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Young Person aged 16-18 years INFORMATION SHEET

Go-OSCA Trial

We'd like to invite you 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. 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 parent/carer to take part in a project to **compare** a **new online therapy** to **treatment as usual** for treating **social anxiety disorder in young people**.

The **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 are being **offered the chance to take part** in the trial. Young people who take part can't choose which treatment they get. This decision will be **random**.

Young people complete several **assessments** while taking part. This will include **measures** they **would be completing anyway** as part of their **routine care**, and some **extra questionnaires specifically for the study** which ask about social anxiety symptoms and processes, functioning, and use of health care services. We will also ask **parents/carers** to fill in some **questionnaires** about their views on how you are and also about their own use of health care services.

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 ensure 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, 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.

Young person aged 16-18 Information Sheet Version 1.3_08.04.2025
IRAS Project number: 339554 REC Reference number: 24/LO/0641
Chief Investigator: Eleanor Leigh
Study title: Go-OSCA Trial: Examining the Efficacy of OSCA for the Treatment of Social Anxiety Disorder in Adolescents

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Why have I been invited?

You have been invited because you:

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

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

Do I have to take part?

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

What will happen to me if I decide to take part?

The project will last just over a year in total.

Random allocation to treatment	• You will be assigned to **receive either OSCA or graded CBT**. • This decision is **totally random**, and will be done using a computer programme.
Treatment	• In **either treatment**, you will be **assigned one of the therapists in the clinic you are already coming to.** They will guide and **support** you throughout your treatment. • All of the therapists at your clinic will be delivering both treatments, so **you will have the same trained and experienced therapist whichever treatment you receive**. • **Before treatment starts**, you will **meet your therapist** and **discuss how your treatment** will work and **answer any questions** you may have. • You will complete **regular questionnaires to guide therapy**. • Both treatments take the **same amount of time in total** and include the **same amount of contact with your 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 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 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**.

<u>Here is some more information about the two treatments:</u>

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 sessions with your **individual therapist** will **either** be delivered **face-to-face in clinic** or **remotely via video call**.	▪ In OSCA, you will have scheduled **weekly phone or video calls** lasting around **20 minutes with your 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. ▪ You will also **receive regular messages from your therapist and send messages to them between calls** to help with your progress. ▪ Your therapy will be **supported by an online programme** including an app and a website.
▪ Your therapist will work with you in sessions to learn **ways to manage anxious feelings**, **change negative thoughts** and **gradually face your fears** • You will also have **homework tasks** to help you independently carry on this learning. These will be **reviewed in sessions**.	▪ You will work through **personalised modules** that help you to **understand what keeps your social anxiety going** and then to **test out your fears** in order to **build your 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 needs. ▪ Modules include **written material, video examples, and exercises** for you to try. • **Your therapist** will **review** how you are getting on using the modules **throughout the week**, and **discuss them** as well as completed questionnaires in your weekly calls to help build on learning, agree plans for the next week and practice behaviours or techniques to **make sure you get the most out of the treatment.**

Your questionnaires will ask about:

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

Other information we will gather:

- We will collect information on your school attendance and attainment from the National Pupil Database.
- If you receive OSCA, we will collect information on your usage of OSCA, such as time spent and activity on the programmes.

What should I consider?

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

Are there any possible disadvantages or risks from taking part?

- Some of the **questionnaires may ask things which you find upsetting**. These measures are **similar to the ones that are used in usual treatment**. You can always decide what you would like to discuss in assessment and therapy sessions.
- You 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 you 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 possible benefits of taking part?

- You will be **receiving an evidence-based therapy for social anxiety** whichever you are allocated to.
- You may **learn about your social anxiety** through taking part in the study.
- You will take part in **more thorough assessments** throughout which will be used to **guide your treatment.**
- You will be **invited back for assessments over a longer period after treatment** than would be typical as part of routine care, meaning your **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 GP will be informed of your 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 will be compensated for the additional time completing research assessments that are not part of routine care. **You will be paid in shopping vouchers worth £20 at each of the 3 additional assessment points** after finishing treatment (16, 26, and 40 weeks after the start of the study).

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

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

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 medical records** for as long as those records are retained.

A **fully de-identified (anonymized) dataset will be stored 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 can **change your mind at any time** and withdrawal will not affect the care you 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. Our Young People’s Advisory Group meets regularly to discuss all of our research activities and two members sit on our trial steering committee which oversees this particular project. A charity called McPin helps us to monitor and continually improve our young people involvement.

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 the 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 to take part:

- You will be asked to fill out a consent form to say you are happy to take part.

We will then contact your GP to let them know that you are taking part in the study

If you do not want to take part:

- You don't have to do anything else! You 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.