Effectiveness of Response Restriction (RR) with prompting and the add-on training of a restoring procedure on day-time urinary incontinence/non-retentive faecal incontinence in children.

No registrations found.

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

Summary

ID

NL-OMON22763

Source
Nationaal Trial Register

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 adhering to the least-to-most intrusive guidelines for treatment and determining the effectiveness of standard urotherapy, behavioural training procedures based on response restriction and a restoring procedure.

Research question

What is the effectiveness of RR training with prompting on DUI/NFI in children and adolescents with ND? What is the effectiveness of an add-on training consisting of a restoring procedure, for children who do not attain self-initiated toileting with RR training plus prompting alone?

Participant characteristics and setting

Twelve participants (5-18 y) will participate in this study. The intervention and add-on sessions will be conducted in a therapy room, 3 x 3m, at SeysCentra. Adjacent to the therapy room is a toilet room, 1,5 x 1,5m. In the therapy room is a table, two chairs, and a cupboard.

Study design

A non-concurrent multiple probe design across participants (Kazdin, 2011) will be used to investigate the effectiveness of RR with prompting and the add-on training consisting of a restoring procedure on DUI and/or NFI in participants.

Procedures

For informed consent, see study 1. Parents will measure urinary/faecal accidents, self-

initiated toileting habits at home during at least five probe sessions (baseline). After the home baseline measurement, the participant visits the training centre for 3 additional probe sessions measured by a therapist.

Informed consent of parents and child (>12 y) for this study will be obtained. Participants will visit the training centre for ten workdays (no weekends) from 9:00 AM to 3:00 PM for RR training with prompting during five sessions (phase B). Protocolized RR will be using prompting and ABA procedures. Participants who do not attain a predetermined criterion after five training sessions, will receive an add-on training consisting of a restoring procedure and positive practice for an additional five sessions (phase C). Participants will continue with the treatment procedure without the addition of the restoring procedure, when RR with prompting is effective based on reaching criteria after training session five. Participants who do reach criterion after five sessions in phase C, will continue treatment as outlined in phase C for the remaining training sessions at SeysCentra. After week 2 of training, post-intervention will start. During post-intervention, parents will foster generalization in the natural environment (e.g., at home) of the participant. Parents will receive protocolled feedback and instruction. The post-intervention will end after a pre-set criterion will be reached or after 10 weeks. Eight weeks following post-intervention maintenance will be measured in the follow-up phase for three days. Parents will not receive any feedback or instructions.

Measures and materials

Parents will be asked to measure urinary/faecal 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/faecal accidents and self-initiated toileting habits (rate per 3 hours) will be conducted. Data on procedural fidelity will be collected by an independent observer (i.e., research assistant) in 30% of all sessions across participants during the treatment phase. Interobserver agreement will be calculated using mean count per three hours. Procedural fidelity of VM and RR will be calculated per session based on the ratio of executed components versus planned components.

Study objective

RR with prompting results in a higher rate of self-initiated toileting and a decrease in urinary/faecal accidents. For children who do not attain continence with RR and prompting alone, an add-on restoring procedure will result 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
- Intervention

- Post-intervention
- Follow-up

Intervention

Restoring procedure
Response Restriction (RR) with prompting
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, (f) have no visual impairment, and (g) SU training at SeysCentra has already been conducted, and did not result in continence.

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) do not have NFI or DUI, (e) received a completed SU training according to the ICCS criteria (von Gontard, 2013b) at a different facility, or (f) completed a SU training which was effective in attaining continence.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	12
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	NL8971
Other	ECSW Radboud University : ECSW-2021-151R2

Study results