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Online remote behavioural intervention for tics

Submission date	Recruitment status	[X] Prospectively registered
10/07/2025	Recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
10/07/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/01/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tourette Syndrome (TS) is a condition that affects around 1 in 100 children and young people in England. It can cause distress and impact quality of life. Behavioural therapy is known to help, but many young people can't access it due to a shortage of trained therapists.

The ORBIT-UK study aims to test a new online behavioural therapy platform that helps young people manage tics. The therapy is guided by trained "Coaches" and delivered remotely, making it easier to access. The goal is to see if the platform is easy to use, acceptable to families, and suitable for use in the NHS.

Who can participate?
Young People (Aged 9–17 years) who:
- Have suspected or confirmed Tourette Syndrome or chronic tic disorder.
- Have moderate to severe tics.
- Can give informed consent (or have parental consent if under 16).
- Have internet access and use a device regularly.
- Are clinically suitable for the intervention.

Supporters (e.g., parent or guardian):
- Must be 18 or older.
- Will help the young person through the therapy.

What does the study involve?
- Duration: Each participant is involved for up to 12 weeks, 10 weeks of coach support.
- Therapy: 10 chapters of online therapy using Exposure and Response Prevention (ERP) techniques.
- Support: Regular contact with a Coach via messages on the platform.
- Activities: Watching videos, completing exercises, and tracking progress.
- Assessments: Questionnaires and interviews before, during, and after the therapy to measure tic severity, quality of life, and satisfaction.

What are the possible benefits and risks of participating?
Possible Benefits
- Easier access to behavioural therapy.

- Potential reduction in tic severity.
- Improved quality of life.
- Support for both young people and their families.
Possible Risks
- Some participants may experience temporary increases in tics, anxiety, or low mood.
- These effects are monitored closely, and support is available.
- Participants can withdraw at any time without affecting their care.

Where is the study run from?
The study is delivered through the Nottinghamshire Healthcare NHS Foundation Trust (NHCFT) Tic Disorder Service and coordinated by the University of Nottingham (UK).

When is the study starting and how long is it expected to run for?
Starting on 21st August 2025 and runs for 13 months

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK) under the i4i Product Development Award

Who is the main contact?
ORBIT-UK study team at: orbit@nottingham.ac.uk

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
351072

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
67208

National Institute for Health and Care Research (NIHR)
205467

Study information

Scientific Title
Online remote behavioural intervention for tics: a single cohort usability study

Study objectives
PURPOSE - The purpose of this study is to substantially increase access to evidence-based behavioural therapy for tic disorders in CYP and improve their outcomes by developing ORBIT-UK as an NHS ready clinical product for commercial investment, adoption, and NHS commissioning in the UK.
OBJECTIVES - As this is not a clinical trial, we do not differentiate between primary and secondary objectives. The objectives for this study are as follows:
1. To test the acceptability of the ORBIT-UK platform: a Coach-guided, remotely delivered behavioural intervention for tics in Young People, and the feasibility of the ORBIT-UK service pathway in the NHS. Acceptability and feasibility will be measured through achievement of recruitment and adherence targets.
2. To gather feedback from Young People, Supporters, Coaches and clinicians on the acceptability and usability of both the platform and the service pathway. This will be investigated through the following outcome measures:
• Semi-structured exit interviews
• An 8-item satisfaction questionnaire created and used in the previous ORBIT trial (Hollis et al., 2021)
3. To identify strengths and weaknesses of the platform through usability testing. Usability will

be investigated through the following outcome measures:
• The system usability scale (SUS) (Brooke, 1996)
• Chapter usability ratings collected at the end of each intervention chapter
• Semi-structured exit interviews
• Platform usability metrics including:
• Completion and engagement metrics (chapters completed, number of logins)
• Duration metrics (session timers, content consumption)
• Error metrics (error rate, crash reports, accessibility issues)
4. To present the change from baseline to post-intervention clinical outcomes to explore symptom changes following completion of the ORBIT-UK platform. The following measures will be used:
• The Yale Global Tic Severity Scale (YGTSS) (Leckman et al., 1989) at baseline and 10-12 weeks including the total tic severity score (TTSS) and the impairment scale
• The Parent Tic Questionnaire (PTQ) (Chang et al., 2009) at baseline, 5 weeks and 8 weeks
• The Child and Adolescent Gilles de la Tourette Syndrome - Quality of Life Scale (GTS-QoL) (Cavanna et al., 2013) at baseline and 8 weeks
• The Clinical Global Impressions – Improvement Scale (CGI-I) (Guy, 1976) at 10-12 weeks Goal-based Outcomes (GBOs) (Law & Jacob, 2013) assessed each week
5. To investigate the safety of the ORBIT-UK platform. This will be assessed through AE/SAE reporting throughout the study.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/04/2025, North West – Greater Manchester (GM) Central (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048023; gmcentral.rec@hra.nhs.uk), ref: 25/NW/0107

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tic disorders

Interventions
ORBIT-UK is a web-based platform that has been specifically designed for use by children and young people, with age-appropriate appearance, animations, and interactive scripts, developed and hosted by Blum Health (https://blumtechgroup.com/). The overall duration of the study will be 13 months and each participant will spend 12 weeks participating in the study.

