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ORIGINAL PAPER

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The effect of hydrotherapy on the incidence of common cold episodes in children: a randomised clinical trial

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Abstract Few interventions have proved to be effective in the prevention and treatment of common colds. Anecdotal reports suggest the possible beneficial effect of hydrotherapy (stimulation of the body surface with warm and cold water). This study's objective was to evaluate the clinical effect of hydrotherapy on common colds in children. Children aged 3–7 years with six or more common cold episodes during the preceding 12 months were randomised to receive either daily inhalation of normal saline in the control group or daily inhalation plus daily hydrotherapy in the experimental group for 12 months. The main outcome measurements were incidence, duration and severity of common cold episodes as reported by the children's parents in a daily symptom diary. Groups did not differ at baseline with regard to age, gender, or number of cold episodes in the year before the study. Diaries were available from 81 patients in the control group and 65 patients in the experimental group. In the study period, there were no significant differences in the incidence of colds (control vs. experimental group, mean ± SD, 4.8 ± 3.5 vs. 4.1 ± 3.3 episodes) or the average duration of episodes (7.7 ± 3.5 vs. 7.6 ± 3.8 days). *Conclusion*: This study does not demonstrate any beneficial effect of hydrotherapy on preschool children with frequent common colds.

Keywords Hydrotherapy · Common cold · Child · Alternative medicine · Prevention and control · Randomised controlled trials

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Introduction

The average incidence of the common cold in preschool children has been estimated at five to seven episodes per year [26]. Preschool children who are intensely exposed to respiratory infections and whose immune system is not fully developed belong to the major risk groups. Frequent cold episodes are a burden on children and their families, particularly those at risk of infection-triggered asthma exacerbation. Although generally not severe, colds contribute to a great extent to absenteeism from education [26]. A variety of modalities is available for prophylaxis (e.g. vitamin C, hydrotherapy, nasal washing) and treatment (e.g. steam inhalation, topical sodium cromoglycate), and there is a widespread use of over-the-counter medication [1, 12, 21]. However, few if any have been proven to be effective [22, 23].

The lack of environmental thermal stimuli in our modern society may increase susceptibility to common colds. Hydrotherapy, defined as systematic stimulation of the body surface with warm and cold water, is thought to compensate the deficiency of natural stimuli and to increase the tolerance of an individual against a variety of stressors including infections. Hydrotherapy is enjoyable, its technique is easy to learn, and it can be easily integrated into clinical practice. While there is a large lay movement practising hydrotherapy (''Kneipp's therapy''), its clinical utility is unclear. Earlier reports

suggested a possible ''toughening up'' and prevention of common colds [7, 8], but suffered from methodological limitations including uncontrolled designs, small sample sizes and poorly defined outcome measures. Randomised trials are lacking.

Topical airway treatment with normal saline improves common cold symptoms mildly compared with observation only [4, 21]. Since antiquity it has been observed that navigators suffered less from bronchitis than inland inhabitants. While hypertonic saline inhalation improves mucociliary clearance and may thus prevent common cold symptoms [6], topical airway treatment with isotonic saline does not seem to have any effect on common cold symptoms [4, 21].

This study was designed to evaluate hydrotherapy in addition to inhalation of normal saline in comparison with inhalation therapy alone for its effect on the incidence and the duration of common cold episodes in children. Both regimens were compared in a 1-year clinical trial with randomised assignment of patients. In addition, the effect on occurrence and severity of symptoms was determined.

Materials and methods

Protocol

Preschool children (aged 3–7 years) with six or more parent-reported common cold episodes during the preceding 12 months were invited to take part in the study via the local news media. A common cold episode was defined as the presence of two or more of the following symptoms for three or more consecutive days: runny nose or nasal congestion, sore throat, earache, cough and fever (>38°C). Patients were ineligible if they had cellular or humoral immunodeficiency, allergic airway disease, known structural abnormalities of the airways, other severe organ dysfunctions, psychiatric deviations, cold intolerance or if they were already practising sauna bathing or hydrotherapy.

