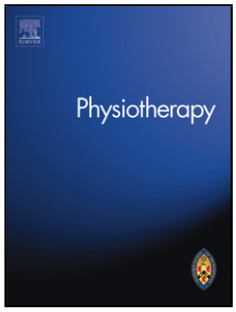

Title: Clinical effects of on-call physiotherapy in mechanically ventilated children: A randomised crossover trial

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PII: S0031-9406(15)00009-7
DOI: http://dx.doi.org/doi:10.1016/j.physio.2014.12.004
Reference: PHYST 804

To appear in: *Physiotherapy*

Received date: 13-5-2014
Accepted date: 27-12-2014

Please cite this article as: Shannon H, Stocks J, Gregson RK, Dunne C, Peters MJ, Main E, Clinical effects of on-call physiotherapy in mechanically ventilated children: a randomised crossover trial, *Physiotherapy* (2015), http://dx.doi.org/10.1016/j.physio.2014.12.004

Title: Clinical effects of on-call physiotherapy in mechanically ventilated children: a randomised crossover trial

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Word Count: 3 230 words

ABSTRACT

Objectives: The study investigated treatment outcomes when respiratory physiotherapy was delivered by non-respiratory on-call physiotherapists, compared with specialist respiratory physiotherapists.

Design: Prospective, randomised crossover trial.

Setting: Paediatric, tertiary care hospital in the United Kingdom.

Participants: Mechanically ventilated children requiring two physiotherapy interventions during a single day (independently assessed) were eligible. Twenty two physiotherapists (10 non-respiratory), and 93 patients were recruited.

Interventions: Patients received one treatment from a non-respiratory physiotherapist and a second from a respiratory physiotherapist, in a randomised order. Treatments were individualised to the patients' needs, often including re-positioning followed by manual lung inflations, chest wall vibrations and endotracheal suction.

Main outcome measures: The primary outcome was respiratory compliance. Secondary outcomes included adverse physiological events and clinically important respiratory changes (according to an *a priori* definition).

Results: Treatments delivered to 63 patients were analysed. There were significant improvements to respiratory compliance (mean increase [95% confidence intervals], 0.07 and 0.08ml/cmH_2O^{-1}·kg^{-1} [0.01 to 0.14 and 0.04 to 0.13], $p<0.01$, for on-call and respiratory physiotherapists' treatments respectively). Case-by-case, there were fewer clinically important improvements following non-respiratory physiotherapists' treatments compared with the respiratory physiotherapists' (n=27 [43%] versus n=40 [63%], p=0.03). Eleven adverse events occurred, eight following non-respiratory physiotherapists' treatments.

Conclusions: Significant disparities exist in treatment outcomes when patients are treated by non-respiratory on-call physiotherapists, compared with specialist respiratory physiotherapists. There is an urgent need for targeted training strategies, or alternative service delivery models, to be explored. This will address the quality of respiratory physiotherapy services, both during and outside of normal working hours.

Clinical Trial Registration number: Clinicaltrials.gov, NCT01999426.

Key-words: After-hours care, Acute Respiratory, Pediatric Intensive Care Units, Physiotherapy Specialty

INTRODUCTION

Increased mortality for NHS patients during out-of-hours care has been reported within many clinical settings, including both paediatric and adult patient populations [1-4]. While significant steps have been taken to reduce time-dependent discrepancies in medical care, the pattern of respiratory physiotherapy service provision has remained largely unchanged. In the United Kingdom (as with other countries), a common approach to providing emergency on-call cover is for physiotherapists who ordinarily work in other clinical areas to undertake respiratory on-call duties in intensive care. Treatments that aim to optimise ventilation and remove excess secretions are not without risk. They often involve disconnections between the patient and mechanical ventilator, manual lung inflations, manual techniques and endotracheal suction [5-7]. The safety and efficacy of such treatment components, as well as decisions about the timing and duration of interventions, may be affected by the level of expertise and frequency of exposure to intensive care for the physiotherapist providing the intervention.

The 2009 report from the National Confidential Enquiry into Patient Outcome and Death found instances of poor decision-making and a lack of input from senior staff, particularly in the evenings and at night, and these were highlighted in a series of retrospectively reviewed case studies where advisors felt that the lack of senior input had been a direct contributory factor in the death of a patient [8]. This is supported by other evidence suggesting that level of staff expertise may be important to patient outcome [9,10]. While there is no suggestion that these are directly related to physiotherapy care, independent research has shown that physiotherapy competence is vital if adverse events are to be avoided [11].

