

Can Daily Drills of Ventilation Corrective Steps Improve Mask Ventilation of Preterm Infants in the Delivery Room? – A Randomized Controlled Trial

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Abstract

Objective: To determine whether brief daily simulation drills of the MR SOPA ventilation corrective steps improve mask ventilation during delivery (DR) room resuscitation of preterm infants compared with self-directed review of the neonatal resuscitation program (NRP) algorithm.

Methods: This prospective parallel-group randomized controlled trial was conducted between May 2015 and September 2016 in three phases (2-month baseline observations, 3-months intervention period, and 2-month after trial period). Healthcare professionals were randomized 1:1 to either daily MR SOPA simulation drills or self-directed review of the NRP algorithm during the intervention period. DR resuscitations of preterm infants <33 weeks' gestation were recorded before and after the educational intervention using a concealed respiratory function monitor and video recording. The primary outcome was mask leak during PPV in the DR. Secondary outcomes included respiratory parameters, DR interventions, neonatal outcomes, and performance of ventilation corrective steps.

Results:

Seventy healthcare professionals were randomized to daily MR SOPA simulation drills (n=35) or self-directed review (n=35). Fifty preterm infants were included in the final analysis: 24 during the pre-intervention phase and 26 during the post-intervention phase (14 in the MR SOPA group and 12 in the self-directed review group). A total of 5,586 PPV inflations were analyzed. During the post-intervention phase, median (IQR) mask leak was lower with daily MR SOPA simulation drills than with self-directed review (32% [15–58] vs. 36% [20–60]; P=0.001).

Conclusions: Brief, daily MR SOPA simulation drills reduced mask leak during PPV in actual DR resuscitations of preterm infants compared with self-directed review. Focused, repeated simulation training can translate into measurable improvements in clinical mask ventilation performance.

Trial Registration: ClinicalTrials.gov NCT02375230.

Background

Effective positive-pressure ventilation (PPV) is the cornerstone of neonatal resuscitation and the single most important intervention for newborn infants who fail to establish spontaneous breathing at birth^{1,2}. Successful lung aeration initiates the transition from fetal to neonatal life by reducing pulmonary vascular resistance, increasing pulmonary blood flow, and improving oxygen delivery to vital organs^{3–5}. Conversely, delayed or ineffective mask PPV prolongs hypoxia, delays cardiovascular transition, and remains a major contributor to neonatal morbidity and mortality^{1,2}. Delivering effective mask PPV is therefore one of the most important technical skills required of healthcare providers attending newborn deliveries^{1,2}.

Despite regular neonatal resuscitation training and certification, providing effective mask PPV remains technically challenging^{6–9}. Studies using respiratory function monitoring (RFM) have consistently demonstrated that mask leak and airway obstruction occur frequently during mask PPV in the delivery room (DR)^{10–15}, even among experienced providers, resulting in inadequate tidal volume (V_T) delivery and potentially delaying effective lung aeration^{11,16,17}. Furthermore, clinicians receive little objective feedback regarding the quality of mask PPV, making ineffective PPV difficult to recognize in real time^{18,19}. These findings highlight an important gap between learning the principles of neonatal resuscitation and consistently delivering effective ventilation in clinical practice.

Recognizing that ineffective ventilation is the most common reversible cause of persistent bradycardia during neonatal resuscitation, the Neonatal Resuscitation Program (NRP) introduced the MR SOPA sequence of ventilation corrective steps (Mask adjustment, Reposition airway, Suction mouth and nose, Open mouth, Pressure increase, and Airway alternative)^{20,21}. This structured approach provides clinicians with a systematic method to identify and correct mask leak and airway obstruction before progressing to more invasive airway interventions. Although MR SOPA as part of ventilation corrective steps is now universally taught during neonatal resuscitation training, evidence demonstrating that repeated practice of these corrective steps improves performance during actual neonatal resuscitation remains limited²².

