levels which take approximately 30-45 minutes to complete. The child will be asked to complete 1 level a week for 7 weeks. Some of the levels contain tasks that the child has to practice in their own time. There are 7 levels to complete, and this usually takes about 7 weeks.
3. Supported SPARX with eCoach. This version of SPARX is the same as the above, but the child will also have support from a member of the team (called an "eCoach") and personalised to the child's preferences so they can choose how they wish to talk to their eCoach (e.g. email, text or video call), how often (e.g. 5 or 15 minutes per week), and how many levels the child wants to complete of SPARX each week.

The researcher will explain more about the SPARX intervention at the Teams assessment. After 8-10 weeks the child should have completed all 7 levels of SPARX. The child will still be able to access SPARX for a couple of months from when they started. However, they will no longer have access to the eCoach after the 8-10 weeks, so the child cannot send messages or emails to them.

If the child is randomised to the waitlist group, they will not have any access to SPARX, however, they will be given gift vouchers for completing the measures at different timepoints. While in the study (regardless of which group the child is in) the researchers would like to follow the child' s progress and will ask them to complete questionnaires at the start of the study and again at 4 weeks and at 8-10 weeks. During week 4 of the study, they will be asked to complete a quick

questionnaire about their depression symptoms, and any adverse effects that may have occurred. Altogether, these questionnaires will take about 10 minutes to complete. At 8-10 weeks, the child will be asked similar questions to the initial assessment. Additionally, at this point, the researchers may wish to interview the parent and the child for about 30 minutes by telephone or Teams. They will be asked about the support received (if they received any), the things participants found useful or most helped, the things they didn't find useful, and their overall views of SPARX.

What are the possible benefits and risks of participating?
We cannot promise the study will help the parent or the child but the information from this study will help to plan a larger study to test how effective SPARX is at supporting adolescents with depression. In the future, this could help improve access to evidence-based services for other young people with depression. No disadvantages or risks to the parent or the child are expected. Any interviews and appointments will be arranged at times to suit participants to not inconvenience them.

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

When is the study starting and how long is it expected to run for?
September 2021 to June 2025

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Camilla Babbage (Trial Manager), Camilla.Babbage@nottingham.ac.uk (UK)

# Contact information

### Type(s)
Scientific

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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Integrated Research Application System (IRAS)**
316644

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
CPMS 54175, IRAS 316644, Medical Research Council Grant Code: MR/W002450/1

# Study information

**Scientific Title**
Developing precision computerised cognitive behavioural therapy for adolescent depression: a pilot and feasibility randomised controlled trial (SPARX-UK)

**Acronym**
SPARX-UK

**Study objectives**
The purpose of the trial is to test the feasibility of conducting a future definitive randomised controlled trial. A process evaluation will be conducted concurrently with the trial to explain the findings and to gain in-depth perspectives of adolescent participants, parents/guardians of participants, eCoaches, and referring clinicians/practitioners.

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**

approved 15/12/2022, South West - Cornwall & Plymouth Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8019; cornwallandplymouth.rec@hra.nhs.uk), ref: 22/SW/0149

## Study design
Pilot and feasibility randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Mild to moderate depression

## Interventions
Current interventions as of 08/04/2025:
Study design and justification for the control arm
The study design is a single-blind pilot randomised controlled feasibility trial, with an embedded process evaluation. Participants will be followed up mid-intervention (4 weeks post-randomisation) and 8-10 weeks post-randomisation. In the intervention arms, participants receive 8-10 weeks of 7 levels of a serious game called SPARX delivered online via a website or app. One group will receive supported SPARX, where they will have human support from an eCoach who will be there to motivate and engage participants but will not deliver any therapy. Another group will receive purely self-directed SPARX (i.e., no human support). The team will compare the two SPARX groups as to how many levels they completed and whether they persisted with the game. In the control arm, participants will not receive SPARX during the trial.

Sample size
There are multiple methods suggested for sample sizes in pilot studies, but here the numbers are aimed at the overall smallest sample size (pilot plus subsequent trial), for which 40 per arm (Total sample size = 120) is reasonable.

