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Limited caffeine consumption as first-line treatment in managing primary monosymptomatic enuresis in children: how effective is it? A randomised clinical trial

Sadra Rezakhaniha ,[1] Bijan Rezakhaniha ,[2] Soheila Siroosbakht [3]

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[1]Nutrition, Islamic Azad University Science and Research Branch Faculty of Basic Sciences, Tehran, Iran (the Islamic Republic of)
[2]Urology, Aja University of Medical Sciences, Tehran, Iran (the Islamic Republic of)
[3]Pediatrics, Aja University of Medical Sciences, Tehran, Iran (the Islamic Republic of)

Correspondence to
Dr Soheila Siroosbakht;
soheilasirousbakht@gmail.com

ABSTRACT

Objective Evidence about the negative caffeine effect on enuresis in children remains understudied or poorly understood. The study aimed to investigate the effect of caffeine restriction on the improvement and severity of primary monosymptomatic nocturnal enuresis (PMNE).

Design Randomised clinical trial.

Setting Two referral hospitals in Tehran, Iran, from 2021 to 2023.

Patients Five hundred and thirty-four PMNE children aged 6–15 years (each group 267).

Interventions Amount of caffeine consumption was recorded by the feed frequency questionnaire and was estimated by Nutrition 4 software. Caffeine consumption per day in the intervention group was <30 mg, and in the control group, 80–110 mg. All children were asked to return 1 month later to check the recorded data. The ordinal logistic regression analysis was used to assay the effects of caffeine restriction on PMNE by relative risk (RR) at a 95% CI.

Main outcome measures The effect of limited caffeine consumption on the improvement and severity of PMNE.

Results The mean age of the intervention and control groups was 10.9±2.3 and 10.5±2.5 years, respectively. The mean number of bed-wetting before caffeine restriction in the intervention and control group was 3.5 (SD 1.7) times/week and 3.4 (SD 1.9) times/week (p=0.91) and 1 month after intervention were 2.3 (SD 1.8) times/week and 3.2 (SD 1.9) times/week, respectively (p=0.001). Caffeine restriction significantly reduced the severity of enuresis in the intervention group. Fifty-four children (20.2%) improved (dry at night) in caffeine restriction and 18 children (6.7%) in the control group with RR 0.615 at 95% CI 0.521 to 0.726, p=0.001. The caffeine restriction significantly reduced the enuresis in children with a number-needed-to-treat benefit 7.417. It means you must treat 7.417 PMNE children with caffeine limitation to improve one child with enuresis (become dry).

Conclusion Caffeine restriction can be helpful in reducing PMNE or its severity. Constructive limitation of caffeine is suggested as one of the first-line treatments in the management of PMNE.

Trial registration number IRCT20180401039167N3.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous findings about the relationship between caffeine and enuresis are inconclusive. The role of caffeine on the severity of primary monosymptomatic nocturnal enuresis (PMNE) has yet to be studied, and the effect of caffeine on PMNE is still controversial. Furthermore, limited studies have been performed on the effect of caffeine materials on urinary incontinence, but not specifically on PMNE. It seems essential to establish actual evidence about this issue in more detail.

WHAT THIS STUDY ADDS

⇒ According to the finding of this study, caffeine restriction can help reduce PMNE or its severity. Constructive limitation of caffeine is suggested as one of the first-line treatments in the management of PMNE.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Although it is not recommended to have caffeine restriction for every child, it may be considered in cases resistant to treatment. Preliminary evidence according to the caffeine limitation and PMNE is accumulating, but a more comprehensive study is needed to clarify topics of uncertainty. This study was the initial way to define clues to the reasons for PMNE and its severity.

