



Participant Information Sheet – Feasibility trial: Young person version (age 11 – 15 years)

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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're inviting you to take part in our research. Before you decide, we would like you and your parent to understand why the research is being done and what it would involve. Feel free to talk to your friends and family about the study, your parents have also been given an information sheet. Please ask if there is anything that is not clear using the contact details at the bottom of this form or in the meeting that will be set up with the researcher.

What is this study about?

Each year there are more young people being diagnosed with depression, so it's important we find good ways to help young people like you manage your feelings. Many young people with depression do not get the therapy they need because of long waitlists or once they start accessing therapy, they drop out because they don't enjoy it. To increase young people's access to support and to make it more engaging, a team in New Zealand developed a computer game called SPARX. In the game you are an avatar who completes levels in a fantasy world where you learn different ways to manage your mood. There are 7 levels in total, and in each level, you have different tasks to do. SPARX has been shown to have positive results in New Zealand and other areas of the world. We now want to see whether SPARX may be helpful for young people in the UK and if adding online human support (called an "e-coach") means young people will find SPARX more engaging.

To understand this, we want to compare how young people who don't use SPARX do compared to using the normal version of SPARX, or a personalised version of SPARX with human support. To make sure these groups are as similar as possible, each young person is put into a group by a computer using chance (random selection). None of the researchers or members of the care team will decide or know which group you will be in.

The findings from this study will help us to develop SPARX which will hopefully allow more young people such as you to benefit from this. This study is a practice-run before doing a bigger study with more young people. We can then make changes before we do a bigger study. We need to make sure that research meets



your needs and are asking for your help to do this. If you are interested in taking part, please continue reading to find out what we'll be asking you to do.

Why have I been asked to help?

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

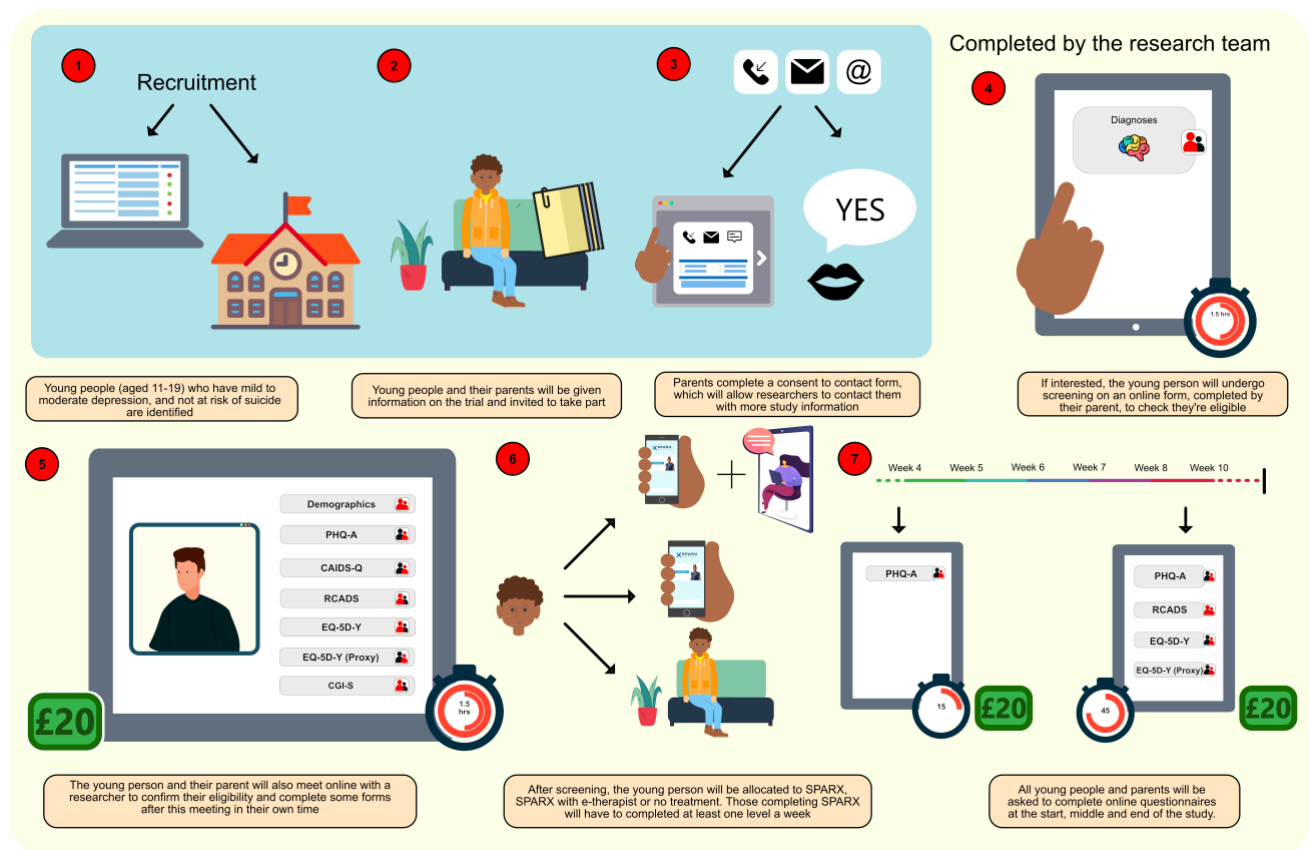
Do I have to take part?