Stages of the research
Participant recruitment is expected to start on 31st January 2023 and end on 31st March 2025. No interim analyses are planned. The final follow-up is scheduled to occur end of June 2025. Findings from the trial will undergo final analysis and interpretation between June 2025 and November 2025. Project management group meetings are scheduled once a month, with more regular weekly meetings between core research team members. The Digital Youth Scientific Advisory Board will meet to discuss the study's progress. There will be regular patient and public involvement throughout the trial to aid with recruitment and participant retention techniques.

Patient identification
Participants will be identified by 5 streams:
1. Clinicians at the main study site (Oxford Health) and our Child and Adolescent Mental Health Services (CAMHS) Participant Identification Centres (PICs) will inform potentially eligible patients about the study and seek their consent (via online or verbal methods) to provide their contact details to the research team.
2. Practitioners at our school-based Mental Health Support Teams (MHST) PICs will inform potentially eligible patients about the study and seek their consent to provide their contact

details to the research team.
3. GP practices will identify potential participants using an approved search of their database for appropriate participants. Staff at the GP will send study information via letter, email, or SMS. Parents/guardians can provide consent to be contacted through a QR code or website link. Those who consent will be contacted by the research team for further screening and consent.
4. MyHealthE (MHE), an online register of families referred to NHS CAMHS who have completed screening data and consent for contacts from approved research teams, will be used to identify eligible participants via the Clinical Record Interactive Search (CRIS) system and contact parents by email with study information to invite them to the study.
5. The NIHR BioResource will recruit participants from it's register of those who have agreed to take part in health-related research. Potential participants will be identified based on inclusion /exclusion criteria and invited by email or post to join the study, including study information. Interested parents will complete a consent to contact form ahead of having an initial screening appointment with the research team.
For those recruited from streams 3-5 (GPs, BioResource and MHE), prior to randomisation, a medical expert (the Principal Investigator) will review screening and baseline assessment information to confirm eligibility. The decision will be made within 2 weeks of screening, and if eligible, randomisation will be confirmed by the researcher. A log will record the assessment outcomes.

Participants will be recruited from Oxford Health and Nottinghamshire Healthcare NHS Foundation Trust, the research sites for the study, including CAMHS and MHST services. There will be additional PICs, which will be other mental health trusts with CAMHS and/or MHST services and GPs. All individuals conducting initial patient identification at sites will be given information sheets to provide to parents of patients. These information sheets include full information about the study and information about what will happen if they agree to give their contact details. If interested, the care team will take verbal permission from the parent to share the parents' contact details (i.e., verbal consent to contact) with the research team or at the end of the information sheets will be a QR code and a direct link to an online form where the parent can directly submit their contact details (i.e., online consent to contact). Parents who provide 'consent to contact' (C2C) will be contacted by a research team member who will explain the study process and ascertain some screening eligibility over the phone to determine the presence of any obvious exclusion criteria.
If participants meet the initial eligibility check, they will be invited to attend an online (videoconferencing) screening/baseline appointment and complete a DAWBA assessment online. The participant will be provided with login details for the DAWBA. The parent DAWBA must be completed before the participant can be enrolled in the study. The DAWBA takes between 20 minutes to 2 hours to complete.

Screening/baseline appointment
Potential participants will be invited to attend an online screening appointment via videoconferencing (e.g., Microsoft Teams). The participant will be consented to the trial by a live link sent on Microsoft Teams and undertake the Child and Adolescent Intellectual Disability Questionnaire (CAIDS-Q) to ascertain the presence of an intellectual disability (with the researcher). They will then complete the Patient Health Questionnaire for adolescents (PHQ-A) to ensure they are in the mild to moderate range for depression. The researcher will then confirm the eligibility criteria once all screening measures are completed. The CAIDS-Q takes 5 minutes to complete and the PHQ-A between 5 to 10 minutes. If they meet the final eligibility checks (provided by CAIDS-Q and PHQ-A), they will then be asked to complete the rest of the baseline questionnaires with the researcher. These questionnaires include:
1. Demographics questionnaire: To understand the characteristics of the sample. The questionnaire takes approximately 10 minutes to complete (the parent completes it with the

researcher).
2. Revised Child Anxiety and Depression Scale (RCADS) to measure anxiety and depression symptoms. The questionnaire takes approximately 10 minutes to complete (parent/adolescent completed with the researcher).
3. EQ-5D-Y and EQ-5D-Y (Proxy version) to measure the child's quality of life. The questionnaire takes approximately 5 minutes to complete (parent/adolescent completed with the researcher).
4. Adverse events/side effects – to measure the baseline presence of any potential side effects during the trial. The questionnaire takes 5 minutes to complete (parent/adolescent completed with the researcher). A clinician-rated measure of global function (Clinical Global Impressions Scale-Severity [CGI-S]) will also be completed by the researcher. This takes 1 minute. Further details on each questionnaire can be found in section A18. Participants will then be randomised in the study.

The intervention
In the intervention arms, participants receive 8-10 weeks of 7 levels of a serious game called SPARX delivered online via a website or app. One group will receive supported SPARX where they will have human support from an eCoach who will be there to motivate and engage participants but will not deliver any therapy. Another group will receive purely self-directed SPARX (i.e., no human support). In the control arm, participants will not receive SPARX during the trial period.

Mid-intervention measures
Four weeks into the intervention, parents/adolescents will be asked to re-complete the PHQ-A and the adverse events questionnaire. These measures will be completed online.

Follow-up measures
8-10 weeks after the intervention, participants will be asked to complete the following measures with the researcher via videoconferencing:
1. Patient Health Questionnaire modified for adolescents (PHQ-A)
2. Revised Child Anxiety and Depression Scale (RCADS)
3. Clinical Global Impressions Scale-Improvement (CGI-I)
4. EQ-5D-Y and EQ-5D-Y (Proxy version)
5. Adverse events
6. Concomitant interventions

Interviews
A sub-sample of adolescents and one of their parents will also be invited to interview (telephone or videoconferencing as dictated by patient preference) as part of the Process Evaluation. Interviews will be conducted with the eCoach supporting the intervention, clinicians /practitioners recruiting to the study, adolescents in the intervention arms (approximately 20% in total), and parents of adolescents in the intervention arms (approximately 20% in total). Four semi-structured interviews, interview schedules will be prepared and piloted with relevant stakeholders. eCoach and clinician/practitioner interviews will be commenced during the first three months of intervention delivery. Parent and adolescent interviews will commence after the adolescent has completed the 8–10-week outcome measures. Interviews will be conducted via telephone or videoconferencing (e.g., Microsoft Teams) but audio recorded only.

Interim analysis
There are no planned interim analyses.

Previous interventions as of 15/04/2024:
Study design and justification for control arm

The study design is a single-blind pilot randomised controlled feasibility trial, with an embedded process evaluation. Participants will be followed-up mid-intervention (4 weeks post-randomisation) and 8-10 weeks post-randomisation. In the intervention arms, participants receive 8-10 weeks of 7 levels of a serious game called SPARX delivered online via a website or app. One group will receive supported SPARX where they will have human support from an e-coach who will be there to motivate and engage participants but will not deliver any therapy. Another group will receive purely self-directed SPARX (i.e., no human support). The team will compare the two SPARX groups as to how many levels they completed and whether they persisted with the game. In the control arm, participants will not receive SPARX during the trial.

Sample size
There are multiple methods suggested for sample sizes in pilot studies, but here the numbers are aimed at the overall smallest sample size (pilot plus subsequent trial), for which 40 per arm (Total sample size = 120) is reasonable.

Stages of the research
Participant recruitment is expected to start on 31st January 2023 and end on 31st December 2024. No interim analyses are planned. The final follow-up is scheduled to occur end of March 2025. Findings from the trial will undergo final analysis and interpretation between April 2025-August 2025. Project management group meetings are scheduled once a month, with more regular weekly meetings between core research team members. The Digital Youth Scientific Advisory Board will meet to discuss the study's progress. There will be regular patient and public involvement throughout the trial to aid with recruitment and participant retention techniques.