BACKGROUND

Primary monosymptomatic nocturnal enuresis (PMNE) is the most common type of nocturnal enuresis (NE) in school-age children.[1 2] Multiple medications are effective in the treatment of PMNE, but behavioural interventions are the first-line modalities, such as void before sleeping, resolve constipation, decrease amounts of salt, and protein and fluid intake during dinner time, especially before bed.[3 4]

Caffeine has positive and negative effects on various human organs.[5] Regarding the effect of caffeine on the urinary system and increasing urine production, different results have been seen.[6] Some studies have shown that caffeine has diuretic properties and increases urine production, exacerbating incontinence.[7] On the other hand, Sun *et al*, in a meta-analysis study, showed no evidence of an association between caffeine and the risk of urinary incontinence.[8]

The negative caffeine effect on NE in children needs to be further studied.[9] Despite kids being one of the most caffeine consumers worldwide, limited studies have been conducted at this age.[10] The role of caffeine on the severity of PMNE has not been studied, and the effect of caffeine on PMNE is still controversial. Furthermore, limited studies have been performed on the effect of caffeine materials on urinary incontinence, but not specifically on PMNE.

OBJECTIVES

The main aim of this study was to investigate the effect of caffeine restriction on the improvement and to reduce the severity of PMNE to suggest a proposal to build a new bridge for further behavioural studies.

MATERIAL AND METHODS

Study design and setting

This study was a randomised clinical trial with a parallel control group without blinding that was conducted in two tertiary referral hospitals in Tehran, Iran, from September 2021 to January 2023.

Subjects

The participants were recruited by convenience sampling methods. One thousand one hundred and twelve children aged 6–15 years with bed-wetting that referred to referral enuresis clinics were eligible for the study. These children used a different amount of caffeinated material daily. A urologist and paediatrician evaluated all children. If they had PMNE according to the definition of the International Children's Continence Society (ICCS),[11] they would be enrolled in the research. Inclusion criteria were children aged 6–15 years, with only night-time bed-wetting, ≥2 bed-wetting/week, more than 3 weeks, primary (no dry more than 6 months), without other urinary tract symptoms, and normal ultrasound of the kidneys and urinary tract. Exclusion criteria were children with urinary tract infection, urological anomalies, spinal cord anomalies, neurogenic bladder, obstructive sleep apnoea, diabetes (insipidus and mellitus), children using diuretics and those with congenital heart diseases and heart failure. By using the formula, $n = \frac{2\left(Z1-\frac{\alpha}{2}+Z1-\beta\right)^2\sigma}{d^2}$, $\sigma = 2.52$, $\beta = 20\%$, $\alpha = 5\%$ and d=1, 199 subjects were considered for each group (total 398 children). With a drop-out of 20%, 478 children were considered for the study. There was no lost to follow-up and drop-outs. Finally, 534 subjects with PMNE (each group of 267 children) were enrolled in the study and analysed (figure 1).

The parents completed a dietary questionnaire including children's demographic information and caffeine consumption. The amount of caffeine consumption in children was recorded based on the feed frequency questionnaire (FFQ) (Shahid Beheshti University of Medical Sciences, Tehran, Iran, valid questionnaire for Iranian people). It was estimated by N4 software (nutrition 4, N-Squared computing, New Zealand, V.2.5.3). To collect the data, a table is set up to record the number of bed-wetting/week by the parents. Constipation was defined by ROME III criteria: at least two criteria, including faeces, straining, dry and hard faeces, and perception of incomplete defecation.[12]

Confounders were controlled in three ways: study participants' restriction, matching of groups and pooled data stratifications. The main confounders were excluded by precise attention to the inclusion and exclusion criteria (all subjects with PMNE without other urinary tract symptoms, abnormal ultrasound of the kidneys and urinary tract, urinary tract infection, urological anomalies, spinal cord anomalies, neurogenic bladder, obstructive sleep apnoea, diabetes, using diuretics and heart failure). Restricting the children to two groups with the age range of 6–15 years would minimise confounding variables. Furthermore, the other main and potential confounders were matched in two study groups (age, sex, body mass index, constipation, parents' education and enuresis history). For effect modification, pooled data were classified into stratified variables, and stratified data were analysed.

