

Group work for children with Tourette Syndrome (TS)

Submission date 16/01/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study aims to find out the effectiveness of group work for children with Tourette Syndrome (TS). It will find out the effects of a Habit Reversal Treatment (HRT) and a psycho-education on changes in tic severity, neuropsychological function and quality of life.

Who can participate?

A group of 9 to 13 year-old children diagnosed with a chronic tic disorder (e.g. TS) will be enrolled into the study.

What does the study involve?

Participants will be randomly assigned to one of the two groups: HRT group or psycho-educational, each child participating in just one condition. During HRT, children will be taught about how to manage tics and in psycho-education, they will learn about tic conditions and co-occurring psychosocial difficulties.

What are the possible benefits and risks of participating?

These particular groups have never been tested for children with tic disorders and therefore we do not know whether the children will experience any benefit from participation. The groups have been designed, based on what is currently known, to help children with chronic tic disorders. We therefore hope that children might experience some benefit in areas such as their quality of life or the intensity of their tics. There are no specific risks from taking part in the study. The children's treatment will not be changed in any way by participating in the study. If a child gets tired when we are doing the tasks and puzzles then they will be able to take breaks. It is possible that thinking about their life and the effect of having a chronic tic disorder could be upsetting for children. Parents are asked that if the questionnaires do cause any distress, to let us know so that we can offer support and think about what further help is needed. Parents may be concerned about their child being exposed to other children with different tics in case their child's tics become worse or they adopt new tics. While this is possible in the short-term, clinical experience has tended to show that this is not a lasting effect. Nonetheless, those with concerns during the study are asked to discuss these with the team and would be entirely free to withdraw from the study at any time should they wish. If children are currently receiving treatment at Great Ormond Street Hospital, they would continue to be seen as a patient here

throughout the study. Any school liaison work, or medication, would continue as normal and be unaffected by participation. The only difference would be that children would not be able to participate in any individual therapy during the study. Parents are advised that if their child has been offered this, and they would prefer this to a group based intervention, it would be best not to participate in the study. Should it be felt during the course of the study that a child may benefit from individual therapy, they would be able to withdraw from the study and receive this treatment as appropriate.

Where is the study run from?

Great Ormond Street Hospital, London, UK.

When is the study starting and how long is it expected to run for?

The study began recruiting in June 2013 and it is expected that the study will continue to collect follow up data on the children involved until February 2015.

Who is funding the study?

Tourette Action (UK)

Who is the main contact?

Dr Tara Murphy

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Group work for children with Tourette Syndrome (TS): A randomised pilot study to evaluate the efficacy of a tic-specific behavioural intervention versus psycho-education in improving tic severity, quality of life and neuropsychological functioning

Study objectives

To compare the efficacy of group based Habit Reversal Therapy (HRT) to a psycho-educational group treatment for children with Tourette Syndrome (TS), in terms of quality of life (QoL), tic severity and specific aspects of neuropsychological functioning (response inhibition, impulsivity and fine motor skill).

Design Randomised, longitudinal single blind pilot study with parent groups run in parallel.

Method 48 children aged 9 to 14 years with a chronic tic disorder to be assigned to either an HRT group (n=24; 12 per group) or a psycho-educational group (n=24; 12 per group). Recruitment will be from a specialist TS Clinic at Great Ormond Street Hospital. Assessments of outcome variables will be conducted pre- and post-intervention.

Expected findings This study is very exploratory due to the limited evidence base in this area. We expect that HRT delivered in a group format will lead to significant tic reductions and associated improvements in QoL and neuropsychological functioning. It is likely that those in the psycho-educational group will also show improvements in QoL, but not a reduction in tics.

Implications Exploring the differential efficacy of group programs for improving tic severity, QoL and key aspects of neuropsychological functioning could provide vital knowledge of what benefits can be expected from attending these groups, increase the number of treatment options available to families, increase the cost-effectiveness of treatment and possibly reduce waiting times to access treatments.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London Queen Square, May 2013, 13/LO/0511

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions

Each child will only attend one group, either HRT or psychoeducation. Randomisation will be carried out by researchers (with coded data in an attempt to remain blind to treatment condition) using relevant software following a minimisation process, which will allow subjects to be randomised sequentially as they are recruited while balancing for age and gender.

HRT group: 8-week weekly group-based behavioural treatment

During HRT, the children will be asked to record their most troublesome tics. Through the course of therapy they are taught to increase their awareness of these tics and then to develop an alternative competing response which is then practiced.