STUDY CONFIGURATION
A 10/12-week, single cohort usability study for children and young people with tics. Participants will receive 10 weeks of online, remotely delivered, therapist-supported behavioural therapy for tics.

Primary endpoint
The primary endpoint will be 3-months post completion of baseline measures.

There are 10 chapters of the intervention, which is designed to last a total of 10 weeks. Patients have regular contact with an experienced, trained therapist (termed 'ORBIT-UK coach', but 'coach' will be used hereafter for brevity) during this time via messages that can be sent inside the ORBIT-UK platform (resembling an email). There will be 2 coaches total employed to support the delivery of ORBIT-UK throughout this study. The coach can directly comment on exercises that the patient has been working on and give specific feedback to motivate the patient. The patient typically has contact with their coach several times a week.

If necessary, it is possible to allow the coach guided intervention to be given over a 12-week period, providing the coach only offers support for a maximum of 10 weeks during the 12-week period. This may be needed if the participant is unable to engage with the ORBIT-UK intervention for a period of time for reasons such as holidays, exam periods, illness or bereavement.

For the tic-focused intervention 'ORBIT-UK', the intervention manual (constructed by the co-applicants) (Hall et al., 2019, Hollis et al, 2023b) consists of evidence-based interventions adapted from previously published intervention manuals on Exposure and Response Prevention (ERP) and established behavioural intervention for tics protocols (Piacentini et al., 2010, Woods et al., 2008, Verdellen et al., 2011b). Each of the 10 modules includes texts, animations and exercises. The first four modules cover the main content of the intervention, completion of these four CYP modules is a minimum requirement to meet intervention completion criteria. The intervention is based on ERP techniques. During the intervention, participants are instructed to practice controlling their tics, this is known as 'response prevention'. Then, with the help of their designated supporter, the participant is instructed to provoke premonitory urges (the urge to tic often felt before the tic is expressed) and try to suppress the need to express/demonstrate the tic, this is known as 'exposure'. A supporter can be a parent, caregiver, or any family member with the capacity to support CYP through the intervention.

The breakdown for the module content is as follows:
Child: Learn about tics. Supporter: Introduction
Child: More about tics. Supporter: Thoughts and behaviours of supporters
Child: Practicing stopping your tics. Supporter: Praise
Child: Making the practice more difficult. Supporter: Prompts
Child: Continued practice. Supporter: Situations and reactions
Child: School and College. Supporter: Troubleshooting
Child: Talk about your tics. Supporter: Continued practice
Child: Continued practice. Supporter: Continued practice
Child: The final sprint. Supporter: Continued practice
Child: Plan for the future. Supporter: Plan for the future

The child/young person and their supporter are provided with their own separate login to the ORBIT-UK platform. The supporter login allows them to access information regarding coping strategies, social support and functional analysis relating to tics. Both supporters and CYP have the same access to the coach.

Follow-up activities
At the end of each chapter, participants will complete:
- A review of progress towards goal based outcomes

- A chapter usability rating
- On-going AE reporting, if necessary, through an in-built 'Report AE' function

Mid-intervention (Week 5)
At mid-intervention (Week 5), supporters will complete the PTQ to give an indication of how the young person is coping with their tics.

End of the intervention
The end of intervention has been defined as Week 8, based on findings from the previous ORBIT trial that showed most participants reached this stage, and all therapeutic content will have been delivered. At this stage, participants will complete a series of outcome measures within the platform including:
- The PTQ (completed by supporter)
- The GTS-QoL (completed by young person)
- The CGI-I (completed by the Coach)
- The System Usability Scale (SUS) (Brooke, 1996) (completed by young person and supporter)

The SUS is a widely used, ten item Likert questionnaire designed to assess the usability of a website or platform. Participants will rank each statement from 1 to 5, based on how strongly they agree with the statement about the usability of the platform, with 1 being strongly agree and 5 being strongly disagree. To calculate a total score, for each of the odd numbered questions subtract 1 from the score. For items 2, 4, 6, 8, 10, subtract the score from 5. Multiply the sum of these scores by 2.5 to obtain the total score. SUS scores have a range of 0 to 100.

