

ORIGINAL ARTICLE

Predictors of response and adherence to enuresis alarm therapy—a confirmatory study

Amadeus Bergsten¹ | Jens Larsson² | Malin Borgström^{1,3} | Birgitta Karanikas¹ | Tryggve Nevéus¹ 

¹Dept of Women's and Children's Health, Uppsala University, Uppsala, Sweden

²Urotherapy Unit, Section for Pediatric Surgery, Skåne University Hospital, Lund, Sweden

³Center for Clinical Research Dalarna, Falun, Sweden

Correspondence

Tryggve Nevéus, Dept of Women's and Children's Health Uppsala University Children's hospital 751 85 Uppsala, Sweden.

Email: tryggve.neveus@kbh.uu.se

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Abstract

Aim: To look for predictors to response and adherence to the enuresis alarm while exploring the possibility of families managing therapy independently.

Methods: We used a body-worn alarm linked to a smartphone app. Subjects with enuresis were recruited both via paediatric nurses and independently as families bought the alarm and downloaded the app on their own.

Results: We recruited 385 nurse-supported and 1125 independent subjects. Many (79.9%) dropped out before 8 weeks, but among adherent subjects 48.2% had a full or partial response. Age was a predictor of non-response ($p=0.019$). Daytime incontinence did not influence response. If enuresis frequency did not decrease during the first 4 weeks of therapy the chance of response was very small ($p<0.001$). Adherence was higher among subjects supported by a nurse ($p<0.001$), but for adherent subjects the outcome was similar regardless of nurse support ($p=0.554$).

Conclusions: Daytime incontinence is no contraindication to enuresis alarm therapy. Treatment can be managed independently by the families, but adherence is enhanced by nurse support. Alarm treatment should be reassessed after 4 weeks. Enuresis alarm treatment guidelines need to be updated.

KEYWORDS

adherence, enuresis, enuresis alarm

1 | BACKGROUND

The enuresis alarm is an established first-line therapy of nocturnal enuresis. The therapy works by consistently waking the child immediately at the moment of voiding, thereby somehow helping them to gradually modify sleep and arousal mechanisms and become dry. The success rates reported vary widely depending on selection criteria, but most studies claim that substantially more than half of those treated will become reliably dry after 2–3 months

of therapy.¹ According to current international guidelines, enuresis alarm therapy is indicated from the age of six or more provided that there is no concurrent daytime incontinence. Treatment should be used for at least 6–8 weeks or until 14 consecutive dry nights have been achieved.²

The main asset of alarm therapy is that a majority of the children successfully treated are cured.^{3,4} This differs from pharmacological antienuretic therapy which usually only works as long as it is taken (if at all).

Amadeus Bergsten and Jens Larsson contributed equally to the manuscript.

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There are, however, several drawbacks with the alarm therapy. One obvious problem is the amount of hard work and motivation required by the child as well as their guardians and the healthcare provider. Treatment needs to be continuous; parents need to sleep close to the child and help them wake up as the alarm goes off and the healthcare provider needs to follow the family with frequent contacts for encouragement and problem-solving.² Many children and families will not be able to adhere to the treatment as prescribed, and their treatment will be suboptimal.⁵ It should be kept in mind that neuropsychiatric conditions such as attention-deficit hyperactivity disorder is overrepresented among children with enuresis,⁶ as well as, presumably, their parents, and this can be expected to affect adherence.

Another problem is the lack of known predictors to alarm treatment success or adherence, although motivation of the patient and family can be suspected to be crucial.⁷ There are data suggesting that voiding chart data give some predictive clues⁸ and that low-frequency enuresis is unlikely to respond to alarm treatment.⁹ This lack of predictors is extra problematic for the alarm non-responders: they will have to endure months of labour-intensive and socially disruptive therapy just to end up where they started, possibly with low expectations of future treatment attempts.

Finally, there is an availability problem. The alarm is often not offered by healthcare providers and very few general practitioners or non-paediatric nurses are familiar with its use.

