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ORIGINAL ARTICLE

Caregivers' education vs rhinopharyngeal clearance in children with upper respiratory infections: impact on children's health outcomes

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Abstract Upper Respiratory Tract Infections (URTI) are very common in children having no effective pharmacological treatment. This study aimed to compare the effect of caregivers' health education regarding children's respiratory infections and the effect of a rhinopharyngeal clearance protocol in children with URTI. A factorial trial was conducted in 138 children up to 3 years, attending day-care centres. Children were distributed into four groups: control group (CG) (n = 38); education group (EG) (n = 34); intervention group (IG) (n = 35); and education and intervention group (E + IG) (n = 31). A Diary of Records was kept by caregivers during 1 month. There were significant differences between groups concerning: Lower Respiratory Tract Infections (CG = 29.4%; EG = 10.7%; IG = 3.8%; E + IG = 0.0%; p = 0.014); acute otitis media (CG = 32.4%; EG = 7.1%; IG = 11.5%; E + IG = 7.7%; p = 0.014); medical consultations (CG = 70.6%; EG = 42.9%; IG = 38.5%; E + IG = 30.8%; p = 0.021); antibiotics (CG = 44.1%; EG = 7.1%; IG = 23.1%; E + IG = 15.4%; p = 0.006); days missed from day-care (CG = 55 days; EG = 22 days; IG = 14 days; E + IG = 6 days; p = 0.020); days missed from employment (CG = 31 days; EG = 20 days; IG = 5 days; E + IG = 1 day; p = 0.021); and nasal clearance techniques (CG = 41.4%; EG = 78.6%; IG = 57.7%; E + IG = 84.6%; p = 0.011).

Conclusion: This study showed that the most positive impact on children's health outcomes occurred when combining health education of caregivers, regarding children's respiratory infections, with a rhinopharyngeal clearance protocol in children with URTI.

What is Known:
- *Upper Respiratory Tract Infections are very common in children but still do not have an effective pharmacological treatment.*
- *This generates a great burden of disease for the child and families, increasing the use of antibiotics.*

What is New:
- *This study is the first one that aims to analyze the effects of caregivers' health education in comparison to non-pharmacological intervention in acute respiratory infections in children.*
- *It shows a positive impact on children's health outcomes, empowering caregivers regarding their child's health and reducing the burden of disease, medical consultations and the use of antibiotics.*

Keywords Health education · Health impact assessment · Respiratory disorders. Children · Nasal irrigation · Rhinopharyngeal clearance

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Abbreviations

AOM	Acute otitis media
CG	Control group
DRR	Désobstruction Rhinopharyngée Rétrograde
E + IG	Education and intervention group
ED	Education group
HES	Health Education Session
IG	Intervention group
LRTI	Lower Respiratory Tract Infections
PRSS	Paediatric Respiratory Severity Score
URTI	Upper Respiratory Tract Infections

Introduction

Upper Respiratory Tract Infections (URTI) are very common in children, especially those attending day-care centres, at a rate as high as up to 12 episodes a year [8].

In fact, the high density of children in day-care increases the dissemination of URTI, aided by the immaturity of their respiratory system [1, 11]. The recurrent illness becomes a burden for the children and their families, leading to the increased use of medication and healthcare services, affecting public health [5, 13].

Despite this, there is to date a lack of an effective pharmacological treatment of URTI in children, since antibiotics are not recommended and narcotics, antihistamines and antihistamine/decongestant combination, have not provided sufficient evidence as effective in the treatment of cold symptoms in children [18, 28].

Non-pharmacological methods to treat URTI, such as nasal saline irrigations, are often recommended for children, since they are well-tolerated and potentially reduce the use of medication, as well as not having any significant adverse side effects [8, 24]. However, parents and caregivers still have many concerns regarding nasal irrigation, because many aspects of the procedure are not very clear, such as the frequency of use, method of administration or volume irrigated, and this reduces their compliance [15].

