NICE National Institute for Health and Care Excellence

Evidence generation plan for digital therapy for chronic tic disorders and Tourette syndrome: ORBIT

Implementation support

Published: 7 May 2025

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Contents

1 Purpose of this document

NICE's assessment of digitally enabled therapy for chronic tic disorders and Tourette syndrome recommends that more evidence is generated while the Online Remote Behavioural Intervention for Tics (ORBIT) technology is being used in the NHS. NICE has produced a separate evidence generation plan for Neupulse.

This plan outlines the evidence gaps and what data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps.

The technology developer is responsible for ensuring that data collection and analysis takes place.

Guidance on commissioning and procurement of the technology will be provided by NHS England, who are developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the developer does not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years), the technology developer should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether the technology can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The developer can strengthen their evidence base by addressing any other evidence gaps (see section 2.2). This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Impact of ORBIT on health-related quality of life

The impact of the Online Remote Behavioural Intervention for Tics (ORBIT) technology on people's daily lives is uncertain. Further analysis of the data collected in the ORBIT-UK trial is needed to reduce the uncertainty. The data includes information on the impact that the technology has on people's symptoms measured using the Yale Global Tic Severity Scale, the Clinical Global Impression Score – Improvement, and ideally the Goal Based Outcomes scale. Qualitative data should include those collected from the child or young person, and their parents or carers. Ideally, this should include the impact on daily life, for example on self-esteem, social interactions and school or work attendance and performance.

To supplement existing data collected at 6 and 18 months, further analyses of the ORBIT-UK trial data is needed on outcomes collected at 3 and 12 months after the intervention. Further analyses at these time-points will support health-economic modelling and reduce uncertainty in projections to distant time horizons.

Resource use

More information on how using the technology would affect resource use in the NHS, during and after implementation, is needed to help the committee understand the technology's cost effectiveness. Resource estimates should include the impact of the

technology on services, for example those provided by local specialist clinics (including 'e-coach' time) and carers. This could free up resources that could be used to increase access to treatment or clinical assessment. The ongoing ORBIT study will collect some of these data as part of a budget impact assessment.

2.2 Evidence that further supports committee decision making

Clinical and cost effectiveness in different subgroups

There is limited evidence for subgroups of children and young people with diagnosed comorbidities, including:

- attention deficit hyperactivity disorder (ADHD)
- obsessive-compulsive disorder
- autism spectrum disorder
- mood disorders and
- anxiety.

More information is also needed on the efficacy of ORBIT in people who have severe tic disorders, and in people from different ethnic backgrounds. There is no evidence for ORBIT in adults. Evidence on the use of ORBIT in adults would support future assessments on the impact of the technology in this population.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

The committee was made aware of one ongoing study, the Clinical translation and commercialisation of ORBIT study (NIHR205467).

The study is investigating the potential use of ORBIT within the NHS and aims to:

- define how the technology should be used
- assess the usability and acceptability of the platform
- conduct a budget impact assessment
- develop a commercialisation and NHS adoption strategy.

Table 1 summarises the evidence gaps. Information about evidence status is derived from the EAG's report; evidence that does not meet the scope and inclusion criteria is not included. The table shows the evidence available to the committee when the guidance was published.

Table 1 Evidence gaps and ongoing studies

Evidence gap	ORBIT
Impact of ORBIT on people's symptoms and health-related quality of life	Limited evidence Ongoing study
Resource use	Limited evidence Ongoing study
Clinical and cost effectiveness in different subgroups	Limited evidence Ongoing study

3.2 Data sources

Data should be sourced from the ORBIT-UK randomised controlled trial, as well as the ongoing ORBIT study.

3.3 Evidence collection plan

Quantitative and qualitative data on the clinical impact of ORBIT was collected as part of the ORBIT-UK study at 3, 6, 12 and 18 months, and could be made available for future cost-effectiveness assessments. Additional evidence around the clinical impact of ORBIT, resource use, useability and acceptability is currently being collected through the ongoing NIHR205467.

Statistically robust data about the effectiveness of the technology in different subgroups requires very large study populations that are not feasible in this context. Analysis of any data that are available at the end of the evidence generation period will nevertheless support future NICE decision making.

The study should enrol a representative population; that is, people who would be offered standard care, including behavioural therapy, without digital technologies. This may include face-to-face appointments and monitoring. Eligibility for inclusion, and the point of starting follow up should be clearly defined and consistent during the study, to minimise selection bias.

Data should be collected from the point at which a person would become eligible for standard care. The study should also capture information on people who were eligible but chose not to use the technology or could not access it. Ideally, the studies should be run across multiple centres, aiming to recruit centres that represent the variety of care pathways in the NHS.