Eligible patients were recruited over 12 months and randomly allocated to receive either daily inhalation of normal saline (control group) or daily hydrotherapy in addition to saline inhalation (hydrotherapy group) over a treatment period of 12 months.

Hydrotherapy was performed once a day on the basis of an individualised programme designed by qualified hydrotherapists. The programme consisted of alternate washing with warm (39°C over 10 min) and cold water (15°C over 10 to 30 s) every day. The intensity of the cold stimulus (involved body surface regions, duration) was adapted to the individual susceptibility and targeted to achieve a pleasant sensation of warmth shortly after cold exposure. With habituation over the study period, the cold stimulus was increased. Parents were instructed to withhold hydrotherapy during respiratory infections. Inhalation of normal saline (2 ml) was performed by a Pariboy nebuliser with face mask (Pari GmbH, Starnberg, Germany). At the beginning of the treatment period, patients and their parents were instructed in the study centre. Thereafter, therapy was performed at home. Parents recorded in a daily diary whether the treatment was performed.

At baseline, parents were questioned about their child's history and a physical examination was carried out. Baseline evaluations included an analysis of serum immunoglobulins (IgA, IgG and subclasses, IgM) and intradermal testing with multiple recall antigens (Multitest Mérieux, Leimen, Germany) to screen for humoral or cell-mediated immune deficiency. Total serum IgE and IgE to common air-borne allergens (CAP-Phadiatop, Pharmacia, Uppsala, Sweden) were analysed to support the diagnosis of allergic airway disease. The German version of the Child Behavior Checklist was employed to screen for child psychopathology [2, 3].

Written informed consent for this investigation was received from the parents or guardians of all participants. The study was approved by the Institutional Ethics Committee of the Free University, Berlin.

Randomisation

The allocation schedule was provided by the outcome assessors. The randomisation was performed blockwise with a block size of 10. The data analysts were blinded to the treatment in both groups. The code was not broken until after the main analysis of the data.

Laboratory studies

Serum and urine samples were obtained at baseline and stored at −20°C until analysis. Screening for the presence of specific serum IgE levels to nine common inhalant and food allergens was performed by Phadiatop test (Pharmacia, Freiburg, Germany) using 0.35 kU/l as a cut-off level [11]. As an indicator for environmental tobacco smoke burden, the urine concentration of cotinine and the cotinine-creatinine ratio was determined [15]. IgG, IgM, and IgA serum levels were determined by automated immunoturbidimetry.

Evaluation

The occurrence and therapy of cold symptoms of all study subjects were prospectively recorded by their parents in a daily diary. A list of symptoms based on the form used in the Tecumseh respiratory study was provided [18]. Boxes were to be ticked for each symptom. In addition, parents recorded the severity of each symptom on a three-point scale (mild, moderate, severe). Definitions of these degrees were provided with the diary. If there were no symptoms, no entries were expected. Absenteeism from kindergarten or school and use of medication were also recorded. Every 3rd week, parents were contacted via telephone and asked about the therapy performance at home and about any symptoms their child may have experienced. Every 3rd month, visits in the study centre were scheduled and diaries were collected.

An common cold episode was defined as described above provided that at least one of the symptoms was rated medium or severe. Tri-weekly telephone interviews were carried out to clarify whether fever was likely to be related to the common cold.

The primary outcome measurement was the cumulative incidence of common cold episodes during the treatment period. The secondary outcome measurements included the duration of cold episodes and the severity of the five specified symptoms. The study was designed to discover a reduction in incidence from nine cold episodes per year to six at a level of 1% (two-sided) and with a power of 80%. To that end we needed approximately 20 patient years per group. A 50% increase in observation time was planned in order to account for possible overdispersion in the observations. Therefore, the study was based on a requirement of at least 360 patient months per group or a combined total of 60 patient years.

The primary endpoint was evaluated using a generalised linear model with a binomial error and a log-link function. An adjustment was made for overdispersion [14]. The evaluation of the mean duration of a cold episode was based on linear mixed effect models to account for clustered observations [5]. For exploratory purposes, monthly incidence rates and mean cold episode duration were plotted together with their 95% confidence intervals. In addition, the product of intensity (0–3 points) and days with occurrence of the particular symptom was calculated. Group results were expressed as means with standard deviations in text and tables. Data sets were analysed using the statistical program Splus (Version 3.3, MathSoft Inc., Seattle, WA, 1995).

