

# Frequent body position changes and physical activity as effective as standard care for infants hospitalised with acute respiratory infections - a randomised controlled trial

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**Background:** No definite consensus has been reached yet on the best treatment strategy for the large group of infants hospitalised with bronchiolitis or pneumonia. Minimal handling is often recommended, although not evaluated scientifically. There is a need to evaluate the management, as the infants often are critically affected, and the costs for society are high. The aim of this RCT was to evaluate the most common physiotherapy intervention in Sweden for this patient group, including frequent changes in body position and stimulation of physical activity, compared to standard care.

**Methods:** Infants 0-24 months old, without previous cardiac or respiratory diagnoses and born in gestational week 35+, were recruited in two Swedish hospitals. The participants (n=109) were randomised to either interventions in addition to standard care (intervention group) or to standard care alone (control group). The primary outcome measure was time to improvement. The secondary outcomes were immediate changes in oxygen saturation, heart rate and respiratory rate, time to improved general condition (parents' assessment), and lung complications.

**Results:** The median time to improvement was 6 hours in both groups (p=0.54). The result was similar when we adjusted for age in months, sex, tobacco smoke exposure, heredity for asthma/atopic disease, and early stage of the infection (for those with RSV), p=0.69. Analyses of the immediate changes showed no significant differences either (p=0.49-0.89). Time to improved general condition was median 3 hours in the intervention group and 6 hours in the control group, p=0.76. No lung complications occurred.

**Conclusions:** No statistically significant differences in outcomes were detected between the intervention group and the control group. Both strategies were found to be equally effective and safe, indicating that the current recommendation of minimal handling for these infants should be reconsidered. Furthermore, the findings suggest that this treatment can be safely continued.

**Key words:** Physical therapy modalities; bronchiolitis; pneumonia; respiratory tract infections; infants; randomized controlled trial.

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**Contributions:** All authors participated in the design of the study. SAM performed the data collection, analysed the data, and wrote the first versions of the manuscript. All authors read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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

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**Availability of data and materials:** All data are archived according to the Swedish Act concerning the Ethical Review of Research Involving Humans to attain confidentiality and are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate:** Parents/guardians to all participating infants received written and oral information of the trial and signed a written consent form before inclusion. The study was carried out following definitions of Good Clinical Practice, according to the Declaration of Helsinki, and was approved by the Swedish Ethical Review Authority (2017/190).

**Consent for publication:** Consent for publication was obtained from all individuals or their parents/guardians who shared person's data, videos, in the Additional files of this manuscript.

# Introduction

The most common cause of hospitalisations for infants all over the world is acute airway infections due to, among other agents, the respiratory syncytial virus (RSV), leading to serious illness and hospitalisation for 1-3 % of the infants below 24 months [1-4]. The infection and the following inflammatory response cause oedema in the mucosa as well as increased mucus production, which leads to an obstruction or narrowing of the airways [5,6]. As a consequence, the infants suffer from reduced lung volumes, reduced gas exchange and oxygenation, and thus increased work of breathing, which may lead to muscular exhaustion, inadequate feeding, apnoea, or acute respiratory failure [7,8].

To date, no definite consensus has been established on a general treatment strategy for the infants hospitalised with bronchiolitis or pneumonia, but supportive care such as hydrogenation and oxygen supply is most often advocated [9-14]. High flow nasal cannula (HFNC) is frequently used [15], and some infants are treated with continuous positive airway pressure (CPAP) or may need care at an intensive care unit (ICU) [16]. Furthermore, a wide range of physiotherapy treatments are often additionally used for this patient group to reduce their symptoms [17-27], although this is sometimes questioned or not recommended in guidelines. The general terms 'physiotherapy' or 'chest physiotherapy' are often used, and uncertainties remain about what specific physiotherapy treatment methods, if any, should be selected and, if so, to which patients [18,28-32]. Some therapies have been rejected although the studies were under-powered [26], and some studies have been carried out with only a small number of participants [21,24]. More evidence on treatment strategies is needed to increase the understanding about how to manage the often severely affected infants and their families in hospitals.