We describe a prospective, randomised crossover trial designed to test the following null hypothesis: there are no clinically significant differences to respiratory outcomes when patients are treated by non-respiratory on-call physiotherapists, compared with interventions delivered by specialist respiratory physiotherapists.

METHODS

Study design and participants

The trial is presented according to Consolidated Standards of Reporting Trials guidelines [12]. The study was a prospective, randomised crossover trial. This is the most appropriate design given the heterogeneity of patients in intensive care because it controls for variability associated with diverse clinical circumstances [13]. Carry-over effects from one physiotherapy treatment to the next were anticipated to be relatively small. Ethical approval was granted by the UCL, Institute of Child Health and Great Ormond Street Hospital for Children NHS Foundation Trust ethics committee (Reference number 06/Q0508/56). The study is registered with Clinicaltrials.gov (NCT01999426). Written, informed consent was gained from the parents/guardians of recruited children, and from participating physiotherapists. No changes to the methods were made after trial commencement.

Inclusion criteria for patients were children (aged from birth to 16 years) who were mechanically ventilated, and whose ventilatory requirements were relatively stable. Patients were recruited if they were likely to require at least two physiotherapy treatments in a single day, and were deeply sedated or pharmacologically paralysed. This was to reduce the likelihood of artefactual confounders in our measurements of respiratory mechanics. Clinical indications for physiotherapy were assessed by an independent, senior respiratory physiotherapist. Indications included consolidation or atelectasis on chest radiograph, added

or decreased breath sounds on auscultation, increased ventilatory requirements and/or deteriorating blood gases. Inclusion criteria were deliberately broad to encompass a similar patient population to those whom physiotherapists would treat when on-call. Patients at risk of haemorrhage, rib fracture or other contraindications to receiving manual techniques were excluded from the study. Patients with an endotracheal tube leak greater than 20% were excluded (either prospectively or retrospectively), since this is associated with inconsistent tidal volume delivery and significant overestimation of respiratory compliance and resistance [14].

Non-respiratory on-call physiotherapists (NRP) and specialist respiratory physiotherapists (SRP) were recruited to the study. The NRP were physiotherapists, of band 6 grade (senior physiotherapists, who have normally specialised within a specific area of physiotherapy) or higher, with a minimum of three years post-qualifying experience, who specialised in non-respiratory areas of paediatric physiotherapy. Staff undertaking clinical rotations as part of their training, who had not worked on the respiratory wards for at least 3 months prior to the study, were also classed as NRP. The SRPs were those physiotherapists who were currently working in respiratory care and had been doing so for at least 3 months prior to recruitment, were of band 6 grade or higher, and had a minimum of three years post-qualifying experience.

The specialist paediatric hospital in which the study took place is a tertiary care centre with one of the largest intensive care units for children in the United Kingdom and Europe. It encompasses an 18 bedded cardiac-specialist intensive care unit and 12 bedded general intensive care unit. The hospital's physiotherapy department employs approximately 30 clinical physiotherapists. Physiotherapists undertake approximately one weekend or night on-call duty per month.

Randomisation and masking

Physiotherapists were assigned identification numbers on recruitment. A computerised random numbers generator, in Microsoft Excel (2007, version 12), was used to determine the allocated sequence of events (i.e. NRP or SRP as the first treatment), and the selection of individual physiotherapists undertaking each treatment. The researcher recruited all participants, both patients and physiotherapists. No masking was undertaken for this study. Physiological data, using the equipment described, were recorded electronically and automatically, with direct transfer to the analysis software. There was negligible risk of transcription error or researcher bias. A random sample of patient data were dually analysed by a second, independent researcher who was blinded to the nature of the intervention, to further increase confidence in the accuracy of results.

Procedures

Recruited patients received two physiotherapy treatments during a single day, one delivered by an NRP and another delivered by an SRP, in a randomised order. The first selected physiotherapist (either NRP or SRP) assessed the patient and confirmed whether a treatment was clinically indicated. If a treatment was deemed necessary, the $NICO_2$® Respiratory Profile Monitor (Philips Respironics, Wallingford, CT, USA), was inserted between the patient's endotracheal tube and ventilator circuit. Baseline data were recorded for at least 15 minutes prior to the physiotherapy treatment. No instructions were given concerning the use or order of any specific treatment components, the physiotherapists applied treatments according to their own clinical judgment. After physiotherapy, the $NICO_2$® remained in place for at least 30 minutes in the absence of any subsequent medical or nursing intervention (e.g. patient

repositioning by nursing staff or ventilation alterations). Adverse physiological events occurring during or up to 30 minutes after treatments were recorded.

Where a second treatment was indicated, the protocol was repeated following an interval of at least 3 hours. If an SRP had treated the patient in the morning, an NRP treated in the afternoon, or vice versa. If the first physiotherapy intervention resulted in complete resolution of atelectasis, or removal of copious secretions so that a cross-over treatment was not indicated, a second treatment would not take place, and the patient's data were excluded from analysis.

The sample size was determined using the known normal variability of respiratory compliance (C_{rs}), based upon data collected from 33 children during a period of mechanical ventilation with no intervention [15]. A sample size of 58 patients would be required to detect a change in C_{rs} of 7%, with 90% power. Given the high anticipated attrition between identification of subjects and full data collection, it was necessary to aim for recruitment of 150% of the calculated sample size.

Outcome measures

Primary outcome: The primary outcome measure was change in C_{rs}, measured in $ml/cmH_2O^{-1} \cdot kg^{-1}$. Compliance represents the elasticity of the respiratory system, being a measure of volume change per unit of pressure applied. An increase in C_{rs} might reflect improved lung aeration following secretion removal [16].

Secondary outcomes: Secondary outcomes were adverse physiological events, and clinically important changes to respiratory resistance, a decrease in which would reflect reduced airway

obstruction, expired tidal volume or peak inspiratory pressure, depending upon mode of ventilation (tidal volume for patients ventilated in pressure-controlled modes, peak inspiratory pressure for those on pre-set volume ventilation modes). Adverse physiological events were defined as clinically significant alterations in respiratory, haemodynamic, metabolic or intracranial parameters necessitating a rescue intervention [11]. A rescue intervention might range from increasing sedation or ventilatory support to cardiopulmonary resuscitation, depending upon the nature and severity of the event. No attempts were made to identify a causal relationship between physiotherapy and adverse event, neither is this suggested.

Statistical analysis

All data were downloaded into SPSS vs. 18 prior to analysis. Normality of data was determined using a Kolmogorov-Smirnov test, with supporting histograms. A non-significant result suggested normality of distribution. Minute-by-minute data were aggregated into three 15-minute epochs, comprising one epoch immediately prior to treatment (baseline) and two immediately after treatment. Percentage changes from baseline in respiratory outcomes were calculated for the two 15 minute epochs after treatment. A paired samples t-test was used to compare post-treatment C_{rs} and respiratory resistance between NRP and SRP treatments.

An *a priori* definition for clinically important changes to physiological outcomes was developed. Within-subject changes in excess of the 95% limits of agreement of normal variability were assumed to be clinically important [15]. This resulted in an improvement being defined as an increase in C_{rs} and tidal volume or a reduction in respiratory resistance which exceeded 7%, 5.5%, and 15% respectively. Conversely, a clinically important deterioration was defined as a decrease in C_{rs} and tidal volume or an increase in respiratory resistance exceeding these limits of normal variability.

One-way repeated measures ANOVA was used to compare the effects of NRP and SRP physiotherapy treatments on respiratory outcomes, provided data were normally distributed. Since respiratory resistance was non-normally distributed, values were log-transformed for the purposes of statistical analysis. Data were then compared on a case-by-case basis using Fisher's two-tailed exact test to compare outcomes for NRP and SRP treatments.

RESULTS

Recruitment and participant flow

Ninety three children were recruited to the study between 2008 and 2010 (Figure 1). Paired data were successfully collected in 63 (68%) of these patients, aged between 3 days and 16 years (Table 1). Most patients were nasotracheally intubated with uncuffed tubes. Twenty five of the recruited patients had a primary cardiac diagnosis (of whom 8 had delayed sternal closure post cardiac surgery at the time of testing), 19 had a primary respiratory diagnosis, 14 were admitted for tracheal surgery, 3 had traumatic head injuries and the remaining 2 were admitted for other medical reasons. Of these, 12 patients had nitric oxide entrained into their ventilatory circuits. There were no significant differences in baseline data or demographics between patients receiving either NRP or SRP as the first intervention (Table 1).