An ORBIT satisfaction questionnaire (completed by young person and supporter)

Once participants have completed all chapters, their coach will schedule a Teams call to administer the YGTSS with the young person and their parent/caregiver (Week 10-12). The coach is only available to support the participants during the 10-week intervention window (or a maximum of 10 weeks delivered over a 12-week period). Access to the ORBIT-UK platform is granted for 1-year, however, after the 10-weeks of coach support, this access is without coach support. Regardless of how far through the chapters the participant got within the 10-week supported intervention, all the chapters are open to the family for the 1-year period. ORBIT-UK intervention completion is defined as finishing the first four child ERP chapters.

Qualitative Exit Interviews
At the end of the intervention, participants will be invited to participate in an exit interview with the researcher, which may be face-to-face or via videoconferencing. The interview is optional, and participants will have indicated whether they wish to be contacted regarding the interview when completing the ICF. The interview will last approximately 30 minutes and is designed to gather qualitative feedback on intervention usability, acceptability and preliminary effectiveness. A member of the research team will conduct separate interviews with the following people:
- The young person
- The supporter
- The coach
- The coach's clinical supervisor

Where participants are under the age of 16, they will be accompanied in the interview by their parent/caregiver. Where participants are over 16, they will be given the choice whether they would like their parent/caregiver to accompany.

Intervention Type
Behavioural

Primary outcome(s)
1. Tic severity is measured using the Parent Tic Questionnaire (PTQ) at baseline, mid-intervention (Week 5), and end of intervention (Week 8)
2. Health-related quality of life is measured using the Child and Adolescent Gilles de la Tourette Syndrome - Quality of Life Scale (C&A GTS-QoL) at baseline and end of intervention (Week 8)
3. Usability of the platform is measured using the System Usability Scale (SUS) at end of intervention (Week 8)
4. Satisfaction with the intervention is measured using the ORBIT satisfaction questionnaire at end of intervention (Week 8)
5. Global symptom improvement is measured using the Clinical Global Impression - Improvement scale (CGI-I) at Week 10–12
6. Tic severity is measured using the Yale Global Tic Severity Scale (YGTSS) at Week 10–12
7. Goal-based outcomes progress is measured using participant self-report at the end of each chapter during the intervention period
8. Chapter usability is measured using a chapter usability rating at the end of each chapter during the intervention period
9. Adverse events are monitored using the in-built 'Report AE' function throughout the intervention period

Key secondary outcome(s))
Qualitative feedback on usability, acceptability and preliminary effectiveness is measured using semi-structured interviews at end of intervention (Week 10–12)

Completion date
03/03/2027

Eligibility

Key inclusion criteria
1. Aged 9 to 17 years: patient confirmed at screening.
2. Suspected or confirmed Tourette syndrome/chronic tic disorder: Including moderate/severe tics with a score >15 on the Yale Global Tic Severity Scale (YGTSS) Total Tic Severity Score (TTSS); TTSS score >10 if motor or vocal tics only. Coach will assess this at initial assessment via video conference.
3. Competent to provide written, informed consent (parental consent for child aged <16): referring clinician confirms at screening appointment.
4. Broadband internet access and regular PC/laptop/Mac/mobile device user, with mobile phone SMS: patient confirmed at screening.
5. Clinical suitability for ORBIT confirmed by referrer from patient's usual care team.
6. A parent, carer or legal guardian aged 18+ who is willing and able to act as a Supporter.
7. Supporters: A Supporter can be a parent, caregiver, or legal guardian chosen by the Young Person. They must be at least 18 years of age or over and have capacity to support the Young Person through the intervention.
8. Clinicians: Only clinicians who appear on the ORBIT-UK site delegation log will be eligible to be approached to be interviewed.
9. Coaches: Only Coaches who appear on the ORBIT-UK site delegation log will be eligible to be approached to be interviewed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 years

Upper age limit
17 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Presentation of functional tics (Functional Neurological Disorder)
2. Moderate/severe intellectual disability: Confirmed through qualitative judgement of the referrer from the patients' usual care team.
3. Immediate risk to self or others: Confirmed through referrer from the patients’ usual care team.
4. Parent or child not able to speak or read/write English: Patient confirmed through screening by the referring clinician.

Date of first enrolment
26/01/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham

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NG3 6AA

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request via bbsponsor@nottingham.ac.uk after the study endpoint in March 2027

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/01/2026	08/01/2026	Yes	No
Statistical Analysis Plan	version 1.0	04/12/2025	04/12/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes