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Extended Research Article

Digitally enabled therapy for chronic tic disorders and Tourette Syndrome: a systematic review and economic evaluation

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Scientific summary

Digitally enabled therapy for chronic tic disorders and Tourette Syndrome: a systematic review and economic evaluation

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Scientific summary

Background

Tic disorders are neurodevelopmental conditions characterised by fast, irregular and repetitive muscle movements that can manifest in any part of the body. Tics can affect body movements (known as motor tics), while involuntary repetitive sounds are known as vocal or phonic tics. Persistent or chronic tic disorders (CTDs) refer to single or multiple motor or vocal tics (but not both) that have persisted for more than 12 months since the first tic onset. Tourette syndrome (TS) refers to multiple motor tics and one or more vocal tics that have been present at the same time (but not necessarily concurrently) during the course of the disease and have persisted for more than 12 months since the first tic onset. The mean age of onset for tic disorders is around 5 years, with severity typically worsening between 10 and 12 years of age and then improving through adolescence into early adulthood. People with CTDs commonly experience psychiatric comorbidities, such as attention deficit hyperactivity disorder and obsessive–compulsive disorder. Tic disorders can vary in severity and impact various aspects of people's lives, contributing to a reduced quality of life (QoL). Current practice varies between countries and according to the availability of local services, but, in general, treatment options for CTDs include psychoeducation, behavioural therapy, pharmacological therapy and deep brain stimulation. Digitally enabled interventions have the potential to improve access as well as equity of access to treatment for people with tic disorders.

Objectives

The specific objectives of this assessment were to:

- Evaluate the safety and effectiveness of digitally enabled non-pharmacological therapy for treating CTDs and TS in UK clinical practice [Online Remote Behavioural Treatment for Tics (ORBIT) and Neupulse].
- Develop an economic model to assess the cost-effectiveness of digitally enabled technologies for the non-pharmacological treatment of CTDs that are available or likely to become available in UK clinical practice.

Methods

This manuscript contains reference to confidential information provided as part of the NICE appraisal process. This information has been removed from the report and the results, discussions and conclusions of the report do not include the confidential information. These sections are clearly marked in the report.

Clinical effectiveness

Comprehensive searches of major electronic databases, including MEDLINE, EMBASE, Cochrane Library, Web of Science and Cumulative Index to Nursing and Allied Health Literature, were conducted to identify relevant reports of published studies. Evidence was considered from randomised controlled trials and non-randomised comparative studies published in English and assessing the relevant digitally enabled technologies. Data on the characteristics of the studies, participants' intervention and comparator were extracted along with relevant patient-reported, clinical and intermediate outcomes, as well as information relating to the use of digital technologies. The risk of bias of included studies was assessed using the Cochrane risk-of-bias tool (version 2). Where sufficient data were available and it was appropriate, data were pooled using random-effects meta-analyses.

Cost effectiveness

A systematic literature search for all full economic evaluation studies of interventions for tic disorders in adults or children was conducted. A decision-analytic, Markov cohort, model was developed, based on the ORBIT study, to assess the cost-effectiveness of ORBIT compared to online psychoeducation and Neupulse compared to a waiting list control. The model base case was run for a lifetime horizon and results reported as incremental cost per quality-adjusted life-

year (QALY) gained from a UK NHS perspective. Costs and outcomes occurring beyond the first year were discounted at 3.5% per annum. Five health states were included in the model. Health states were defined according to quintiles of the Yale Global Tic Severity Scale – Total Tic Severity Score (YGTSS-TTSS) (very mild, mild, moderate, severe and very severe tics). Transition probabilities between health states were obtained up to 18 months from the ORBIT study and up to 4 weeks from unpublished data obtained through personal communication with the company for Neupulse. Given uncertainty surrounding the long-term outcomes of Neupulse, the External Assessment Group (EAG) consider this comparison to be more in line with National Institute for Health and Care Excellence's early value assessment approach. Intervention costs were obtained from the published literature and directly from companies. Health state costs and Child Health Utility-9 Dimensions utilities were based on data reported within the ORBIT study. The model was fully probabilistic, and a range of scenario analyses were undertaken to explore uncertainty in the base-case conclusions.

Results

Nature, description and quality of the available evidence

The database search identified 379 unique publications, and three further reports were identified. Three trials reported in 14 publications were included in the review. Two studies compared ORBIT with psychoeducation (one in the UK and the other in Sweden) and one UK-based study Neupulse active stimulation with sham stimulation. The two ORBIT studies recruited people aged 9–17, and the Neupulse study recruited people aged at least 12 years. All three studies were assessed as being at low risk of bias according to the Cochrane risk-of-bias tool (version 2).

Summary of benefits and risks

We were able to combine results of two outcomes assessed at two time points across the two ORBIT studies (445 participants in total). Pooled results at 3 and 12 months for YGTSS-TTSS in the ORBIT studies showed statistically significantly lower scores for the intervention groups than the control groups. However, no significant improvements in tic-related impairment and distress measured using the impairment score of the YGTSS were observed between treatment groups. In each ORBIT study, secondary outcome measures did not show a consistently greater response in the exposure and response prevention (ERP) group compared to the psychoeducation group at all assessed time points. In the UK ORBIT study, Clinical Global Impressions Improvement showed a greater response in the ERP group at 3, 12 and 18 months but not at 6 months. In the Swedish ORBIT study, Clinical Global Impressions Severity showed a difference in favour of the ERP group at 3 months, but not at 6 months. In both studies, the Children's Global Assessment Scale showed no differences between intervention groups at 3 months and a positive difference in favour of the ECHURP group at 12 and 18 months in the UK ORBIT study. The estimated mean difference in the Parent Tic Questionnaire favoured the ERP group in the UK ORBIT study at 3, 6 and 12 months but not at 18 months and was not significant at 3 and 12 months in the Swedish ORBIT study. Similarly, in the UK ORBIT study, other measures evaluating anxiety and mood, emotional and behavioural functioning did not show a consistent pattern of response at all assessed time points. In general, participants' engagement with the interventions, adherence and dropouts were reported to be similar between intervention groups.

The Neupulse study reported statistically significantly lower YGTSS-TTSS scores at 4 weeks in the active stimulation group compared to the sham stimulation group. Greater reductions in YGTSS motor and phonic scores were also observed among participants receiving active stimulation than among those receiving sham stimulation. However, no significant differences between treatment groups were observed for the YGTSS-Impairment score or the Premonitory Urge for Tics Scale – Revised.

Summary of costs and cost-effectiveness

It was not possible to determine a definitive base-case incremental cost-effectiveness ratio (ICER) due to a lack of long-term follow-up data and uncertainty about the long-term intervention costs that might be required to maintain, if possible, intervention effectiveness at the observed trial follow-up time points. For the comparison of ORBIT versus online psychoeducation, transition probabilities were broadly similar in both groups, suggesting a lack of clear evidence of long-term benefit. This was reflected in substantial uncertainty surrounding the estimated ICERs. Probabilistic ICERs ranged from £642 per QALY gained to ORBIT being dominated. The probability of ORBIT being cost-effective at a threshold value of £20,000 per QALY ranged from 52% to 89% across a range of scenarios explored.

Cost-effectiveness results for Neupulse were highly uncertain due to a lack of published transition probability data, short 4-week follow-up and uncertainty surrounding the most likely intervention device and subscription costs if the device were rolled out to the UK NHS. Transition probabilities were based on small counts, and longer follow-up is required to determine whether initially optimistic Neupulse improvements can be sustained in the longer term.

Conclusions

Two studies comparing ORBIT with psychoeducation (one each in the UK and Sweden) and one UK study comparing active stimulation with sham stimulation showed that tic severity in terms of YGTSS-TTSS scores was lower in the intervention groups as compared to the comparator groups at follow-up periods ranging from 4 weeks to 12 months. No improvements in the YGTSS-Impairment scores were evident, and secondary outcome measures showed a mixed response across time points and ORBIT studies. The EAG do not consider it possible to make any recommendations in favour, or against Neupulse, given the current evidence base for cost-effectiveness. The evidence base for ORBIT is stronger. ORBIT appears to be cost-effective over shorter modelling time horizons compared to psychoeducation, but there remains some uncertainties regarding the long-term trajectory of disease and long-term maintenance of treatment benefit beyond 18 months.

Strengths, limitations and uncertainties

Thorough and robust methods were used for this assessment. However, there was limited evidence available for the technologies of interest and inconsistencies in the outcomes assessed, and their timing and further meaningful analyses were hampered. The comparators of the included studies did not include face-to-face behavioural therapy and it is not possible to differentiate the effects of online delivery from those of ERP. The reason(s) for selection of only the YGTSS-TTSS score as the primary outcome in the included studies, rather than the YGTSS-Impairment score, is unclear. Currently, available data for Neupulse refer to stimulation delivered for a maximum period of 4 weeks.

Published transition probabilities were not available for Neupulse and the intervention cost that might be incurred if the device were used in NHS practice is unclear. Economic modelling required several major assumptions around the most appropriate long-term extrapolations of clinical benefit in the model and what, if any, intervention costs would be required to maintain observed treatment effectiveness over the longer term.

Key areas for future research

- Replication of studies is needed to confirm observed results.
- Future studies should be of longer duration and compare the clinical and cost-effectiveness of digitally enabled with face-to-face behavioural therapy. In addition, inclusion of a non-active intervention, such as waitlist, would allow the natural course of the disease to be monitored over time.
- Future studies should consider the impact of interventions on participants' daily lives as the primary outcome.
- Appropriate subgroup analyses according to sex and common comorbidities should be planned in future studies.
- Future studies should include economic evaluations and collect longitudinal data to improve long-term modelling of treatment effectiveness. Emphasis should be placed on determining the impact clinical outcomes on QoL and costs.

Study registration

This study is registered as PROSPERO CRD42024508045.

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This article

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