Randomisation description

The randomisation method was simple randomisation with allocation concealment. The children's randomisation was done unbiasedly by a computer-generated randomisation number. A number was randomly selected on the table with closed eyes, and the direction of movement was downward. The children were randomly assigned to the control and intervention study groups by the random numbers table, one by one. Furthermore, we considered 'randomisation blinding' or 'allocation concealment' to decrease the selection bias. Trial participants were allocated into treatment groups so they could not exploit this knowledge.

Training of participants and recruitment start date

The amount of caffeine contained in each substance was informed to the parents, and they were taught how to calculate the amount of daily caffeine consumption. In order to achieve the compliance of parents and children for the correct calculation of daily caffeine consumption, their reports for 1 week were checked (1-week training). After ensuring their correct performance, the participants started the study.

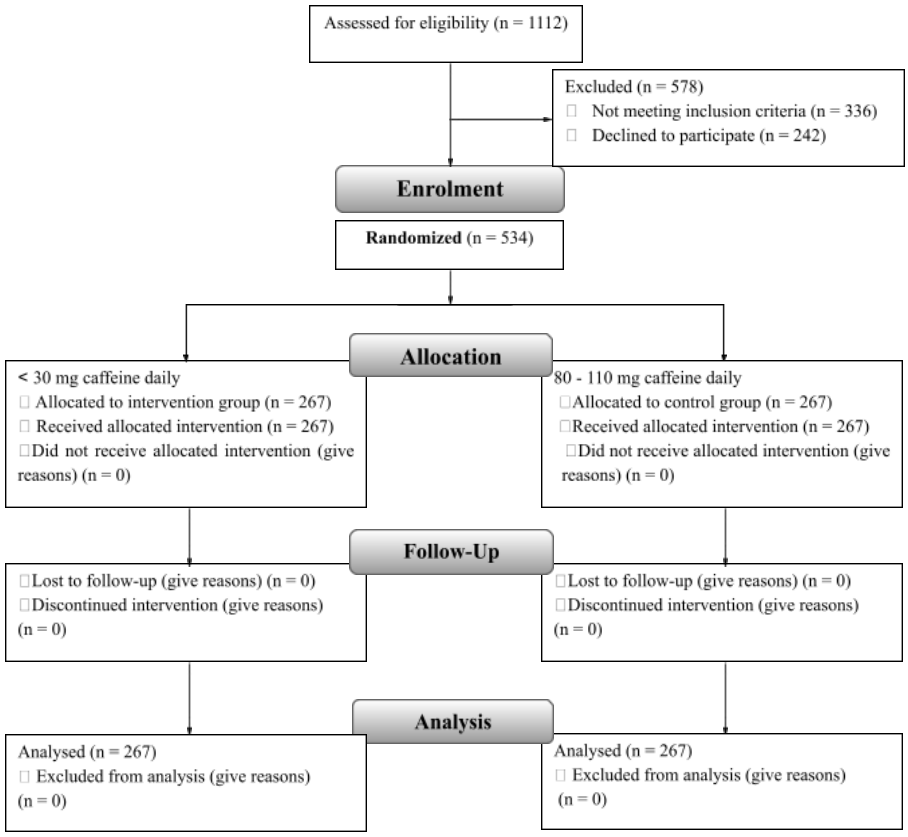

Figure 1. Flow diagram of the study

Figure 1 Flow diagram of the study.

Control group

In this group, the consumption of caffeinated foods included a glass of cocoa milk (100 cc cup contains 2–7 mg of caffeine) and 2–3 cocoa ice creams per week (weighing 75 g, each containing an average of 25 mg of caffeine) and 1–2 cups of tea (100 cc containing less than 50 mg caffeine) or coffee (75 cc contains 25–35 mg caffeine) or cappuccino (75 cc contains 30–40 mg caffeine) and 2–3 cans of cola per week (each 300 cc can contain 20–30 mg caffeine) and 1 chocolate a day (50 g each pack contains approximately 10 mg caffeine)) or a chocolate cake (weighing 100 g contains 5–7 mg caffeine) or a chocolate biscuit (weighing 100 g contains 4–6 mg caffeine).In the control group, the daily caffeine consumption limit was about 80–110 mg per day by N4 software and FFQ.

