

treatment is best at helping reduce tics. Regardless of which group you are in the ORBIT treatment will last for 10-weeks. During these 10-weeks you will be asked to complete 10 chapters online. For each chapter there is a version for parents to complete and one for children/young people to complete. Each chapter will take approximately 30-45 minutes. During the 10-weeks a therapist will provide support via messages through the online intervention website or telephone you to provide help with the chapters if you need it. The therapist will respond to your questions about the ORBIT intervention only, he/she will not replace your usual care from your GP/CAMHS. The researchers will explain this in more detail before you consent into the study.

The ORBIT team will ask you and your child to complete questionnaires before you start the treatment, and then again midway through the treatment, at the end of treatment (3 months) and then 6, 12 and 18-months after you started the ORBIT treatment. This will be fully explained to you before you consent into the trial. An adult member of your family will receive £20 vouchers as a thank you each time you complete questionnaires for us (at baseline, 3, 6, 12, & 18-month follow-ups). The questionnaires will probably take you between 15 and 1 hour 30 minutes to complete, depending on which time point you are at.

Who is organising and funding the research?

This research was funded by the NIHR Health Technology Assessment (ref 16/19/02). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

To register your interest in the study go to the following website, where you will be asked to provide your contact details:

<https://orbit.webcbt.se/registration/1563>

Contact for further information

Dr Charlotte Hall (Trial Manager)

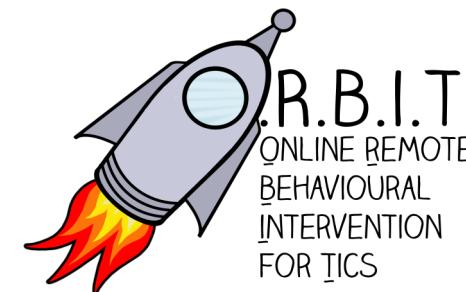
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A collaboration between: Nottinghamshire Healthcare NHS Foundation Trust and Great Ormond Street Hospital for Children NHS Foundation Trust



Online Remote Behavioural Intervention for Tics (ORBIT) Trial

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please contact us if there is anything that is not clear.

What is the purpose of the project?

It can be difficult for people with tics to get access to therapy, and for their families to get support to learn how best to help their child. This is because there are limited therapists who offer treatment to children with tics in the UK. There is a new online delivered treatment that could help children and young people with tics and their families. The ORBIT trial is looking at how effective this online treatment is.

Who is eligible to take part?

We are asking families in England who have a child or young person (aged between 9 and 17) with tics to take part. Both the child/young person who experiences tics AND one parent/carer need to take part.



Do I have to take part?

No. It's your choice. We would like families to chat about whether they would like to be considered to take part in the study. If you and your family do decide you would like to be considered for the study you will need to complete the Consent to contact form which your therapist will send on to us. If you do provide your details it doesn't mean you have to take part. Participation is entirely voluntary.

What will happen to me if I give my contact details?

There are 3 stages involved:

1. The ORBIT research team will arrange a time that suits you to have a telephone conversation to provide more information and assess your family's eligibility for the study. This will include asking details about the child or young person with tics, such as their age, gender, and what health services they have been using. This call will take approximately 30-40 minutes.

2. If you would like to take part and the researcher thinks you may be eligible, they will arrange a time for the parent/carer and child/young person to attend a face-to-face screening appointment. This one-off screening appointment will take place at either the Queen's Medical Centre (Nottingham) or Great Ormond Street Hospital (London). We will pay for your travel expenses.

3. Before you attend this screening appointment the parent/carer will be asked to complete a questionnaire online. The questionnaire is called the Development And Well-Being Assessment (DAWBA). This helps us understand a range of different difficulties the child/young person may experience. It can take between 1 and 2.5 hours to complete. It doesn't have to be done all in one go. We also ask you to ask the child/young person's teacher (or staff member who you feel knows them best e.g. form tutor, teaching assistant etc.) to complete a shorter (20 minute) DAWBA. If we find that the intervention is not suitable for your family from this information, we will telephone you to let you know. We may contact your GP if the information suggests that alternative medical treatment should be sought. The researcher will explain this in more detail at the time of your telephone appointment.

Expenses and payments

We will pay for your and your child's travel costs for attending the face-to-face appointment. If you are travelling from a very long way and it isn't possible to do this in one day we will also pay for overnight accommodation.

What happens to the information I provide as part of screening?

The data collected will be looked at by authorised persons from the ORBIT team, some of the ORBIT team members are based in Sweden. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you, this means that your information will not be shared to anyone outside the research team. We will not have access to your child's medical records, only your normal clinical team (e.g. your GP) will be able to access these. All information that is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database. Any information about you will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it. Questionnaire data such as that you provide in the DAWBA, will be stored only by your unique code so that no one other than the research team will be able to identify your data.

Your personal data (address, telephone number) may be kept for up to 12 months after the end of the study if you give explicit consent for us to contact you about the findings of the study. The questionnaire data may be kept for 5-years. Even if you are not eligible for the study we may use your data in reports we write to explain reasons why patients did not take part in the trial. This will always be anonymous. Your data storage will comply with the UK Data Protection Act 2018 and any amended laws in relation to data protection in the UK and Europe.

What would I have to do if I was part of the trial?

After screening, if you agree to take part in the study you will be placed in one of two treatment groups. Both groups will receive a tic intervention delivered over the internet, however, the content of the two interventions differs slightly. We want to see which