Results

Study population

One hundred and seventy-five children who were eligible based on the inclusion and exclusion criteria were randomised. Of these, 88 children were enrolled in the control group and 87 children in the hydrotherapy group over a period of 12 months. Eighty-four children in the control group and 76 children in the hydrotherapy group completed the 12 treatment months (Fig. 1).

Demographic and clinical baseline data are summarised in Table 1. There were no large differences between the two treatment groups in age, gender, incidence of cold episodes and absenteeism from day care or school in the preceding year, serum IgA, history of wheezing or atopic disease of close family members, positive screening test for IgE to respiratory allergens, indicators of high exposure to common colds such as household composition and day care attendance, environmental tobacco smoke, household net income and use of conventional and unconventional therapy for treatment of colds. The control group contained fewer girls and more boys compared with the hydrotherapy group. There were no cases of humoral or cell-mediated immune deficiency.

Completeness of data

There was a difference between the groups in the proportion of participants who had filled in their diaries. Diaries were available from 81 out of 88 patients (92%) in the control group and 65 out of 87 patients (74%) in the hydrotherapy group. A combined total of 42,168 treatment days (115.5 treatment years) were documented correctly, 293 days per patient in the control group and 284 days in the hydrotherapy group. More than 50% of the 366 treatment days were documented by 70 out of 81 controls (86%) and by 53 out of 65 hydrotherapy patients (82%). Documentation rates declined over the treatment course in both groups, but they were fairly stable per seasonal month (data not shown).

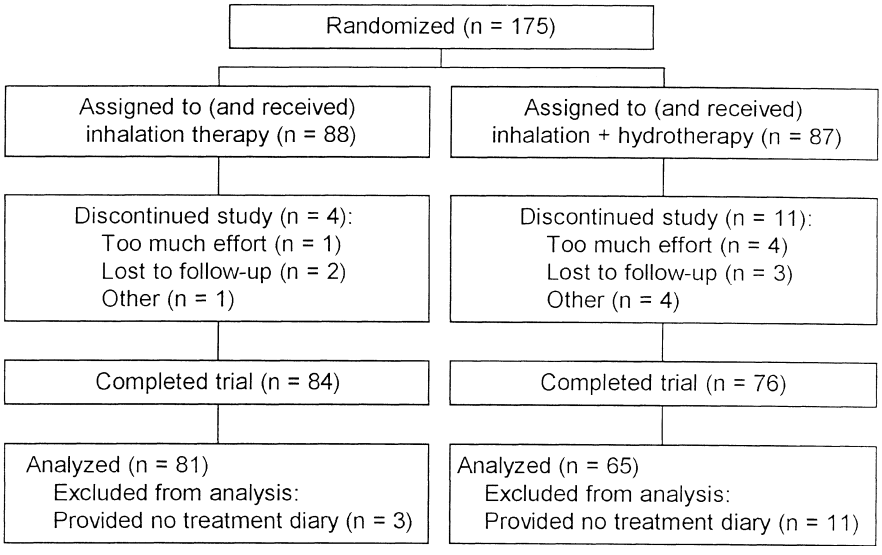

Fig. 1 Trial profile and participant flow

Table 1 Baseline characteristicsof the patients with frequent common colds, treated with normal saline inhalationplus hydrotherapy or inhalation only (control group)

Descriptive parameter	Control ($n=88$)	Hydrotherapy ($n=87$)
Age (months)[a]	56.8 ± 17.3	56.5 ± 15.6
Gender, female	32 (36.4)	42 (48.3)
Coldepisodes in the preceding 12 months	8.8 ± 2.3	9.3 ± 3.0
Absenteeismin the preceding 12 months (days)	19.3 ± 15.4	17.1 ± 16.3
Serum IgA g/l	1.0 ± 0.5	1.0 ± 0.5
Atopic family history	55 (62.5)	61 (70.1)
Phadiatop > 0.35 kU/l	12 (13.2)	13 (16.7)
Children per household	1.6 ± 0.7	1.7 ± 0.7
Inhabitants/100 m^2	4.0 ± 0.9	4.1 ± 1.3
Enrolment in day-care or school	56 (93.3)	50 (92.6)
Cotinine/creatinine > 30 ng/mg	21 (26.3)	17 (21.5)
Household net income per month, < EUR 1,500	12 (17.6)	9 (14.8)
Use of conventional therapy for colds before randomisation	73 (84.9)	73 (86.9)
Use of unconventional therapy for colds before randomisation	64 (76.2)	69 (81.2)

