



## Participant Information Sheet – Feasibility trial: Young person version (age 16 – 19 years)

(Final version 3.1: 15.05.24)

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

Chief Investigator: Professor Chris Hollis

Researchers: Dr Camilla Babbage, Mrs Holly Griffiths, Miss Lily Roberts and Mr Adam Parker

IRAS Project ID: 316644

#### **Introduction**

We would like to invite you to take part in our research study. Before you decide whether you wish to take part or not, we would like you to understand why the research is being done and what it would involve for you. A meeting will be set up with a member of the SPARX team who will go through the information sheet with you and answer any questions you have. Talk to family and friends about the study if you wish. Ask us if there is anything that is not clear using the contact details at the bottom of this form or in the meeting with the researcher.

The decision to take part or not is entirely yours and only when you have had all your questions answered satisfactorily and are happy to continue will we ask you to sign a consent form.

#### **What is this study about?**

As adolescent depression is on the rise in the UK, it's very important we 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 digital therapy may also not complete all the sessions or find it difficult to engage with. 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 mood. 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 we need to try it 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. We 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 we will randomly allocate a third of all adolescents 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 personalised version of SPARX where an e-coach will provide 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 you will be allocated to.

The findings from this study will help us to further develop SPARX which will hopefully allow more young people such as you to benefit from evidence-based interventions. This is a feasibility study (a practice-run before doing a large-scale study). It will help us find out more about:

- a. We want to know how helpful young people with depression find the additional support; and how we can improve the support and SPARX going forward
- b. We want to find out 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
- c. Whether young people taking part can complete the questionnaires we plan to use, without difficulty
- d. To estimate how many young people we will need to recruit for the larger trial

We can then implement these changes before we do a larger study. We need to ensure that research meets patient needs and are asking for your help to do this. If you are interested in taking part, please read the rest of this information sheet.

### **Why have I been asked to help?**

We are asking you because you are aged between 11 and 19 years with mild to moderate levels of depression.