Twenty two physiotherapists were recruited to the study, of whom 10 were SRP. Physiotherapists ranged in clinical experience from clinical specialists with greater than 10 years clinical experience (n=2, one SRP), senior physiotherapists with greater than 5 years clinical experience (n=9, two SRP) and band 6 physiotherapists undertaking clinical rotations as part of their training (n=11, 7 SRP). The NRP worked in clinical areas which included orthopaedics (n=3), haemophilia (n=2), haematology and oncology (n=2), neurosurgery

(n=2), rheumatology (n=1), neuromedicine (n=1) and the community (neurodevelopmental physiotherapy), (n=1).

Physiotherapy treatments consisted of a combination of techniques, including postural changes, endotracheal instillation of saline or mucolytics, manual or ventilator lung inflations, endotracheal suction and manual techniques, including chest wall vibrations, which have been described previously [17].

Group analysis of changes in respiratory outcomes following physiotherapy treatments

At baseline (pre-treatment), there were no significant differences in respiratory mechanics between the NRP and SRP groups. Following both NRP and SRP treatments, there was a statistically significant increase in C_{rs} (Tables 2 and 3). There was a significant immediate fall in respiratory resistance in both physiotherapy treatment groups, which remained significant 30 minutes later. In those patients ventilated in a preset volume mode, there was no significant change in peak inspiratory pressure in either group, apart from a mean decrease in peak inspiratory pressure of 0.9cmH_2O in epoch 2 after treatment in the NRP group, a change unlikely to be clinically important (Table 2).

There were no significant between-group differences in C_{rs} or respiratory resistance post-treatment (mean change [95% CI], -0.05 [-0.11 to 0.05]ml.cmH_2O^{-1}.kg^{-1} and 1.1 [-6.7 to 7.8]cmH_2O.L^{-1}.s^{-1} p=0.61 and p=0.57 respectively). The study was underpowered to detect such changes, for this section of the analysis, since the direction of change was in the same direction, but of different magnitudes, in both groups.

Case-by-case analysis of clinically important changes in respiratory outcomes

There were clinically important improvements to respiratory outcomes following 27 (43%) NRP treatments, compared with 40 (63%) SRP treatments. The number of patients who improved following NRP was compared with those receiving SRP treatments and the difference was statistically significant (Fisher's two-tailed exact test, odds ratio [95% CI], 2.3 [1.1 to 4.7], p=0.03).

Clinically important deteriorations in respiratory outcomes occurred twice as frequently following NRP treatments as with SRP treatments (n=12 and n=6 respectively), although this difference was not statistically significant (Fisher's two-tailed exact test, odds ratio [95% CI], 0.4 [0.2 to 1.3], p=0.20). The remaining 41 treatments (24 of which were delivered by NRP), resulted in changes within the range of normal variability for those outcomes.

Adverse events occurred following 8 (12.7%) NRP and 3 (4.8%) SRP treatments, ranging in severity from mild to severe. Seven of these (five of which followed NRP treatments) were categorised as 'mild' and involved transient alterations in oxygen saturation or haemodynamic stability. One adverse event – during the SRP treatment of a patient with a traumatic head injury – was described as 'moderate', being a rise in intracranial pressure (from 12 to 26mmHg), with accompanying fall in cerebral perfusion pressure (72 to 53mmHg). The remaining three adverse events, which occurred following NRP treatments, were 'severe'. These comprised a case of acute haemodynamic instability (left atrial and pulmonary arterial pressures rising from 15 to 21mmHg and from 22 to 30mmHg respectively), requiring considerable pharmacological intervention; a patient who developed a pneumothorax, identified on chest radiograph after physiotherapy; and an increasingly haemodynamically unstable patient who had a cardiac arrest 30 minutes after physiotherapy.

DISCUSSION

No previous study has investigated whether there are quantifiable differences in respiratory outcomes when patients are treated by NRP compared with SRP treatments. This study found that, when analysed as a group, both NRP and SRP treatments resulted in statistically significant improvements in respiratory function. However, when analysed on a case-by-case basis within the context of clinically important changes, being treated by an NRP was associated with significantly fewer successful treatments, with more patients suffering deteriorations or adverse events. A numbers-needed-to-treat calculation suggests that for every 5.7 patients treated by an SRP rather than an NRP, one additional deterioration was avoided (95% CI, 3.1 to 32.5).