Simulation-based education has become an integral component of neonatal resuscitation training and has evolved beyond traditional certification courses toward concepts such as deliberate practice, mastery learning, and low-dose, high-frequency training. These educational strategies aim to improve skill acquisition, retention, and performance. However, simulation training is only valuable if it changes what clinicians do when caring for patients. Most studies evaluating neonatal simulation have focused on knowledge acquisition, confidence, or performance within simulated environments, whereas relatively few have examined whether simulation training translates into measurable improvements in actual DR clinical care^{23,24}. Whether repeated, focused practice of MR SOPA improves mask PPV during actual DR resuscitation therefore remains unknown.

We conducted a prospective randomized controlled trial to determine whether brief daily MR SOPA simulation drills improved mask PPV during DR resuscitation of preterm infants. We hypothesized that repeated, focused simulation training would improve mask ventilation performance, resulting in reduced mask leak during mask PPV compared with self-directed review of the neonatal resuscitation algorithm.

Methods

Study design and setting

This prospective, parallel-group randomized controlled trial evaluated whether brief daily simulation-based MR SOPA drills improved mask ventilation performance during DR resuscitation of preterm

infants. The study was conducted in the Neonatal Intensive Care Unit (NICU) at the Royal Alexandra Hospital, Edmonton, Alberta, Canada, a regional tertiary perinatal center.

Participants

All members of the hospital's Resuscitation Stabilization Team (RST), including neonatal fellows, neonatal nurse practitioners, respiratory therapists, and neonatal transport nurses, were eligible to participate. Participants were required to hold current NRP provider certification.

The study evaluated mask PPV of preterm infants born at < 33 weeks' gestation at birth. Infants with major congenital anomalies affecting cardiorespiratory transition or airway management, including congenital diaphragmatic hernia, complex congenital heart disease, and Pierre Robin sequence, were excluded.

Because RFM and video recordings were obtained during emergency neonatal resuscitation, a deferred parental consent process was approved by the Research Ethics Board. Parents were approached during the infants NICU admission for consent to use the recorded study data.

Randomization and masking

Participants were randomly assigned in a 1:1 ratio to either daily MR SOPA simulation drills (intervention group) or self-directed review of the NRP algorithm (control group). Randomization was computer-generated using permuted blocks of variable size (2–4) and stratified according to professional role (neonatal fellow, nurse practitioner, respiratory therapist, or transport nurse).

Because of the educational nature of the intervention, participants could not be blinded to group allocation. However, investigators responsible for data collection, respiratory function analysis, and outcome assessment remained blinded throughout the study.

Study intervention

The study consisted of three sequential phases: a pre-intervention baseline phase, an intervention phase, and a post-intervention evaluation phase.

Pre-intervention phase

Before the educational intervention, DR resuscitations of eligible preterm infants were recorded to establish baseline mask ventilation performance for a duration of two months. RFM continuously recorded V_T , airway pressure, gas flow, and expired carbon dioxide using a respiratory profile monitor (NM3, Philips Healthcare, Markham, Canada)²⁵.

The monitor remained concealed from the clinical team throughout all resuscitations to avoid influencing clinical management. These recordings were used to establish baseline measures of mask leak, airway obstruction, ventilation characteristics, and the frequency of ventilation corrective maneuvers.

Intervention phase

Participants assigned to the intervention group completed brief, instructor-led MR SOPA simulation drills at the beginning of each clinical shift (approximately five minutes). Simulations were conducted using the NeoNatalie newborn simulator (Laerdal Medical, Stavanger, Norway) and followed a standardized scenario based on the contemporaneous Neonatal Resuscitation Program curriculum. The scenario required participants to initiate positive-pressure ventilation, recognize ineffective ventilation, systematically perform the MR SOPA corrective sequence, confirm effective ventilation by demonstrating chest movement and bilateral breath sounds, and continue ventilation before reassessing heart rate. Standardized instructor feedback was provided following each session.

