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PARENT/CARER INFORMATION SHEET

Go-OSCA Trial

We'd like to invite you and your child to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you and your child. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Summary

We would like to invite you and your child to take part in a project to **compare** an **new online therapy** to **treatment as usual** for treating **social anxiety disorder in young people**.

This **new therapy** is a **type of Cognitive Behaviour Therapy (CBT)** called Online Social anxiety Cognitive therapy for Adolescents or **OSCA**.

Treatment as usual is **graded CBT**, which is delivered **face-to-face or via video call**.

Both treatments are the **same type of therapy (CBT)**, but they use **different methods** to try to change some of the unhelpful thoughts and behaviours which contribute to social anxiety.

Young people referred for treatment of social anxiety in an NHS-commissioned service will be offered the chance to take part in the trial where they will be **randomly allocated** to receive one of these treatments.

Young people and families will take part in several **assessments** while taking part. This will include **standard outcome measures used in NHS treatment**, and **additional assessments** of social anxiety symptoms and processes, functioning, and use of health care services as part of the research project.

It is **routine** practice in the services **to record therapy sessions**. We will **ask your consent** for the video or audio **recordings to be shared with us** so that **5% of sessions** can be **reviewed** to make sure that the two treatments were delivered as intended and they are sufficiently different.

Purpose of the Study

We would like to **understand if one of the treatments is more effective than the other** in improving social anxiety and functioning, and to **compare their cost-effectiveness**. The results will help decide if the NHS adopts the new treatment, and make it widely available. This sort of research is needed to improve the care families receive in the NHS.

Why have I/my child been invited?

You and your child have been invited because your child is:

- between 11 and 18 years of age
- has been diagnosed with Social Anxiety Disorder
- has been offered treatment for social anxiety.

In total we are aiming to recruit 220 young people with social anxiety disorder.

Do I/my child have to take part?

You and your child **do not have to take part!**
If you and your child decide not to take part, this **will not affect your child's treatment in the NHS at all.** If you and your child do decide to take part, you can withdraw without giving a reason if you or your child later change your mind.

What will happen to me and my child if we decide to take part?

The project will last just over a year in total.

Random allocation to treatment	• Your child will be assigned to **receive either OSCA or graded CBT**. • This decision is **totally random**, and will be done with a computer programme.
Treatment	• In **either treatment**, your child will be **assigned one of the therapists in the clinic you are already attending** to **guide** and **support** them throughout their treatment. • All of the therapists at your clinic will be delivering both treatments, so **your child will have the same trained and experienced therapist whichever treatment they receive**. • **Before treatment starts**, you and your child will **meet with their therapist** to **discuss how their treatment** will work and **answer any questions** you may have. • As in all good practice, they will complete **regular questionnaires to guide therapy**. • Both treatments take the **same amount of time in total** and include the **same amount of contact between your child and their therapist,** but **OSCA** lasts **14 weeks with 3 monthly follow-up calls** and **graded CBT** lasts **12 weeks** (see below for more details of the therapies).
Assessments	• You and your child will **complete** some **questionnaires** at the following times **after starting the project**: 6 weeks, 16 weeks, 26 weeks (about 6 months), and at 40 (about 9 months) weeks. • If we are able to secure further funding, we will also ask you and your child to complete questionnaires at 66 weeks (about 17 months) after the start of the project. • Questionnaires can be completed **online or on paper**. They **do not require in person visits**.

Here is some more information about the two treatments:

Graded CBT	OSCA
▪ This is a **type of CBT** which was developed based on **anxiety disorders in general**.	▪ This is a **type of CBT** developed to treat **social anxiety disorders in adolescents specifically**.
▪ Graded CBT is delivered in **7** scheduled **sessions**, lasting **about 1 hour.** ▪ Graded CBT takes **12 weeks**, with **4 weekly sessions**, **2 fortnightly sessions,** and a **final session 1 month later**. ▪ Your child's sessions with their **individual therapist** will **either** be delivered **face-to-face in clinic** or **remotely via video call**.	▪ In OSCA, your child will have **structured weekly phone or video calls** lasting around 20 minutes **with their individual therapist.** In the **first 2 weeks**, there are **2 calls per week** and there is also one longer 45-minute call in the second week of treatment. ▪ OSCA takes **14 weeks,** with weekly calls. **3 monthly follow-up calls** are also offered afterwards. ▪ They will also receive **regular messages from their therapist** and be able to reach out to their therapist with messages between calls. ▪ Their therapy will be **supported by an online programme** including an app and a website
▪ Your child's therapist will work with them in sessions to learn **ways to manage anxious feelings**, **change negative thoughts** and **gradually face their fears** ▪ Your child will also have **homework tasks** to help them independently carry on this learning. These will be **reviewed in sessions**.	▪ Your child will work through **personalised modules** that help them to **understand what keeps their social anxiety going** and then to **test out their fears** in order to **build their confidence**. ▪ There are some **core modules** that all young people work through and then a number of **modules** that are **focused on particular concerns or problems**, so the **treatment can be tailored** to best meet your child's needs. ▪ Modules include **written material, video examples, and exercises** for your child to try. ▪ Your **child's therapist** will **review** how your child is getting on using the modules **throughout the week**, and **discuss them** as well as completed questionnaires in weekly calls to **tailor the treatment, draw out and build on learning, and practice techniques or behaviours**.

Your child's questionnaires will ask about:

- Social anxiety symptoms and behaviours
- General wellbeing
- Their bond with their therapist
- Social relationships
- How much social anxiety bothers them in their daily life
- Questions about their quality of life
- Questionnaires on how acceptable and suitable your child found therapy.