Limitations

Practical limitations precluded night-time or weekend data collection. Patients in the current study were treated during the day by both the NRP and SRP. Patients in this study were largely haemodynamically stable and there was not the same level of urgency regarding respiratory physiotherapy interventions. This compares to an on-call scenario where retained secretions compromising ventilatory support might necessitate an emergency callout. During the day, physiotherapists were also unlikely to have the same raised level of anxiety associated with an out-of-hours callout, as they had support from senior SRPs if required, and didn't have the level of sleep deprivation associated with a night's on-call. The combined effect of these factors meant that the study may have underestimated the differences between NRP and SRP, which may only become more apparent during hasty or less well-anticipated treatments.

Since deteriorations and adverse events in clinical outcome occurred infrequently in both

groups, the study was underpowered to detect significant differences. For example, 215 patients would be required to detect a difference in the number of deteriorations with 90% power (5% significance).

Although there was the potential for carry-over effects between the first and second treatment, the randomisation of treatment order and use of statistical comparisons between pre- and post-treatment respiratory status would have alleviated the risk of this factor altering the results of the study. Follow-up times were also necessarily brief in this study, since the direct effectiveness of the physiotherapy treatment could only be measured when no other interventions (either nursing or medical) were being undertaken. Therefore the impact of treatment on healthcare costs and disease burden across the entire patient stay could not be addressed. However, the aim of the study was to explore in detail the differences between two specific types of intervention (ie NSP versus SRP), rather than the global costs of non-specialist physiotherapists to the NHS. Further research would be required to explore the current on-call scenario from the perspective of health economics.

Generalisability

The high frequency with which on-call physiotherapists at the recruiting hospital undertake on-call duties, and relative seniority of all staff means that this hospital is likely to attain near optimal conditions for a good on-call service. This compares with many other NHS hospitals which might employ a greater number of staff (perhaps up to 150 clinical physiotherapists), many at a more junior level (including new graduates with little undergraduate respiratory training). This has the potential to leave the intensive care unit still more vulnerable to unsupported and potentially inexperienced physiotherapy practitioners. This would further aggravate the impact of outcomes following on-call physiotherapy treatments, but it is

impossible to speculate on the relative impact of such factors. This study still found significant differences between NRP and SRP treatments under favourable conditions, suggesting that differences may be greater still elsewhere.

Interpretation

Improvements in respiratory function following physiotherapy have been documented in previous studies in both adults [18-20] and children [15,21]. However, being treated by an NRP had clinically significant disadvantages compared with the SRP treatments.

The number of deteriorations and adverse events following physiotherapy interventions was small in both the SRP and NRP groups. Given the critical status and complex medical conditions of children in intensive care at a tertiary centre, the potential for acute instability is high, and can occur spontaneously without a preceding stressor [22]. However, it is of note that such events occurred more frequently in the NRP group. Poor decision making, prolonged treatments and differences in choice of treatment components may have contributed to some of these deteriorations.

The on-call physiotherapy scenario is akin to the use of cross-cover in medical wards that allows physicians to cover wards they do not usually work on, particularly overnight. A case-control study of 3,146 patients admitted over a 4-month period revealed that such practice was strongly associated with an increase in potentially preventable adverse events, 26% occurring during cross-cover compared with 12% whilst patients were under their normal medical team (odds ratio, 3.5; p=0.01) [23]. In 2010, Sir Richard Thompson, President of the Royal College of Physicians, recommended that, in the face of growing evidence of time-of-day-dependent discrepancies in care delivered to patients, a consultant should be on-site at least 12 hours per

day, seven days a week [24].

Significant changes in ethos are required within allied health professions to support such a change in practice. It is no longer acceptable that the delivery of physiotherapy outside of normal working hours should be anything other than equitable with that provided during the day. This current study has demonstrated that this is not currently the case and, as a result, patients are less likely to improve when treated by NRPs. There is an urgent need for targeted training strategies, or alternative service delivery models, to be explored.

Acknowledgements: The authors wish to thank the patients and their families, and the physiotherapists who agreed to participate in the study. Also thanks are due to Tim Cole, Professor of Medical Statistics at the UCL Institute of Child Health for his invaluable statistical support.

Ethical approval

Ethical approval was granted by the UCL, Institute of Child Health and Great Ormond Street Hospital for Children NHS Foundation Trust ethics committee (REC number 06/Q0508/56).

Funding

The study was funded in part by the Physiotherapy Research Foundation (Chartered Society of Physiotherapy), and in part by the Great Ormond Street Hospital Children's Charity Board of Special Trustees.