Incomplete records and potentially demographically imbalanced selection can lead to bias if unaccounted for. Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

3.4 Data to be collected

Study criteria

- At recruitment, eligibility criteria for suitability of using the digital technology and inclusion in the real-world study should be reported, and include:
  - a clinical diagnosis of tic disorder or Tourette's syndrome
  - position of the technology in the clinical pathway
  - the point that follow up starts.

Baseline information and patient outcomes

- Information about individual characteristics at baseline, for example, sex, age, ethnicity, socioeconomic status, clinical diagnosis (and date of diagnosis), details of any comorbidities and treatments. Other important covariates should be chosen with input from clinical specialists.
- Changes in tic severity using the Yale Global Tic Severity Rating Scale total score, the Clinical Global Impression Score – Improvement, and ideally the Goal Based Outcomes scale, at baseline and over follow up.
- Qualitative information about the impact of ORBIT on daily life, ideally including self-esteem, social interactions and school or work attendance and performance.
- Information on healthcare resource use and exacerbation-related hospitalisation costs related to tic disorders and Tourette syndrome. This should include emergency department visits, hospital admissions, length of stay and GP visits.
- Changes in a person's medication and any referrals to other services.

Implementation

- Costs of digital technologies for supporting treatment of tic disorders and Tourette syndrome, including licence fees, healthcare professional staff time and training costs to support the service and costs of integration with NHS systems.
- Access and uptake, including the number and proportion of eligible people who were

able to, or accepted an offer to, access the technology, and reasons for refusal.

- Engagement and drop-out information, including reasons for stopping treatment.

Safety monitoring outcomes

- Any adverse events arising from using digital technologies to support treatment of tic disorders and Tourette syndrome.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world evidence studies.

3.5 Evidence generation period

The evidence generation period should be 3 years. This aligns with the planned duration of NIHR205467.

4 Monitoring

The developer must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The developer should tell NICE, as soon as possible, about anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the developer should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Minimum evidence standards

There is some clinical evidence that suggests that the Online Remote Behavioural Intervention for Tics (ORBIT) technology may improve symptoms of tic disorders and Tourette syndrome in children and young people. The developer did not report any safety concerns when using the digital technologies to support treatment of tic disorders and Tourette syndrome.

For new technologies, the committee has indicated that it may in the future be able to recommend technologies in this topic area that have evidence for:

- a beneficial impact of the digital technologies compared with standard care for treating tic disorders and Tourette syndrome without digital technologies
- a clinical improvement in tic disorders and Tourette syndrome using the Yale Global Tic Severity Rating Scale total scores, the Clinical Global Impression Score – Improvement, and ideally the Goal Based Outcomes scale
- improvements in overall patient quality of life
- resource use associated with the technologies and NHS standard care
- intervention acceptance, completion rates, patient preference, and uptake rates
- the safe use of the technology (including all adverse events).

The developer can strengthen the evidence base by also having evidence for the effectiveness of the technology in people with different comorbidities.

6 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

System considerations

- There is high variation in services available to the population. The contributing services or centres should be chosen to maximise the generalisability of evidence generated. For example, by including groups of people with different socioeconomic status, or to improve data collection for any relevant subgroups. Developers should provide clear descriptions of the services and settings in which the study is done, and the characteristics of the included children, young people and adults.
- There is an unmet need for diagnosing and treating tic disorders and Tourette syndrome, and access to treatment also varies across the NHS. This will bias which centres or services are selected for data collection. This could also bias which centres adopt the technology and increase health inequalities.
- The developer should provide training for staff to support use of the technology.
- The ORBIT 'e-coaches' need time for training and supervision, and to get a thorough understanding of the digital content. They also need time to support people accessing the technologies and to review their progress. Oversight of the e-coaches by more senior professionals also requires staffing time.

Evidence generation

- There is an unmet need for diagnosing tic disorders and Tourette syndrome. This should be considered when assessing the inclusion criteria for future studies and is likely to lead to selection bias.
- Evidence generation should be overseen by a steering group including researchers, commissioners, healthcare professionals, and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff, and by using suitable real-world data to

collect information when possible.

- Careful planning of the approach to information governance is vital. The developer should ensure that appropriate structures and policies are in place to ensure that data is handled in a confidential and secure manner, and to appropriate ethical and quality standards. Once the evidence generation period has concluded, ideally further data about the clinical impact of the digitally enabled therapy for chronic tic disorders and Tourette syndrome could be collected to support planning and decision making.

Accessibility

- The technology may not be suitable for everyone, for example people without access to, or who cannot use, a smartphone or computer. People with cognitive impairment, problems with manual dexterity or learning disabilities may need additional help from carers or advocates.
- The digital technology could be more beneficial if it is set up to ensure that language and cultural considerations of its users are met, and the digital literacy of people using it is considered.
- People from ethnic minority backgrounds are underrepresented in terms of accessing the appropriate services for tic disorders and Tourette's syndrome. This could impact study recruitment and access to the technology.

ISBN: 978-1-4731-6993-7