In a pilot investigation, we tried to address the lack of predictors to treatment success.¹⁰ We chose to look only at (1) data that would be readily available for the healthcare professional at the first visit, that is, demographic and anamnestic data, and (2) data acquired as the treatment progressed. We found that background data gave no predictive information. Interestingly, we did not find that current daytime incontinence diminished the chance of treatment response. We did, however, find that data gathered during the first 3–4 weeks of therapy reliably predicted which children had a chance to become dry. Specifically, if there was no reduction of enuresis frequency during the first 4 weeks there was basically no chance for the child to become dry, and if there were more than one or two missed registrations during this period it was very likely that the child would drop out from therapy before the recommended 6–8 weeks. Incidentally, we noted that many children did not follow the instruction and that this gave extra information: (1) many continued therapy beyond 14 consecutive dry nights and then had relapses of enuresis and thus switched from full to partial responders, whereas (2) some children continued partially successful therapy beyond 8 weeks and then became completely dry.

We also looked at whether it was possible to bypass the healthcare professionals and see whether the families were able to manage therapy on their own, supported by a smartphone application. We found that this was, in principle, the case but that adherence to therapy was much higher if a nurse was involved.¹¹

But these were pilot investigations based on a limited number of patients (196 nurse-supported and 202 independent). We now

Key Notes

- Our aims were to find predictors to response and adherence to enuresis alarm therapy, and explore whether treatment can be managed independently by the families
- Alarm response and adherence could be predicted by the results of the first weeks of therapy, and adherence was poor if a nurse was not available for support
- Our results provide grounds for modifying guidelines for enuresis alarm therapy

aimed to see if the results are replicable in a larger sample and thus potentially can serve as grounds for changed recommendations.

2 | METHODS

We used an alarm device developed by Pjama Inc which incorporates a body-worn detector linked to an alarm unit and an application downloaded to a parent's mobile phone or tablet. Into the application the families entered relevant data, such as age, gender, estimated baseline enuresis frequency, previous alarm or desmopressin treatment, previous dry periods and whether urgency or daytime incontinence was present. Furthermore, the application documented alarm use and the actual time of the wetting episodes automatically, which minimises recall bias (as well as wishful thinking).

The families were instructed in accordance with the guidelines of the International Children's Continence Society,² by the application only or by a healthcare provider as well. The application also gave reminders and prompts in case the families forgot to use the alarm. The instructions included:

- Treatment should be continuous, every night without interruption
- A guardian should help the child to wake up immediately when the alarm goes off
- One alarm per night is enough
- Treatment can stop after two consecutive dry weeks
- Otherwise, treatment should continue at least 8 weeks

2.1 | Subjects

Children were recruited from several sources. Paediatric nurses from nine participating paediatric outpatient wards (at one tertiary centre and eight regional hospitals) in Sweden acquired written informed consent from the guardians of children aged at least six who suffered from enuresis and had no symptoms or findings suggesting urinary tract infection, malformation or any condition affecting sleep/arousal or the function of the kidneys or urinary tract. Daytime incontinence was not

an exclusion criterion, and neither was neuropsychiatric conditions. Furthermore, families around Europe who had bought the alarm and downloaded the application on their own initiative were also included in the analyses. Among these subjects the healthcare provider support varied; some could call a nurse accustomed to the treatment and some managed treatment only supported by the application.

2.2 | Statistics

In order to have a suitable cut-off for patient recruitment in this ongoing project, and make all participants comparable, we chose to only evaluate subjects whose therapy had reached 8 weeks, that is, 56 days, and therapy duration for subjects choosing to continue beyond 8 weeks were still evaluated after 56 days. Subjects who discontinued therapy after just one or a few nights were still included in the analysis provided 56 days had elapsed since start of therapy.

Treatment outcome was determined in a stepwise fashion. First, the ones who withdrew prematurely, that is, before 8 weeks, without achieving two consecutive dry weeks, were grouped into the Dropout category. Second, the enuresis frequency week for week was determined, only taking weeks with at least 4 days of alarm use into account. For weeks with 1–3 missing nights enuresis frequency was extrapolated to wet nights per seven nights (example: if only five nights were registered and one of them was wet the enuresis frequency for that week would be $[1/5] \times 7 = 1.4$). Patients with two consecutive dry valid weeks, without subsequent recorded wet nights, were labelled full responders. The remaining patients were then grouped into the intermediate or non-response groups according to the reduction of enuresis frequency between the first 2 weeks and week 7–8, in accordance with the terminology of the ICCS. Please note that subjects who chose to continue therapy for more than 8 weeks were still evaluated at week 7–8. Finally, the patients who had too many nights without registrations for a response rate to be assigned were grouped into the sporadic use group. The groups and definitions are summarised in [Table 1](#).