Moreover, respiratory physiotherapists often add nasal inspiration after nasal irrigation, which helps to release secretions and solution residues from the nasopharynx ensuring complete clearance [10, 21]. Both procedures can be taught to caregivers, encouraging thus their self-efficacy and capacity-building regarding URTI [4].

This study aimed to compare the effect of caregiver health education regarding children's respiratory infections, as well as the effect of a rhinopharyngeal clearance protocol in children with Upper Respiratory Tract Infections, on their health outcomes.

Materials and methods

A factorial clinical trial was conducted during a winter period (January to March 2015) in six private day-care centres in Porto.

Following Ethical approval, 201 caregivers of children under 3 years of age of both genders were contacted and informed about the aims and procedures of the study, after which 175 gave formal written consent in accordance with the Declaration of Helsinki. Then, caregivers were asked to fill in a registration form in order to collect sociodemographic data, anthropometric data and risk-profile history. After an analysis of the caregivers' responses, three preterm children were excluded and one presented a chronic cardiopulmonary disease.

A baseline assessment (M0) of the children was conducted by a blinded respiratory physiotherapist, who determined eligible participants by applying the selected inclusion criteria (URTI in the first 3 days of onset, reported by caregivers, together with the presence of rhinorrhoea by direct observation) and exclusion criteria (normal respiratory condition, given by a total score of 8 on the *Paediatric Respiratory Severity Score* (PRSS), otherwise a severe respiratory condition (PRSS equal to or above 16), as well as any sign of lower respiratory tract impairment detected by pulmonary auscultation). Thirty-three children were then excluded after this baseline assessment (11 of the children's caregivers reported they had had URTI for more than 3 days, 18 children had a normal respiratory condition, with no signs of rhinorrhoea, and 4 children had crackles in pulmonary auscultation), so a final sample of 138 children was obtained.

It was followed a two-by-two factorial design, having two types of intervention (education and intervention protocol) and four groups to which children were randomly distributed: (1) control group (CG)—not intervened (n = 38); (2) education group (EG)—children whose caregivers attended a Health Education Session (HES) (n = 34); (3) intervention group (IG)—children to whom the rhinopharyngeal clearance protocol was applied (n = 35); and (4) education and intervention group (E + IG)—children to whom the rhinopharyngeal clearance protocol was applied and whose caregivers attended the HES (n = 31).

Instruments

The PRSS was used to assess the children's baseline respiratory condition. It summarises the main subjective and objective parameters that are present in children with acute respiratory infections, allowing to assess the severity of the respiratory impairment. The subjective parameters (cough, nutrition, fever and rhinorrhoea) are obtained from a clinical interview to caregivers, who are asked to report the children's symptoms from the past 24 h. The objective parameters (dyspnoea,

respiratory sounds, adventitious sounds and secretions) are obtained from a clinical assessment of the health professional. The evaluator must give a punctuation between 1 (normal) and 3 (severe) to each parameter, according to the severity of the health condition of the child. The final score is calculated as the sum of all the 8 parameters, varying from 8 to 24. The child's health condition is considered to be *Normal* if the total score is 8, *Moderate* if the total score is between 9 and 16, and *Severe* if total score is between 17 and 24. The PRSS obtained excellent values of content validity (Cronbach's $\alpha = 0.80$) and test–retest reliability (ICC 2.1 = 0.91) [3].

Caregivers were asked to keep a *Diary Record* during a 1-month follow-up period after the baseline assessment (M0). This diary was designed by an expert panel (three blinded respiratory physiotherapists with at least 5 years of experience) and included a checklist with the following children's health outcomes: (1) *acute respiratory infections*: (a) signs observed (cough, rhinorrhoea, nasal congestion, sputum, fever, otorrhoea, eating or sleep disorders or others); (b) *respiratory infections experienced* (Upper Respiratory Tract Infections (URTI): common cold, pharyngitis, tonsillitis or acute otitis media (AOM); Lower Respiratory Tract Infections (LRTI): laryngeal or tracheal infection, acute bronchiolitis, acute bronchitis or pneumonia); (2) *healthcare services*: use of medical consultations, emergency services or medication (antibiotics, antihistamines, paracetamol, antiinflammatory drugs, mucolytics, antitussives and bronchodilators); (3) *absenteeism*: number of days the child missed day-care, and the caregivers missed work; (4) *use of nasal clearance techniques*: nasal aspiration, nasal irrigation or nebulisation. The questions in the *Diary Records* obtained a *Cohen's Kappa* coefficient between *moderate* and *very good* ($0.412 \leq$ *Cohen's Kappa* ≤ 0.818).

