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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20684

Source
NTR

Brief title
TBA

Health condition

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

Sponsors and support

Primary sponsor: SeysCentra
Source(s) of monetary or material Support: SeysCentra

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

self-initiated toileting and urinary/faecal accidents during follow-up.

Study description

Background summary

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.

Study objective

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

Study design

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

- SU
- Baseline 2
- Follow-up

Intervention

Standard Urotherapy (SU)

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	71
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results