When looking for predictors for treatment response intermediate and full responders were lumped together and compared with the non-responders. When looking for predictors to adherence the dropout and sporadic use groups were merged and labelled the non-adherent group. All the background information listed above were considered potential predictors. Adherence (recorded nights per week) and enuresis frequency (for weeks with at least four recorded nights as explained above) were analysed for every week.

At the end of therapy treatment response and treatment duration were recorded. *T*-tests or non-parametric alternatives were used, depending on the distribution of the data. A statistical significance level of 95% ($p < 0.05$) was chosen. The analyses were made using SPSS version 28 for Mac.

2.3 | Ethics

Ethical approval was granted by the Swedish Regional Ethics Authority (2021-00206). All procedures were in accordance with the Helsinki Declaration. The data entered by the patients' guardians (or the patients themselves) in the application were accessed via a web portal administered by Pjama, the use of which was cleared according to the General Data Protection Regulation. Only the patients' treating nurse had access to the identities of patients recruited from paediatric outpatient wards and no researcher knew the identities of independent subjects.

The alarm unit, including the application, was provided by Pjama® Inc. The researchers did not receive any compensation and none of the researchers have any economic interest in the company. This study was supported by a grant from Sweden's Innovation Agency (2020-04131).

3 | RESULTS

3.1 | The subjects

All in all, 1530 subjects were included. Their median age was 8 years (range 3–78 years). All children below age 6 and all adults, aged 18 years or more, belonged to the independent participants. The finding of 121 adult subjects was so surprising that we chose to describe this group in a separate publication (forthcoming).

The subjects' estimated median baseline enuresis frequency was 5 (range 0–7) nights per week. The background data for all subjects are described in [Table 2](#). All the missing data belong to independent participants.

3.2 | Treatment outcome

One immediate observation was that many subjects dropped out of treatment early. Treatment duration ranged from one to 56 nights,

TABLE 1 Response definitions.

Response	Criteria
Full response	Last 2 weeks completely dry
Intermediate response	Treatment for at least 8 weeks. Enuresis reduction $\geq 50\%$
Non-response	Treatment for at least 8 weeks. Enuresis reduction $< 50\%$
Dropout	Treatment interrupted before 8 weeks without full response
Sporadic use	Too many missing nights for response to be calculated

Variable	N	Proportion (%)
Gender	1510	385 (25.2) female, 1125 (73.5) male
Recruitment group	1529	122 (8.0) nurse-supported 1407 (92) independent
Primary enuresis	1511	1173 (77.6)
Daytime incontinence	1455	256 (17.6)
Urgency	1455	756 (52.0)
Previous alarm therapy	1455	362 (24.9)
Previous desmopressin therapy	1455	442 (30.4)

TABLE 2 Available demographic and anamnestic baseline data for all participants.

TABLE 3 Response and adherence categories of all subjects (N = 1530).

Category ^a	Proportion (%)		
Full response	46 (3.0%)	149 (48.2%)	309 (20.3%)
Partial response	103 (6.7%)		
Non-response	160 (10.5%)	160 (51.8%)	
Dropout	1177 (76.9%)		1219 (79.9%)
Sporadic	38 (2.5%)		
Only dry	6 (0.4%)		

^aFull response: ≥ 14 consecutive dry nights; Partial response: $\geq 50\%$ enuresis reduction; Non-response: $< 50\%$ enuresis reduction; Dropout: treatment interrupted before 8 weeks without achieving dryness; Sporadic: alarm intermittently used without clear success; Only dry: only dry nights recorded.

with a median of just eight (mean ± 1 SD 18.6 ± 20.9 days). Only 594 of 1530 participants remained if subjects with less than seven recorded nights during the first 2 weeks were removed. The response and adherence categories, as explained above in the Methods section, are shown in Table 3. As can be seen in Table 3, around 3/4 of participants were not able to complete the therapy according to the instructions given but approximately half of the adherent subjects had a favourable response. There were also six subjects who only produced dry nights and thus finished early, these are not included in the further analyses.