Case definitions: A child was considered as having experienced a URTI if caregivers reported an episode of common cold along with one of the following symptoms—(i) cough, (ii) rhinorrhoea and (iii) nasal congestion—or if caregivers reported a diagnosis by the child's doctor. Moreover, the child was considered as having experienced LRTI or AOM if caregivers reported an episode diagnosed by the child's doctor.

Health Educational Session

The caregivers in the education groups (EG and E + IG) attended a Health Education Session (HES) on respiratory infections among children at their day-care centre. The HES was developed as a multi-stage process according to the caregivers' needs, described elsewhere [2]. The HES covered the following five domains: (A) *prevention of acute respiratory infections* (*ARI*): primary and secondary prevention measures; (B) *first signs and symptoms of ARI:* correct management of rhinorrhoea, cough and nasal congestion; (C) *worsening signs of ARI:* appropriate actions regarding fever, loss of appetite, dehydration or signs of increased difficulty in breathing; (D) *medication:* decide with the child's doctor when antibiotics should be taken, the appropriate dosage and frequency of medication and when to stop; (E) *Nasal clearance techniques*: demonstrative and shared practice about the appropriate way to use nasal irrigation according to the child's age; remarks about the use of nasal aspirators and nebulisation.

The HES was conducted by a respiratory physiotherapist with small groups of 10 to 15 caregivers at the day-care centre, having a mean duration of 1 h 30 min. At the end, the participants received a booklet with a summary of the information. The HES was assessed in another study, concluding that it met the caregivers' needs and increased their knowledge and attitudes in relation to ARI [2].

Intervention protocol

Children from the intervention groups (IG and E + IG) participated in a standard intervention protocol performed by a respiratory physiotherapist, consisting of nasal irrigation with a saline solution (NaCl 0.9%). The child was seated with his/her head bent slightly forward and inclined to the side of the nostril to be cleaned. The same procedure was applied to the other nostril. Then, a sudden and profound nasal inspiration was stimulated by briefly closing the child's mouth in order to ensure the complete clearance of the nasopharynx. This procedure was adapted from a respiratory physiotherapy technique called *Désobstruction Rhinopharyngée Rétrograde* (DRR), which is based on the Hering–Breuer deflation reflex and on the active inspiratory effort induced by lung deflation [10, 21]. The intervention protocol was repeated once a day for three consecutive days [22].

Statistical analysis

The statistical analyses were performed using the IBM® SPSS® Statistics 22 software for Windows 8®, with a confidence interval of 95% (significance level of $\alpha = 0.05$).

The descriptive statistical measures used were mean and standard deviations for continuous variables and relative frequency for dichotomous and ordinal variables.

The comparisons between the four groups (CG vs ED vs IG vs E + IG) were made with the *chi-square test* and *Fisher's exact test*, for dichotomous variables, and with *one-way ANOVA*, for continuous variables.

The group-to-group comparisons (CG vs ED; CG vs IG; CG vs E + IG; EG vs IG; EG vs E + IG; and IG vs E + IG) were performed with the *chi-square test* and *Fisher's exact test,* for dichotomous variables, and with *Student's t test for independent samples* for continuous variables.

Results

Participants

Figure 1 shows the flow of participants through each stage of the randomised trial. Baseline sociodemographic characteristics and the risk-profile history of children and caregivers from each group are summarised in Table 1.