[a]Values are numbers (percent) and mean ± SD unless stated otherwise

Compliance with therapy

The proportion of days with inhalation therapy was slightly higher among individuals from the control group compared with the hydrotherapy group (82% vs. 75%).

Incidence of common cold episodes

In the control group, 385 cold episodes were observed over 69 patient years, while there were 268 cold episodes during 54 patient years in the hydrotherapy group. This corresponds to an annual cold incidence of 5.5 in the control group and of 4.9 in the hydrotherapy group. The number of common cold episodes per patient was not much higher in the control (4.8 ± 3.5 episodes) compared with the hydrotherapy cohort (4.1 ± 3.3 episodes; $P = 0.306$). The incidence declined over the first 4 treatment months in both treatment groups (Fig. 2A) There was no evidence of a systematic trend in favour of either treatment group. Both groups showed a seasonal pattern with lower incidence rates during the summer months at the same level (Fig. 2B).

Duration of common cold episodes

This analysis is conditional on the observed cold episodes. The assessment of differences in duration between the groups based on the linear mixed effects model was not significant ($P = 0.423$); the observed mean duration of common cold episodes was 7.7 ± 3.5 days in the control

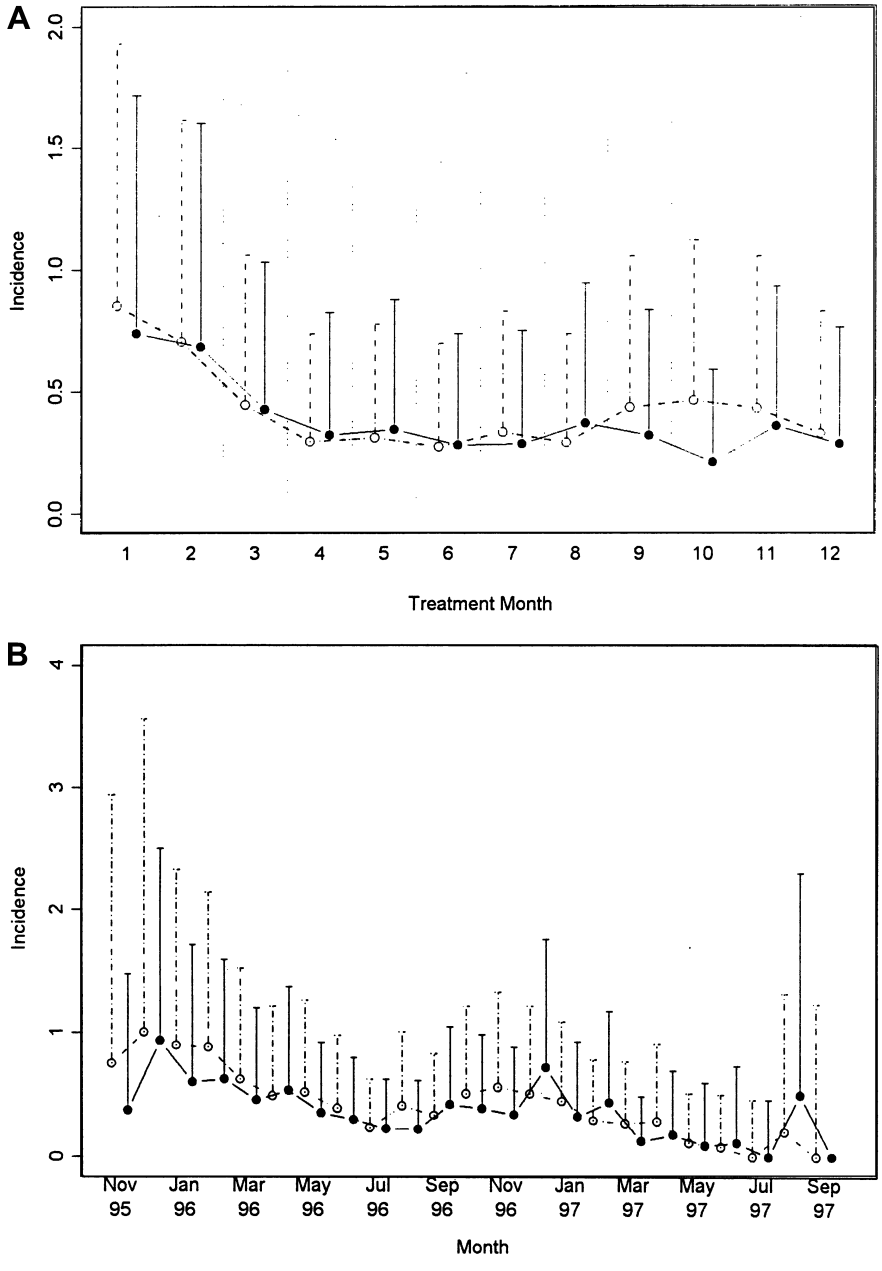

Fig. 2 Monthly incidence of common cold episodes (95% confidence interval) per patient during **A** the treatment period and **B** season. *Dashed line* and *open circles*–inhalation; *solid line* and *full circles*–hydrotherapy and inhalation