Your questionnaires will ask about:

- Background information about you and your child
- Your child's social anxiety symptoms and behaviours
- How much social anxiety interferes with your child's life
- Questions about your quality of life
- Information about healthcare services that you and your child have used both as part of and outside of the study.
- Questionnaires on how acceptable and suitable you felt your child's therapy was.
- A diary of your and your child's health service use and your work/their school attendance.

Other information we will gather:

- We will collect information on your child's school attendance and attainment from the National Pupil Database.
- If your child receives OSCA, we will collect information on their usage of OSCA and your usage of the supporting parent OSCA app, such as time spent and activity on the programmes.

What should I consider?

- If your child has been on a stable dose of **medication** for the last 8 weeks, we ask that this dose does not change, and that they not start any new medication for the duration of their participation in the study.
- **After finishing taking part** in the project, your child will go **back to usual NHS care**. Their therapist will review their progress and decide on the next steps with you and your child. This may include further therapy or alternative treatment, ongoing monitoring, or discharge.

Are there any <u>possible disadvantages</u> or risks from taking part?

- Some of the **questionnaires may ask things which you or your child find upsetting**. These measures are **similar to the ones that are used in usual treatment**. You and your child can always decide what you would like to discuss in assessment and therapy sessions.
- You and your child will be **completing more measures than in usual treatment** which you may find frustrating or tiring, but you will be **reimbursed for your time**.

We don't expect your child to experience any harm as a result of taking part in this study. All researchers involved are experienced and have been approved to work with children and vulnerable adults.

What are the <u>possible benefits</u> of taking part?

- Your child will be receiving an **evidence-based therapy for social anxiety whichever arm they are allocated to**.
- You and your child may **learn about their social anxiety** through taking part in the study.
- Your child will take part in **more thorough assessments** compared to if you didn't take part which can be used to **guide their treatment more effectively**.
- Your child will be **invited back for assessments over a longer period after treatment** than would be typical as part of routine care, meaning their **progress will continue to be monitored**.
- **Other young people with social anxiety may benefit** from your participation, through **building knowledge about how to improve treatment**.

Will my General Practitioner (GP) be informed of my participation?

Yes, your child's GP will be informed of their participation.

Will my taking part in the study be kept confidential?

Yes, confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

All study records will be identified only by a code. We will only use names where this is necessary to contact you. Information that can identify you will only be held securely by the study team for the purposes of the study. Responsible members of the University of Oxford, and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

Yes, you and your child will be compensated for the additional time completing research questionnaires that are not part of routine care with **shopping vouchers** to the value of **£20 for your child and £10 for you at each of the 3 additional assessment points** after finishing treatment (16, 26, and 40 weeks after the start of the study).
Reasonable **travel expenses** for any visits additional to usual care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate, although we do not anticipate that this will be necessary.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is '**a task in the public interest**'. The University of Oxford is the

sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from you, your child, the NHS service from which they are receiving treatment, and the National Pupil Database in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any **research documents with personal information**, such as consent forms, securely **at the University of Oxford for 3 years after publication of the study findings** as part of the research record.

Both **audio and video recordings will be stored on University servers**. All recordings will be **deleted at the end of the study** once they have been processed.

A **copy of the consent form from this study will be kept in your child's medical records** for as long as those records are retained.

A **de-identified dataset will be made available in a secure archive for 20 years**, 3 years after publication of study findings.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting eleanor.leigh@psy.ox.ac.uk.

What will happen if I don't want to carry on with the study?

Participation is entirely voluntary. You/your child **can change their mind at any time** and withdrawal will not affect the care your child receives from the NHS. If you withdraw from the study, we will destroy all your identifiable data, but will use the data collected up to your withdrawal.

What will happen to the results of this study?

The results of the study will be shared with participating families and services, presented in journal articles, at conference presentations, and to policy makers and stakeholders.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with your clinician or the research team. They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within

the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Dr Eleanor Leigh (01865 271444 & eleanor.leigh@psy.ox.ac.uk) or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact by phone: 0118 904 3467 or by email: PALS@berkshire.nhs.uk.

How have patients and the public been involved in this study?

Potential participants were involved in all aspects of this study including deciding the research questions and study design and developing study materials.

Who is organising and funding the study?

The University of Oxford is sponsoring the study which is funded by Medical Research Council and Oxford Health Biomedical Research Centre. The study is also funded by the National Institute for Health and Care Research (NIHR) through the NIHR i4i and OLS Real World Evidence Programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by NHS Health Research Authority, the London-Riverside Research Ethics Committee and the University of Reading Research Ethics Committee.

Participation in future research:

We also ask your consent to approach you about other research in future. If you agree to this, all contact will come from the research team of this study in the first instance, **agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish**. Your contact details would be held securely, separately from this study on a password protected computer in the Department of Experimental Psychology accessible by the research team.

What should I do now?

If you would like for you and your child to take part:

- You will be asked to fill out a consent form to say you are happy to take part.
- We will also ask your child to complete a form to say they are happy to take part

We will then contact your child's GP to let them know that your child is taking part in the study

If you do not want you and your child to take part:

- You don't have to do anything else! Your child will continue to receive care in the NHS as normal

Further information and contact details:

Please contact Dr Eleanor Leigh

Email: eleanor.leigh@psy.ox.ac.uk

Email: go.osca@psy.ox.ac.uk

Thank you for considering taking part.