Health outcomes—comparisons between the four groups

The data provided in the caregivers' reports in the *Diary Record* over a 1-month period after the baseline assessment were compared in the four groups.

Acute respiratory infections

The E + IG showed the lowest frequency of children who experienced LRTI (0%) and AOM (7.7%), while the control group showed the highest frequency of LRTI (29.4%) and AOM (32.4%) in comparison with the other groups (Fig. 2).

Indicators of healthcare use

A lower percentage of medical consultations was observed in the E + IG, and the lowest antibiotic consumption was found in the EG. The results are summarised in Table 2.

Days of absence from day-care and from work

Significant differences between the groups were found regarding the total number of days the children missed day-care (CG = 55 days; EG = 22 days; IG = 14 days; E + IG = 6 days; $p = 0.020$), as well as the caregivers missed work (CG = 31 days; EG = 20 days; IG = 5 days; E + IG = 1 day; $p = 0.021$), due to ARI.

Use of nasal clearance techniques

The results showed that the caregivers in the education groups (EG and E + IG) applied nasal irrigation more often than the other caregivers (Table 2).

Health outcomes—group-to-group comparisons

The group-to-group comparisons that achieved statistical evidence are shown in Table 3 (CG vs ED; CG vs IG; CG vs E + IG). There were no significant differences between EG vs IG, EG vs E + IG and IG vs E + IG.

A lower frequency of children who experienced URTI in the E + IG and LRTI in the intervention groups (IG and E + IG) can be observed, as well as a lower percentage of children with AOM in the EG, in comparison with the CG. Children in the EG, IG and E + IG groups had fewer medical consultations, when compared to the CG. Caregivers in the EG made less use of antibiotics than those in the CG. Absenteeism from day-care was lower in the IG and absenteeism from work was

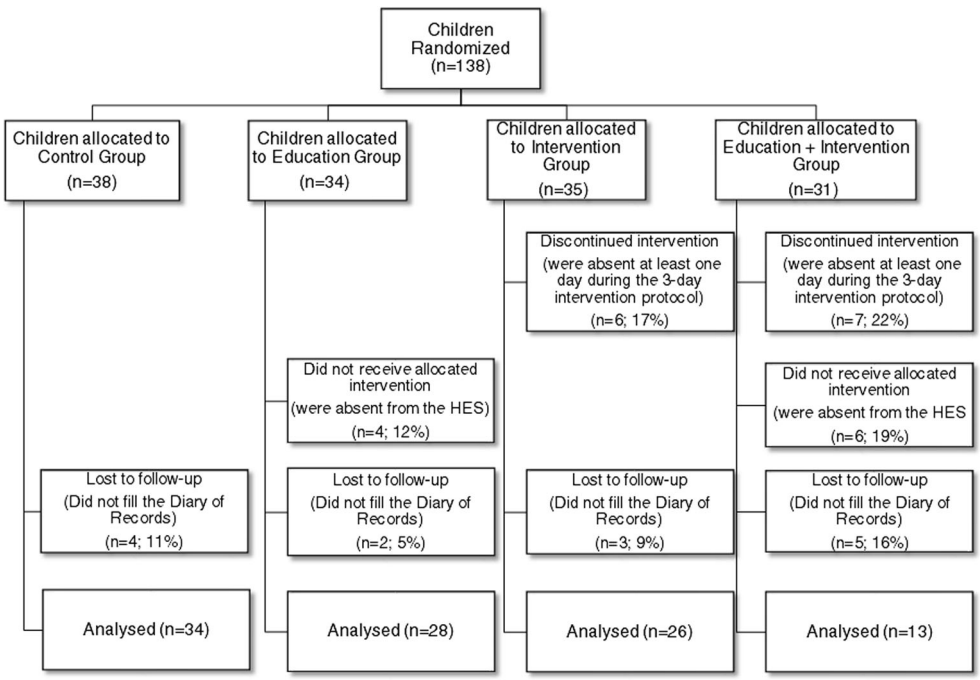

Fig. 1 Patients' diagram flow chart

Table 1 Baseline sociodemographic characteristics and risk-profile history of children in the intervention (n = 52) and comparison groups (n = 63)