group and 7.6 ± 3.8 days in the hydrotherapy group. From an exploratory point of view, the curves for both groups fluctuated over the treatment period around a common level. Again, no systematic trend was evident in favour of one of the two treatment groups (Fig. 3A). Neither group showed a seasonal pattern of shorter episodes during summer (Fig. 3B).

The cumulative number of days within common cold episodes was lower in the first treatment month, but no systematic trend in favour of either treatment group was evident (Fig. 4).

Cold symptoms

Cough symptoms were documented in a smaller proportion of cold episodes in the hydrotherapy group (88.4% vs. 94.3%, $P = 0.007$). No statistically significant differences were found with regard to fever, rhinitis, sore throat, or earache. (Table 2) The intensity of symptoms on days with cold episodes is summarised in Table 3. Coughing and rhinitis, the symptoms with a high prevalence rate, were mainly recorded as "mild". However, parents of children in the hydrotherapy group assessed a higher proportion of cough or rhinitis episode days as being "moderate" or "severe".

Borderline significance was reached for the proportion of days with consultation of a physician (2.2 ± 2.5% vs. 1.4 ± 1.8%; $P = 0.041$), of days with acute medication (16.2 ± 19.4% vs. 10.3 ± 14.2%; $P = 0.054$) and of days absent from school or day care (4.3 ± 5.8% vs. 2.4 ± 3.4%; $P = 0.059$).

