Participant Information Sheet – Feasibility trial: Parents/Guardians

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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)

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Researchers: Dr Kareem Khan, Dr Camilla Babbage and Mr Adam Parker

IRAS Project ID: 316644

Introduction

We would like to invite you and your child 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 and your child. 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 your child's 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 the purpose of this study?

As you may know, adolescent depression is on the rise in the UK and so 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 computerised 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 supported and personalised version of SPARX where an e-coach 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 your child will be allocated to.

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). 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 and your child's help to do this. If you are interested in your child taking part, please read the rest of this information sheet.

Why have I and my child been invited?

We are asking families in England who have a young person (aged between 11 and 19) who experiences mild to moderate levels of depression to take part. Both the young person who experiences depression AND *one* parent/guardian need to take part.

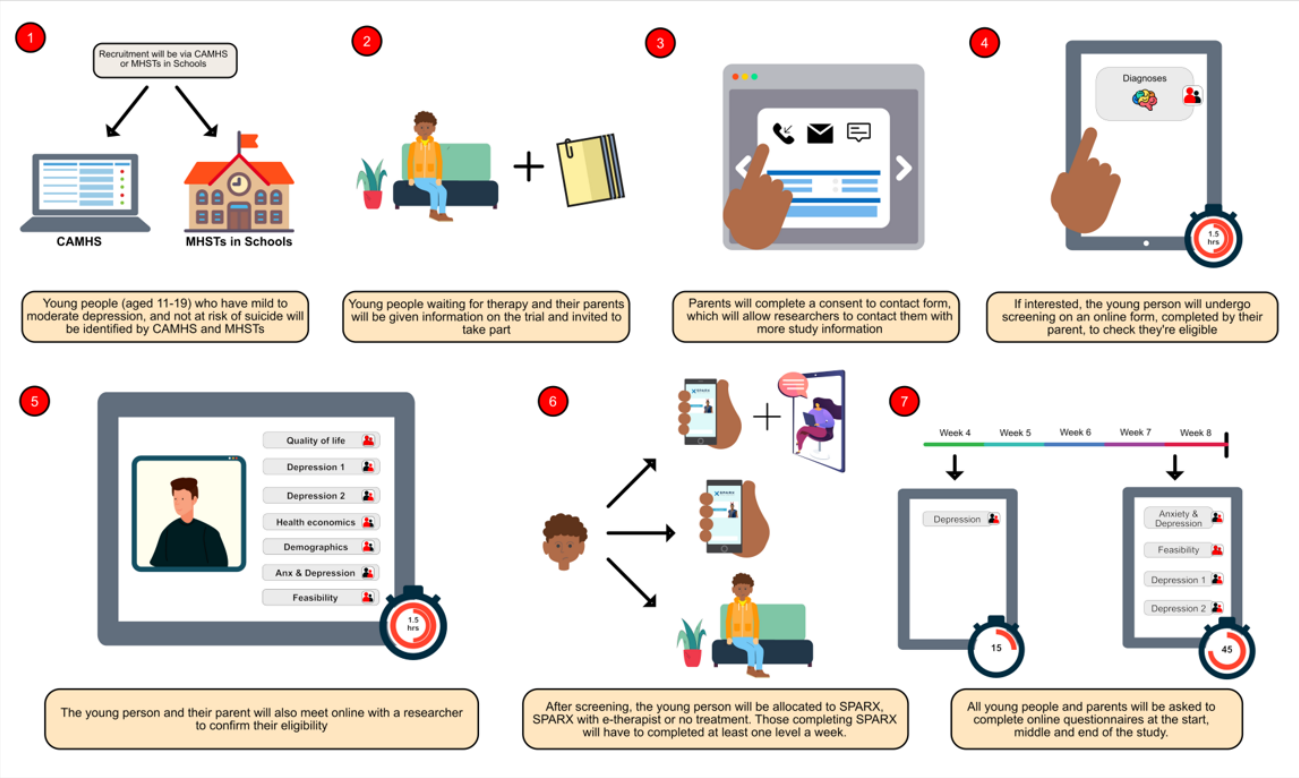
Do we have to take part?

It is up to you and your child to decide 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.

What will happen to us if we agree to take part?