3.3 | Predictors of response and adherence

Comparing those with or without a favourable treatment response (intermediate or full responders vs. non-responders), with non-adherent subjects discounted, it was found that gender did not differ between the groups, but high age was associated with a poor outcome (non-responders age 9.5 ± 6.5 years, responders age 8.1 ± 3.5 years, $p = 0.019$). The background demographic and anamnestic data compared between the two groups are shown in Table 4. None of these variables, including daytime incontinence or previous alarm attempts, differed significantly between the groups. Subjects recruited and followed by a nurse had the same chance of success as the independent participants, provided they adhered to therapy.

However, when looking at the number of wet nights per week during treatment it was obvious that the subjects with different alarm treatment efficacy could be distinctly differentiated already from the second week of therapy, as illustrated in Figure 1. The p -values when comparing subjects with or without a favourable outcome (full or partial response vs. non-response) for weeks one and two were 0.162, and 0.032, respectively, whereas for weeks three to eight, they were consistently < 0.001 .

When examining predictors of adherence to treatment, it was clear that age was a disadvantageous factor, with the average age of 297 adherent subjects being 8.8 ± 5.3 as compared to 1114 non-adherent participants whose age was 10.2 ± 7.7 , $p < 0.001$. The estimated baseline enuresis frequency was similar in the two groups (wet nights per week for both adherent and non-adherent participants 5.1 ± 2.0 , $p = 0.627$). Anamnestic and demographic data are shown in Table 5. Secondary enuresis was more common in the non-adherent group. Interestingly, previous treatment attempts did not differ. What stood out most clearly, however, was that being recruited and actively supported by a nurse increased the chance for adherence. Expressed in another way: only 253/1403, or 18.0%, of the independent subjects completed the full treatment course.

When comparing the number of nights without registrations during treatment, week by week, it was clear that the non-adherent subjects differed already from the first week, but this is not very informative since many non-adherent participants dropped out of treatment after just a few nights of therapy, and the variable that interested us was the adherence before end of therapy. Thus, in the analyses we chose for every treatment week only to include subjects whose last registered night happened after the week in question. For example, a subject who used the alarm continuously for 10 consecutive nights and then dropped out should be regarded as having full adherence until early dropout. The results are shown in Table 6. From Table 6, it is clear that the non-adherent subjects even with this modification had significantly more missing registrations already from the start of treatment. In other words, their premature withdrawal from treatment could be predicted by their lack of ability to use the alarm consistently.

4 | DISCUSSION

We analysed a large number of subjects with enuresis to see if our earlier findings regarding predictors of enuresis alarm effect and

TABLE 4 Demographic and anamnestic data as predictors of treatment response.

	Full or partial responders	Non-responders	<i>p</i>
Female gender	32/147 (21.8%)	36/160 (22.5%)	0.877
Primary enuresis	130/149 (87.2%)	130/156 (83.3%)	0.335
Daytime incontinence	18/143 (12.6%)	25/150 (16.7%)	0.324
Urgency	64/143 (44.8%)	80/150 (53.3%)	0.142
Previous alarm therapy	28/143 (19.6%)	41/150 (27.3%)	0.118
Previous desmopressin therapy	51/143 (35.7%)	54/150 (36.0%)	0.952
Supported by paediatric nurse	25/149 (16.8%)	31/160 (19.4%)	0.554

FIGURE 1 Weekly enuresis frequency.

