

Tackle your Tics: effectiveness of a brief, intensive group-based exposure therapy programme for children with tic disorders: a randomized controlled trial

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The aim is to study the effectivity of a brief, intensive, outpatient group treatment (ERP) for youths with chronic tic disorders/Tourette Syndrome (TS), to improve treatment outcome, daily functioning/quality of life and treatment satisfaction. If...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON49057

Source

ToetsingOnline

Brief title

Tackle your Tics: an intensive tic training

Condition

- Psychiatric and behavioural symptoms NEC

Synonym

tic disorder / Tourette Syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: academische gelden VNG/De Bascule

Intervention

Keyword: behaviour al therapy, exposure, ticdisorder, Tourette

Outcome measures

Primary outcome

Assessments will be done pre- (T1), post-treatment (T2), and in follow-up assessments (T3 after 3-4 months and T4 after 6-7 months).

Key-outcome: tic severity (Yale Global Tic Severity Scale; YGTSS)

Secondary outcome

Demographic variables/patient characteristics: semi-structured interview , medical files, psychiatric comorbidities (Anxiety Disorder Interview Schedule; ADIS).

Secondary outcomes:

- quality of life (Gilles de la Tourette Syndrome Quality of Life Scale for children and adolescents; C&A-GTS-QOL).
- emotional / behavioral functioning (Child Behavior Checklist; CBCL).
- premonitory urges (Premonitory Urges for Tics scale; PUTS)
- family functioning: parental stress
- treatment alliance/preference
- cost effectivity

Study description

Background summary

Tic disorder, like Tourette Syndrome (TS), can have a serious and long-lasting negative impact on daily functioning and quality of life of children and families. Behavioural treatment for tics is recommended as first-line intervention according to European guidelines.

Although research into behavioural treatments for tics reports moderate to high effect sizes (0.57-1.5), tic reductions remain relatively low (on average 30% on the YGTSS questionnaire). Thus, there is much room for improvement. In addition, utilization rates for evidence-based behavioural therapies remain low. The lack of locally available trained therapists is a common treatment barrier. Families have to travel far and home exercises demand a lot of motivation and discipline. As a consequence of low access, many children get medical treatment although they prefer behavioural treatments.

Recently, case studies in the USA and UK have suggested that brief, intensive forms of behavioural therapy for TS are as effective as weekly therapy sessions. Besides, promising treatment outcomes have been found for an intensive outpatient grouptherapy (ERP) for children with OCD (*OCD-week* at expertise centre the Bascule). Also in other patient populations (e.g. adolescents with post-traumatic stress disorder, PTSD, intensive forms of behavioural treatment have been successful. Moreover, research in anxiety disorders showed that treatment success may even be larger using intensive brief treatment compared to traditional approaches. However, we currently lack knowledge on the feasibility of an intensive form of ERP for tic disorders. Our previous pilot study showed the brief, intensive treatment program Tackle your Tics was feasible, parents and children were satisfied about this form of treatment, and we found indications of improvement of tic severity as well as quality of life.

Study objective

The aim is to study the effectivity of a brief, intensive, outpatient group treatment (ERP) for youths with chronic tic disorders/Tourette Syndrome (TS), to improve treatment outcome, daily functioning/quality of life and treatment satisfaction. If found effective, we aim to implement this programme (inter)nationally to make it available to all patients with tic disorders. In addition, this project offers opportunities for personalizing treatment and training opportunities for new therapists.

Study design

Design: randomized controlled trial (RCT), consisting of 4-day intensive group-based exposure and response prevention (ERP).

Recruitment: participants will be recruited by the Dutch Tourette Association.

Sample size/power calculation: This pilot study will consist of 7 patient groups of 8 children per group and a waiting list condition group (total

sample: N= 104).

Intervention

Tackle your Tics is a 4-day treatment programme, based on the evidence-based ERP-protocol for tics developed by Verdellen et al. (2011) and positive outcomes of the Bascule *OCD-week*. Therapy sessions are executed in small groups of 2 children, in which children assist each other (by timing, registering tics and encouraging). By adding psychoeducation, group support and relaxing activities, motivation and fun will be enhanced and drop out reduced. We will utilise BT-Coach, a mobile application that helps patients to practice ERP exercises in the absence of a therapist. Additionally, there will be two parent meetings. One week after the first 3 therapy days, there will be a booster day. After 1 months there is a follow up afternoon.

Study burden and risks

No burden or risks are expected from participation. Children and their families will have better access to brief behavioural treatment, that can be followed during holidays or short breaks from school.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Inclusion criteria: (a) youths aged 9 to 17 years, (b) diagnosed with Tourette Syndrome or persistent (motor/vocal) tic disorder, using DSM-5 criteria, (c) with moderate or greater severity as measured by the YGTSS total score >13 (>9 for children with motor or vocal tics only).

Exclusion criteria

Exclusion criteria (examined during intake interviews): (a) Behavioural treatment for tics in the past 12 months, (b) pharmacological treatment (for tics or diagnosed psychiatric disorders) that is not been stable the past six weeks or with planned changes during study participation, (c) poor mastery of the Dutch language, (d) $IQ < 75$, (e) serious physical disease, (f) substance abuse, (g) suicidality, (h) psychotic disorders, (i) poor group functioning. Since tic disorders are seldom seen without comorbidities, co-occurring attention deficit-hyperactivity disorder, obsessive-compulsive disorder, other anxiety disorders or depressive disorders are allowed, unless the disorder requires immediate treatment or change in current treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 02-07-2020
Enrollment: 104
Type: Actual

Ethics review

Approved WMO
Date: 21-02-2020
Application type: First submission
Review commission: METC Amsterdam UMC
Approved WMO
Date: 25-06-2020
Application type: Amendment
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29243
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71514.018.19