Conflict of interest statement

There are no competing interests associated with this study.

Role of the funding source

Funders were not involved in the design of the study; data analysis, data interpretation, writing of the report; or the decision to submit the paper for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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TABLES

Table 1 Baseline demographic and clinical characteristics

	Randomised to NRP as first treatment (n=29)	Randomised to SRP as first treatment (n=34)	Median difference, SRP-NRP (95% CI)
Age *(years)*	1.2 (0.01 to 15)	1.2 (0.15 to 15)	0 (-1.5 to 3.11)
Gender *(M:F)*	15:13	17:17	
Weight *(kg)*	9.2 (3.3 to 58)	10.2 (3.2 to 60)	1 (-0.65 to 9.64)
Ventilation, Pressure: volume preset mode	25:4	27:7	
ETT size (mm)	4.5 (3.0 to 7.5)	4.5 (3.5 to 7)	0 (-0.3 to 1.01)
PaO_2/FiO_2 ratio	263 (86 to 450)	214 (49 to 416)	-49 (-130 to 7.88)
OI	3.9 (1.7 to 19)	5.0 (2.5 to 18.8)	1.1 (-1.0 to 4.5)
PIM2	0.05 (0.0001 to 0.34)	0.12 (0.0001 to 0.58)	0.07 (-0.05 to 0.32)
Days since ICU admission *(n)*	2 (1 to 13)	1.5 (1 to 25)	-0.5 (-3.16 to 0.98)

Data are presented as median (interquartile range), apart from gender and mode of ventilation, which are presented as a ratios. ETT: endotracheal tube, OI: Oxygenation Index (mean airway pressure*FiO_2/PaO_2), PIM2: Pediatric Index of Mortality 2 [25], ICU: Intensive Care Unit

Table 2 Effect of non-respiratory physiotherapists' treatments on respiratory outcomes

	Before Treatment (A)	Epoch 1 after treatment (B)	Epoch 2 after treatment (C)	Mean change (95% CI) B – A	Mean change (95% CI) C – A
C_{rs} *($ml/cmH_2O^{-1}.kg^{-1}$)*	0.62 (0.29)	0.70 (0.39)	0.66 (0.37)	0.07 (0.01, 0.14)**	0.04 (0.01, 0.15)*
R_{rs} *($cmH_2O.L^{-1}.s^{-1}$)*	54 (10 to 323)	43 (10 to 338)	46 (10 to 315)	-6.5 (-11, -1.5)*	-9.0 (-14, -4.0)*
$^{\$}V_E$ *($ml.kg^{-1}$)*	7.1 (1.9)	7.7 (2.7)	7.4 (2.6)	0.6 (0.3, 1.0)***	0.4 0.1, 0.8)*
$^{\$\$}$PIP *($cmH_2O$)*	21 (2.8)	20 (2.1)	20 (2.5)	-0.5 (-2.1, 1.2)	-0.9 (-1.7, -0.1)*

C_{rs}: compliance, R_{rs}: respiratory resistance, V_E: expired tidal volume, PIP: peak inspiratory pressure. Data are presented as mean (SD), apart from R_{rs} which is presented as median (interquartile range) due to non-normal distribution of data. $^{\$}$n=52, $^{\$\$}$n=11. ***<0.001, **<0.01, *<0.05

Table 3 Effect of specialist respiratory physiotherapists' treatments on respiratory outcomes

	Before	Epoch 1 after	Epoch 2 after	Mean change	Mean change

	Treatment (A)	treatment (B)	treatment (C)	(95% CI) B – A	(95% CI) C – A
C_{rs} *(ml/cmH_2O^{-1}.kg^{-1})*	0.57 (0.20)	0.65 (0.31)	0.61 (0.22)	0.08 (0.04, 0.13)***	0.05 (0.03, 0.09)***
R_{rs} *(cmH_2O.l^{-1}.s^{-1})*	56 (10 to 370)	44 (10 to 331)	45 (11 to 325)	-12 (-18, -5.7)***	-10 (-17, -4.0)**
$^{\$}V_E$ *(ml.kg^{-1})*	6.9 (1.6)	7.8 (1.8)	7.6 (1.8)	0.8 (0.5, 1.2)***	0.7 (0.4, 1.0)***
$^{\$\$}$PIP *(cm$H_2O$)*	21 (3.5)	21 (3.1)	21 (3.4)	-0.9 (-2.2, 0.4)	-0.9 (-2.2, 0.4)