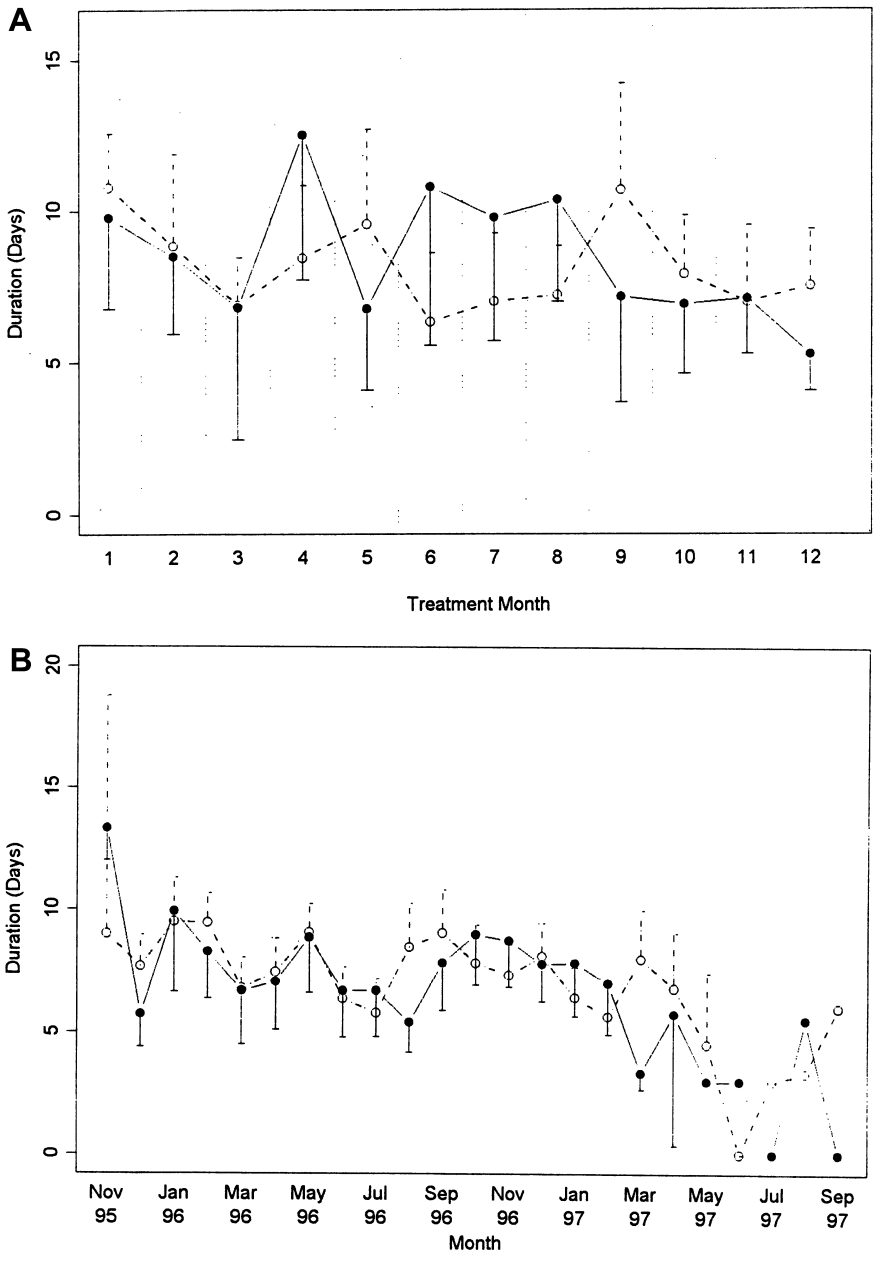

Fig. 3 Duration of common cold episodes (95% confidence interval) during **A** the treatment period and **B** season. *Dashed line* and *open circles*–inhalation; *solid line* and *full circles*–hydrotherapy and inhalation