Intervention group

The caffeine consumption limit per day in this group was less than 30 mg (one or two cups containing 100 cc of light tea, which was calculated by N4 software and FFQ). All children in this group were prevented from taking caffeinated materials such as cocoa milk, cocoa ice

creams, coffee, cappuccino, cans of cola, chocolate, chocolate cake and chocolate biscuit from the recruitment start date until 1 month later. Both groups were advised to urinate just before bed. All children were asked to return 1 month later to check the recorded data.

Main outcome measures

The effect of limited caffeine consumption on the improvement (dry at night) of PMNE and its severity was studied as the main outcome measures. The severity of enuresis was defined as mild ≤2 times/week, moderate 3–4 times/week and severe ≥5 times/week.

Statistical analyses

SPSS statistical software V.21 (SPSS) was used for data analyses. Quantitative data were expressed by mean and SDs and qualitative data by frequency and frequency per cent. The Kolmogorov-Smirnov test was used to test the normality of data distribution. The samples were with normal distribution. Group's data were compared by χ^2 and t-test. The Spearman correlation test was used to investigate the relationship between the amount of caffeine and bed-wetting. Furthermore, ordinal logistic regression analysis was used to assay the effects of caffeine consumption restriction on the PMNE by OR at a 95% CI. P values <0.05 were defined as significant.

Randomised clinical trial registration ID

This study was approved by the Iranian Randomised Clinical Trial registration office (ID: IRCT20180401039167N3; recruitment start date in the registration: 29 September 2021, Trial protocol available link: https://www.irct.ir/trial/58736. It was submitted as online supplemental file 1.

Patient and public involvement

The results of this study will be provided as a bulletin to the academic paediatricians, primary care workers and participants' parents.

This article was edited by native editor. The certificate was submitted as online supplemental file 2.

RESULTS

Anthropometrics and basic variables of both groups

The mean age of the subjects was 10.7±2.3 years including 227 (42.5%) girls and 307 (57.5%) boys. Anthropometric parameters and other qualitative

Table 1 Anthropometrics measures and basic qualitative data in caffeine restriction (N=267) and control group (N=267)*

Anthropometrics measures										
	Caffeine restriction			Control group			Overall			
	Min	Max	Mean±SD	Min	Max	Mean±SD	Min	Max	Mean±SD	P value
Age, years	6	15	10.9±2.3	6	15	10.5±2.5	6	15	10.7±2.3	0.16
Weight, kg	30	91	54.3±14.8	30	88	53.1±15.5	30	91	53.7±14.9	0.28
Height, cm	123	166	146±12.2	123	166	145±12.3	123	166	145.6±12.2	0.3
BMI, kg/m^2	15.2	34.2	25.2±5	13.6	35.1	24.9±5.1	13.6	35.1	25.1±5.1	0.58
Stratified basic qualitative data (N, %)										
			Caffeine restriction		Control group		Overall			
Sex	Girl		113 (42.3)		114 (42.7)		227 (42.5)			0.93
	Boy		154 (57.7)		153 (57.3)		307 (57.5)			
Constipation	No		199 (74.5)		193 (72.3)		392 (73.4)			0.56
	Yes		68 (25.5)		74 (27.7)		142 (26.6)			
Education, father	<diploma		48 (18)		46 (17.2)		94 (17.6)			0.95
	Diploma		134 (50.2)		133 (49.8)		267 (50)			
	>diploma		85 (31.8)		88 (33)		173 (32.4)			
Education, mother	<diploma		24 (9)		21 (8)		45 (8.4)			0.52
	Diploma		133 (49.8)		123 (46)		256 (47.9)			
	>diploma		110 (41.2)		123 (46)		233 (43.6)			
Parents' enuresis history	None		216 (80.9)		216 (80.9)		432 (80.9)			0.41
	Father		17 (6.4)		25 (9.4)		42 (7.9)			
	Mother		22 (8.2)		15 (5.6)		37 (6.9)			
	both		12 (4.5)		11 (4.1)		23 (4.3)			

*Caffeine restriction and control groups were matched according to anthropometrics measures and basic qualitative characteristics (p>0.05).
BMI, body mass index; Max, maximum; Min, minimum.