Psycho-educational groups: 8-week weekly group-based psycho-educational work

During these groups the children will attend sessions covering topics such as self-esteem, anger, OCD, school and bullying. The psycho-educational group does not aim to reduce tics but focuses on understanding commonly associated psycho-social difficulties and psychiatric co-morbidities. Learning to manage distressing and disruptive tics, or to understand and manage the various additional symptoms of TS, could potentially have far-reaching implications for children and their families. Areas of possible improvement include quality of life, neuropsychological functioning, home life, relationships, school performance and self-esteem. Group interventions are promising as they would enable tic-specific and psycho-educational interventions to be carried out while simultaneously encouraging peer support and a sharing of experiences. Demonstrating effectiveness of group based treatments for TS would enable children to be treated in a more cost-effective manner, as well as increasing the number of options for treatment available to families.

Assessments will be run before and after the intervention to assess any changes associated with the therapy. These will take place within one month before starting the group and again within one month of finishing. There will also be a follow-up assessment conducted 1 year later. A quiet room will be used. Allowing for breaks, it is expected that time one assessments will be completed within three hours and time two assessment within 1 ½ hours, although clearly this will vary depending on the child. Both assessments include 20 minutes during which the child will be videoed while watching a DVD. Time three follow-up assessments will be the same as time two assessments.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Tic severity, which will be measured using the Yale Global Tic Severity Scale (Leckman et al., 1989), is a well validated semi-structured clinical interview carried out with parent and child. Questions relate to tic severity over the previous week. Separate ratings are recorded for motor and phonic tics in terms of number, frequency, intensity, complexity, and interference. These are combined to give an overall tic severity score.

Measures to characterise the groups

1. Parent and child versions of the 32-item ChOCI-R self-report scale (Uher et al., 2008) as a measure of OCD symptomatology.
2. A seven subtest short-form version of the Wechsler Intelligence Scales for Children (Crawford et al., 2010) as a measure of intellectual ability.

Secondary outcome measures

1. Tics will be directly observed for 15 minutes and five minutes of tic suppression. This will follow the protocol used by (Himle et al., 2006)
2. Premonitory Urge for Tics Scale (Woods et al., 2005) Gilles de la Tourette Syndrome Quality of Life scale - Child versions (Cavanna et al., 2008)
3. Paediatric Quality of Life Inventory Version 4.0 (Varni, Seid, & Kurtin, 2001)
4. Strengths and Difficulties Questionnaire (Goodman, 1997)
5. A brief 4-item anger outbursts screen included at the beginning of the Rage Attacks Questionnaire (used in Budman et al., 2003)
6. Tourette Syndrome Questionnaire is a 5-item visual analogue scale which assesses participants' confidence with and acceptance of their tics. The scale was developed by Dr Murphy and is used clinically within group work for children with TS at GOSH
7. The Dimensional Change Card Sort Test Executive Function (NIH Toolbox) is a measure of cognitive flexibility
8. The Flanker Inhibitory Control and Attention Test Executive Function (NIH Toolbox)
9. The Motor Dexterity Test (NIH Toolbox) is a simple measure of fine motor skills
10. SNAP-IV - a 26-item parent-report scale (Swanson et al., 2001) as a measure of ADHD symptomatology

Overall study start date

11/07/2013

Completion date

10/11/2013

Eligibility

Key inclusion criteria

Participants will be recruited from the specialist TS Clinic at Great Ormond Street Hospital. All children seen at the clinic over the past five years will be invited retrospectively. New referrals to the clinic during recruitment will also be considered.

Inclusion criteria will be:

1. Male or female children aged 9-14yrs
2. Diagnosis of Tourette Syndrome or Chronic Tic Disorder
3. Score on YGTSS (Yale Global Tic Severity Scale) > 13
4. Ideally live within one hour of London

Participant type(s)

Patient

Age group

Child

Lower age limit

9 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

Planned Sample Size: 48; UK Sample Size: 48

Key exclusion criteria

1. Learning Disability [Full Scale Intelligence Quotient (FSIQ) < 80, following Piacentini et al., 2010 and Woods et al., 2011]
2. Psychotic symptoms
3. Those who have had more than four sessions of HRT or Comprehensive Behavioral Intervention for Tics (CBIT) before (as in Piacentini et al., 2010 and Woods et al., 2011)
4. Those who have attended a psycho-educational group within the last two years
5. Children who do not speak English as a first language
6. Current substance abuse / dependence
7. Those who do not have internet access at home (a requirement for the tests used during home visits)

Date of first enrolment

11/07/2013

Date of final enrolment

10/11/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

DCAMH

London

United Kingdom

WC1N 3JH

Sponsor information

Organisation

Great Ormond Street Hospital For Children NHS Foundation Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03zydm450>

Funder(s)

Funder type

Charity

Funder Name

Tourettes Action (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	01/05/2016	Yes	No
HRA research summary		28/06/2023	No	No