No, you do not have to take part, but we would be very grateful if you did. If you do not take part, no one will be upset with you. If you decide to take part, you can stop at any time without giving a reason or refuse to do bits of it that you are not keen on.

What will happen to me if I take part?

Step 1: Consent to contact

If you and your parent agree to take part, then your parent will first complete a Consent to Contact form. Please see the diagram below which shows the process for this trial.



Once our research team get this form, one of our researchers will contact your parent by telephone or Teams. They will arrange a suitable day and time to conduct an initial assessment by Microsoft Teams and your parent



will be sent a link to complete a questionnaire, before attending the face-to-face Teams assessment. This questionnaire will ask and collect information on your possible diagnoses. If your parent does not complete this questionnaire, then you will not be able to attend this assessment. If we find that the intervention is not suitable for you from the information your parent provides in this questionnaire, we will call you to let you know and will also inform your doctor.

If you do not end up being in the trial, your details will be stored securely and safely and only accessed by members of our team.

Step 2: Full consent into the study

You and your parent will then be asked to answer some questions on the computer and with one of our researchers on Microsoft Teams. These questions help us to understand about your mental health and about your general wellbeing. This will take about 1 and a half hour to complete.

The researcher will also explain more about SPARX, and you will be able to ask any questions you may have. The researcher may need to check your eligibility with a clinical team member if this hasn't been done for a while. After this, a computer will randomly put you in one of the two SPARX versions or to be put on a waitlist group without access to SPARX. You may be disappointed by which group you have been put in, but each of the groups is **equally important** to understanding if SPARX is useful for young people with low mood, and we hope that whatever happens you will continue to take part.

If you are getting one of the two SPARX interventions, you will have 7 online delivered levels to complete. Each level will take about 30-45 minutes. If you get the human-supported SPARX version, you will be allocated an e-coach who will give you a menu of options to choose how you'd like your support to look. This will include how you wish to talk to your e-coach (e.g. email, text or video call), how often (e.g. 5 or 15 minutes per week), and how many levels you want to complete each week. If you are having any problems, they may also call you.

While in the study (whichever 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.

If you are randomised to the waitlist group, you will not have a chance to use SPARX, but we will give you vouchers for completing the questions at all the timepoints.

At the end of the study, you and your parent may be given the opportunity to be involved in an interview for about 30 minutes to find out what you found useful, or what wasn't helpful, and your views of SPARX. 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 that gave the interview.

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

There are no specific risks from taking part in the study.



What are the possible benefits of taking part?

We cannot promise the study will help you or your child but the information we get from this study will help us plan a larger study to test how effective SPARX is at treating 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?

We will write a report about the study once it has finished, and your parents will be able to see it and you can too. Your name will not be mentioned in the report.

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

You don't have to take part in the study, and you are free to stop at any time, without giving any reason.

Who will know I am taking part?

The information collected about you will be kept totally confidential. Only the study team will see this information. Any information about you that goes outside of the study will have your name and address removed so that you cannot be recognised from it. Only members of the research team, your doctors (including those at CAMHS) and your parents will know that you are taking part in the study. However, if we found at any time during the trial that you were a risk to yourself or others then we may have to break confidentiality and let the relevant people know (e.g. GP, clinicians).

I'm interested, what do I do now?

That's really great! It would now be a good idea to sit down and talk to your parent about getting involved in this trial and making sure they're happy for you to take part too. If they are happy for you to take part, they will need to complete the Consent to Contact form they should have received with their information sheet. Once this has been sent to us, we will be in touch with an online form and to book in an online meeting.

I'm not interested, what do I 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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