Table 2 The effect of caffeine restriction in improvement PMNE 1 month after intervention

Bed-wetting	Caffeine restriction, N (%)	Control group, N (%)	Regression coefficient (B)	RR 95% CI (lower-upper)	NNT	P value
Dry enuresis	54 (20.2) 213 (79.8)	18 (6.7) 249 (93.3)	−1.25±0.288	0.615 (0.521 to 0.726)	7.417	0.001

The caffeine restriction significantly reduced the enuresis in children. It seems that the probability of bed-wetting in the caffeine restriction group was about 14% lower than control group. Furthermore, a caffeine restriction had an NNT benefit 7.417; it means you have to treat 7.417 PMNE children with caffeine limitation to prevent one additional bad outcome as a child with enuresis become 'dry'.
N, number; NNT, number needed to treat; PMNE, primary monosymptomatic nocturnal enuresis; RR, relative risk.

information of both groups are shown in table 1. All pooled data were stratified to minimise confounders' effects, and stratum-specific parameters were analysed. The intervention and control groups were matched according to anthropometric measures and basic characteristics.

The effect of caffeine restriction in the improvement of PMNE 1 month after intervention

According to the improvement of PMNE (dry night), 54 children (20.2%) improved in the caffeine restriction group, and in the control group, 18 children (6.7%) with relative risk (RR) 0.615 at 95% CI 0.521 to 0.726, p=0.001. The caffeine restriction significantly reduced enuresis in children. The probability of bed-wetting in the caffeine restriction group was about 14% lower than that in the control group. Furthermore, a caffeine restriction had a number-needed-to-treat benefit (NNT) of 7.417; it means that 7.417 PMNE children with caffeine limitation should be treated to prevent one additional bad outcome as a child with enuresis becoming 'dry' (table 2).

The effect of caffeine restriction in reduction of PMNE severity 1 month after intervention

The mean number of bed-wetting before caffeine restriction in the intervention and control groups was 3.5 (SD 1.7) times/week and 3.4 (SD 1.9) times/week, respectively (p=0.91). Both groups were matched according to bed-wetting before intervention. After the intervention, the mean number of bed-wetting per week in the caffeine restriction and control groups was 2.3 (SD 1.8) times/week and 3.2 (SD 1.9) times/week, respectively (p=0.001).The severity frequency of enuresis (N, %) before intervention in the caffeine restriction group and control groups were: mild, 105 (39.3) and 100 (37.5); moderate, 60 (22.5) and 60 (22.5); and severe, 102 (38.2) and 107 (40), respectively (p=0.99). After the intervention, the severity frequency (N, %) of bed-wetting in caffeine restriction and control group were: no enuresis (dry), 54 (20.2) and 18 (6.7), mild, 101 (37.8) and 91 (34.1), moderate, 78 (29.2) and 75 (28.1), severe, 34 (12.7) and 83 (31.3), respectively (p=0.001). The restrictions on caffeine consumption significantly reduced severe enuresis in the intervention group (38.2% reduced to 12.7%). Furthermore, the rate of severe enuresis was significantly lower in the caffeine restriction group versus the control group (12.7% vs 31.3%) (table 3).

According to the effect of caffeine restriction on the severity of enuresis in the intervention group, severe versus mild enuresis had shown regression −0.997 with OR 0.369 at 95% CI 0.226 to 0.602, p=0.001. The severe enuresis was 63% lower than mild. Severe versus moderate enuresis had shown regression −0.932 with OR 0.394 at 95% CI 0.327 to 0.656, p=0.001. The severe enuresis was 60% lower than moderate. The moderate versus mild enuresis had shown regression −0.065 with OR 0.937 at 95% CI 0.613 to 1.43, p=0.764. Moderate enuresis was 6.3% lower than mild but insignificant (table 4). Caffeine restriction was significantly more effective in reducing severe and moderate enuresis than mild PMNE.

