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Efficacy of working with parents to reduce punishment frequency of children with enuresis

Submission date
13/06/2013

Recruitment status
No longer recruiting

Registration date
12/07/2013

Overall study status
Completed

Last Edited
15/09/2020

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Enuresis (bedwetting) can cause innumerable problems for the child and his parents and affects about 10% of the seven-year-old children. The lack of understanding of the parents about their childrens bedwetting has punishment as one of the results. The aim of this study is to find out the how good the psychological method given to the parents during the treatment of the child with bedwetting is. Along with this we aim to define the profile of the family of such children, to identify the perception of family support and to describe the frequency of punishment practiced by the parents in the study group compared with the control group.

Who can participate?
60 bedwetting children aged between 6 and 18 years can participate in this study.

What does the study involve?
Participants will be randomly allocated to one of two groups: study group and the control group. Parents in the study group will receive psychological counselling and children will receive treatment in an environment that has toys and playful materials. Parents and children belonging to the control group receive treatment as usual.

What are the possible benefits and risks of participating?
There may be improvement in bedwetting, reduction in punishment frequency and improvement in behaviour problems.There are no risks of participating in the study and all children who are not included in the study, received other types of treatment, offered to all children who seek care in the outpatient uropediatria HU-CAS/UFJF.

Where is the study run from?
The University Hospital of the Federal University of Juiz de Fora (Hospital Universitário da Universidade Federal de Juiz De For a), Brazil.

When is the study starting and how long is it expected to run for?
The study will start in December 2015 and will run for one year.

Who is funding the study?
The study is funded by the investigator.

Who is the main contact?
Mr Cacilda Andrade de Sá
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Efficacy of working with parents to reduce punishment frequency of children with enuresis: a randomized, blinded trial

Study objectives
Punishment reduction in children, with monosymptomatic enuresis, who presented to psychological service with their family, compared with the control group, where the family did not receive the service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on Ethics in Human Research - UFJF (CEP-UFJF): 075-420-2011 FR:432875 CAAF: 0050.0.420.000-11

Study design
Randomized blinded interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Enuresis

Interventions
The participants are randomised to two groups:
1. Intervention group:
The parent psychological appointment will be conducted by the researcher, in a place and time different from the child's. It will take 30 minutes in a private room, every 15 days. After 6 months of treatment, the parent will have an appointment every 30 days for a period of 6 months.
The child will be seen separately from his/her parent, in separate place and time. The appointment will last 30 minutes, every 15 days, and a playful material will be used to facilitate the childs care. After 6 months the children will be seen once every month for a period of 6 months.
2. Control Group: Children receive the care without psychological support to parents. After 6 months the children will be seen once every month for a period of 6 months.
Clinical outcome data will be recorded for further evaluations. Those who need follow-up assistance, after the survey period, will be forwarded to the psychology service.
Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The results, that will be evaluated, after six months of intervention, are enuresis improvement (Nocturnal Diary), punishment frequency reduction, improvement in behavior problems, and evasion decrease.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/12/2016

Eligibility

Key inclusion criteria
Patients between 6 and 19 years old who are attending the enuresis clinic and with monosymptomatic enuresis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
19 years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Those unwilling to participate in the research, or has difficulty in understanding the goals of it.
2. Patients with psychiatric, renal, neurological disorders, non-monosymptomatic enuresis
3. Those who are already undergoing other treatment for enuresis in the last six months

Date of first enrolment
01/12/2015

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Rua: Coronel Severiano de Resende, 191, centro.
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36240000

Sponsor information

Organisation
Federal University of Juiz de Fora (Universidade Federal de Juiz de Fora) (Brazil)

ROR
https://ror.org/04yqw9c44

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	15/09/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes