# Multimedia versus written information for nocturnal enuresis education: a cluster randomized controlled trial

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# Abstract

*Objective* This study evaluated the impact of child-focused information provision using a multimedia software package 'All About Nocturnal Enuresis' and written leaflets containing the same information for bedwetting children.

*Design* A stratified cluster randomized controlled trial with data on 270 children collected longitudinally.

Setting Fifteen school nurse-led community enuresis clinics in Leicestershire, UK. Main outcome measures The outcome measures were becoming and remaining dry and time to dry, non-attendance and dropout rates. The psychological measures completed by children were the impact of bedwetting and Coopersmith self-esteem scales. Parents completed the maternal tolerance scale.

*Results* No significant intervention effect was found for any of the outcome measures recorded during treatment, at discharge or six-months post discharge.

*Conclusions* Multimedia educational programs and written leaflets are widely used to enable children to learn more about their health-related conditions. However, our result suggests that multimedia is no more effective than traditional materials at effecting health-related behavioural change.

#### Keywords

multimedia, patient information, bedwetting, nocturnal enuresis

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# Introduction

## Prevalence

Nocturnal enuresis (bedwetting) is a chronic medical condition, which is often distressing for a child and their family. The prevalence of bedwetting at aged 7 years has been estimated at between 7% and 10% (Krantz *et al.* 1994; Wille 1994). However, bedwetting decreases with age (Wille 1994) and a spontaneous cure rate of 15–17%, per annum, has been estimated (Forsythe & Redmond 1974). A higher prevalence rate is usually reported among boys (Foxman *et al.* 1986), although by adolescence the rate is similar between the genders. The majority of bedwetting children do not have either an organic or a functional cause for the wetting (Jarvelin *et al.* 1990; Hjalmas 1992) and the aetiology is thought to be multicausal.

## Treatment

The buzzer alarm, a behavioural treatment, is the most effective treatment for bedwetting (University of York NHS Centre for Reviews and Dissemination 1997). It is based on the theory that the ability to stay dry at night is a learned response and bedwetting is attributed to habit deficiencies, poor learning experiences (Crawford 1989) and the lack of appropriate re-enforcement contingencies (Houts 1991). The success of alarm treatment demonstrates that being dry can be learnt by a child, however there is no empirical evidence showing that providing children with opportunities to learn bladder control decreases the frequency of their bedwetting.

## Explanations for children

For a successful outcome it is preferable that children understand how their bladder works and, if the alarm is chosen, how to participate in this treatment option. Rushforth (1999) suggests the most effective method of enhancing children's understanding of their illness and enabling them to actively participate in their treatment is appropriate information provision. Computer games are now an integral part of children's leisure time and educational software is being developed for a number of illness conditions (Thomas et al. 1997; Bartholomew et al. 2000a). Working through educational software encourages children to experiment, succeed or fail and see the consequences of their decisions within a relatively safe environment (Brown et al. 1997). Learning skills through educational software can enhance children's self-efficacy leading to improvements in their self-esteem (Brown et al. 1997). The evidence suggests that some children who wet the bed have a low selfesteem (Redsell and Collier 2001) and it was hypothesized that engaging with the multimedia program may lead to improvements.

#### Information provision

Formative evaluation showed the multimedia program used in this study was informative and easy to use and working through the material improved children's understanding of their condition and the treatments available (Evans et al. 1998). Improvements in knowledge have also been reported in other evaluations of multimedia programs (Glazebrook et al. 1998; Buller et al. 1999; Bartholemew et al. 2000b; Homer et al. 2000). However, to date, there is little evidence demonstrating that multimedia has a superior impact on behavioural outcomes, and one study found no difference in the improvements gained by asthmatic children engaging with multimedia and those provided with traditional written materials (Homer et al. 2000).

It was therefore hypothesized that teaching a child the process of their bedwetting treatment, e.g. how to use a buzzer alarm will enable them to actively participate in their treatment regime. The aim of this study was to evaluate the impact of a multimedia software program and written leaflets on clinical, healthcare utilization and psychosocial outcomes for bedwetting children.

## Method

#### Study design

Leicestershire and Rutland Healthcare NHS Trust have a well-established treatment protocol for the treatment of bedwetting (Leicestershire and Rutland Healthcare NHS Trust 1995). The protocol applies to three service levels: primary care, community paediatrics and tertiary hospital-based services. There are standard assessment and treatment procedures to carry out and recommendations for referral to the next level if failure to progress in treatment occurs. In this study treatment was delivered by a school nurse using the standard treatment protocol which involved a 4-week period of assessment using star charts followed by the buzzer alarm treatment.

The method used was a stratified, cluster, randomized controlled trial. The variables used for stratification were the Jarman indices and ethnicity rates (OPCS 1991), allocated according to the electoral ward in which the clinic was located. The cluster level was school nurse-led enuresis clinics.

Thirty-three enuresis clinics were stratified and matched into groups. Five sets of clinics were selected and within each set clinics were randomly allocated to one of the three conditions, multimedia, leaflets or control. To identify if any systematic differences existed between the areas covered by the intervention(s) and control clinics a prospective analysis was conducted. As no account was taken for the clinic's population crossing electoral boundaries, a retrospective analysis of individual children's postcodes was conducted to identify whether there were any significant socio-economic differences between the groups.

Longitudinal data was collected as children progressed through treatment.

## Sample size

The outcome measure selected for the sample size calculation was the most clinically useful number of weeks it takes to become dry, however, there are wide variations in the means in the literature. The minimum standards outlined by the bedwetting charity ERIC suggest that a child should take no longer than 16 weeks to get dry (Hunt 1997). This is complicated by children who do not become dry within the duration of the published studies as it is impossible to judge whether such children would get dry over a longer period of time. In the report by Butler et al. (1988) the mean time to be dry using an alarm was used (10.2 weeks), but as no standard deviation was reported expert clinical opinion was sought and an estimate of 3 weeks was used for the calculation (Day & Graham 1989). A sample size of 100 children per group was calculated as sufficient to show an intervention effect.

The sample size calculation was therefore based upon a paper reporting time to dry on individual children and the standard deviation had to be estimated by an experienced clinician at the individual level. To calculate the sample size required, taking into account the effects of clustering would have, a further estimate of the difference in the variance between groups of children treated at different clinics and in the variance within groups of children treated at the same clinics. It was not possible to identify any empirical sources for such data nor an individual willing to make such estimates. In light of this and the strenuous efforts to stratify the clusters in each group, it was decided to use the sample size calculated at the individual level and account for the cluster effect in the analysis. The variance inflation factor was calculated from the intraclass coefficient once the study data was available. The variance inflation factor can be used to correct confidence intervals and *P*-values to account for any correlation of observations within clusters.

#### Intervention(s)

#### Multimedia software

This consisted of an interactive, multimedia CD-ROM entitled 'All About Nocturnal Enuresis' which provides information to bedwetting children (and their parents) ( Collier *et al.* 1997). The program uses multimedia to create action sequences of an animated key character, which accompany the text. The use of multimedia allows the information to be stored under tiered headings enabling the user to access the information most relevant to them. The information modules for the main screen or first level of selection are:

- · Welcome to the clinic
- · How your bladder works
- · Why some children wet the bed
- · Boss of your bladder
- Treatments
- · Information for grown-ups
- Knowledge tree

The modules can be worked through any order taking approximately 10 min each; however, the recommended route follows the order as listed. A 'passport' is provided at clinic for children to indicate the modules they have worked through and record any comments for later discussion.

#### Written leaflets

The written materials consist of a set of six leaflets. The contents of the leaflets are the same as the multimedia program without the interactive elements.

## Control group

The control group were not given any specific additional information although the school nurses, parents and children were aware that they were participating in a trial.

## Study population

The target population was all children referred to the 15 enuresis clinics over 18 months. All children newly referred to the service were invited to participate as well as re-referrals. However, children treated less than 6 months previously for the same condition were excluded.

# Data collection

The school nurses obtained child and parental consent and recruited participants to the study. At the initial assessment (time 1), social, demographic and clinical details were recorded and participants completed a number of psychosocial measures. A second set of psychosocial measures was completed to correspond with the minimum recommended treatment time of 16 weeks (Hunt 1997) (time 2). Clinical and healthcare utilization measures were collected as they arose throughout treatment and at discharge (time 3). Six months after discharge a third set of psychosocial measures were sent to participants at home along with questionnaires asking about the child's treatment outcome (time 4).

#### Outcome measures

The clinical outcome measures were whether or not a child became dry and remained dry 6 months after discharge, together with the length of time it took for children to achieve 14 consecutive dry nights [this is considered an adequate length of time without a wet night to assume the child is 'dry' (Butler *et al.* 1988)]. These were recorded at discharge from the clinic.

The healthcare utilization measures were the number of failed attendances and 'dropout rates' (failure to attend two consecutive appointments with no explanation). These were recorded as they arose during the treatment programme.

The psychosocial measures were as follows:

- 1 Parents completed the maternal tolerance questionnaire (Morgan & Young 1975) which had been factor-analysed and revised to include 16items (Butler *et al.* 1993). An example item would be 'the bedwetting is a nuisance to the rest of us'. A score is derived from the number of cumulative negative statements with higher scores indicating lower tolerance.
- 2 Children completed the 17-item impact of bedwetting scale (Butler *et al.* 1994). This scale measures psychological and non-psychological components. A psychological item would be 'Mum/Dad get upset with me'. A non-psychological item would be 'my bedroom smells'. A score is derived by summing the checked items with 0 indicating no impact, 1 for sometimes and 2 for yes.
- **3** Children also completed the 25-item shortened version of the Coopersmith (1967) self-esteem scale. This scale measures attitudes towards the self. An example would be 'It's pretty tough to be me'. The scale is scored as 0 for agree, 1 for disagree with higher scores equal to a higher self-esteem.

## Results

## Participant characteristics

Two hundred and seventy out of two hundred and eighty-seven participated in the study (94% recruitment rate). One hundred and eight were recruited to the multimedia, 87 to the leaflets and 75 to the control group (Fig. 1).

The number of boys in the sample (n = 176, 63.3%) was greater than the number of girls (n = 93, 37.7%). Participants had a mean age of 7.98 years (range 5.0–16.0 years, SD ± 2.23 years). A one-way ANOVA showed no statistically significant differences in age between the groups (P = 0.56).

There were 214 (79.3%) children with primary and 56 (20.7%) children with secondary onset nocturnal enuresis. There were 207 (76.5%) children

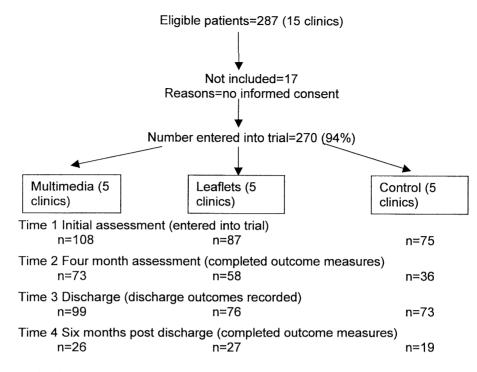


Figure 1. Profile of trial

newly referred to the clinic and 63 (23.3%) rereferrals. The mean age of the new referrals was 7.38 years and re-referrals 9.96 years. A *t*-test showed a statistically significant difference between age and newly/re-referred to the service (t = 9.238, d.f.238, P < 0.001).

#### Socio-economic and psychosocial background

Before recruitment, a one-way ANOVA found no statistically significant differences between the Jarman indices (P = 0.99) or ethnicity rates (P = 0.46)of the clinics allocated to the experimental groups. However, a retrospective analysis of the individual children's postcode revealed significant differences in Jarman indices (one-way ANOVA F = 11.08, d.f. 2,252, P < 0.001). The multimedia group was sampled from a more advantaged population and the leaflets from a more deprived population (mean Jarman scores multimedia 0.76, leaflets 15.28, control 8.28). There were statistically significant differences in ethnicity rates ( $\chi^2 = 6.54$ , d.f. 2, P = 0.03) with the number of minority ethnic children lower in the multimedia group n = 3 (3%) compared with the leaflets n = 26 (29.8%) and control groups n = 10 (13.6%). There were also statistically significant differences in maternal tolerance rates ( $\chi^2 = 10.48$ , d.f. 2, P < 0.01), and impact of bedwetting scores (one-way ANOVA F = 3.07, d.f. 2,247, P < 0.05).

## Impact of intervention(s)

## Clinical treatment outcomes

The proportion of children discharged dry was similar across the groups with 36 (48%) children in the control group, 41 (47.1%) children in the leaflets group and 51 (47.22%) children in the multimedia group discharged dry. A chi-square test found no statistically significant differences between the groups (P = 0.84).

The leaflets group had the highest proportion of children who were dry 6 months after treatment ended. Twenty-six (30%) children in the leaflets group, 18 (24%) children in the control group, and 21 (19.4%) children in the multimedia group reported being dry. A chi-square test found no statistically significant differences between the groups (P = 0.69).