Some guidelines recommend 'minimal handling' as part of the supportive care, which may have impacted many clinicians [33-35]. It is unclear, however, what rationale underlies this recommendation. In contrast, as opposed to merely lying supine, there is evidence on increased oxygen saturation and reduced work of breathing for infants with bronchiolitis or pneumonia when they are placed in a prone position, which has been mostly studied on mechanically ventilated and pre-term infants [36,37]. Nursing preterm infants with either the head of the bed elevated or prone with the head and thorax in an elevated position has also had a favourable effect on oxygenation [38,39]. Additionally, mucus transportation is larger in the dependent lung compared to the nondependent when side-lying, in adults with cystic fibrosis (CF), which Lannefors and Wollmer hypothesise is due to high air flow and mechanical squeeze [40]. It is not clear if this is also valid for infants, although if mucus transportation is furthered by mechanical pressure on the chest wall, infants might benefit even more from these changes of position since they have a more compliant chest. The distribution of ventilation in infants is reported to be more similar to that in adults than was previously known, with increased ventilation in the dependent lung (and not the reverse) [41,42]. Moreover, general physiological evidence and observations supports changes in body position and physical activity to increase lung volumes, enhance mucus transportation, and increase oxygenation [43-46].

Physiotherapists in Sweden commonly use frequent changes in body position and stimulation of physical activity to increase mucus transportation and support the work of breathing for the infants [47], which build on physiological principals and experiences from the physiotherapy treatment in CF [48-51]. To our knowledge, there have been no studies yet to investigate the effect of this treatment for infants with acute lower respiratory tract infections (ALRI) such as bronchiolitis and pneumonia. The main objective of the present study is thus to investigate the effect of physiotherapy treatment with frequent changes of body positionon full-term infants with acute respiratory infections.

#### Methods

The specific aim of this study was to evaluate the effect of frequent changes in body position and stimulation of physical activity compared to standard care for infants aged 0–24 months hospitalised due to acute respiratory infections.

#### Study design

This was a clinical individually randomised controlled trial with parallel groups at two sites. The overall design as well as the interventions are thoroughly described in a study protocol [52], and the analysis plan was adjusted after a feasibility study [53]. A safety analysis was also performed in the feasibility study, which did not find any risk of harm associated with participation in this trial. During the COVID-19 pandemic, the inclusion rate was severely reduced, and to reach a feasible sample size, we have chosen to analyse the two intervention groups together. This is possible as the interventions are very similar, both stimulating frequent changes of the body position and physical activity, although with a somewhat different intensity. The Consolidated standards of reporting trials (CONSORT) checklist for pragmatic trials [54] was used when reporting this trial. The following sections briefly describe the procedure of the study.

## **Participants**

The participants were enrolled between November 2017 and April 2022 at two paediatric hospital wards in the South of Sweden. The participant flow is displayed in Figure 1.

## **Inclusion criteria**

Inclusion criteria were as follows: age 0-24 months, hospitalised due to an acute respiratory infection, born in gestation week 35 or later. At least one of the parents needed to understand written Swedish, English, Arabic or Persian.

#### **Exclusion criteria**

Exclusion criteria were previous respiratory or cardiac diagnoses. Participants who were enrolled in the study later than 24 h after hospital admission were also excluded.

#### Randomisation

The participants were randomised to an individualised physiotherapy intervention, a non-individualised intervention, or a control group. A statistician independent of the research group performed the randomisation, stratified by the two sites, and prepared opaque paper envelopes. The staff in care of the recruited participant at the ward opened the top envelope in the study binder to reveal the allocation group.

## Interventions

All participants received standard care at the wards without limitation. The standard care at the wards consisted of information to the parents about the importance of fluid intake for their infant, oxygen supplementation, nose drops and suctioning, HFNC, inhalations, fluid supplementation, and analgesics, according to need. The participants in the intervention groups were given extra treatment in addition to the standard care, which the control group was not.



#### Controls

The control group did not receive any additional treatment apart from standard care, and the parents were not encouraged to perform extra changes of the body position on their infant.