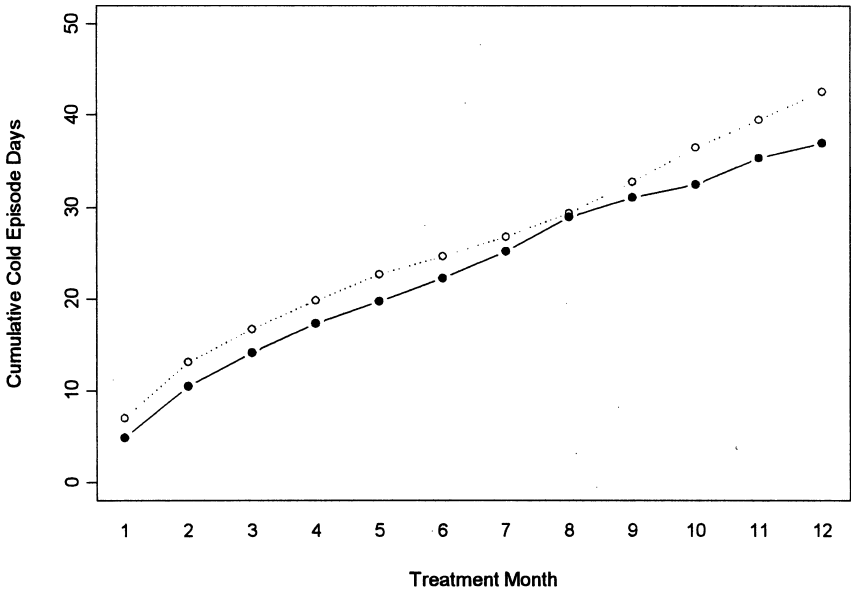

Fig. 4 Cumulative number of common cold episode days per treatment month. *Dashed line* and *open circles*–inhalation; *solid line* and *full circles*–hydrotherapy and inhalation

Table 2 Occurrence of symptoms in common cold episodes

Symptoms	Control ($n=385$)		Hydrotherapy ($n=268$)		P*
	Episodes	%	Episodes	%	
Fever > 38°C	100	26.0	69	25.7	0.948
Rhinitis	366	95.1	249	92.9	0.247
Cough	363	94.3	237	88.4	0.007
Sore throat	148	38.4	111	41.4	0.444
Ear ache	76	19.7	49	18.3	0.641

*Calculated by chi-squared test

Responder analysis

Clinical efficacy was also assessed by means of a responder analysis. For this analysis therapy response was defined as the difference in the incidence of common cold episodes during the first 2 and the last 2 treatment months. Provided that at least 40 days of both periods were documented by diary, patients in the upper tertile ($n=35$) were defined as responders and those in the lower tertile ($n=34$) as non-responders. The distribution of therapy responders and non-responders in both treatment groups did not show a statistically significant difference in favour of the hydrotherapy group (control group, 23 responders, 13 indifferent, 19 non-responders; hydrotherapy group, 12 responders, 19 indifferent, 15 non-responders). Responders and non-responders did not differ with regard to the demographic data listed in Table 1, use of additional medication or the proportion of documented treatment days when therapy was actually performed (data not shown).

Safety

Three parents reported that their child felt cold for a prolonged period after hydrotherapy. In these cases, the dose of hydrotherapy was reduced. No subsequent cold intolerance was reported.

Discussion

This study failed to support the hypothesis that hydrotherapy prevents common colds in childhood. Specifically, no significant differences in the incidence and the duration of common cold episodes were seen between the control and hydrotherapy groups. A confirmative analysis based on individual patients also failed to demonstrate the superiority of hydrotherapy.

Both groups improved during the study period suggesting that the observed decline in cold episodes was either attributable to the natural course of the disease, to a placebo effect, or to inhalation therapy. Common colds are particularly frequent in preschool children but their incidence decreases continuously with age [17]. In this study the incidence rate halved during the first 4 months in both groups, thus exceeding the expected age-related reduction.

Both hydrotherapy and inhalation feature characteristics that could function as placebo amplifiers (e.g. technical equipment, salty aerosol, cold as a potentially unpleasant stimulus). The technical equipment used for the delivery of inhalation seemed to impress parents at the start of the study and at the end of the treatment period. Many of them were willing to buy such a device. Unlike some aerosols for asthma therapy, which provide no sensation of the substance delivered, the aerosol in

Table 3 Severity of symptoms on days with common cold episodes

Symptoms and severity	Control ($n = 3{,}012$)		Hydrotherapy ($n = 2{,}073$)		P*
	Days	%	Days	%	
Fever					0.009
No	2,534	84.1	1,718	82.9	
≤ 38°C	179	5.9	99	4.8	
38.1–39°C	162	5.4	153	7.4	
> 39°C	137	4.5	103	5.0	
Rhinitis					< 0.001
No	133	4.4	124	6.0	
Mild	1,841	61.1	1,064	51.3	
Moderate	843	28.0	704	34.0	
Severe	195	6.5	181	8.7	
Cough					< 0.001
No	202	6.7	217	10.5	
Mild	1,833	60.9	1,018	49.1	
Moderate	765	25.4	659	31.8	
Severe	212	7.0	179	8.6	
Sore throat					< 0.001
No	2,388	79.3	1,654	79.8	
Mild	339	11.3	280	13.5	
Moderate	189	6.3	100	4.8	
Severe	96	3.2	39	1.9	
Earache					0.165
No	2,771	92.0	1,902	91.8	
Mild	130	4.3	111	5.4	
Moderate	69	2.3	37	1.8	
Severe	42	1.4	23	1.1	