		Control group	Education group	Intervention group	Education + intervention group	P value (95%)
Caregivers	Mother's age at child's birth (X ± SD)	30.9 ± 4.49	31.5 ± 4.48	31.6 ± 4.44	32.4 ± 4.68	$p = 0.796$
	Months of breastfeeding (X ± SD)	6.95 ± 3.11	7.09 ± 4.78	7.11 ± 3.94	6.87 ± 5.01	$p = 0.348$
	Higher education (%)	28.1	46.4	23.1	23.1	$p = 0.228$
Household	Household > 3 (%)	39.4	42.9	50.0	23.1	$p = 0.428$
	Parents' respiratory diseases (%)	45.5	35.7	38.5	53.8	$p = 0.568$
	Smoking household (%)	15.2	17.9	15.4	30.8	$p = 0.680$
Children	Male gender (%)	61.8	46.4	57.7	3.1	$p = 0.099$
	Months of age (X ± SD)	24.5 ± 8.21	21.1 ± 9.78	23.7 ± 8.08	24.0 ± 6.26	$p = 0.425$
	Weight at birth (kg) (X ± SD)	3.1 ± 0.49	3.3 ± 0.45	3.2 ± 0.38	3.2 ± 0.38	$p = 0.743$
	PRSS (X ± SD)	10.3±1.09	10.0±1.02	10.1±1.20	10.5±1.13	$p = 0.522$
Day-care	Room size (m^2) (X ± SD)	28.3 ± 8.79	27.4 ± 8.05	32.0 ± 7.52	28.7 ± 8.02	$p = 0.178$
	Number of children per room (X ± SD)	10.8 ± 2.48	9.6 ± 2.27	10.9 ± 2.75	9.6 ± 1.56	$p = 0.083$

IG intervention group, *CG* comparison group, *X* mean, *SD* standard deviation

*$p \leq 0.05$ is considered to be significant;

lower in both intervention groups (IG and E + IG), in comparison to the CG. Caregivers in the education groups (EG and E + IG) made more use of nasal irrigation than caregivers in the CG.

Discussion

This study aimed to compare the effect of both caregiver health education on children's respiratory infections and a rhinopharyngeal clearance protocol in children with URTI on their health outcomes.

The results showed that the children in groups who applied the rhinopharyngeal clearance protocol, together with caregiver education, showed the lowest occurrence of respiratory infections, namely URTI, LRTI and AOM.

This highlights that it is fundamental to provide adequate health information to caregivers besides a proper intervention plan. Health education should rely on the nature and extent of health needs in a selected population, as well as the causes and contributing factors to those needs [29]. This may explain our