Patient identification
Participants will be identified by two main streams:
1. Clinicians at the main study site (Oxford Health) and our Child and Adolescent Mental Health Services (CAMHS) Participant Identification Centre (PIC) will inform potentially eligible patients about the study and seek their consent to provide their contact details to the research team.
2. Practitioners at our school-based Mental Health Support Teams (MHST) PICs will inform potentially eligible patients about the study and seek their consent to provide their contact details to the research team.
Participants will be recruited from Oxford Health, which is the research site and includes CAMHS and MHST services, and there will be additional PICs which will be other mental health trusts with CAMHS and/or MHST services. All individuals conducting initial patient identification at sites will be given information sheets to provide to parents of patients, these information sheets include full information about the study and information about what will happen if they agree to give their contact details. At the end of the information sheets will be a QR code and a direct link to an online form where they can submit their contact details. Parents who provide ‘consent to contact’ (C2C) will be contacted by a research team member who will explain the study process and ascertain some screening eligibility over the phone to determine the presence of any obvious exclusion criteria.
If participants meet the initial eligibility check, they will be invited to attend an online (videoconferencing) screening/baseline appointment and complete a DAWBA assessment online. The participant will be provided with login details for the DAWBA. The parent DAWBA must be completed before the participant can be enrolled in the study. The DAWBA takes between 20 minutes to 2 hours to complete.

Screening/baseline appointment
Potential participants will be invited to attend an online screening appointment via videoconferencing (e.g., Microsoft Teams). The participant will be consented to the trial by a live link sent on Microsoft Teams and undertake the Child and Adolescent Intellectual Disability

Questionnaire (CAIDS-Q) to ascertain the presence of an intellectual disability (with the researcher). They will then complete the Patient Health Questionnaire for adolescents (PHQ-A) to ensure they are in the mild to moderate range for depression. The researcher will then confirm the eligibility criteria once all screening measures are completed. The CAIDS-Q takes 5 minutes to complete and the PHQ-A between 5 to 10 minutes. If they meet the final eligibility checks (provided by CAIDS-Q and PHQ-A), they will then be asked to complete the rest of the baseline questionnaires with the researcher. These questionnaires include:
1. Demographics questionnaire: To understand the characteristics of the sample. The questionnaire takes approximately 10 minutes to complete (the parent completes it with the researcher).
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The intervention
In the intervention arms, participants receive 8-10 weeks of 7 levels of a serious game called SPARX delivered online via a website or app. One group will receive supported SPARX where they will have human support from an e-coach who will be there to motivate and engage participants but will not deliver any therapy. Another group will receive purely self-directed SPARX (i.e., no human support). In the control arm, participants will not receive SPARX during the trial period.

Mid-intervention measures
Four weeks into the intervention, parents/adolescents will be asked to re-complete the PHQ-A and the adverse events questionnaire. These measures will be completed online.

Follow-up measures
8-10 weeks after the intervention, participants will be asked to complete the following measures with the researcher via videoconferencing:
1. Patient Health Questionnaire modified for adolescents (PHQ-A)
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3. Clinical Global Impressions Scale-Improvement (CGI-I)
4. EQ-5D-Y and EQ-5D-Y (Proxy version)
5. Adverse events
6. Concomitant interventions

Interviews
A sub-sample of adolescents and one of their parents will also be invited to interview (telephone or videoconferencing as dictated by patient preference) as part of the Process Evaluation. Interviews will be conducted with the e-coach supporting the intervention, clinicians /practitioners recruiting to the study, adolescents in the intervention arms (approximately 30 in total), and parents of adolescents in the intervention arms (approximately 30 in total). Four semi-structured interview schedules will be prepared and piloted with relevant stakeholders. E-coach and clinician/practitioner interviews will be commenced during the first three months of

intervention delivery. Parent and adolescent interviews will commence after the adolescent has completed the 8–10-week outcome measures. Interviews will be conducted via telephone or videoconferencing (e.g., Microsoft Teams) but audio recorded only.

Interim analysis
There are no planned interim analyses.

Previous interventions:
Study design and justification for control arm
The study design is a single-blind pilot randomised controlled feasibility trial, with an embedded process evaluation. Participants will be followed-up mid-intervention (4 weeks post-randomisation) and 8-10 weeks post-randomisation. In the intervention arms, participants receive 8-10 weeks of 7 levels of a serious game called SPARX delivered online via a website or app. One group will receive supported SPARX where they will have human support from an e-coach who will be there to motivate and engage participants but will not deliver any therapy. Another group will receive purely self-directed SPARX (i.e., no human support). The team will compare the two SPARX groups as to how many levels they completed and whether they persisted with the game. In the control arm, participants will not receive SPARX during the trial.