*The *P*-value refers to thedifference in the proportions between the control and hydrotherapy groups and wascalculated by chi-squared test

this study tasted salty. Some parents initially anticipated cold washings as a potentially unpleasant stimulus. Families may thus have believed in a powerful therapy, which may have contributed to the improvement observed. However, analysis of compliance rates among responders and non-responders indicated no dose–response relationship between inhalation or hydrotherapy and cold reduction. Since both treatment groups received the daily inhalations in a fixed dose, it is impossible to determine to what extent the observed improvements may have been caused by the inhalation therapy. Inhalation therapy may be not an inert control treatment. The expected effect, however, was small as indicated by previous trials in which topical airway treatment with isotonic saline showed little impact on common cold symptoms compared with observation only [4, 6, 20, 21].

The proportion of cold episodes with coughing was slightly lower, but statistically significant, in the hydrotherapy group (Table 2). Regarding the severity of coughing, however, a higher proportion of symptom days was rated as moderate or severe in the hydrotherapy group than in the control group (Table 3). While a biologically plausible explanation is lacking, the significance of these results should be investigated in further trials.

There was a tendency towards less use of other therapeutic resources such as physician consultations or acute medication in the hydrotherapy group. In addition, absenteeism from day care was lower. This could lead to the assumption that more active participation in the hydrotherapy group resulted in a stronger parental internal health locus of control. However, a validated test for the health locus of control revealed no significant differences between the start and the end of the treatment period. The downside of the higher therapy burden in families may have been a lower compliance rate regarding inhalation plus hydrotherapy and more withdrawals.

The lack of evidence of the efficiency of hydrotherapy in this study may be related to individual subtherapeutic chronic cold stimulation. The individualised dose of hydrotherapy was not quantitatively monitored. However, the dose introduced during the initial training period was selected by qualified hydrotherapists.

An inverse relationship between the size of the effect of a tested therapy and the methodological rigor of trials has been demonstrated before [13, 25]. Prior studies testing hydrotherapy or sauna bathing in controlled trials reported a reduction of cold episodes and less absence from school and work [7, 8, 16, 19]. In a small study evaluating adults, patients treated with hydrotherapy or sauna bathing had significantly fewer cold episodes than patients in the untreated control group. Interestingly, no significant difference was found between the two treatment groups [9]. This parallels to some extent our results comparing two treated groups. Two studies described a latency of 2–3 months of

treatment (hydrotherapy or sauna bathing) before a reduction of common cold episodes or days with a cold was seen [7, 8, 9]. In contrast, our study results show a decline in cold incidence and duration over the first 3 months of treatment with inhalation or hydrotherapy, which then stabilised. It is unclear whether seasonal effects co-influence the latency previously described [8, 9]. Taken together, the scientific evidence based on previous trials is weak because of methodological flaws and their positive findings should be viewed with caution. Our study evaluating hydrotherapy among children includes a sufficient sample size in a study with an accepted experimental design and its results are negative.

Taking into account the duration of the observation period, the documentation rates in this study are comparable to rates found before [10]. The data on colds provided by the parents were prospectively collected. The theoretical advantage of daily diaries over interviews is a smaller chance of recall bias. On the other hand, an interviewer may retrieve information that was initially omitted by parents. Previous studies investigating interviews and diaries as surveillance instruments in respiratory disease found both to be equivalent with regard to upper respiratory symptoms [10, 24].

This trial investigated whether preventive hydrotherapy in addition to normal saline inhalation is more effective against frequent common colds in childhood than inhalation therapy alone. Both groups improved considerably, but hydrotherapy showed no significant advantage with regard to incidence or duration of frequent common colds. Our findings do not support the concept of ''toughening'' as a preventive measure against colds. However, further studies are warranted. They may clarify whether other hydrotherapy regimes are more effective and to what extent inhalation therapy may have contributed to the improvement observed.

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