Participants allocated to the control group completed five minutes of self-directed review of the current NRP algorithm and MR SOPA cue card at the beginning of each clinical shift. Educators were available to answer questions but did not provide structured simulation training. At the end of the three months intervention period, participants completed a questionnaire evaluating satisfaction, perceived educational value, confidence, and preparedness using a five-point Likert scale.

Post-intervention phase

Following completion of the educational intervention, DR resuscitations of eligible preterm infants were recorded using identical equipment and procedures for two months. Respiratory variables and clinical outcomes were collected using the same methodology as during the baseline phase.

Delivery room management

All newborn resuscitations were performed according to the contemporaneous NRP recommendations²⁶. Respiratory support was provided using a T-piece resuscitator with a fresh gas flow of 10 L/min, an initial peak inspiratory pressure of 24 cmH₂O, and a positive end-expiratory pressure of 6 cmH₂O. Initial oxygen concentration was 30% as per local DR practice during the study period. RFM remained concealed from the resuscitation team throughout the study. Criteria for endotracheal intubation included persistent bradycardia despite effective positive-pressure ventilation, persistent apnea, or the need for chest compressions.

Outcomes

The primary outcome was mask leak during PPV in the DR. Secondary outcomes included V_T , minute ventilation, airway pressures, DR interventions, respiratory support following NICU admission, and neonatal morbidities including chronic lung disease, patent ductus arteriosus, necrotizing enterocolitis, severe intraventricular hemorrhage or periventricular leukomalacia, retinopathy of prematurity, and death before hospital discharge. Video recordings were independently reviewed to assess adherence to correct mask application and appropriate performance of the MR SOPA corrective sequence. Demographics and clinical characteristics of preterm infants and birth as well as participants were also compared.

Statistical analysis

Continuous variables were summarized as mean (standard deviation) or median (interquartile range), depending on data distribution. Categorical variables are presented as counts and percentages. Comparisons between study groups were performed using parametric or non-parametric statistical tests according to data distribution. Relative risks with 95% confidence intervals were calculated for categorical outcomes, whereas continuous variables are presented as mean or median differences with corresponding 95% confidence intervals where appropriate. Statistical significance was defined as a two-sided P value < 0.05.

Results

Study participants

The study was conducted between May 2015 and September 2016 in three phases (2-month baseline observations, 3-months intervention period, and 2-month after trial period) and comprised three sequential phases: a pre-intervention baseline phase, an educational intervention phase, and a post-intervention evaluation phase (Fig. 1).

A total of 71 members of the resuscitation team were assessed for eligibility. Seventy consented and were randomized: 35 to daily MR SOPA simulation drills and 35 to self-directed review of the neonatal resuscitation algorithm. Seven did not complete their assigned intervention. Participant flow and reasons for noncompletion are shown in Fig. 1. During the study period, 55 eligible preterm infants had delivery room respiratory function monitor recordings. Five were excluded because the respiratory function monitor files could not be reviewed for technical reasons. The final analysis included 50 infants: 24 in the pre-intervention phase and 26 in the post-intervention phase (14 in the MR SOPA group and 12 in the self-directed review group). Baseline demographic characteristics are shown in Table 1. Baseline characteristics are shown in Table 1.

Table 1
Demographics of enrolled infants and distribution of RST-team member

Gestational Age (weeks)*	Pre intervention phase	MR. SOPA Drills n = 14	Self-directed revision n = 12	p value
	n = 24			
	28 [25–30]	26 [24–27]	27 [26–29]	NS
Birth weight (grams)*	930 [750–1470]	857[700–1030]	955 [855–1275]	NS
Female (%)	12 (50)	6 (42)	4 (33)	NS
Vaginal Delivery (%)	8 (33)	8 (57)	2 (16)	NS
Antenatal Steroids (%)	19 (79)	13 (92)	8 (66)	NS
Magnesium Sulphate (%)	16 (66)	11 (78)	5 (41)	NS
Delayed Cord Clamp > 20 seconds	12 (50)	10 (71)	5 (41)	NS
Data are presented as n (%), unless stated otherwise *Median [Inter Quartile Range]; NS = Not significant				

Primary outcome

A total of 5,586 PPV inflations were analyzed, including 3,641 during the pre-intervention phase and 1,945 during the post-intervention phase.