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Stages of the research
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(videoconferencing) screening/baseline appointment and complete a DAWBA assessment online. The participant will be provided with login details for the DAWBA. The parent DAWBA must be completed before the participant can be enrolled in the study. The DAWBA takes between 20 minutes to 2 hours to complete.

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3. EQ-5D-Y and EQ-5D-Y (Proxy version) to measure the child's quality of life. The questionnaire takes approximately 5 minutes to complete (parent/adolescent completed with the researcher).
4. Adverse events/side effects – to measure the baseline presence of any potential side effects during the trial. The questionnaire takes 5 minutes to complete (parent/adolescent completed with the researcher). A clinician-rated measure of global function (Clinical Global Impressions Scale-Severity [CGI-S]) will also be completed by the researcher. This takes 1 minute. Further details on each questionnaire can be found in section A18. Participants will then be randomised in the study.

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Mid-intervention measures
Four weeks into the intervention, parents/adolescents will be asked to re-complete the PHQ-A and the adverse events questionnaire. These measures will be completed online.

Follow-up measures
8-10 weeks after the intervention, participants will be asked to complete the following measures with the researcher via videoconferencing:
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Interim analysis
There are no planned interim analyses.

### Intervention Type
Behavioural

### Primary outcome(s)
Mood measured using the Patient Health Questionnaire modified for adolescents (PHQ-A) at baseline (pre-intervention), 4 weeks (mid-intervention), and 8-10 weeks post-randomisation

### Key secondary outcome(s))
Feasibility measures:
1. Willingness of adolescent participants to be randomised (i.e., number withdrawing due to randomisation and numbers approached versus numbers consented/recruited) measured using trial data throughout the trial
2. Willingness of clinicians/MHST practitioners to recruit participants measured using trial data throughout the trial
3. Number of adolescents eligible, follow-up rates, response rates and adherence/compliance rates (i.e. SPARX module completion rates), numbers of outcome measure completion, retention to primary outcome measure, and recruitment rate (actual versus expected) measured using trial data throughout the trial
4. Demographics measured using the demographics questionnaire at baseline
5. Quality of Life measured using the EuroQol child EQ-5D-Y and EQ-5D-Y (Proxy version) at baseline and 8-10 weeks post-randomisation
6. Anxiety measured using the Revised Child Anxiety and Depression Scale (RCADS) at baseline and 8-10 weeks post-randomisation
7. Overall disease severity and change using the Clinical Global Impressions-Severity (CGI-S) scale at baseline
8. Symptom severity, treatment response and the efficacy of treatments measured using the Clinical Global Impressions-Improvement (CGI-I) scale at 8-10 weeks post-randomisation

### Completion date
30/06/2025

# Eligibility

### Key inclusion criteria

Current inclusion criteria as of 08/04/2025:
1. Adolescents aged 11 to 19 years on the date of consent
2. Identified to have symptoms indicative of mild to moderate depressive disorder
3. Able to provide written consent or, if under age 16, written parental consent and written /verbal child assent
4. Has access to a computer with internet access or smartphone or device to use SPARX and must be able to install and log in
5. Parent and adolescent able to read and write in English

Previous inclusion criteria:
1. Adolescents aged 11 to 19 years on the date of consent referred to CAMHS or MHST
2. Presented at CAMHS/MHST for treatment with symptoms indicative of mild to moderate depressive disorder as confirmed by the PHQ-A
3. Able to provide written consent or, if under age 16, written parental consent and written /verbal child assent
4. Has access to a computer with internet access or smartphone or device to use SPARX and must be able to install and log in
5. Parent and adolescent able to read and write in English

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
11 years

### Upper age limit
19 years

### Sex
All

### Total final enrolment
126

### Key exclusion criteria
1. Depression assessed as being too severe to make SPARX an appropriate intervention as confirmed by the PHQ-A
2. High risk of current self-harm or suicide as confirmed by a clinician
3. Intellectual disability or physical limitations precluding the use of SPARX
4. Had (in the past three months) or currently having treatment with CBT/interpersonal therapy
5. 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
6. Safeguarding concerns that are currently not being managed (i.e., the young person is the subject of a safeguarding investigation) as confirmed by a clinician

