Parental variables affecting parent competence and acceptability of elimination disorder treatment procedures.

No registrations found.

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

Summary

ID

NL-OMON28131

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

The scores on each questionnaire during pre-test.

Secondary outcome

The scores on each questionnaire during post-test.

Study description

Background summary

Research questions

Which levels of stress, self-efficacy and parental coping, do parents of a child with DUI/NFI experience? What is the effect of the incontinence treatment on parental stress, parental self-efficacy, coping, parental competence and acceptability of treatment? What is the effect of the incontinence treatment on parental competence and acceptability, controlled for parental stress, parental self-efficacy and parental coping?
Study design

Longitudinal research

Participant characteristics and setting

Parents of a child with enuresis/encopresis. Participants are the parents of the participants receiving treatment at the centre (57 participants in total).

Procedures

Informed consent of parents will be obtained. To explore parent variables, pre-tests and post-tests will be conducted. Parents of trainees in study 1, 2 and 3 or parents of children receicing treatment at the centre will be asked to fill out questionnaires during the baseline phase (i.e., pre-training) and follow-up phase (i.e., post-training).

Measures and materials

To measure parental stress, the Dutch version of the Parental Stress Index (i.e., Nijmeegse Ouderlijke Stress Index [NOSIK], De Brock, Vermulst, Gerris, & Abidin, 1992) will be used. Parental competence and coping will be measured using the Questionnaires Family and Upbringing (i.e., Vragenlijsten Gezin en Opvoeding [VG&O], Vermulst, Kroes, De Meyer, Van Leeuwen, & Veerman, 2011). Oosterman and Schuengel (2008) used a Dutch translation of the Self-Efficacy in the Nurturing Role (SENR) (Pedersen, Bryan, Huffman, & Del Carmen, 1989), a questionnaire to measure self-confidence of mothers with a new-born child. The SENR will be evaluated on its use for the present study. To measure acceptability of components of toileting procedures a social validity questionnaire will be developed.

Strategy of analyses

To answer the first research question ‘what is the effect of the incontinence treatment on parental stress, parental self-efficacy, coping, parental competence and acceptability of the treatment’, a paired sample t-tests will be completed (Field, 2013). This entails that five t-test will be completed, one for each dependent variable. Bonferroni will be used to correct for multiple testing on the same sample of data. In order to determine the effect of the covariates and to answer the research question: “What is the effect of the incontinence treatment on parental competence and acceptability, controlled for parental stress, parental self-efficacy and parental coping”, a repeated measures ANCOVA will be completed. Specifically, 2 ANCOVA’s will be completed for each variable with a Bonferroni correction.

Finally, the research question ‘Which levels of stress, self-efficacy and parental coping, do parents of a child with DUI/NFI experience?’ will be answered by completing a descriptive analysis. A one sample t-test will be completed for each variable in order to descriptively state the average scores, standard deviations and ranges of the scores of the sample population on the dependent variables. When applicable, a t-test will be conducted to analyse if the results differ significantly compared to a reference group. This will solely be completed if the scores are available in the manual of the questionnaire (i.e., De Brock, Vermulst, Gerris, & Abidin, 1992; Vermulst, Kroes, De Meyer, Van Leeuwen, & Veerman, 2011), due to the complexity of creating a reference group for this specific research project. Statistical analyses will be executed using IBM SPSS Statistics Version 25.

Power calculation

The sample size of study 5 has been determined by completing a power analysis.

A paired sample t-test (pre-test and post-test scores as the pair) will be conducted. Five different paired sample t-tests will be conducted pertaining to the following variables: parental competence, acceptability, stress level, self-efficacy, and parental coping. Due to multiple testing being a concern, a Bonferroni correction will be applied. A power estimation (G*power V. 3.1.9.4) indicated that a paired sample t-test test with a mediumb effect size, f = .5, α = .01 and power = .80, requires a total sample size of 51 participants. To compensate for the drop-out the sample size was adjusted to 57.

Study objective

Parents of a child with DUI/NFI experience higher stress levels, reduced self-efficacy, and reduced parental coping. The treatment of DUI/NFI of the child increases the self-efficacy and parental coping of parents and it decrease parental stress.

Study design

Questionnaires will be completed pre- and post-training of DUI/NFI.

Intervention

In order to measure parental stress, the Dutch version of the Parental Stress Index (i.e., Nijmeegse Ouderlijke Stress Index [NOSIK], De Brock, Vermulst, Gerris, & Abidin, 1992) will

be used. Parental competence and coping will be measured using the Questionnaires Family and Upbringing (i.e., Vragenlijsten Gezin en Opvoeding [VG&O], Vermulst, Kroes, De Meyer, Van Leeuwen, & Veerman, 2011). Oosterman and Schuengel (2008) used a Dutch translation of the Self-Efficacy in the Nurturing Role (SENR) (Pedersen, Bryan, Huffman, & Del Carmen, 1989), a questionnaire to measure self-confidence of mothers with a new-born child. The SENR will be evaluated on its use for the present study. To measure acceptability of components of toileting procedures a social validity questionnaire will be developed.

Contacts

Public
Radboud Universiteit/SeysCentra
Maayke van Galen

0634030491
Scientific
Radboud Universiteit/SeysCentra
Maayke van Galen

0634030491

Eligibility criteria

Inclusion criteria

Participants are the parents of the participants of study 1, 2, and 3 and parents of children receiving treatment at the treatment centre.

Exclusion criteria

Parents of children not receiving standaard treatment at the centre

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	57
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	NL8973

Register	ID
Other	ECSW Radboud University : ECSW-2021-151R2

Study results