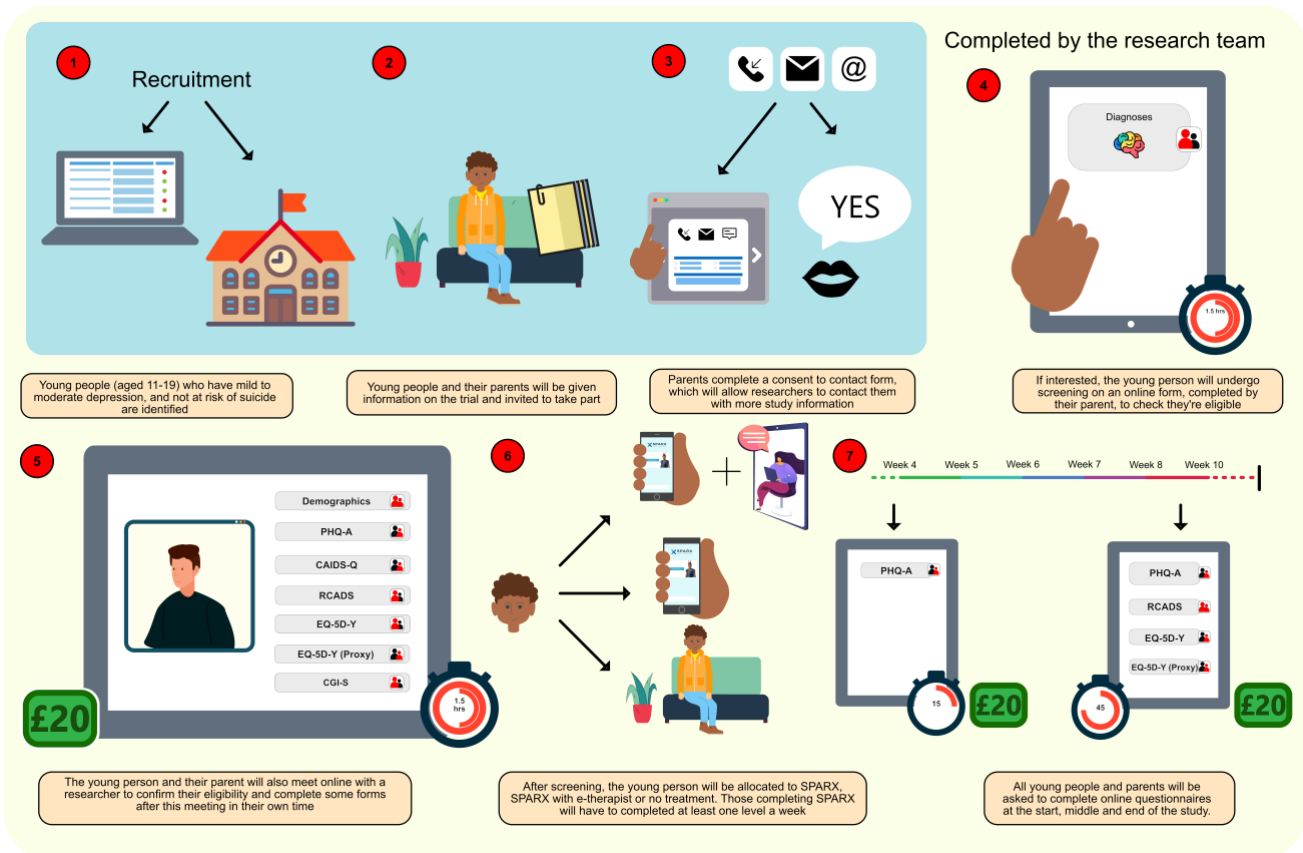
### **Do I have to take part?**

It is up to you whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

### **What will happen to me if I take part?**

#### **Step 1: Consent to contact**

If you agree to take part in the screening assessment, then your parent can either give consent to the research team to make contact with them or make contact with them via the online form. They can do this by giving your practitioner verbal consent that they are happy for them to pass their contact details onto the research team, or they can complete the Consent to Contact form (link and QR code on the Parent information sheet). They only need to complete one of these actions, not both. Not everyone that takes part in the screening phase will take part in the full trial however as part of this process, we need to collect personal information about you and your parent. Please refer to the diagram below for the recruitment and consent process for this trial.



Once our research team receive consent to contact from your parent (either by your parent telling who referred you into the trial that they are happy to be contacted by the research team or by completing the online consent to contact form), one of our researchers will contact your parent through their preferred method. They will arrange a suitable day and time to conduct an initial assessment by Microsoft Teams (we will provide guidance on how to use Teams) with you and your parent. Your parent will also be sent a link to complete the Development and Well-Being Assessment (DAWBA) questionnaire before attending the face-to-face Teams assessment. If your parent has not completed the DAWBA you will not be eligible to attend this assessment. If we find that the intervention is not suitable for you from the information your parent provides in the DAWBA form, we will call you to let you know and will also inform your doctor (including those at CAMHS).

If you are not eligible, your details will be stored securely and safely and only accessed by members of our team. See section entitled **Will my taking part in this study be kept confidential?** for more details on how your data will be stored and handled.

### Step 2: Full consent into the study

At the initial assessment on Teams, the researcher will go through various assessments with you. This will include asking about your symptoms of depression and anxiety and whether you may have any learning difficulties. The researcher will also collect background information including recording your age, gender, ethnicity, and what other treatments, therapies, and medication you are currently receiving. They will also ask



information about your parent's education and current employment, as well as use of services over the last three months (such as use of health services, voluntary services, and education services). If you have not recently had a clinical review of your mood, the researcher may need to check your screening results with our clinical investigator to ensure you still meet the criteria. If the researcher finds you meet the study inclusion criteria, you will be asked to complete more questionnaires online. It is expected that the whole Teams assessment will take approximately 1 hour.

You will then be randomly allocated to one of the following groups:

a. **Waitlist**

You will continue to receive your usual care plan, without getting access to SPARX. You will still be in the trial and will be asked to complete questionnaires after 4 weeks and again at 8-10 weeks.

b. **SPARX only**

You will complete SPARX through your computer or mobile phone. SPARX consists of 7 online delivered levels which take approximately 30 minutes to complete. You will be asked to complete 1 level a week for 7 weeks. Some of the levels contain tasks for you to practice in your own time. There are 7 levels to complete, and this usually takes about 7 weeks.

c. **Supported SPARX with e-coach**

This version of SPARX is the same as the above, but you will also have support from a member of the team (called an "e-coach") and personalised to your preferences so you can choose how you wish to talk to the e-coach (e.g. email, text or video call), how often (e.g. 5 or 15 minutes per week), and how many levels you would like to complete of SPARX each week. If you are having any problems, your e-coach may also call you.

The researcher will explain more about the SPARX treatment at your Teams assessment. If you are randomised to receive SPARX, you will agree a start date for the treatment that is convenient to you, and the researcher will provide you with log-in details, your password, and written instructions on how to use SPARX. We will also tell you who your e-coach is and provide you with their contact details if you are allocated the personalised and supported SPARX group. You will also have a practice of logging on to the system with the researcher, so you feel confident in how to use the treatment before you leave the clinic. **It is very important you start the treatment on your set date. If there are any unexpected problems, we would ask you to let your e-coach know.**

After 8-10 weeks you should have completed all 7 levels of SPARX, and you will no longer have access to SPARX.

If you are randomised to the waitlist group, you will not have access to SPARX, however we will give you vouchers for completing the measures at different timepoints. There is a possibility that you may be disappointed by which group you have been allocated to, but each of the groups is **equally important** to developing this programme and we hope that whatever the outcome you will continue to take part.

Follow-up

While in the study (regardless of which group you are in) we would like to follow your progress and will ask you 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, you will be asked more questions. You will be asked to complete a quick questionnaire about your depression symptoms and adverse events that may have occurred. Altogether, these questionnaires will take about 10 minutes to complete. For those just receiving SPARX, this will pop up when you login to SPARX, so you don't have to remember to do this. For those in the waitlist group, one of our researchers will contact you to arrange the questionnaire completion.