Step 1: Consent to contact

If you agree to take part in the screening assessment, then please complete the Consent to Contact form (link and QR code below). 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 child. Please refer to the diagram below for the recruitment and consent process for this trial.



If your child would like to take part, please click here to complete the online Consent to Contact form or scan the QR code.

If you and your child would like to take part, please complete the online Consent to Contact form. Once our research team receive consent to contact you, one of our researchers will contact you through your preferred method. They will arrange a suitable day and time to conduct an initial assessment by Microsoft Teams and you will be sent a link to complete the Development and Well-Being Assessment (DAWBA) questionnaire before attending the face-to-face Teams assessment (we will also provide guidance on how to use Teams). The DAWBA will ask and collect information on your child's possible diagnoses. If you have not completed the DAWBA you will not be eligible to attend this assessment. Only the parent DAWBA needs completing prior to the assessment. If we find that the intervention is not suitable for your child from the information you provide in the DAWBA form, we will call you to let you know and will also inform your child's doctor (including those at CAMHS). It will take between 45-60 minutes to complete the DAWBA.

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/our child 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 and your child and consent will also be taken at the beginning of the session. The assessments will include asking about your child's symptoms of depression and anxiety and whether your child has any learning difficulties. The assessor will also collect background information including recording your child's age, gender, ethnicity, and what other treatments, therapies, and medication your child is currently receiving. They will also ask information about your 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 the assessor finds your child 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.

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

a. **Waitlist**
   Your child will continue on the waitlist for CAMHS/MHST without getting access to SPARX. You and your child 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**
   Your child will complete SPARX through their computer or mobile phone. SPARX consists of 7 online delivered levels which take approximately 30 minutes to complete. Your child will be asked to complete 1 level a week for 7 weeks. Some of the levels contain tasks your child has to practise in their own time. There are 7 levels to complete, and this usually takes about 7 weeks. You may help your child go through their levels if you like.
c. **Supported SPARX with e-coach**
   This version of SPARX is the same as the above, but your child will also have support from a member of the team (called an "e-coach") and personalised to your child's preferences so they can choose how they wish to talk to their e-coach (e.g. email, text or video call), how often (e.g. 5 or 15 minutes per week), and how many levels your child wants 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 SPARX at your Teams assessment. If your child is randomised to receive SPARX, you will agree a start date for the intervention that is convenient to you and your child, and your assessor will provide your child with log-in details, a password, and written instructions on how to use SPARX. If your child is randomised to the supported SPARX version, we will also tell you who their e-coach is and provide you with their contact details. Your child will also have a practice of logging on to the system with the researcher, so they feel confident in how to use the intervention before you leave the assessment. **It is very important you start the intervention on your set date. If there are any unexpected problems, we would ask you to let your e-coach know.**

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

If your child is randomised to the waitlist group, they will not have any 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 and your child 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.

<u>Follow-up</u>

While in the study (regardless of which group your child is in) we would like to follow your 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 your child will be asked more questions. 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. For those just receiving SPARX, this will pop up

when your child logins 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 child's 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. Your child will be asked similar questions to the initial assessment.

Additionally, at this point, we may wish to interview you and your child 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 child 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 3rd parties.

What if we need healthcare support?

If you need support from a healthcare professional for your child's depression after the study you must contact your normal healthcare provider, this may be your GP or a CAMHS or MHST or Community Paediatric clinician. If your child has any problems with medication throughout the SPARX study, you must also contact your normal healthcare provider. If you have any difficulties related to other health issues throughout the SPARX study, you must contact your normal healthcare provider. In case of a medical emergency dial 999. If you have access to an e-coach, they will only be able to support you and your child in relation to completing SPARX.

Expenses and payments

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

What are the possible disadvantages and risks of taking part?

We do not expect any disadvantages or risks to you or your child. 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 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 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, your child will continue with their usual care from CAMHS/MHST or their 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 child'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 Kareem Khan by email: kareem.khan@nottingham.ac.uk or telephone: 0115 82 32438. If you remain unhappy and wish to complain formally, you can contact *<local PALS details>*). 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/our child 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 and your child 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.

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

What will happen if I/my child don't want to carry on with 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, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally identifiable information possible.

Involvement of the General Practitioner (GP)

If you do decide to take part in this study, we will inform your child's 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 and your child! If you have 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 and to book in an 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.

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