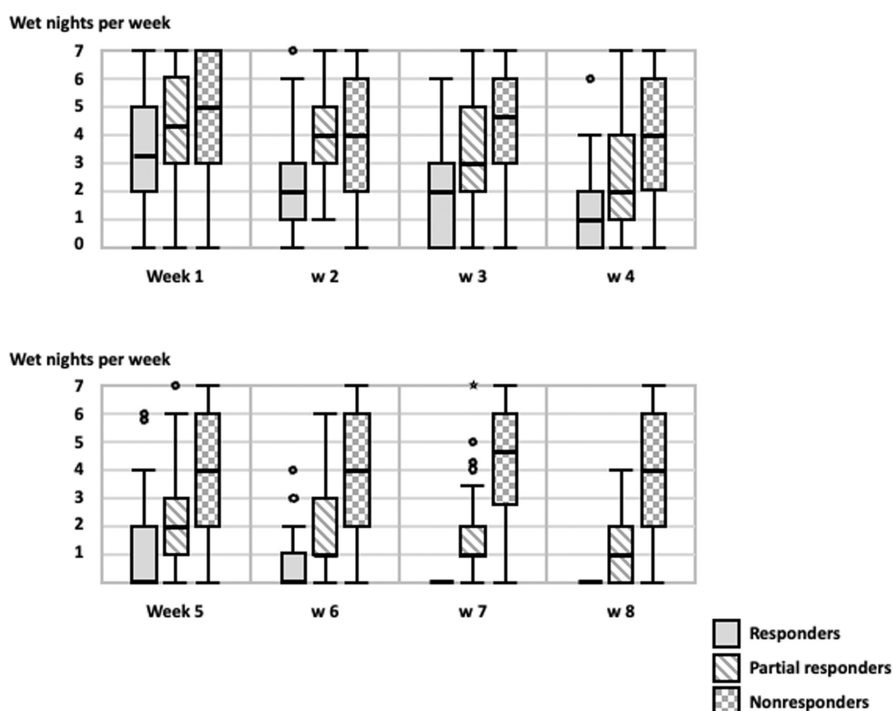


TABLE 5 Baseline characteristics of adherent and non-adherent participants.

	Adherent	Non-adherent	<i>p</i>
Female gender	68/307 (22.1%)	314/1197 (26.2%)	0.143
Primary enuresis	260/305 (85.2%)	907/1200 (75.6%)	<0.001
Daytime incontinence	44/293 (15.0%)	212/1156 (18.3%)	0.183
Urgency	143/293 (48.8%)	610/1156 (52.8%)	0.225
Previous alarm attempt	69/293 (23.5%)	291/1156 (25.2%)	0.566
Previous desmopressin attempt	106/293 (36.2%)	334/1156 (28.9%)	0.015
Supported by paediatric nurse	56/309 (18.1%)	64/1214 (5.3%)	<0.001

adherence^{10,11} could be replicated. We found that this was the case and can therefore with great confidence say that, firstly, treatment success and treatment adherence can reliably be predicted after, at most, 4 weeks of therapy; secondly, concomitant daytime incontinence is probably no contraindication for enuresis alarm therapy; and thirdly, that active support by a nurse is crucial for treatment adherence.

We found that almost the only baseline data that had any predictive value was age which both predicted non-response and, more definitely, non-adherence. Also, support by a nurse predicted

adherence. Interestingly, neither concurrent daytime incontinence nor previous alarm treatment attempts gave any predictive information. An extra factor, which we did not address in our previous studies, was primary or secondary enuresis. We found that previous dryness did not predict response or non-response to therapy but was significantly more common among non-adherent subjects. This is probably an age effect, since previous dryness was more common among older participants. Overall, the alarm does not seem to be very successful in adults, which we will report separately.

TABLE 6 Missing registrations per week during treatment.

	Adherent		Non-adherent		p value
	N	Mean ± SD	N ^a	Mean ± SD	
Week 1	308	0.9 ± 1.3	483	2.5 ± 2.5	<0.001
2	308	0.4 ± 1.0	307	2.6 ± 2.6	<0.001
3	308	0.3 ± 1.0	204	2.3 ± 2.4	<0.001
4	306	0.4 ± 1.1	135	2.3 ± 2.4	<0.001

^aOnly subjects with total treatment length at least equal to the week number times 7 included.

Our main focus was predictors of alarm benefit, not the efficacy of the enuresis alarm, and neither was it an evaluation of the specific device chosen. But the many dropouts and the modest success rate among adherent families still deserve commenting. Our study population comes close to reflecting a real-world situation. Also, we only evaluated the first 56 days of treatment, which means that we probably missed a number of subjects who ultimately became dry after prolonged therapy. Our earlier research indicates that some children who have an intermediate response after 2 months will be full responders if treatment is prolonged.¹⁰ Furthermore, the application we used diminished or eliminated the risk of recall bias or wishful thinking from families reporting wet and dry nights. We believe that we received a picture more representative of the population at large than most published studies.