Overall, median (IQR) mask leak was 29% (13–49) during the pre-intervention phase and 34% (18–60) following the educational intervention (P = 0.001). Within the post-intervention phase, participants who completed daily MR SOPA simulation drills demonstrated significantly lower mask leak than those assigned to self-directed review (32% [15–58] vs. 36% [20–60]; P = 0.001) (Fig. 2, and Table 2).

Table 2
Primary and secondary outcome outcomes

	Pre-intervention phase n = 24	MR SOPA Drills n = 14	Self-directed revision n = 12	p- value
Respiratory Parameter				
Mask leak (%)*	28.5 [13- 48.8]	32 [14.5– 57.6]	36 [19.5–60]	0.001
Minute ventilation (L/kg/min)**	102 (82)	16 (16)	71 (73)	NS
Tidal volume (mL/kg)**	6.7 (4)	8(4)	6 (1.6)	NS
Peak inspiratory pressure (mmHg)**	19 (9)	17 (8)	17(10)	NS
Positive End Expiratory Pressure (mmHg)**	7.4 (1.4)	7.6 (1.6)	7(2)	NS
Delivery room Outcome				
Apgar at 1 and 5 minutes**	7 (2)	6 (2)	7(2)	NS
Intubation in delivery room	4 (16)	3 (21)	2 (16)	NS
Surfactant in delivery room	3 (12)	2 (15)	0	NS
Chest compression	1 (4)	0	0	NS
Epinephrine	0	0	0	NS
Volume expanders	1(4)	1 (7)	0	NS
NICU outcomes				
Intubation in first 72 hours	8 (33)	7 (50)	1 (8)	NS
Surfactant	8 (33)	4 (28)	2 (16)	NS
Pneumothorax	0	2 (14)	1(8)	NS
Postnatal steroids	1 (4)	1 (7)	0	NS
Total duration of mechanical ventilation* (h)	10 [2–50]	26 [16–34]	11[6–25]	NS
Total duration of non-invasive ventilation* (h)	37[2.5–52]	34 [20–48]	20 [7–50]	NS
Chronic lung disease	3 (13)	1 (7)	1 (8)	NS
Medically treated Patent Ductus Arteriosus	3 (13)	5 (36)	3 (25)	NS
Data are presented as n (%), unless stated otherwise *Median [Inter Quartile Range] **Mean (Standard Deviation); PPV=Positive Pressure Ventilation, NS = Not significant				

	Pre-intervention phase n = 24	MR SOPA Drills n = 14	Self-directed revision n = 12	p- value
Respiratory Parameter				
Necrotizing enterocolitis	6 (25)	0	1 (8)	NS
Retinopathy of prematurity II-III	2 (8)	1 (7)	1 (8)	NS
Intraventricular Hemorrhage Stage III-IV	2 (8)	1 (7)	1 (8)	NS
Death before discharge	1 (4)	3(21)	1 (8)	NS
Video analysis of the PPV technique				
Correct application of mask**	11 (45)	6 (42)	4(33)	NS
Correct sequence of MR. SOPA in response to bradycardia and hypoxia	2/9 (22%)	1/4 (25%)	3/8 (37%)	NS
Data are presented as n (%), unless stated otherwise *Median [Inter Quartile Range] **Mean (Standard Deviation); PPV=Positive Pressure Ventilation, NS = Not significant				

Respiratory performance

No statistically significant differences were observed in respiratory parameters between study groups (Table 2). Although participants receiving daily MR SOPA simulation drills demonstrated numerically higher delivered V_T than those in the self-directed review group, this difference did not reach statistical significance.

Delivery room and neonatal outcomes

DR interventions, including intubation, surfactant administration, chest compressions, and medication use, were similar between study groups (Table 2).

