Tackle your Tics: effectiveness of an intensive tic training

Gepubliceerd: 27-09-2019 Laatst bijgewerkt: 15-05-2024

1. We expect that the brief, intensive ERP-therapy with additional supporting components will lead to better treatment outcomes, compared to the waiting list condition, i.e.: more tic reduction, better quality of life, emotional/behavioural, social…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29243

Bron
NTR

Verkorte titel
Tackle your Tics

Aandoening

tic disorders, Tourette Syndrome, tics, tourette, behaviour therapy, exposure and response prevention

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC Medical Research), Amsterdam
Overige ondersteuning: Levvel, academic center for Child and Adolescent psychiatry, expert centre for OCD, anxiety and tics, Amsterdam.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

tic severity

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Tic disorders, such as Tourette Syndrome (TS) can have a serious negative impact on daily functioning and quality of life of children and families (5)(18). Behavioural treatment for tics has shown its efficacy in tic reduction and is considered a first-line intervention for tic disorders (25). The lack of specialized therapists is a barrier for local treatment. Consequently, families suffer from time-consuming travel distances, financial barriers and the impact of travelling for long series of sessions on working and family life. Moreover, the therapy and individual daily exercises at home require a lot of motivation and discipline. Patient associations stress the urgent need for more easy-to-undergo treatments.
Objective: This study aims to reduce these barriers, by studying the effectiveness of a brief, intensive group-based programme for children with TS, called Tackle your Tics (TyT) on tic severity (primary outcome) and premonitory urges, quality of life (of children/parents), children's emotional/behavioral, social and school functioning, parenting stress, treatment satisfaction and cost effectiveness from a societal perspective. Also, we aim to explore which children benefit most from this brief intensive treatment, to improve personalized treatment advice.
Study design: randomized controlled trial, comparing TyT (N=52) versus a waitlist control group (WLCG: N=52).
Population: children and adolescents (9-17 years old) with tic disorders
Intervention: Tackle your Tics is a brief, intensive five-day therapy program. It is based on the evidence-based exposure and response prevention (ERP)protocol, in which weekly sessions are provided over a longer period of time. Tackle your Tics offers the same amount of therapy hours as regular ERP in a shorter period of time, and adds on top of this supporting and motivating components: group support, coping strategy workshops, psycho-education, parent meetings, a training app and relaxation activities . Our previous feasibility study showed feasibility, treatment satisfaction and promising, positive results. In this larger trial (N=104), we will study the effectiveness of this program in 7 groups of 8 children per group, and compare treatment outcomes with a waiting list condition.
Main study parameters/endpoints: Tic-reduction and improvement, quality of life and daily behavioural/emotional/school functioning, parenting stress, treatment satisfaction and cost effectiveness as assessed by (semi)structured interviews and questionnaires.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Behavioural therapy for tics is proven effective and reduces tics by an average of 30%. With this brief, comprehensive format (treatment provided in 4 days) of the standard evidence-based therapy, we aim to accelerate this effect . In addition, we offer supportive and motivating activities, which may improve treatment outcomes, but also aim to improve the quality of life and treatment satisfaction.
Behavioural therapy has no known adverse effects in the short or long term. This also applies to the short interview or questionnaires. The research is intended to reduce the burden on

children and their parents, by offering effective therapy in a shorter period, with supporting elements. Our previous feasibility study (N=14) showed no adverse events and 1 dropout.

Doel van het onderzoek

1. We expect that the brief, intensive ERP-therapy with additional supporting components will lead to better treatment outcomes, compared to the waiting list condition, i.e.:
more tic reduction, better quality of life, emotional/behavioural, social and school functioning, less parental stress, more treatment satisfaction and better cost effectiveness. From the perspective of the patients' organisation, better outcomes on quality of life, treatment satisfaction and reduction of stress are considered very important.
2. We expect to find first indications on how treatment can be better attuned to patient characteristics, to improve personalized treatment.

Onderzoeksopzet

T1=pre-treatment
T2=post-treatment TyT-group (key outcome)
T3=3-4 months follow up
T4=6-7 months follow up

Onderzoeksproduct en/of interventie

Tackle your Tics is based on positive outcomes of an intensive outpatient group therapy (ERP) for children with OCD ("OCD- week" at expertise center the Bascule), in which a brief intensified form (4 consecutive days of treatment) was successfully provided to youth with OCD (instead of weekly session for a longer time period). Tackle your Tics is based on the same evidence based protocol 'Tics' by Verdellen et al., 2011 (26), that is used in regular individual behavioral therapy for tic.
Tackle your Tics (TyT), however, is provided in a more compact, intensive groupformat in 3 consecutive days, and 2 follow-up 'booster' days to prevent relapse, to repeat and 'boost' the ERP-exercises. The first boosterday 1 week after TyT week and the second booster day 1 month after TyT.
New supporting elements to optimize treatment effectiveness will be added: peer and family support by the TyT-group format, (with group meetings for youth and parents separately), coping strategies, a training app, extra and intensive psycho-education and relaxation activities. An innovative, crucial element is that workshops for coping strategies are provided by trained patient members (experts by experiences) from the Dutch Tourette association, who are licensed educational professionals themselves.

Contactpersonen

Publiek

Amsterdam UMC/Levvel
Annet Heijerman

+31636342241

Wetenschappelijk

Amsterdam UMC/Levvel
Annet Heijerman

+31636342241

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
(a) 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 a YGTSS total tic score >13 (>9 for children with motor or vocal tics only).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
(a) Behavioural treatment for tics in the past 12 months,
(b) pharmacological treatment for tics or diagnosed psychiatric disorders that has 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 and/or low motivation (as reported by child, parents or local

therapist).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Considering the fact that for this project we have gathered highly sensitive and privacy protected data (protection legislated by Dutch law), we can share the following:
Relevant supporting documents will be made publicly available after an embargo period (i.e. after publication of our results/ the intended PhD thesis on this project, and in accordance with informed consents), in case of relevant research questions.
For this study the following study information will be published in a public repository:
Metadata about the study: the study protocol, statistical analysis plan, data management plan, metadata schema, and a global description of the intervention protocols (as described in our trial design paper, by Heijerman-Holtgrefe et al., to be published)
Metadata about the data: documentation on study procedures, a data dictionary, and syntaxes.

Ethische beoordeling

Positief advies

Datum:	27-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49057
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8052
CCMO	NL71514.018.19
OMON	NL-OMON49057

Resultaten

Samenvatting resultaten
https://doi.org/10.1007/s00787-020-01532-5