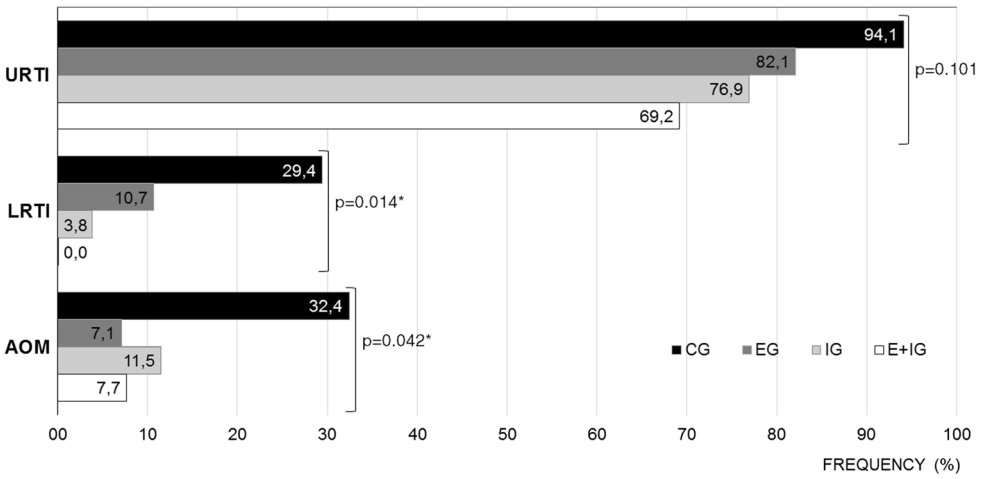

Fig. 2 Comparison between groups of the frequency of day-care children who experienced acute respiratory infections over a 1-month period

CG – Comparison Group; EG – Education Group; IG – Intervention Group; E+IG – Education + Intervention Group
URTI – Upper Respiratory Tract Infections; LRTI – Lower Respiratory Tract Infections; AOM – Acute Otitis Media
*p ≤ 0.05 is considered to be significant;

Table 2 Comparison between groups regarding absolute and relative frequencies of children who used healthcare services, medication and nasal clearance techniques over a 1-month period

			CG (n = 34)	EG (n = 28)	IG (n = 26)	E + IG (n = 13)	p value
Healthcare services	Medical consultations	n	24	12	10	4	0.021*
		%	70.6	42.9	38.5	30.8	
	Emergency room	n	7	4	3	0	0.375
		%	20.6	14.3	11.5	0.0	
Medication	Antibiotics	n	15	2	6	2	0.006*
		%	44.1	7.1	23.1	15.4	
	Antihistamines	n	17	8	10	3	0.225
		%	50.0	28.6	38.5	23.1	
	Paracetamol	n	16	11	9	2	0.248
		%	47.1	39.3	34.6	15.4	
	Antiinflammatory drugs	n	7	5	6	2	0.955
		%	20.6	17.9	23.1	15.4	
	Mucolytics	n	8	3	3	0	0.201
		%	23.5	10.7	11.5	0	
	Antitussives	n	1	0	1	0	0.811
		%	2.9	0.0	3.8	0.0	
	Bronchodilators	n	8	5	3	1	0.559
		%	23.5	17.9	11.5	7.7	
Nasal clearance techniques	Nasal aspiration	n	9	10	6	3	0.737
		%	26.5	37.5	23.1	23.1	
	Nasal irrigation	n	15	22	15	11	0.011*
		%	41.4	78.6	57.7	84.6	
	Nebulisation	n	14	8	9	2	0.384
		%	41.2	28.6	34.6	15.4	

*$p \leq 0.05$ is considered to be significant

CG comparison group, *ED* education group, *IG* intervention group, *E + IG* education and intervention group

Table 3 Comparison within groups regarding relative frequencies of children's health outcomes

		Control group vs education group	Control group vs intervention group	Control group vs education + intervention group
URTI	(%)	94.1 vs 82.1%	94.1 vs 76.9%	94.1 vs 69.2%
	P value	p = 0.228	p = 0.067	*p = 0.042**
LRTI	(%)	29.4 vs 10.7%	29.4 vs 3.8%	29.4 vs 0.0%
	P value	p = 0.116	*p = 0.016**	*p = 0.043**
AOM	(%)	32.4 vs 7.1%	32.4 vs 11.5%	32.4 vs 7.7%
	P value	*p = 0.026**	p = 0.072	p = 0.136
Medical consultations	(%)	70.6 vs 42.9%	70.6 vs 38.5%	70.6 vs 30.8%
	P value	*p = 0.039**	*p = 0.018**	*p = 0.020**
Antibiotics	(%)	44.1 vs 7.1%	44.1 vs 23.1%	44.1 vs 15.4%
	P value	*p = 0.001**	p = 0.109	p = 0.094
Days absent from day-care	(%)	55 vs 22 days	55 vs 14 days	55 vs 6 days
	P value	p = 0.061	*p = 0.014**	p = 0.053
Days absent from work	(%)	31 vs 20 days	31 vs 5 days	31 vs 1 day
	P value	p = 0.511	*p = 0.007**	*p = 0.020**
Nasal irrigation	(%)	44.1 vs 78.6%	44.1 vs 57.7%	44.1 vs 84.6%
	P value	*p = 0.009**	p = 0.435	*p = 0.020**

*$p \leq 0.05$ is considered to be significant

URTI Upper Respiratory Tract Infections, *LRTI* Lower Respiratory Tract Infections, *AOM* acute otitis media

results, since the HES was designed and planned according to the caregivers' expressed needs, in a community-based intervention, which comprised different determinants of health, directly in children's social support network, that is, day-care centres [2].

The significantly lower percentage of children with LRTI and AOM in the education groups can justify, in part, the lower number of medical consultations and antibiotic consumption, in comparison to the CG. However, some studies have found that providing parents with proper health information, prior to their child becoming ill, resulted in lower rates of consultation for respiratory infections [5, 9, 30]. In fact, parents generally seek medical support when their child has symptoms such as pain and fever, believing that antibiotics are necessary to prevent complications and hasten recovery [33]. This is a wrong assumption since the majority of ARI are caused by virus, so antibiotics are only recommended if there exists a concomitant bacterial infection, which happens only in about 2% of the cases [7, 25].

Our study has shown that caregivers from the CG made more use of antibiotics that those from the other groups, among which the education groups had the lowest percentages. There is indeed some evidence that combining a delayed or non-prescribing strategy with parental health education can decrease antibiotic consumption in children with respiratory infections [5, 9].

Although in our study only antibiotics yielded a statistical difference between groups, we found that the education groups showed lower rates of children who used antihistamines, antiinflammatory drugs, mucolytics and antitussives. Similarly, Stockwell et al. found that families that received health education intervention were significantly less likely to use inappropriate "over-the-counter" medication for their child, which illustrates the potential use of non-medical settings for distributing information regarding important health issues [30].

Furthermore, the results suggest that the health education of caregivers is associated with a lower percentage of children who experience AOM. This reinforces that proper health education regarding URTI is vital in order to avoid or reduce the associated episodes of AOM. In fact, many studies reported that URTI are an important predisposing factor for development of AOM, and about 43% of URTI were associated with AOM [19, 35]. Furthermore, assuming that there is a time delay between the first signs of URTI and the onset of AOM, a proper management of URTI could be seen as a prevention of AOM in young children [17, 26].

With regard to URTI, significantly lower rates of children with URTI were only observed in the E + IG when comparing the CG, suggesting that only by combining health education and effective rhinopharyngeal clearance could future episodes of URTI be prevented. In fact, parents seem to know little about the risk of viral transmission through contact with objects or by the hands. They also had particular concerns regarding the use of protective masks and children's social isolation; thus, caregiver health education is vital in the efficient prevention of URTI [7, 25].

However, with regard to LRTI, our findings showed lower frequencies of children with LRTI in both intervention groups (IG and E + IG). This means that, in these cases, proper intervention regarding rhinopharyngeal clearance is needed, besides health education, in order to effectively remove the secretions from the nasopharynx. This is a very important result since the onset of LRTI often follows an URTI, so the correct management of URTI might prevent or mitigate more severe episodes of respiratory infections [7, 8, 14].

In fact, some studies suggest that nasal irrigation is not limited to mere mechanical washing, since it seems that it interacts with inflammatory mediators, helping to reduce oedema and supporting the healing of nasopharyngeal mucosa, capable of clearing germs, allergens and other pollutants from the nasopharynx and thus protecting children against respiratory diseases [8, 24, 27, 32, 34]. Furthermore, we added the stimulation of a sudden and profound nasal inspiration (DRR) to the intervention protocol, so all of the remaining secretions and solution vestiges could be removed from the nasopharynx. This procedure ensures the clearance of the posterior region of nasal cavities (cavum), which may contain a large amount of purulent secretions because of its cryptic anatomical character [22]. The clearance of this region is not fully achieved only with nasal irrigation [36] and no medication can clean the cavum, which is a cofactor of prolonging URTI [22].

The use of DRR leads to the immediate emission of a large amount of secretions from the nasopharynx, after which the clinical results are immediate and sometimes impressive [21, 23]. However, more intervention studies are needed to provide consistent data on the effectiveness of DRR in infants.

The intervention groups also showed significantly lower absenteeism from day-care and from work. This could be due to the lower rates of LRTI in the intervention groups, since the severity of the respiratory disease is generally related to the number of days needed for the child to recover a normal respiratory condition [31]. Nevertheless, the lowest rates of absenteeism were observed in the group whose children were treated and whose caregivers attended to the HES. Although there is a lack of studies on this matter, some studies have shown that parental education interventions on respiratory infections can significantly reduce the absence of children under 3 years old, due to infections, especially during the flu season [6, 20].

Concerning the use of nasal clearance techniques, our study showed that caregivers in the education groups used nasal irrigation more often than the caregivers in the other groups. Furthermore, we also found an association between health education of caregivers and the use of nasal irrigation.

In fact, although the use of saline solutions has been shown to be a valuable non-pharmacological treatment of URTI, being well-tolerated and recommended for infants, it is still not fully accepted by caregivers [8, 24, 27, 32]. This is probably due to the lack of consensus regarding a uniform protocol for nasal irrigation, since recommendations include saline of varying tonicity, a multitude of delivery vehicles and a variety of additives, as well as many doubts about the frequency of application or volume irrigated [15, 32]. This causes insecurity in parents and decreases the use of nasal irrigation due to the difficulty of administration or the supposed invasiveness of the procedure [15]. Once we had identified this insecurity when we assessed the caregivers' needs in order to design the HES, we were able to clarify the procedure and to share practices with them in the HES. This allowed caregivers to acquire experience, which seems to be a key factor reported by parents in increasing their self-efficacy [12]. This highlights the need for an ecological perspective in health care, targeting behavioural changes in individuals, social networks and in the community environment and thus diminishing the burden of respiratory diseases [4, 16].

This study encountered some limitations, such as the number of participants that were lost during the procedures and follow-up. Although the number of dropouts were similar between groups considering each procedure, the E + I group was the one with more procedures allocated, so the total dropout was higher. Also, the children who dropped out could have been those with complications so the results should be interpreted with caution. Another limitation is related to the fact that the data was reported by caregivers so the interpretation of the results should be made with caution. Further studies are needed, with community-based research methodologies, and including more extensive follow-ups that cover a larger number of children as well as public day-care centres from all across the country.

Conclusion

This study showed that the most positive impact on children's health outcomes occurred when combining health education of caregivers, regarding children's respiratory infections, with a rhinopharyngeal clearance protocol in children with Upper Respiratory Tract Infections. Health education had a major impact on the frequency of children who experienced AOM and used antibiotics, while the rhinopharyngeal clearance protocol had a major effect on the frequency of children who experienced LRTI and were absent from their day-care centre.

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Authors' contributions Alexandrino, AS was responsible for the conception and the design of the study, acquisition of data, analysis and interpretation of data and drafting the article; Santos, R took part in the design of the study, acquisition of data, analysis and interpretation of data and revised the paper; Melo, C took part in the design of the study, reviewed the findings and revised the paper; Bastos, JM assured the medical supervision of the study and revised the paper; Postiaux, G developed the intervention procedures and revised the paper. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interests The authors declare that they have no conflict of interest.

Ethical approval and consent to participate All procedures performed in this study were in accordance with the ethical standards of the *Ethics Committee of the School of Allied Health Technologies*, *Polytechnic Institute of Porto* (CE_1744/2014) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in this study.

This study is registered at *ClinicalTrials.gov* with the identifier: NCT02588963.

Availability of data and material The dataset supporting the conclusions of this article is available from the authors.

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