Likewise, no statistically significant differences were observed in neonatal outcomes, including duration of respiratory support, chronic lung disease, patent ductus arteriosus, necrotizing enterocolitis, severe intraventricular hemorrhage or periventricular leukomalacia, retinopathy of prematurity, or mortality before hospital discharge (Table 2).

Video analysis

Video recordings were available for 37 resuscitations and were independently reviewed to assess adherence to mask ventilation technique. No significant differences were observed in correct mask application, assessment of chest movement and bilateral breath sounds, or adherence to the MR SOPA corrective sequence between study groups (Table 2).

Participant evaluation

Training evaluations were completed by 23 participants (32%). Overall satisfaction with both educational interventions was high (Table 3). Participants assigned to daily MR SOPA simulation drills (n = 11) more frequently reported that the intervention improved their practical neonatal resuscitation skills (81% vs. 25%; P = 0.03), positively influenced their clinical practice (81% vs. 8%; P = 0.01), and increased confidence attending neonatal resuscitations (72% vs. 25%; P = 0.03), when compared with the control group (n = 12). Self-reported confidence in providing respiratory support during neonatal resuscitation was not significantly different between groups.

Table 3
Training evaluations by the study participants (response rate 33%)

Satisfaction with training	MR. SOPA Drills n = 11	Self-directed revision n = 12	p-value
	11 (100)	10 (83)	NS
Training was fit for the learners learning style	7 (63)	5 (41)	NS
Training improved trainees' knowledge regarding neonatal resuscitation and ventilation	4 (36)	3 (25)	NS
Training improved trainees' practical skills regarding neonatal resuscitation and ventilation	9 (81)	3 (25)	0.03
Training was effective in preparing for neonatal resuscitation and ventilation	9 (81)	5 (41)	NS
Training would positively impact overall practice	9 (81)	1 (8)	0.01
Feel more confident in delivering respiratory support during neonatal resuscitation after training	5 (45)	2 (16)	NS
Feel more confident in attending neonatal resuscitation after training	8 (72)	3 (25)	0.03
Data are presented as n (%); NS = Not significant			

Discussion

The principal finding of this randomized controlled trial is that brief, daily MR SOPA simulation drills improved mask PPV performance during DR resuscitation of preterm infants. More importantly, our findings demonstrate that focused simulation training can translate into measurable improvements in clinical performance beyond the simulation environment. While simulation has become an integral component of neonatal resuscitation education, relatively few studies have shown that simulation-based educational interventions improve care delivered to real patients^{23,24}. Our findings therefore provide evidence that structured, repetitive practice of ventilation corrective steps can influence clinical performance during neonatal resuscitation.

Effective PPV remains the cornerstone of neonatal resuscitation^{1,2}. Successful lung aeration initiates the physiological transition from fetal to neonatal life and is the primary intervention for newborn infants who fail to establish adequate breathing after birth³⁻⁵. Despite universal training in neonatal resuscitation, ineffective mask ventilation remains common, even among experienced providers, with mask leak and airway obstruction frequently compromising V_T delivery^{10-15,17}.

Our findings suggest that repeated practice of a structured ventilation corrective sequence may improve the quality of mask PPV delivered during clinical resuscitation. Although the absolute reduction in mask leak was modest, improvements in technical performance during the first minutes after birth may have important implications because effective ventilation underpins every subsequent intervention during neonatal resuscitation⁹.

Our findings should also be interpreted within the broader context of simulation-based medical education. Most simulation studies evaluate learner satisfaction, knowledge acquisition, confidence, or performance during simulated scenarios^{27,28}. Although these outcomes are important, they represent intermediate educational endpoints rather than improvements in patient care. Simulation training is only valuable if it changes what clinicians do when caring for patients^{23,24}. By demonstrating improved mask PPV during actual DR resuscitations, this trial moves beyond simulation performance and provides evidence that focused educational interventions can influence real-world clinical practice.