#### Interventions

The individualised intervention, lasting 20 min, was performed by a physiotherapist at least once daily. The physiotherapist was typically sitting on a large ball, firmly supporting the infant in different body positions, while bouncing, to affect the respiratory pattern of the infant: to increase the expiratory air flow and stimulate deep inspirations. They also stimulated active movement according to the infant's ability and might choose additional treatments such as manual cough support on the belly and chest, light sternal compressions, administer or suggest inhalation therapy or other treatments like CPAP. Following the first 20-min intervention, the parents were instructed to continue the movements regularly throughout the day. See Additional file 1 for the printed instructions and a video demonstrating the intervention. The video is also available through the following link: https://play.mediaflowpro. com/ovp/17/41CFKGM4WF

The non-individualised intervention, lasting 20 min, was performed by the nursing staff at least once, shortly after inclusion. It comprised changes of the body position mainly out of bed, and passive arm and leg movements, as well as stimulation of active movement according to the infant's ability. Following the first 20min intervention, the parents were instructed to continue the movements regularly throughout the day. See Additional file 2 for the printed instructions and a video demonstrating the intervention. The video is also available through the following link: https://play.mediaflowpro.com/ovp/17/56CFSG6UV9

## Assessments

Assessments were made at baseline, after 20 min (immediately following the first intervention or interval), and every subsequent third hour. The items reported by the parents were only collected during the parents' waking time, which was typically between 7 am and 10 pm.

At baseline, all infants were lying in a supine position on the bed. For the intervention groups, at the second assessment, the oxygen saturation was measured while the infants were still in an upright position in the arms of the physiotherapist, the nursing staff, or the parent. All other items were assessed on the infant (back) in a supine position. See the study protocol [52] for details about the assessments.

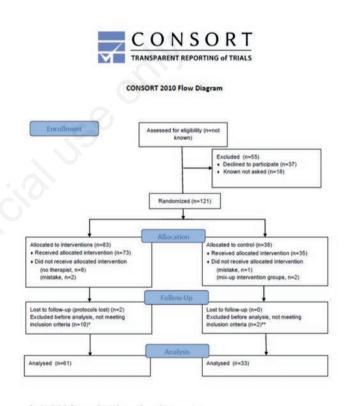
## Outcomes

#### Primary outcome measure

The primary outcome measure in this study was 'time to improvement'. Improvement was defined as any of the following events: reduced total Wang respiratory score [55], ceased use of supplemental oxygen, ceased use of HFNC, ceased use of gastric tube for feeding, or discharge to the home. This item is reported in hours from baseline.

#### Secondary outcome measures

The secondary outcome measures are listed and described in Table 1.



\* n=9 included after more than 24 hours at the ward; n=1 premature \*\* n=2 included after more than 24 hours at the ward

Figure 1. Flow chart of the participants in the study.

#### Table 1. Description of the secondary outcome measures.

Item	Mode of measuring	Definition (time)		
Oxygen saturation	Pulse oximetry*, probe on the foot, %	Change between baseline and assessment 2 (after 20 min) $^{\circ}$		
Heart rate	Pulse oximetry*, probe on the foot, beats per min	Change between baseline and assessment 2 (after 20 min)		
Respiratory rate	Manual count during one min	Change between baseline and assessment 2 (after 20 min)		
General condition, parents' assessment	NRS 0-10 (10 is worst)	Time to first reduction in scores from baseline (assessed after 20 min and every subsequent $3^{\rm rd}h^{\rm f}$ )		
Lung complications	Yes/no	Referrals to an ICU (at discharge)		

\*Carescape Monitor B650 (General Electric Company); ofor the intervention groups, this item was recorded in an upright position in the arms on assessment 2; #except during the night when the parents were asleep, typically between 10 pm and 7 am; NRS, numeric rating scale; ICU, Intensive Care Unit.



