Effectiveness of Standard Urotherapy in children and adolescents with DUI: A Randomized Controlled Trial (RCT).

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SU results in a higher rate of self-initiated toileting and a decrease in urinary/faecal accidents.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20684

Bron
NTR

Verkorte titel
TBA

Aandoening

Day-time urinary incontinence (DUI) and non-retentive faecal incontinence (NFI)

Ondersteuning

Primaire sponsor: SeysCentra
Overige ondersteuning: SeysCentra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

self-initiated toileting and urinary/faecal accidents during treatment/post-intervention

Toelichting onderzoek

Achtergrond van het onderzoek

Children and adolescents with neurodevelopmental disabilities seldom attain continence for urine and faeces through maturation. One-to-one training is often needed to establish continence. There is international consensus about the use of least-to-most intrusive treatment procedures for children with Elimination Disorders (ED) with Standard Urotherapy (SU) being considered a first-line treatment. However, specific guidelines pertaining to additional low intrusive procedures, while still producing the desired effect of attaining continence, are lacking in the literature. Furthermore, few studies describe the content of SU interventions and the effectiveness of SU specifically pertaining to children and adolescents with neurodevelopmental disabilities (ND). This PhD study focusses on determening the effectiviness of SU in children and adolescents with neurodevelopmental disoders (ND).

Research question

What is the effectiveness of SU in children and adolescents with neurodevelopmental disorders (ND)? Does the effectiveness of Standard Urotherapy decrease or increase with certain child variables (i.e., IQ, ASD, ADHD and DS)?

Participant characteristics and setting

Participants are children with DUI who participated in study 1, 2, and 3 (90 participants in total).

Study design

A randomized, waitlist-controlled, between-groups design will be used. Participants in the control group will not be deprived of training but wait to be trained (on the waitlist of SeysCentra). In order to determine the effectiveness of SU, ninety participants will be randomly assigned to experimental group 1 (SU; n: 71) or to the control group (waitlist; n: 71) by using a priori developed table with randomized numbers (0 = control group, 1 = experimental group).

Procedures

Informed consent of parents and child (>12 y) will be obtained, see study 1. In order to measure the effectiveness of SU while controlling for the covariates IQ and neurodevelopmental disorders (I.e., ADHD, ASD and DS), the specific personal information will be obtained during the waiting list period. To explore which childhood variables, reduce or increase the effectiveness of interventions, a post-test will be conducted.

Measures and materials
The child variables will be obtained from the information provided by parents during the intake procedure. This information is included as a standard protocolled intake procedure at SeysCentra, which follows the Dutch national guidelines in regards to obtaining personal

medical information. Personal information relevant for the purpose of the research project will be coded and stored on a secure server in accordance with the university's ethical guidelines. After an intake procedure/assessment, the Dutch version of the Developmental Behaviour Checklist (i.e., vragenlijst voor ontwikkeling en gedrag [DBC-P], Einfeld, & Tonge, 2002), micturition lists and the Dutch version of the Vineland Adaptive Behaviour Scales (i.e., de VINELAND Screener, Sparrow, Carter, & Cicchetti, 2008; Scholte, et al., 2014) will be completed by the parents. The Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV-NL) or the Snijder-Oomen nonverbal intelligence test (SON-R) will be completed during the waitlist period for all participants. If an IQ test has been completed within the last two years, that score will be obtained due to reliability issues when conducting a new IQ-test within two years. For children who are unable to complete the entire test IQ, the short version of the SON-R will suffice. Furthermore, parents will be asked to measure urinary accidents, self-initiated toileting habits at home for at least five probes during the baselines, post-intervention, and follow-up. Event recording during a morning session (9:00 AM-12:00PM) and afternoon session (12:00 PM – 3:00 PM) of urinary accidents and self-initiated toileting habits (rate per three hours) will be conducted. For interobserver agreement and procedural fidelity, see study 1.

Strategy of analyses

Statistical analyses will be executed using IBM SPSS Statistics 25. Analysis of covariance (ANCOVA) will be conducted to test the effectiveness of the different treatment conditions. Specifically, the ANCOVA’s will measure the statistical difference of the of treatment group (SU) and control group on the dependent variables self-initiated toileting and urinary accidents, respectively, while controlling for IQ, ASD, ADHD and DS (covariates).

Power calculation

A power analysis with G*Power (V. 3.1.9.4) indicated that an ANCOVA with two independent groups, a power of .80, a medium effect size, at an alpha of .05 and the covariates, requires a total sample size of 128 participants. However, the following formula was utilized to compensate for potential drop-outs (N1 = n/(1-d)). Therefore the sample size when adjusted to N = 142.

Doel van het onderzoek

SU results in a higher rate of self-initiated toileting and a decrease in urinary/faecal accidents.

Onderzoeksopzet

Rate of self-initiated toileting and urinary/faecal accidents at the end of:
- Baseline 1
- SU
- Baseline 2
- Follow-up

Onderzoeksproduct en/of interventie

Standard Urotherapy (SU)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All participants meet the following inclusionary criteria: They (a) have DUI, assessment and diagnosis using ICCS criteria (von Gontard, 2013b; Austin et al., 2016), and/or (b) have NFI, assessment and diagnosis using Rome IV criteria (von Gontard, 2013a; Hyams et al., 2016), (c) underwent a paediatric examination (d) have an IQ ≥35, (e) have ability to stand and walk, have (f) no visual impairment, (g) have the ability to imitate, (h) SU training hasn't been previously contucted, and (i) participated in study 1, 2, or 3.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Participants will be excluded from this research study based on the following exclusion criteria: They (a) have an IQ ≤ 34, (b) are unable to stand or walk, (c) have a visual impairment, (d) are unable to imitate based on video modelling imitation probes, (e) do not have NFI or DUI or (f) received a completed SU training according to the ICCS criteria (von

Gontard, 2013b) at a different facility, or (g) completed an SU training which was effective in attaining continence.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2022
Aantal proefpersonen:	71
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8972
Ander register	ECSW Radboud University : ECSW-2021-151R2

Resultaten