Several factors may explain the observed improvement in mask PPV performance. Repeated exposure to a standardized approach to ventilation corrective steps likely reinforced psychomotor skills, improved recognition of ineffective ventilation, and promoted a more systematic response to mask leak and airway obstruction. Brief, frequent practice may also facilitate retention of procedural skills between formal NRP recertification courses. Although the educational concepts of deliberate practice and low-dose, high-frequency training were not explicitly incorporated into the original study design, our findings are consistent with these contemporary educational principles and support their application within neonatal resuscitation training.

Interestingly, improvements in mask PPV performance were not accompanied by differences in respiratory or neonatal clinical outcomes²⁹. This finding should be interpreted cautiously. The study was designed and powered to detect differences in mask leaks rather than patient-centered clinical outcomes. Consequently, the absence of statistically significant differences in neonatal morbidity or mortality should not be interpreted as evidence that improving mask ventilation has no clinical benefit. Larger multicenter studies would be required to determine whether improvements in ventilation quality translate into improved neonatal outcomes.

One practical consideration highlighted by our study is the feasibility of implementing frequent simulation training within busy clinical environments. Although participants viewed the intervention positively and reported improvements in practical skills and preparedness, conducting instructor-led simulation sessions at every shift change required dedicated faculty time and protected clinical

resources. Future educational programs should therefore balance educational benefit with the feasibility and sustainability of repeated training and explore innovative approaches that integrate brief simulation training into routine clinical workflows.

Limitations

Several limitations should be considered when interpreting our findings. First, this was a single-center study, which may limit generalizability to other neonatal units with different staffing models or educational practices. Second, the study was powered to detect differences in mask leak and was not designed to evaluate neonatal clinical outcomes. Third, because of the educational nature of the intervention, participant blinding was not possible, introducing the potential for performance bias. In addition, contamination between study groups may have occurred because participants worked within the same clinical environment and could have shared educational experiences despite randomization.

The primary outcome was derived from repeated inflation-level measurements obtained during clinical resuscitations. Because individual inflations within the same resuscitation are not statistically independent, these findings should be interpreted within the context of the original study design and statistical analysis. Finally, the study was conducted using the Neonatal Resuscitation Program recommendations available during 2015–2016. Although subsequent guideline updates have occurred, the fundamental principles of effective mask ventilation and the MR SOPA corrective sequence remain unchanged, supporting the ongoing clinical relevance of these findings.

Conclusion

Brief, daily MR SOPA simulation drills improved mask PPV performance during DR resuscitation of preterm infants. More broadly, our findings support the principle that simulation-based education should be evaluated not by performance during simulation itself, but by its ability to improve clinical performance when caring for patients. Educational interventions that successfully translate into better DR care have the potential to improve the stabilization of newborn infants during the critical transition at birth.

Declarations

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No reprints requested

Conflict of interest statement: None.

Ethical approval: The trial was reviewed and approved by an independent Human Research Ethics Board at the University of Alberta (Pro00054147) and prospectively registered at ClinicalTrials.gov (NCT02375230, registered on 24 Feb 2015) and is reported using the CONSORT guideline.

Consent to participate: Written informed consent was obtained from all participating healthcare providers before enrolment and from parents/ legally authorized representatives of subjects who are under 16, which were the enrolled infants. Consent to Participate was freely-given and informed consent was actively obtained from all participants.

Consent to publish: not applicable.

Data Availability Statement: The data supporting the findings of this study are presented in the manuscript. The underlying data are available from the corresponding author upon reasonable request.