DISCUSSION

This study aimed to evaluate the effect of caffeine restriction on the improvement and reducing the severity of bed-wetting as a first-line behavioural treatment in children with PMNE. The study showed that the frequency of dryness was significantly higher in the limited caffeine

Table 3 The frequency of PMNE severities in children before and after intervention in both groups

Severity	Caffeine restriction, N (%)	Control group, N (%	P value
Before intervention			
Mild	105 (39.3)	100 (37.5)	0.99
Moderate	60 (22.5)	60 (22.5)	
Sever	102 (38.2)	107 (40)	
After intervention			
Dry	54 (20.2)	18 (6.7)	0.001
Mild	101 (37.8)	91 (34.1)	
Moderate	78 (29.3)	75 (28.1)	
Sever	34 (12.7)	83 (31.1)	

The restrictions of caffeine consumption significantly reduced sever enuresis in intervention group (38.2% reduced to 12.7%). Furthermore, the rate of sever enuresis was significantly lower in caffeine restriction group versus control group (12.7% vs 31.3%).
N, number; PMNE, primary monosymptomatic nocturnal enuresis.

Table 4 The effect of caffeine restriction in severity of PMNE after intervention between severity slots

Severity	Regression coefficient	OR 95% CI Lower–upper	P value
Sever/mild	−0.997	0.369 (0.226 to 0.602)	0.001
Sever/moderate	−0.932	0.394 (0.327 to 0.656)	0.001
Moderate/mild	−0.065	0.937 (0.613 to 1.43)	0.764

It seems that caffeine restriction was significantly more effective in reducing sever and moderate enuresis compared with mild PMNE.
PMNE, primary monosymptomatic nocturnal enuresis.

consumption group than in the control group. It means that limited caffeine consumption was significantly effective in improving NE with NNT benefit 7.417. Furthermore, limited caffeine consumption decreased the severity of nocturnal enuresis in PMNE children.

According to ICCS recommendations, simple behavioural interventions (urotherapy) are the first-line strategies in treating NE, such as limited fluid intake in the evening, urination before sleep and limited caffeine intake. These modalities are effective alone, or in combination with other medications, although evidence regarding their efficacy is controversial.[11 13] However, many of these simple recommendations are not considered in treating children with enuresis. A descriptive-analytical study in Italy demonstrated that more than 90% of children did not advise dietary and other simple behavioural recommendations.[14] Our present study determined that caffeine limitation effectively treats PMNE with NNT 7.417.

Caffeine consumption is a common habit among adolescents and children. A mini-review found a positive correlation between age and caffeine utilisation.[15] Caffeine has positive and negative effects on multiple systems in the body.[16] While fluid intake is recognised to affect the severity of NE, the adverse effect of caffeine in PMNE needs to be better understood, and evidence from previous studies is mixed and contradictory.[17] A systematic review defined caffeine as associated with LUTS, mainly frequency, and urgency in women and men.[18]A cohort study showed that caffeine intake increased LUTS in adults (OR 2.09 at 95% CI 1.29 to 3.40).[19] Conversely, a cross-sectional study of 200 patients defined that caffeinated fluid did not affect urinary symptoms (OR 1.00, 95% CI 1.00 to 1.01).[20] These studies were not conducted in children and not especially in PMNE. Our study was conducted on children with PMNE. It showed that caffeine effectively decreased NE and the severity of bed-wetting.

Another cross-sectional study of 262 Chinese enuretic children aged 5–12 years demonstrated that children had more NE if they drank caffeinated beverages during the day.[21] Although the finding of this study was the same as our study, however, this study was conducted in PMNE in 534 children aged 6–15 years who received less than 30 mg and 80–110 mg of all caffeinated materials (beverages and nonbeverages) in 2 parallel randomised groups.