# Statistics

## Sample size

A sample size calculation was performed in PS Power and Sample Size Program (http://biostat.mc.vanderbilt.edu/ wiki/Main/PowerSampleSize) based on the median time to improvement in prior data to be 6 h in the control group and 3 h in the intervention group and the control group being half the size. The minimal clinically important difference to be detected was 3 h, and the planned follow up time was 48 h. We needed to study 49 participants in the intervention group and 25 participants in the control group to be able to reject the null hypothesis that the intervention and control survival curves are equal with a power of 0.80. The Type I error probability associated with this test of this null hypothesis is 0.05.

#### Analyses

An un-adjusted Kaplan-Meier analysis followed by a log-rank test was used for the primary outcome, analysing the time to the first improvement from baseline. We further used a Cox regression model, adjusted for age in months, sex, tobacco smoke exposure, heredity for asthma or atopic disease, and early stage of the infection for those with RSV, to estimate differences between the groups and the hazard ratio (HR). Assumptions about independent events and proportional hazards were met. For overall goodness-of-fit, the Kaplan-Meier and the Cox regression were compared, showing overall similarities.

Independent sample t-tests were used in analysing differences

between the groups in mean change from baseline to the second assessment in oxygen saturation, respiratory rate, and heart rate. The effect sizes were reported using Cohen's d. We follow the suggested interpretation of effect sizes to be: "effect sizes of (a) .20, (b) .50, and (c) .80 are considered small, medium, or large, respectively" [56,57]. The time to improved general condition as assessed by the parents was analysed via Kaplan-Meier, followed by a log-rank test. The IBM SPSS Statistics 27 Windows (IBM Corporation, Armonk, NY, USA) was used for the analyses.

#### Blinding

Due to the nature of the trial, blinding of participants to parents, to staff performing the interventions, or to assessors was not possible. However, we ensured that separate staff performed the interventions and collected the outcome measures. A statistician independent of the study closely observed the analyses.

#### Results

Out of 121 enrolled, 109 participants were included correctly. Demographics and characteristics of the 109 participants are reported in Table 2. The dropouts are individuals who were included correctly but for different reasons (see Figure 1), were omitted after randomisation. The analyses of the primary and the secondary outcomes were performed on the participants who met the inclusion criteria, received the correct interventions according to the randomisation, and for whom correct protocols were collected, n=94.

## Table 2. Demographics and characteristics of the participants (n=109).

	Control (n=33)	Intervention (n=61)	Dropouts (n=15)	
Age in months				
- median (IQR) min–max	2.86 (1.32;10.08) 0.56-22.37	2.80 (1.41;7.52) 0.26-23.65	1.02 (0.86;3.88) 0.20-5.10	
Girls % (n)	33.3 (11)	42.6 (26)	33.3 (5)	
Boys % (n)	66.7 (22)	57.4 (35)	66.7 (10)	
Heredity asthma/atop disease % (n)	57.6 (19)	62.3 (38)	40.0 (6)	
Tobacco smoke exposure % (n)	15.2 (5)	18.0 (11)	6.7 (1)	
RSV, % (n)	66.7 (22)	65.6 (40)	66.7 (10)	
Early* RSV if RSV % (n)	42.4 (14)	49.2 (30)	6.7 (1)	
Oxygen saturation <sup>°</sup> -mean (SD)	94.7 (3.6)	95.1 (4.4)	94.9 (3.3)	
Heart rate° - mean (SD)	156.6 (22.9)	151.6 (19.3)	153.3 (20.9)	
Respiratory rate $^{\circ}$				
- mean (SD)	55.2 (14.6)	51.1 (13.2)	54.1 (15.6)	
Wang total score b - median (IQR) min–max - mean (SD)	6 (3.8;7.3) 2–11 5.7 (2.5)	6 (4.0;7.0) 0–10 5.7 (2.5)		
Supplemental oxygen <sup>#</sup> % (n)	27.3 (9)	50.8 (31)		
HFNC <sup>#</sup> % (n)	18.2 (6)	34.4 (21)		
Gastric tube feeding first 24 hours % (n)	33.3 (11)	32.8 (20)		
Days hospitalised - median (IQR) min–max	2.74 (1.69;3.68) 0.47-10.44	2.86 (1.85;4.50) 0.52-6.86	2.03 (1.23;2.75) 0.48-5.60	