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Figures

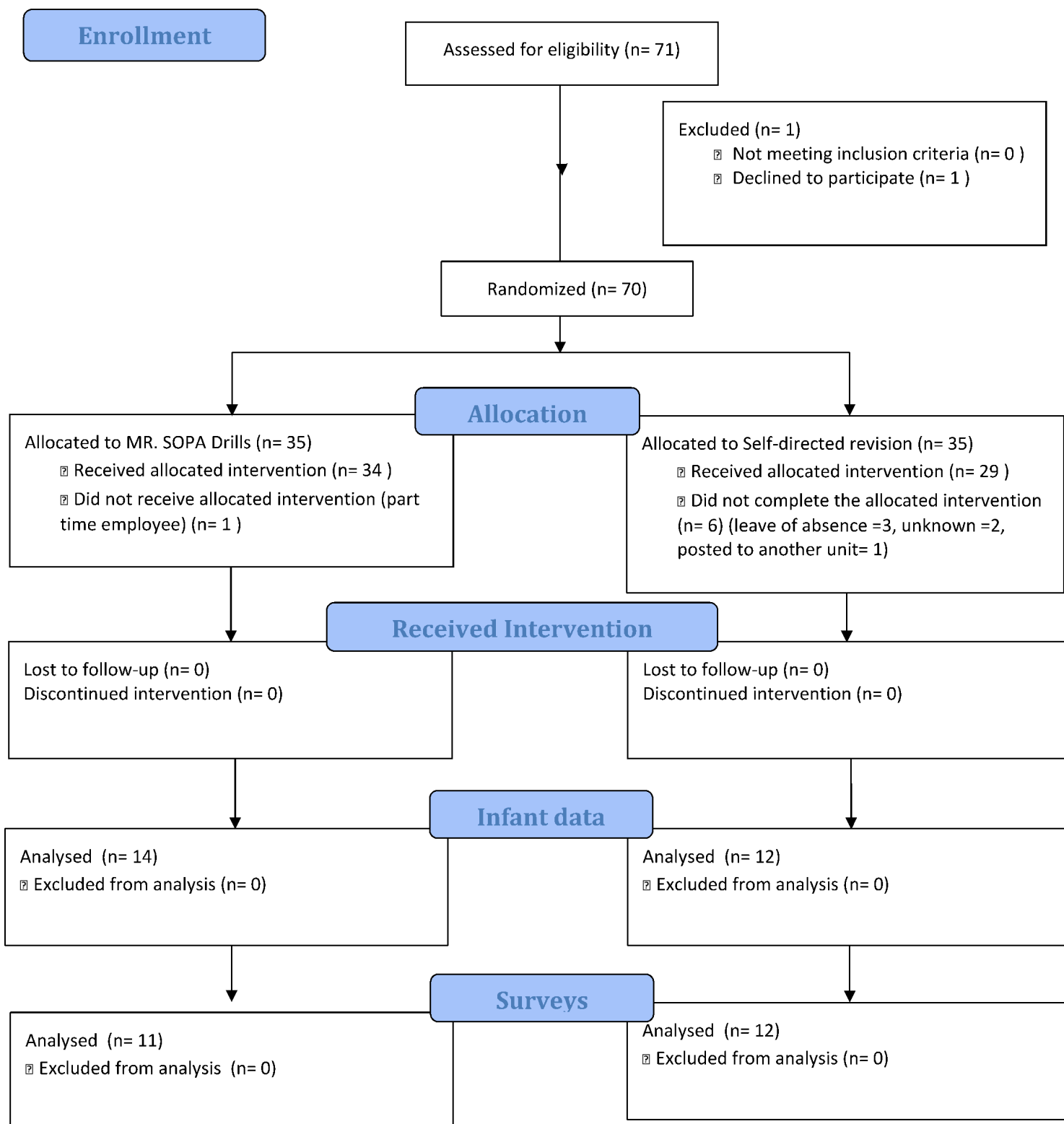


Figure 1

CONSORT Flow Diagram of Healthcare Professionals

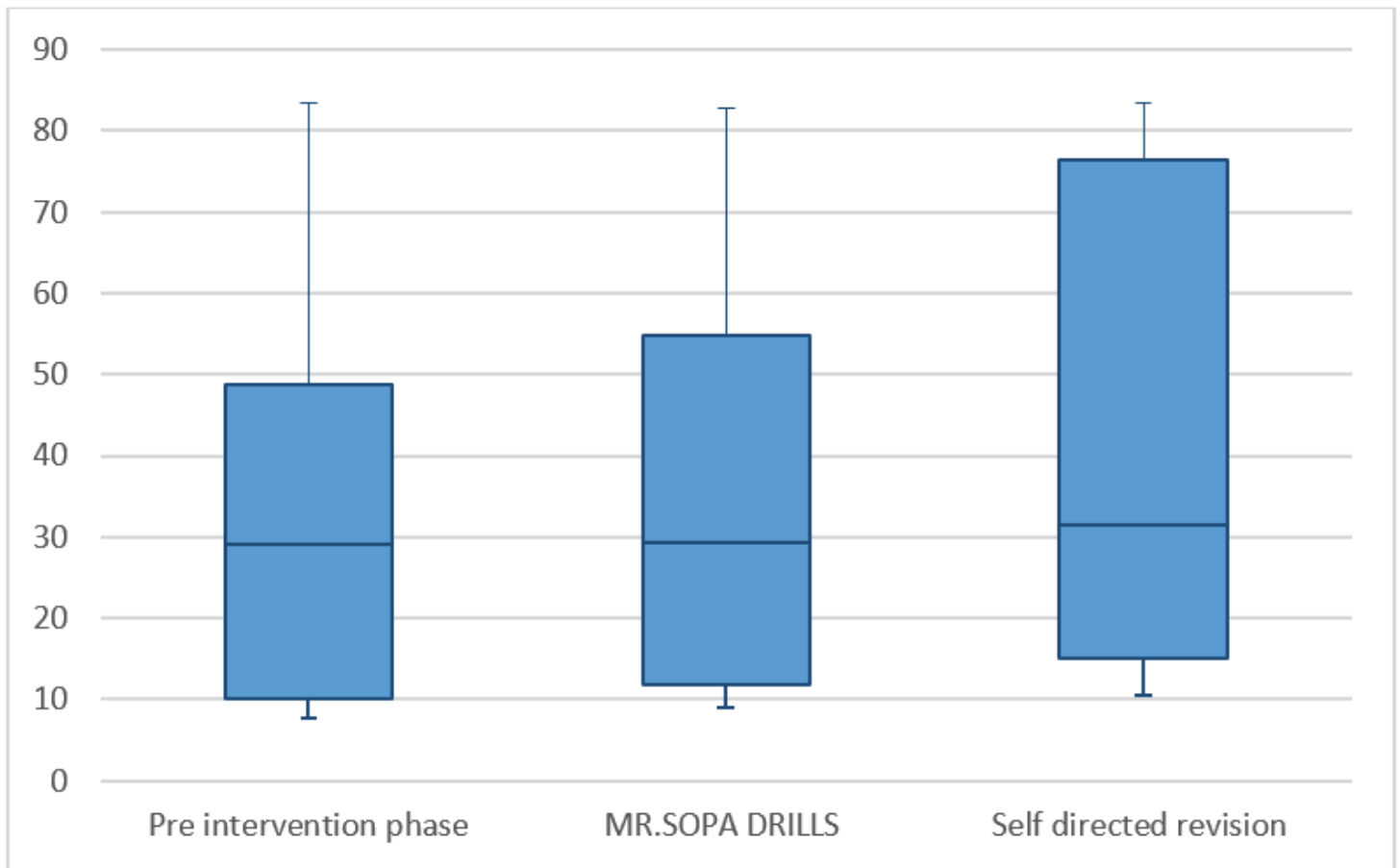


Figure 2

Comparison of mask leak during pre-intervention phase and post-intervention phases (divided into MR. SOPA-Drill group and Self-direct revision group). The Y-Axis represents mask leak in percentage and the X-Axis mask leak during pre-intervention and post-intervention phases. The box plots show median values (solid bar), IQR (margins of box) and 95% Confidence Interval (* $P < 0.05$ intervention vs controls).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [CONSORT2010Checklist1.doc](#)
- [KnowlegdecheckDISPPLAY.doc](#)
- [Scenariodisplaycard.doc](#)
- [ControllIntervention.pdf](#)
- [MRSOPAInterventioneducatorCard.doc](#)
- [MRSOPADRILLprotocolfinal.doc](#)