A study on 228 children aged 5–12 years defined that 52–109 mg daily caffeine intake was not correlated with the severity of enuresis.[22] Another study in Sweden twin suggested that coffee and tea had a limited effect on urinary incontinence.[23] However, a narrative review demonstrated that a high tea intake was positively associated with nocturia.[24] Another cross-sectional study that included 834 children aged 9±2 years showed that caffeine intake was significantly associated with PMNE.[25] Research about the effects of caffeine consumption on NE demonstrates confusing findings. Given existing evidence, lifestyle interventions and caffeine modification may have a significant and central role in the primary prevention of PMNE.

There is limited high-grade evidence to provide that caffeine may contribute to the pathogenesis of enuresis. A greater conception of the impact of caffeine on enuresis is needed to further improve the treatment of enuresis. Furthermore, associated pieces of evidence between LUTS and caffeine are sparse and often observational. Given the matter of these materials in daily life and their realised impact on the severity of PMNE, high-quality evidence is needed. A scoping review defined that caffeine reduction can reduce LUTS and NE. The studies were mainly observational, with a level of evidence 2–4 and a grade of recommendation B-C.[26] However, this study was randomised clinical trial research on children with PMNE.

Issues related to caffeine and the potential for the development and severity of PMNE remain to be clarified. Caffeine has multiple effects on various organs. It still is an interesting topic for further studies to develop and clarifies new therapeutic strategies. Although diverse health effects of caffeine have been expressed in children and adults, few data exist about caffeine consumption effects on PMNE in children. It is recommended that RCT studies with a larger population be conducted to obtain more objective evidence in the future. One of the limitations of this study was that the parents and participants did not believe to simple behavioural treatment. It is suggested to increase parents' perception of simple first-line strategies, such as reducing caffeine intake and fluid, by media and other social communities.

CONCLUSION

According to the finding of this study, caffeine restriction can help reduce PMNE or its severity. Constructive limitation of caffeine is suggested as one of the first-line treatments in the management of PMNE. This study was the initial way to define clues to improving PMNE and severity.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and was approved by the ethics committee of Aja University of Medical Sciences approved research project of this study (Reg No: IR.AJAUMS.REC.1400.151). Link: https://ethics.research.ac.ir/form/rw0kykqzeg4r9v58.pdf. Participants gave informed consent to participate in the study before taking part.

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ORCID iDs
Sadra Rezakhaniha http://orcid.org/0000-0002-8211-070X
Bijan Rezakhaniha http://orcid.org/0000-0001-7426-4875
Soheila Siroosbakht http://orcid.org/0000-0002-0212-0810

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Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Dec 2022

The effect of caffeine restriction on enuresis in children 6 to 15 years old

Protocol summary

Study aim
The effect of caffeine restriction on enuresis in children 6 to 15 years old

Design
A clinical trial with a control group, with parallel groups, not blinded, randomized, no phase on 80 patients. For randomization, the regular randomization method was used one by one of the hospital patients.

Settings and conduct
The study will be performed on children aged 6 to 15 years in Golestan and Imam Reza (AS) hospitals from September 1400. To extract information, a checklist including children's demographic information and caffeine consumption and enuresis control is used. The amount of caffeine consumption in children was recorded based on the food frequency questionnaire and was calculated by N4 software. Counseling is given and the subjects are divided into two groups of control and intervention (caffeine restriction) by regular randomization (one in between). To collect the data, a table is set up and given to the children to record whether or not they have enuresis by mentioning the date. Children are asked to return one month later (to check for side effects and follow up on treatment) to have their enuresis checked or enuresis grade (severe / moderate / ..) checked. Children are followed up by not calling by phone and sending the enuresis recording table.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children 6 to 15 years old with primary enuresis with normal urinalysis and culture tests and ultrasound of normal kidneys and urinary tract

Intervention groups
The intervention group included restriction of consumption of caffeinated foods The control group included no restriction on the consumption of caffeinated foods

Main outcome variables
Changes in the incidence and severity of primary enuresis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180401039167N3**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date
2021-09-29, 1400/07/07

Registrant information

Name
Bijan Rezakhaniha

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2264 6431

Email address
reza.bijan1345@ajaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2021-11-06, 1400/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of caffeine restriction on enuresis in children 6

to 15 years old

Public title
The effect of caffeine restriction on enuresis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with primary enuresis Normal urine analysis and culture tests Normal ultrasound of the kidneys and urinary tract Age range 6 to 15 years
Exclusion criteria:
Age
From **6 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Regular person-to-person randomization in such a way that among the patients referred to the hospital with the initial enuresis complaint, we divide the eligible individuals into the study and intervention group one by one.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Medical Sciences of the Army of the Islamic Republic of Iran
Street address
Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
tehran
Province
Tehran
Postal code
1411718541
Approval date
2021-09-14, 1400/06/23
Ethics committee reference number
IR.AJAUMS.REC.1400.151

Health conditions studied

1

Description of health condition studied
primary enuresis
ICD-10 code
F98.0
ICD-10 code description
Enuresis not due to a substance or known physiological condition

Primary outcomes

1

Description
Create enuresis
Timepoint
Measurement of enuresis at the beginning of the study and one month later
Method of measurement
Record enuresis in the calendar

Secondary outcomes

1

Description
The severity of enuresis
Timepoint
At the beginning of the study and a month later
Method of measurement
Record the number of enuresis days in the calendar

Intervention groups

1

Description
Intervention group: In children 6 to 15 years old with primary enuresis, in this group, the limit of caffeine consumption per day is a maximum of two cups (1-2 cups per 100 cc of light tea containing less than 30 mg of caffeine, which is provided by the software N4 is calculated) applies.
Category
Treatment - Other

2

Description
Control group:In this group, the consumption of caffeinated foods includes a glass of cocoa milk (100 cc cup contains 2 to 7 mg of caffeine) and two to three cocoa ice creams per week (weighing 75 grams, each containing an average of 2 5 mg of caffeine) and one to two cups of tea (2 100 cc cups of medium color tea

containing less than 50 mg of caffeine) or coffee (75 cc each contains 25 to 35 mg of caffeine) or cappuccino (each 75 cc cup contains 30 to 40 mg of caffeine) and 2 to 3 cans of cola a week (each 300 cc can contain 20 to 30 mg of caffeine) and one chocolate a day (50 g each pack contains approximately 10 mg of caffeine)) Or a chocolate cake (weighing 100 grams contains 5 to 7 mg of caffeine) or a chocolate biscuit (weighing 100 grams contains 4 to 6 mg of caffeine). In total, in the control group, the daily caffeine consumption was about 80 to 110 mg per day by N4 software.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital (501 Army)
Full name of responsible person
Bijan Reza Khaniha
Street address
Imam Reza Hospital (501 Army)., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
lms@ajaums.ac.ir

2

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Bijan Reza Khaniha
Street address
Golestan Hospital.,Shahid Sayad Shirazi Highway.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 2277 1541
Email
lms@ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mojtaba yousefi zoshk
Street address
Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
lms@ajaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Bijan Rezakhaniha
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350

Email
reza.bijan@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
bijan rezakhaniha
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
reza.bijan@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
bijan rezakhaniha
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
reza.bijan@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

EDITORIAL CERTIFICATE

This document certifies that the manuscript listed below was edited for proper English language, grammar, punctuation, spelling, and overall style by one or more of the highly qualified native English speaking editors at NedMedica

Manuscript title:

Limited caffeine consumption as first-line treatment in managing primary monosymptomatic enuresis in children. How effective is it? A Randomized Clinical Trial

Authors:

Sadra Rezakhaniha, Bijan Rezakhaniha, Soheila Siroosbakht

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Dr. Seyyed Mohammad Miri
Managing Director

Central Office: Kerkraderweg 13, 6416 CC, Heerlen, The Netherland Tel: +31615314198 | Fax: +31452051123
website: www.Nedmedica.nl | Email: Info@Nedmedica.nl