Danish research has shown that voiding chart data may have some predictive value for alarm treatment. Small voided volumes and absence of nocturnal polyuria may be more common among alarm responders.^{8,9} Yet, we chose not to demand that the families completed a voiding chart. This was because we wanted to include a representative sample of the general population of subjects with enuresis, including those who for various reasons (including neuropsychiatric disorders) may not be able to provide voiding chart data. We wanted to see how much predictive information we could gather with just anamnestic data and data gathered during the actual treatment.

One drawback is that we do not know much about the patients, just what they chose to enter in the application and what the application recorded during treatment. This is especially true for the independent subjects. There were quite a few subjects who did, for instance, not register their age. And we do not know how many participants had neuropsychiatric conditions in addition to their enuresis, information that would have been very interesting. This drawback is balanced by the large number of participants gathered from all over Europe.

This study forms part of a project aimed at making enuresis alarm treatment available even in the many regions where it is not routinely offered by healthcare providers. The ultimate goal is to make the device and application adapted to the children and their guardians so that many can become dry without having to seek the help of healthcare authorities. This is why we included subjects that were not recruited via paediatric outpatient wards. We found, again, that these participants were not easy to motivate for a full treatment

course, but for the minority that did complete therapy the chance of success was equal to those who were supported by a nurse. Another conclusion that can be drawn from our results is that since the nurse is needed for encouragement more than instructions, then a urotherapist or a specialist paediatric nurse is probably not needed; any caring healthcare professional will do. This can increase the number of patients successfully treated with the alarm.

The usual recommendation not to address the enuresis before first making the child dry during the daytime² is presumably based on two assumptions: (1) treatment of daytime incontinence may make the child dry at night, and (2) enuresis treatment will be less successful if concomitant daytime incontinence is not first addressed. Our previous research¹² has put the first assumption into serious doubt and our present study questions the second assumption as well. Probably, we may just as well treat both conditions in parallel, or start with what bothers the child most.

Our results mean that we can modify the treatment recommendations and instruct the healthcare provider (and/or programme the enuresis alarm device) to evaluate the patient after 4 weeks of therapy. If the enuresis frequency has not decreased at that time there is very little chance of treatment success, and alternative treatment should be sought. And if there has been more than the occasional missed night without therapy the risk for premature dropout is imminent and the family should be either recommended to discontinue and save the alarm treatment until later or find ways to become more motivated. Based on our earlier research, we can add that we should recommend compliant families of children who see favourable effects to continue therapy as long as it keeps getting better and better, and that they should not stop after 14 consecutive dry nights but keep going until one full dry month has been achieved.¹⁰

This way many children (and their parents) will be spared the frustrating experience of several months of unfruitful hard work. The only children who will undergo prolonged therapy are those with a fair chance of success and the latter part of their therapy will only involve occasional wet nights and thus not be as labour-intensive as the first weeks.

5 | CONCLUSIONS

We confirm our earlier findings that treatment response as well as treatment adherence can be reliably predicted after 3–4 weeks of therapy, and that daytime incontinence should probably not be a contraindication to enuresis alarm therapy. This means that treatment instructions can be modified so that fewer families will have to endure pointless hard work while success rate remains unchanged. We can also confirm that adherence to the alarm therapy is problematic, especially when no healthcare professional is involved.

AUTHOR CONTRIBUTIONS

Trygve Nevéus: Conceptualization; methodology; supervision; formal analysis; writing – review and editing; project administration; investigation; data curation. **Amadeus Bergsten:** Investigation; writing

– review and editing; conceptualization; data curation; methodology; writing – original draft; formal analysis. **Jens Larsson:** Investigation; data curation; writing – original draft; writing – review and editing; project administration; methodology; formal analysis; conceptualization. **Malin Borgström:** Data curation; investigation; writing – review and editing. **Birgitta Karanikas:** Data curation; investigation; writing – review and editing; formal analysis.

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CONFLICT OF INTEREST STATEMENT

None of the authors have any conflicts of interest to declare.

ORCID

Tryggve Nevéus  <https://orcid.org/0000-0002-4590-4957>

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