Accurate time to dry was not available for all children, but a one-way ANOVA showed no statistically significant differences between the groups (P = 0.23). Table 1 shows the outcomes reported for each of the groups.

The intraclass correlation coefficient was calculated for those children who had a time to dry recorded. The mean square within subjects was larger (400) than the mean square between subjects (175). Using the calculation recommended in a HTA report (Ukoumunne et al. 1999) the average cluster size was 6.84. The intraclass coefficient (ICC) was less than zero (-0.09) indicating that the within-cluster variance was larger than the variance for the sample overall. This ICC resulted in a variance inflation factor (VIF) of less than 1 (0.53) indicating that if the effect of clustering was taken into account in the analysis then it would result in a widening of the confidence intervals from the analysis at individual level. The number of children reported as dry per clinic was less than seven, and examination of the data indicated that the larger within-cluster variance was as a result of the small sample sizes in the clusters rather than being the result of a greater clinical variation within clinic then between clinic. Therefore, as there was no evidence of observations within the clinics being correlated they could be considered as statistically independent. Thus the analysis remained at the (in this case) more conservative individual level, rather than the cluster level.

#### Healthcare utilization

The remaining outcomes are outlined in Table 2. A chi-square test showed no statistically significant difference in respect of the number of children discharged because they 'failed to attend' (P = 0.10).

A total of 46 (61.3%) (median 1, range 0–11) children in the control group, 51 (58.6%) (median 1, range 0–6) children in the leaflets group and 57 (52.7%), 29 (46.77%) (median 1, range 0–7) children in the multimedia group failed to attend at least one appointment. A Kruskal–Wallis test found this difference was not statistically significant (P=0.77).

## Psychosocial measures

The scores on the psychosocial measures at initial assessment, 4 month assessment and 6 months post discharge are outlined in Table 3.

Repeated measures ANOVA's found no statistically significant improvements in maternal tolerance (P = 0.07) and the impact of bedwetting (P = 0.24) between initial assessment, 4 months assessment and 6 months post discharge across the experimental groups. There was, however, a significant difference in self-esteem (F = 5.05, d.f.2, P = 0.01). A *post hoc* LSD test revealed significant improvements in the self-esteem of children in the control group over the three data collection points (mean time 1, 15.51, time 2, 16.05, time 4, 17.67).

Group	No. of children					
	for whom accurate data available	Mean	Standard deviation	95% Confidence interval		
Multimedia	51	30.62	25.19	23.54-37.71		
Leaflets	41	26.56	19.80	20.31-32.81		
Control	34	22.52	16.10	16.91-28.14		
Total	126	27.11	21.41	23.34-30.89		

**Table 1.** Time to dry (in weeks)reported for each of the groups

	Referred elsewhere	DNA discharge	Withdrew from treatment	Still being treated
Multimedia	5 (4.6%)	26 (24.1%)'	12 (11.1%)	5 (4.6%)
Leaflets	5 (5.7%)	12 (13.8%)	14 (16.1%)	4 (4.6%)
Control	5 (6.6%)	20 (26.7%)	9 (12%)	5 (6.6%)

**Table 2.** Treatment outcomes for children in the study who did not become dry

**Table 3.** Scores on the psychosocial measures between the groups

Measure	Group	Initial assessment	Four month assessment	Six months post discharge
Maternal tolerance scale (median)	Multimedia	1.00 ( <i>n</i> = 99)	1.00 ( <i>n</i> = 70)	0.00 ( <i>n</i> = 13)
	Leaflets	1.17 ( <i>n</i> = 82)	1.00 ( <i>n</i> = 58)	1.75 ( <i>n</i> = 15)
	Control	2.00 ( <i>n</i> = 62)	2.00 ( <i>n</i> = 35)	2.00 ( <i>n</i> = 15)
	Total	1.00 ( <i>n</i> = 243)	1.00 ( <i>n</i> = 163)	2.00 ( <i>n</i> = 43)
		Range = 0–7	Range = 0–7	Range = 0–7
Impact of bedwetting scale (mean)	Multimedia	17.12 ( <i>n</i> = 102)	14.94 ( <i>n</i> = 73)	16.67 ( <i>n</i> = 12)
	Leaflets	19.23 ( <i>n</i> = 84)	15.52 ( <i>n</i> = 57)	17.29 ( <i>n</i> = 13)
	Control	18.35 ( <i>n</i> = 64)	15.82 ( <i>n</i> = 36)	20.14 ( <i>n</i> = 13)
	Total	18.14 ( <i>n</i> = 250)	15.33 ( <i>n</i> = 166)	18.07 ( <i>n</i> = 38)
		Range = 4–34	Range = 0–30	Range 8–25
		SD + 5.87	SD ± 7.08	SD + 4.33
Coopersmith self-esteem scale (mean)	Multimedia	16.01 ( <i>n</i> = 98)	16.93 ( <i>n</i> = 71)	19.66 ( <i>n</i> = 26)
	Leaflets	16.11 ( <i>n</i> = 81)	16.53 ( <i>n</i> = 57)	18.53 ( <i>n</i> = 27)
	Control	15.51 ( <i>n</i> = 61)	16.05 ( <i>n</i> = 35)	17.67 ( <i>n</i> = 19)
	Total	15.92 ( <i>n</i> = 240)	16.60 ( <i>n</i> = 163)	18.71 ( <i>n</i> = 72)
		Range = 3–25	Range = 3–24	Range = 8–25
		SD + 4.65	SD ± 4.92	SD ± 4.30