IQR, interquartile range; RSV, infected with the respiratory syncytial virus; \*defined as less than 7 days since the start of coughing or severe infection for those infected with the RSV, at admission to the ward; °at admission to the ward; °at admission to the ward; °at matching and the severe infection for those infected with the RSV, at admission to the ward; °at admission to the ward; °at matching and the severe infection for those infected with the RSV, at admission to the ward; °at matching and the severe infection for the severe infection for the severe infection for the severe infected with the RSV, at admission to the ward; °at matching and the severe infection for the severe in



#### **Primary outcome**

The time to improvement as defined by the first event of reduced total Wang respiratory score, ceased use of supplemental oxygen, ceased of use of HFNC, ceased use of gastric tube for feeding, or discharge to the home was analysed *via* Kaplan-Meier analysis with a log-rank test followed by a Cox regression model.

In the un-adjusted Kaplan-Meier analysis, the median time to improvement was 6.00 hours (95% CI 4.06–7.94) in the intervention group and 6.00 hours (95% CI; 3.44-8.59) in the control group. The difference between the groups was not significant (p=0.54). See graph in Figure 2. The median times to improvement for the separate variables in the primary outcome measure are reported in Table 3.

Cox regression adjusted for age in months, sex, tobacco smoke exposure, heredity for asthma/atopic disease, and early stage of the infection (for those with RSV) showed no significant difference between the two groups, p=0.69. HR: 1.10; 95% CI: 0.68–1.79.

#### Secondary outcomes

In Table 4 the mean values at the two points are reported. The mean changes from baseline to assessment 2, analysed *via* independent samples *t*-test for group differences, are displayed in Table 5. The intervention group increased somewhat more in respiratory

rate and heart rate than the control group did, and less in oxygen saturation. There were no significant differences, however (p=0.49-0.89), and the effect sizes were small.

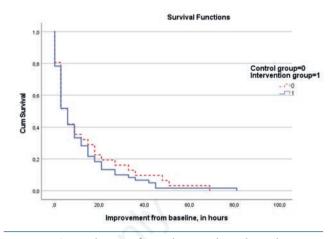


Figure 2. Survival curve from the un-adjusted Kaplan-Meier analysis of the primary outcome, time to improvement.

	Intervention group Median hours (95% CI)	Control group Median hours (95% CI)	р
Oxygen	30.00 (25.95-34.05)	42.00 (24.36–59.64)	0.216
HFNC	15.00 (0.00-31.63)	6.00 (0.00–43.93)	0.902
Wang score	3.00 (1.79–4.21)	3.00 (1.67-4.33)	0.955
Gastric tube	45.62* (30.23-61.00)	42.00* (29.63–54.37)	0.629
Discharge	24.00 (15.54–32.46)	33.00 (14.16-51.84)	0.104

Table 3. The median times to improvement for the separate variables in the primary outcome measure.

HFNC, high flow nasal cannula; \*mean hours.

## Table 4. Descriptions of mean values of oxygen saturation, heart rate, and respiratory rate at baseline and after 20 min.

	Control group, mean (SD)	Intervention group, mean (SD)
Oxygen saturation baseline	95.97 (2.44)	96.49 (2.95)
Oxygen saturation 20 min	96.32 (2.36)	96.80 (3.14)
Respiratory rate baseline	48.55 (11.84)	47.78 (12.53)
Respiratory rate 20 min	48.68 (11.23)	50.02 (10.92)
Heart rate baseline	145.67 (13.17)	146.98 (16.75)
Heart rate 20 min	149.87 (17.92)	152.55 (16.67)

#### Table 5. Group differences in changes from baseline in oxygen saturation, respiratory rate, and heart rate after 20 min.

Control group		In	tervention group	Mean difference (95% CI)	р	Effect size* (95% CI)	
	n	Mean change (SD)	n	Mean change (SD)			
Oxygen saturation	31	0.32 (2.71)	59	0.24 (2.96)	0.09 (-1.18-1.36)	0.89	0.03 (-0.41-0.46)
Respiratory rate	29	0.55 (7.89)	55	1.53 (9.23)	-0.98 (-4.99-3.04)	0.63	-0.11 (-0.56-0.34)
Heart rate	31	3.55 (13.86)	58	6.00 (16.98)	-2.45 (-9.51-4.61)	0.49	-0.15 (-0.59-0.28)

\*Cohen's d.