C_{rs}: compliance, R_{rs}: respiratory resistance, V_E: expired tidal volume, PIP: peak inspiratory pressure. Data are presented as mean (SD), apart from R_{rs} which is presented as median (interquartile range) due to non-normal distribution of data. $^{\$}$n=52, $^{\$\$}$n=11. ***<0.001, **<0.01, *<0.05

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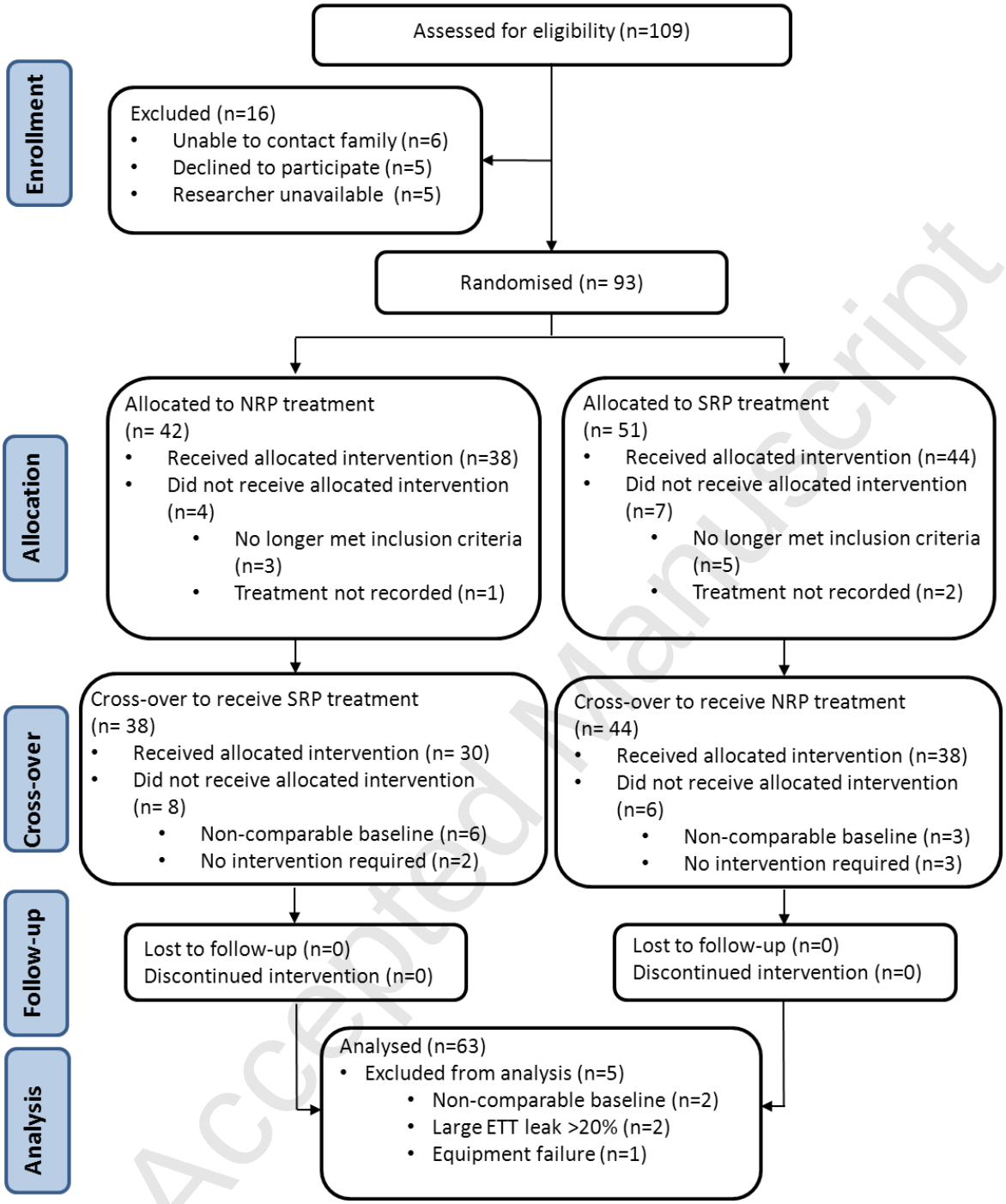

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439 Figure 1 Recruitment Flow Diagram