At 8-10 weeks, we would also like to follow your progress. When these questionnaires are due the researcher will contact you to confirm that you are happy to continue and arrange a mutually convenient time to meet with you over Teams to complete the questionnaires. You will be asked similar questions to the initial assessment.

Additionally, at this point, we may wish to interview you and your parent for about 30 minutes by telephone or Teams. If you are willing to do this, your contact details will be provided to one of the researchers who will contact you to conduct the interview. We will ask you about the support you have received (if you received any), the things you found useful or most helped, the things you didn't find useful, and your views of SPARX. You do not have to agree to this interview to be able to take part in the study. If you do agree to chat to a researcher about your thoughts on SPARX, your interview will be audio recorded only and transcribed. When it is transcribed anything that may give away your identity, such as names or places will be removed so no-one will know it was you or your parent that gave the interview.

The video and audio recordings will only be made available to members of the research team. Transcribing of audio recordings will only be conducted by authorised and approved University of Nottingham transcribing contractors. A confidentiality agreement will be in place with any third parties.

### **What if I need healthcare support?**

Whilst you are involved in the SPARX research trial, your access to care remains under your normal healthcare provider. Therefore, if you have any concerns about your health or mental health during the study or if you think your mental health might be deteriorating, you **must** inform your normal healthcare provider. This may be your GP, a CAMHS or MHST clinician or a Community Paediatrician. If you any problems with medication throughout the SPARX study, please also contact your normal healthcare provider. If you need support from a healthcare professional for your mental health needs after the study, you should also contact your normal healthcare provider. In the case of a medical emergency dial 999.

### **Expenses and payments**

We shall give you £20 worth of vouchers for the time you have to spend completing questionnaires. We will send £20 worth of vouchers to you each time you complete all the questionnaires (at baseline, at the 4-week midpoint, and at the 8–10-week follow-up).

### **Is there anything I should be worried about if I take part?**

We do not expect any disadvantages or risks to you. We will arrange any interviews and appointments at times to suit you.

### **What are the possible benefits of taking part?**



We cannot promise the study will help you, but the information we get from this study will help us 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.

### **What happens when the research study stops?**

When the study ends after 8-10 weeks, you will continue with your usual care from CAMHS/MHST or your GP. We also plan to publish the findings from our study and contact you with the results if you have said you would like to be kept informed. Your name or your parent's name will not be mentioned in any published reports.

### **What if something goes wrong?**

If you have a concern about any aspect of this study, you should ask to speak to your assessor who will do their best to answer your questions. You may also contact the Trial Manager, Dr Camilla Babbage by email: [Camilla.Babbage@nottingham.ac.uk](mailto:Camilla.Babbage@nottingham.ac.uk) or telephone: 01157 484301. If you remain unhappy and wish to complain formally, you can contact [PALSandComplaints@nottshc.nhs.uk](mailto:PALSandComplaints@nottshc.nhs.uk). Any safeguarding concerns or issues of distress will be managed in line with our standard operating procedures.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Will my taking part in this study be kept confidential?**

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.



Where possible information about you which leaves the [site] will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. We will also need this information if we need to follow up your medical records as part of the research, where we may need to ask the Government services that hold medical information about you (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form, you agree to the above.

Your contact information will be kept by the University of Nottingham for 1 year after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's, and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

### **What will happen if I stop taking part in the study?**

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the study analysis.

### **Involvement of the General Practitioner (GP)**

If you do decide to take part in this study, we will inform your GP and provide them with a copy of this information sheet.

### **Who is organising and funding the research?**

This research is being organised by the University of Nottingham.

This research was funded by the Medical Research Council (Ref: MR/W002450/1). The views expressed are those of the author(s) and not necessarily those of the NHS, the MRC, or the Department of Health.

### **Who has reviewed the project?**



All research in the NHS is looked at by independent groups of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by South West - Cornwall & Plymouth Research Ethics Committee (reference 22/SW/0149). We also developed the project alongside young people with lived experience of depression.

### **We're interested, what do we do now?**

That's really great and we're looking forward to getting to know you! If your parent has not yet completed the Consent to Contact form, please complete this and send it on. We're looking forward to receiving this form and once we have it, we will be in touch with the DAWBA assessment for your parent and to book in the appointment on Microsoft Teams.

### **We're not interested, what do we do now?**

That's absolutely fine! If you don't want to take part in the trial, you do not need to do anything else. If you have any questions, do feel free to get in touch with us.

### **Contact for further information**

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### **Finally**

Many thanks for reading this information sheet. Please keep this information sheet. We will ask you to sign a consent form if you agree to take part and we will give you a copy of it to keep.

This research was funded by the Medical Research Council (Ref: MR/W002450/1). The views expressed are those of the author(s) and not necessarily those of the NHS, the MRC, or the Department of Health.