The median time to improved general condition as reported by parents was 3.00 hours in the intervention group (95% CI 1.16-4.84) and 6.00 hours in the control group (95% CI 2.02-9.98); see graph in Figure 3. The log-rank test revealed no significant differences between the groups (p=0.76). There were no lung complications, defined as referrals to an ICU.

# Discussion

This study has evaluated the effect of a physiotherapy intervention compared to standard care for infants with ALRI in hospitals, and the most important finding was the overall similarity of outcomes for the different groups. As this treatment has not been evaluated in a randomised control trial before, it was not known whether the intervention would be more beneficial than the strategy for the control group with no extra movements of the body. This study did not detect any effects of the intervention, but on the other hand no disadvantages either.

The hazard ratio of the Cox regression indicates that the probability for participants in the intervention group to have improved was 1.10 times higher than for the controls at each time. In the analyses of short-term effects, both groups increased somewhat in oxygen saturation, respiratory rate, and heart rate. The median difference in improvement rate in the secondary outcome 'general condition' (parents' assessment) was three hours shorter in the intervention group. Although not statistically significant, and thus not possible to generalise beyond this study, this difference is clinically relevant, especially considering the overall short hospital stay. No referrals to an ICU occurred in either group, which may reflect that the participants in this study were clinically rather stable. Furthermore, it supports the safety in using the interventions for this patient group. No adverse effects were detected in this trial or in the previous safety analysis [53]. In summary, our interpretation of the findings is that there is no reason to abandon this widespread praxis, especially if therapists see clinical benefits from the interventions, also including other possible effects that have not been studied in this trial.

In fact, as other benefits for managing infants in the arms with a close bodily contact are widely recognised in the literature, we can safely recommend the continued treatment if desired. For instance, close bodily contact is generally regarded as positive for infants, as it "conveys feelings of security [and] transmits interactional warmth" [58] as well as supports the psychological maturation [59]. Parenting skin-to-skin is recommended by the World Health Organisation (WHO), especially for pre-term infants, because of increased survival [60,61]. Positive effects of close bodily contact have also been demonstrated on infants' breast feeding, weight gain, prevention of hospital referrals, and increased well-being [62,63]. Furthermore, holding the infants in the arms while bouncing on a large ball has been used in another study to help the infants relax during treatment [64].

The standard care in this study was intended to mimic the basic care recommended in guidelines without the use of physiotherapy treatment, comparable to the previously mentioned 'minimal handling'. We recognise that the recommendation of minimal handling with its implication of constituting supportive care for the infants with ALRI [18,26,33-35] may very well have been suggested from a general concern about the severely affected infants and a wish not to cause them any further distress. Nevertheless, the findings in this study do not support that recommendation, as there was no evidence of a favourable effect of minimal handling (control group) compared to stimulation of physical activity and frequent changes of the body position for the infants. These different approaches need further evaluation.

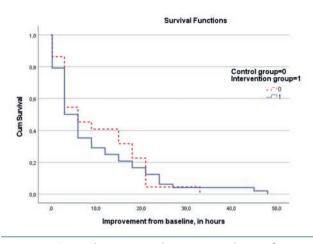


Figure 3. Survival curve, Kaplan-Meier analysis, of time to improved general condition as reported by parents.

A major strength of this study is the design of the so-called pragmatic RCT, which places the research close to clinical praxis, described as aiming to help choose between treatment options and to enhance implementation of the findings to usual care settings [54]. We chose this design to evaluate a treatment that already exists in hospitals, but that has not been scientifically evaluated before, as our aim was to guide future care for this large and vulnerable group of patients. Although this design constitutes a strength, it also offers some limitations. The staff was used to deliver the study interventions in their ordinary work, and we were notified that some infants had mistakenly received the intervention of changing body positions despite being randomised to the control group. In these known cases, the infants were excluded from the study, but we cannot rule out that this may have also occurred without being recorded. Additionally, in the control group, the parents were not actively prevented from lifting their infants up in the arms if they would choose to do so. These aspects may have influenced the results somewhat, contributing to the low difference between the groups. This risk might have been reduced if we had chosen one hospital site for the controls and another for the interventions. In Sweden that would have been difficult to undertake, however, as several hospitals had already declined to join the study. They had high faith in the interventions to be tested and did not want any of their infants to be randomised to controls.