**Date of first enrolment**
31/01/2023

**Date of final enrolment**
31/03/2025

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Warneford Hospital**
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

**Study participating centre**
**Nottinghamshire Healthcare NHS Foundation Trust**
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

**Study participating centre**
**Solent NHS Trust Headquarters**
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

**Study participating centre**
**Leicestershire Partnership NHS Trust**
Bridge Park Plaza
Bridge Park Road
Thurmaston

Leicester
United Kingdom
LE4 8BL

**Study participating centre**
**Lincolnshire Partnership NHS Foundation Trust Hq**
NHS Foundation Trust
Carholme Court
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

**Study participating centre**
**South London and Maudsley NHS Foundation Trust**
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

**Study participating centre**
**Bilborough Medical Centre**
48 Bracebridge Drive
Nottingham
United Kingdom
NG8 4PN

**Study participating centre**
**Parliament Street Medical Centre**
79a Upper Parliament Street
Nottingham
United Kingdom
NG1 6LD

**Study participating centre**
**Grange Farm Medical Centre**
17a Tremayne Rd
Nottingham
United Kingdom
NG8 4HQ

**Study participating centre**
**Greendale Primary Care Centre**
249 Sneinton Dale
Sneinton
Nottingham
United Kingdom
NG3 7DQ

**Study participating centre**
**Belvoir Health Group**
Bingham Medical Centre
3 Newgate Street
Bingham
Nottingham
United Kingdom
NG13 8FD

**Study participating centre**
**Bramcote Surgery**
2a Hanley Avenue
Bramcote
Nottingham
United Kingdom
NG9 3HF

**Study participating centre**
**Bridgeway Practice**
1 Bridgeway Centre
The Meadows
Nottingham
United Kingdom
NG2 2JG

**Study participating centre**
**Brierley Park Medical Centre - Skegby Site**
Mansfield Road
Skegby
Sutton-in-ashfield
United Kingdom
NG17 3EE

**Study participating centre**
**Brierley Park Medical Centre**
127 Sutton Road
Huthwaite
Sutton-in-ashfield
United Kingdom
NG17 2NF

**Study participating centre**
**Chilwell Valley and Meadows Practice**
The Valley Surgery
81 Bramcote Lane
Beeston
Nottingham
United Kingdom
NG9 4ET

**Study participating centre**
**Derby Road Health Centre**
366 Derby Road
Nottingham
United Kingdom
NG7 2DW

**Study participating centre**
**Elmswood Surgery**
Elmswood Gardens
Sherwood
Nottingham
United Kingdom
NG5 4AD

**Study participating centre**
**Fairfields Practice**
Gregory Boulevard
Nottingham
United Kingdom
NG7 5HY

**Study participating centre**
**Giltbrook Surgery**
492 Nottingham Road
Giltbrook
Nottingham
United Kingdom
NG16 2GE

**Study participating centre**
**Hucknall Road Medical Centre**
Kibworth Close
Heathfield
Nottingham
United Kingdom
NG5 1NA

**Study participating centre**
**Jubilee Park Medical Partnership**
61 Burton Road
Carlton
Nottingham
United Kingdom
NG4 3DQ

**Study participating centre**
**Parkside Medical Practice**
Main Street
Bulwell
Nottingham
United Kingdom
NG6 8QJ

**Study participating centre**
**Radford Medical Practice (kaur)**
Radford Health Centre
Ilkeston Road
Radford
Nottingham
United Kingdom
NG7 3GW

**Study participating centre**
**Village Health Group Keyworth Surgery**
Bunny Lane
Keyworth
Nottingham
United Kingdom
NG12 5JU

# Sponsor information

**Organisation**
University of Nottingham

**ROR**
https://ror.org/01ee9ar58

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the Nottingham Research Data Management Repository.

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | protocol for the process evaluation of a pilot randomised controlled feasibility trial | 05/08/2025 | 07/08/2025 | Yes | No |
| Protocol article | | 26/03/2024 | 27/03/2024 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |