ISRCTN70758207 https://doi.org/10.1186/ISRCTN70758207

Online Remote Behavioural Intervention for Tics (ORBIT)

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tourette's syndrome is a condition where a person makes involuntary sounds and movements called tics. This study is comparing the effectiveness of two treatments delivered online for children and young people with Tourette's syndrome or a chronic tic disorder. The aim is to find out whether a therapist-guided, parent-assisted online intervention helps children and young people to manage their tics. The study is also exploring whether the online programme is acceptable to families, identifies any problems in getting families to take part/complete the programme and also healthcare professionals' views about the programme.

Who can participate?
Families in England with a child/young person (aged 9-17) who experiences tics

What does the study involve?
Interested families undergo a telephone interview with a researcher and are then asked to complete an online questionnaire. They then attend an appointment at either Great Ormond Street Hospital (London) or Queen's Medical Centre (Nottingham). Families are randomly allocated to one of two treatments. One treatment uses behavioural therapy (BT), and the other involves psychoeducation. Both treatments last for 10 weeks and involve completing online chapters (for the parent and child) with the support of a therapist, and there are also some tasks to complete offline. After finishing the treatment, families are asked to complete more questionnaires (at 3, 6, 12 and 18 months after starting the treatment). A smaller sample of families and healthcare professionals are also interviewed about their experience of participation.

What are the possible benefits and risks of participating?
It is important to research online treatment for tics because, at the moment, many people with tics do not get any treatment because there are not enough trained tic therapists. If online-delivered treatment is effective, this may mean more children and young people could access tic therapy. Both groups receive an intervention which offers support for tics beyond that typically available for most patients with tics. The therapy content itself has been well established, it is the method of delivery (online) that is being investigated. Families are asked to attend a face-to-face assessment, but they are reimbursed for all their travel costs, even if they do not join the

study. Families are also asked to complete questionnaires at different time points in the study, but they are reimbursed for their time in the form of £20 worth of vouchers. They are able to complete the follow-up questionnaires at home, reducing the burden. This is a low-risk intervention and there are no anticipated serious side effects. Also, participants undergo a thorough assessment before joining the study which decreases the risk of patients in need of more extensive care (e.g. risk management) being included in the study. The participants have contact with both the therapist and the researcher during the 10-week treatment, so are closely monitored for any potential side effects.

Where is the study run from?
1. Queens Medical Centre (UK)
2. Great Ormond Street Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2017 to April 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Charlotte Hall, charlotte.hall@nottingham.ac.uk (UK)

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Hall

ORCID ID
http://orcid.org/0000-0002-5412-6165

Contact details
Division of Psychiatry & Applied Psychology
Institute of Mental Health
University of Nottingham Innovation Park
Triumph Road
Nottingham
United Kingdom
NG7 2TU

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

NCT03483493

Secondary identifying numbers
CPMS 37415

Study information

Scientific Title
Therapist-guided, parent-assisted remote digital behavioural intervention for tics in children and adolescents with Tourette syndrome: an internal pilot study and single-blind randomised controlled trial

Acronym
ORBIT

Study objectives
Does a therapist-guided, parent-assisted online intervention improve tics in children and adolescents with Tourette syndrome or chronic tic disorder?

The ORBIT (Online Remote Behavioural Intervention for Tics) trial is comparing the effectiveness of two treatments delivered online for children and young people with Tourette Syndrome or Chronic Tic Disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2018, Greater Manchester Central (NRES Committee North West; +44 (0)207 104 8379, (0)2071048109; gmwest.rec@hra.nhs.uk), ref: 18/NW/0079

Study design
Randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Tourette Syndrome or Chronic Tic Disorder

Interventions

Families in England with a child/young person (aged 9-17 years) who experiences tics are being asked to take part. Interested families undergo a telephone screen with a researcher and then asked to complete an online questionnaire. They then attend a screening appointment at either Great Ormond Street Hospital (London) or Queen's Medical Centre (Nottingham). Families that are eligible and want to take part are randomly allocated to one of two treatments. One treatment uses behavioural therapy (BT), the other involves psychoeducation. Both treatments last for 10 weeks and involve completing online chapters (for the parent and child) with the support of a therapist, there are also some tasks to complete offline. After finishing the treatment, families are asked to complete more questionnaires (at 3, 6, 12 and 18 months after starting the treatment). A smaller sample of families and healthcare professionals are also interviewed about their experience of participation. The study is looking to see if the online delivered treatment may be effective at helping children and young people manage their tics. The study is also exploring whether the online programme is acceptable to families, identifying any problems in getting families to take part/complete the programme and also healthcare professionals' views about the programme.

The Tourette-focused intervention involves the parent & young person completing 10 chapters online over 10 weeks. The chapters will be delivered online via the BiP web-based platform and can be completed in the participants own home. Participants have remote regular contact with an experienced, trained therapist via messages sent inside the treatment platform (resembling an email). The therapist can directly comment on exercises that the patient has been working on, and give specific feedback to motivate the participant. The psychoeducational information intervention involves the parent & young person completing 10 chapters. The chapters will be delivered online via the BiP web-based platform and can be completed in the participant's own home. Participants have remote regular contact with an experienced, trained therapist via messages sent inside the treatment platform (resembling an email). The therapist can directly comment on exercises that the patient has been working on, and give specific feedback to motivate the participant.

Intervention Type

Behavioural

Primary outcome measure

Tic disorder symptoms assessed using the Yale Global Tic Severity Scale (YGTSS) - Total Tic score; Timepoint(s): Baseline, 3, 6, 12 and 18 months

Secondary outcome measures

1. Number, frequency and intensity of motor/vocal tics measured using the Parent Tic Questionnaire at baseline, 5 weeks, 3 months, 6 months, 12 months and 18 months
2. Symptom severity/improvement measured using the Clinical Global Impressions Scale at 3, 6, 12 and 18 months
3. Tic distress and impairment measured using the Yale Global Tic Severity Scale Impairment Scale at baseline, 3, 6, 12 and 18 months
4. Global functioning measured using the Children's Global Assessment Scale at baseline, 3, 6, 12 and 18 months
5. General functioning measured using the Strengths and Difficulties Questionnaire at baseline, 3, 6, 12 and 18 months
6. Mood measured using the Mood and Feelings Questionnaire at baseline, 1, 3, 6, 12 and 18

months
7. Anxiety symptoms measured using the Spence Child Anxiety Scale at baseline, 3, 6, 12 and 18 months
8. Quality of life measured using the Child Health Utility 9D at baseline, 3, 6, 12 and 18 months
9. Tic-related quality of life measured using the Child and Adolescent Gilles de la Tourette Syndrome at baseline, 3, 6, 12 and 18 months
10. Use of services measured using the Modified Client Service Receipt Inventory at baseline, 3, 6, 12 and 18 months
11. Side effects measured using the adverse events/side effects 17-item scale at baseline, 1, 3, 6, 12 & 18 months
12. Participants' perception of treatment credibility measured using a specifically created 'treatment credibility' questionnaire at 3 weeks
13. Participants' perception of treatment satisfaction measured using a specifically created 'treatment satisfaction' questionnaire at 3 months
14. Participants' perception of their need for further treatment measured using a specifically created 'Need for further treatment' questionnaire at 3 months
15. Participants' change of use of other medication/interventions measured using a specifically created 'Concomitant interventions' questionnaire at baseline, 3, 6, 12 and 18 months

The following measures are used at screening/baseline but may be reported in the final report to describe the sample characteristics in the results section:
16. Sample characteristics described using the Development and Wellbeing Assessment (DAWBA) at screening/baseline
17. Presence of an intellectual disability assessed using the Child and Adolescent Intellectual Disability Screening Questionnaire (CAIDS-Q) at screening/baseline
18. Characteristics of the sample assessed using a specifically created demographics questionnaire at screening/baseline
19. Presence of Autism Spectrum Disorder assessed using the Social Communication Questionnaire (SCQ) at screening/baseline
20. Premonitory urges for tics assessed using the Premonitory Urge for Tics Scale (PUTS) at screening/baseline
21. ADHD symptoms assessed using the Swanson, Nolan, and Pelham Rating Scale (SNAP-IV) at screening/baseline

Other pre-specified outcome measures:
22. Process evaluation of the interventions using qualitative interviews in a subsample of participants at 3 months

Added 13/04/2018: A record of therapist time, parent and child logins and frequency of therapist contact will also be analysed as part of the process evaluation

Overall study start date
01/10/2017

Completion date
12/04/2021

Eligibility

Key inclusion criteria

1. Aged 9 to 17 years
2. Suspected or confirmed Tourette syndrome/chronic tic disorder, including moderate/severe tics: score >15 on the Yale Global Tic Severity Scale (YGTSS) Total Tic Severity Score (TTSS); TTSS score>10 if motor or vocal tics only
3. Competent to provide written, informed consent (parental consent for child aged <16)
4. Broadband internet access and regular PC/laptop/Mac user, with mobile phone SMS

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 220; UK Sample Size: 220

Total final enrolment
224

Key exclusion criteria
1. Previous structured behavioural intervention for tics e.g. HRT/CBIT or exposure and response prevention within last 12 months from baseline. Participants may start any new behavioural interventions for tics outside of the trial intervention only after the initial 6 months of the study
2. Change to medication for tics (starting or stopping medication) within the previous 2 months prior to baseline. Participants may start/change medication for tics only after the initial 6 months of the study
3. Diagnosis of alcohol/substance dependence, psychosis, suicidality, or anorexia nervosa
4. Moderate/severe intellectual disability
5. Immediate risk to self or others
6. Parent or child not able to speak or read English

Date of first enrolment
25/04/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Queens Medical Centre/University of Nottingham (lead site)
Division of Psychiatry and Applied Psychology
E Floor
South Block
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details
c/o Shirley Mitchell
Duncan Macmillan House
Porchester Road
Mapperely
Nottingham
England
United Kingdom
NG3 6AA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/19/02

Results and Publications

Publication and dissemination plan
The study protocol will be published once ethical approval is received. There are no plans to date to publish the statistical analysis plan, however, this may change. At the moment, the statistical analysis plan is available on request from Dr Charlotte Hall. The trialists plan to publish the results of the trial in high-impact peer reviewed journals and present the findings at relevant national and international conferences. They plan to have published the main trial findings by the end of 2022.

Added 22/02/2021:
Intention to publish phase 1: 01/05/2021
Intention to publish phase 2: 31/03/2022

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
Data may be shared with researchers who provide a methodologically sound proposal.
Interested parties must contact Priment UCL to request access to the data (priment@ucl.ac.uk). Data requestors will be required to complete a data access agreement. The request will be reviewed by relevant members of Priment, as well as the Chief Investigator. Analysis will be restricted only to that achieving the aim of the approved proposal. Only individual participant data that underlie the results reported in the trial outcome paper(s) will be made available. This includes results that underlie the texts, figures, tables and appendices. Data will only be available after de-identification. Data considered to be a direct identifier will not be made available (for example but not limited to name/email) and will be removed from the shared database.
The participants consented to the sharing of anonymised data in the consent form by the following statement: “I understand that the information collected about me and my child will be used to support other research in the future, and may be shared anonymously with other researchers”.
The study protocol, statistical analysis plan, and a copy of the informed consent form could be requested. The data will be available for request from 3-months post-publication of the primary outcome and up to 5 years post-publication date.
Data will be transferred via a secure email address. The data will be encrypted and password protected before it is transferred. The password will be shared separately from the email containing the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/01/2019		Yes	No
Protocol article		02/01/2020	06/01/2020	Yes	No
Results article		01/09/2021	06/09/2021	Yes	No
Other publications	Comparison of tic symptoms before and during COVID-19 pandemic	13/04/2022	14/04/2022	Yes	No
Results article	outcome results	17/01/2023	18/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/10/2023	06/11/2023	Yes	No
Other publications		07/11/2024	20/11/2024	Yes	No