It is not obvious what outcomes to choose for studies with this patient group, and we agree with Castro-Roderiguez et al. [11] about the need to discuss and determine relevant outcome measures and the minimal clinically important difference. When changing the originally intended primary outcome measure after the feasibility study [53] to a dichotomised use of supplemented oxygen, HFNC, and gastric tube feeding, we possibly chose a less discriminating outcome. We also abandoned the rather detailed record of oral food intake due to difficulties in collecting that data. It is possible that some effects went undetected because of the less detailed outcome measures chosen for the final analysis. Further, we used a numeric rating scale 0-10 for the parents' assessment of the infants' general condition, even though it has not been validated for this purpose, recognising the value of patient-reported outcomes [65]. The parents, being very close to the infants, normally constitute their most appropriate spokespersons and are likely to detect even subtle changes in the infants' well-being. A custommade questionnaire to the parents at discharge was similarly used by Gajdos et al. [18], evaluating other aspects of their trial. In this study we found it appropriate to treat the Wang respiratory score as an ordinal scale, not using parametric tests, whereas in other stud-



ies this score has been used as a continuous, normally distributed scale in parametric tests [24,27]. The different approaches complicate comparisons between studies.

The decision to analyse the two intervention groups together was necessitated by the COVID-19 pandemic that severely reduced the already low recruitment rate. During the pandemic, initially no infants with bronchiolitis were admitted to the study hospitals for about 15 months, and later, the staff - fatigued after challenging working conditions - had difficulties in recruiting enough participants, despite a large number of infants admitted to the hospitals at times. The two interventions differ somewhat, mainly in intensity and in the professions delivering the interventions, which may have influenced the outcome to some extent. On the other hand, as the interventions are essentially similar, we find that merging the groups made the study more relevant and clinically adapted. Further studies are needed to evaluate other aspects of this intervention, as for example the long-term effects. Moreover, the experiences and opinions of the parents have not been explored yet, whose interactions were used throughout the trial. Some parents spontaneously expressed a feeling of increased control and ability to help their child during the interventions. An experience of increased ability and control may consequently benefit the infants and possibly lead to fewer calls for medical advice or fewer readmissions. Other studies that strictly monitor the physiological responses on isolated changes in body positions would also add valuable knowledge to the area. The oxygen saturation should be monitored without supplemental oxygen to assess if changes of body positions effect low oxygen saturation, and changes in lung volumes may possibly be performed by use of electrical impedance tomography as was done by Heinrich et al. [66].

# Conclusions

The findings in this study contribute to an increased understanding of the management of infants with acute respiratory infections in hospitals. No significant differences were detected between the intervention group and the control group in the rate of improvement or in the immediate changes in oxygen saturation, heart rate, or respiratory rate. Both strategies were found to be equally effective and safe, indicating that the current recommendation of minimal handling for these infants should be reconsidered. Furthermore, the findings suggest that this treatment can safely be continued, which is in line with previous evidence of positive effects for infants to be nursed with close bodily contact as well as changing positions in bed.

## Acknowledgements

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## **Trial registration**

The trial was retrospectively registered at ClinicalTrials.gov NCT03575091 on 2 July 2018 https://clinicaltrials.gov/ct2/show/NCT03575091?term=NCT0357 5091&rank=1

## Abbreviations

ALRI, acute lower respiratory tract infection;

CF, cystic fibrosis; CPAP, continuous positive airway pressure; HFNC, high flow nasal cannula; HR, hazard ratio; ICU, Intensive Care Unit; IQR, interquartile range; RSV, respiratory syncytial virus;

WHO, World Health Organization.

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