The mean scores at initial assessment of children in the control group who responded at all three collection points were lower than the intervention groups and lower than the overall group mean of 15.51.

# Discussion

There were no significant differences between the experimental groups in respect of any the outcome measures tested in this study. A number of explanations may be pertinent; first the pathway from knowledge acquisition to behavioural intent and then to behavioural change is likely to be as complex for children as it is for adults and multimedia programs may not have sufficient power to impact on outcomes. However, improvements in selfefficacy following participation in an educational programme using multimedia software have been previously reported. Our findings may be unique to the group of children studied who may find it difficult to change their health-related behaviour. The intractable nature of bedwetting means that many of the children were not attending clinic for the first time and may already be familiar with much of the information contained in the multimedia program and the leaflets. Mayer (1997) reports that the learning potential of multimedia is stronger for those with low prior knowledge of the

material. Children with existing knowledge about their condition may simply be bored by overexposure to health-related information. Multimedia may not have the potential to hold the attention of children with chronic bedwetting whose parents may have already tried a number of different treatment options. Children's anxiety about the bedwetting and fear of exposure may prevent them participating fully in their treatment and no matter how engaging the information is they may be unable to assimilate it.

There are methodological limitations to this study, which require further consideration. A large number of children did not complete the psychosocial measures on every occasion and the response rate for the follow-up postal questionnaire was only 44%. The study protocol initially asked for the second questionnaire to be completed at discharge, but the school nurses maintained this method would lead to a lower response rate because large numbers of children would be discharged by telephone or simply fail to attend their final appointment. Although the revised protocol took account of this the response rates were still lower than expected. However, this may be a reflection of attitudes towards treatment as well as the study itself.

There may have been a problem with the psychosocial measures used in this study. The maternal tolerance and the impact of bedwetting scale were not designed for use as repeated measures. Some respondents who were 'dry' at discharge and 6 months later produced scores more pertinent to bedwetting children. There may be an ethical issue in administering questionnaires concerned with 'bedwetting' to the proportion of children who are dry on re-administration.

Randomizing the intervention by cluster was the appropriate option for the design of this study. However, the variation in time to dry was a clinical estimate and it was not possible to reliably calculate the increased sample size required when randomizing at cluster level (Donner 1992). On completion of the study and data analysis it was possible to examine the variance for the main outcome, time to dry, within and between the clusters. Two statistical findings arose. First, the actual mean time to dry in this study was much longer than predicted, with a large variation which suggests a much larger sample size would be needed to obtain significance. Second, there was no correlation of observations within the clusters, resulting in a variance inflation factor of 0.53. This suggests that there was no need to either increase the sample size due to clustering, nor to carry out analysis at the cluster rather than the individual level. Furthermore, this suggests that factors other than the provision of care at clinic level were influential in the length of time it took for a child to become dry.

Unfortunately, neither information medium was found independently to produce significant behavioural improvements and the combined effects of both written and multimedia information was not assessed. Because there is such a large variation in success rates and the length of time it takes a child to get dry, it might have been more appropriate to link the outcome measures more closely to the intervention, for example progress goals during treatment. Nevertheless whilst this intensive training input and measurement is likely to motivate some children this will not be the case for all.

# Conclusion

Multimedia educational programs are an acceptable way for children to learn more about their health-related conditions. However, our result suggests that multimedia is no more effective than traditional materials at affecting health-related behavioural change.

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