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Comparison of a Novel Incubator with Standard Incubator Care: A Randomised Multi-Centre, Cross-Over Study

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ABSTRACT

Objective: To test the performance, efficacy and usability of the mOm Essential Incubator, a novel, space-saving infant incubator designed for use in high and low-resource settings.

Design and Setting: Prospective, randomised, multi-centre, cross-over design pilot study. Neonatal Units at three UK centres participated.

Patients: Stable premature infants of ≥30 weeks corrected gestational age who required incubator care were eligible to participate.

Intervention: Babies were randomised to 24-hour care episodes in either standard or mOm incubators with cross-over after 24 hours.

Primary Outcome: Efficacy of temperature maintenance within the normothermic range 36.5°C to 37.5°C.

Staff feedback on the usability of the mOm incubator was collected as a secondary outcome.

Results: There was no significant difference between the performance of the mOm and standard incubators in maintaining normothermia and no adverse incidents were observed. User feedback was positive, with staff reporting the mOm incubator to be easy to use and quicker to clean between patient uses.

Conclusion: For the care of infants ≤6kg who do not require humidification, the mOm Essential Incubator can be considered as an alternative to standard incubators.

Keywords: Neonatal; Incubator; Normothermia; Portable; Space-Saving

What is already known on this Topic?

1. Normothermia is associated with physiological stability and fewer adverse events.
2. Stable babies under 2kg should be warmed if they cannot receive skin-to-skin care.
3. Standard incubators are effective but have a high capital cost and a large footprint.

What this study Adds

1. A portable, space saving incubator can maintain normothermia as effectively as a standard incubator in preterm infants who do not require humidification.

2. The usability of this novel incubator was acceptable to staff.
3. How this study might affect research, practice or policy
4. Demonstration of the effectiveness of the mOm incubator in a high resource setting is important to support further use in other high and lower resource, or in emergency aid situations.

Introduction

The use of incubators to maintain normothermia is a cornerstone of neonatal care [1]. Hypothermia in the premature infant can result in poor weight gain and metabolic stress [2,3]. Babies maintain normothermia via hypothalamic control mechanisms, creating warmth through shivering and non-shivering mechanisms [4]. In the preterm or growth restricted infant, these mechanisms are immature, placing them at additional risk. In lower-resource settings, hypothermia is associated with significant mortality especially in these higher risk patients [5]. The World Health Organisation (WHO) recommends that stable babies ≤2kg should receive external warming (radiant or incubator) if they cannot be given skin-to-skin care [6]. The mOm Essential Incubator, [Mom Incubators Ltd, Nottingham, UK] (Figure 1) meets international safety and performance standards for conventional incubators, is CE marked under the medical device regulations (MDR2017/745), and is suitable, by design, for use in both high- and lower-resource settings. This study evaluated the thermal performance of this novel incubator against standard incubators used on neonatal units, and to investigate usability aspects from staff perspectives.

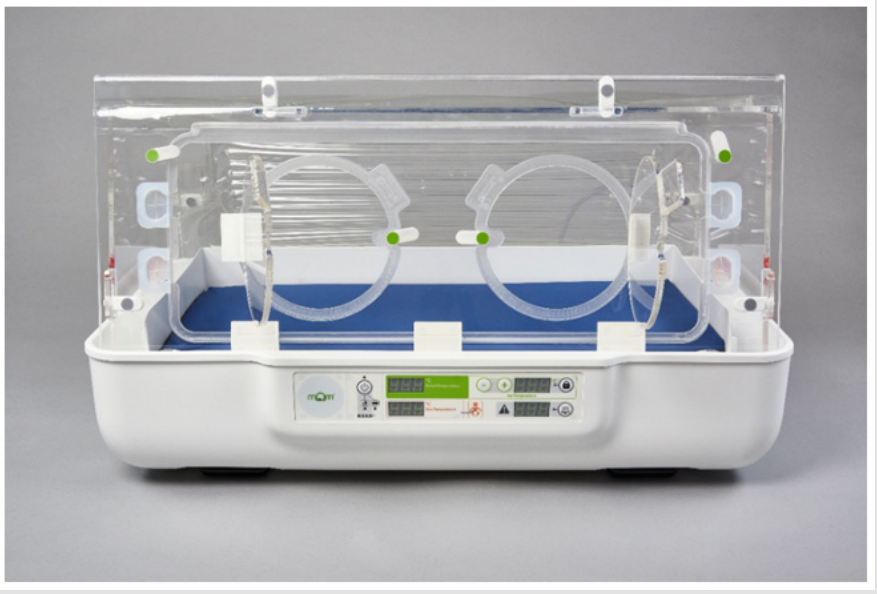

Figure 1: mOm Essential Incubator.

Methods

Patient Population

Eligible infants were at least 30 weeks corrected gestational age (GA) at birth, and ≤6kg at inclusion to the study. They were clinically stable, not needing endotracheal ventilation, had already spent at least 24 hours receiving standard incubator care, and were expected to require at least 48 hours of non-humidified incubator care at ≥30°C at the time of study inclusion. Written consent was obtained from the parent(s) or legal guardian(s) aged 16 years or above and not considered to be in a vulnerable group. Infants with major congenital abnormalities or suspected infection were excluded. The clinical team-maintained responsibility for each infant's care, with the ability, along with the initial consent giver, to withdraw the infant from the study at any time for any reason.

Study Design and Setting

This was a prospective, multi-centre, randomised controlled, cross-over design pilot study, conducted in three hospital Neonatal Intensive Care Units within the United Kingdom: St Peter's Hospital (Ashford and St Peters NHS Foundation Trust, Chertsey), Royal Hospital for Children (Queen Elizabeth University hospital, Glasgow) and the Norfolk & Norwich University Hospital, Norwich. The primary objective of this study was to compare the maintenance of normothermia within each incubator group (mOm or standard) by measurement of each infant's truncal skin temperature, or core temperature. This is expected to fluctuate but remain within normal temperature limits (36.5 to 37.5°C). Variations from this endpoint were analysed and compared statistically between the two incubator groups. Thirty-six completed datasets were required for the analysis to be valid. A complete subject dataset was deemed acceptable if 19 of the 24,

once-hourly temperature observations were recorded for each incubator type (i.e. 79% compliance). This degree of compliance was considered acceptable for analysis because it is still greater than the routine standard for this type of incubator care for clinically stable infants of ≥30 weeks GA, which is often every three hours. The overall mean temperature variance per incubator group (mOm or standard) was compared. Where temperature data from skin probes attached to the incubators, was not available for any technical reason, axillary temperature readings were used instead to maintain dataset integrity. If infants were removed from incubators, (e.g. for skin-to-skin care), the nature and duration of the event was recorded.

A 95% confidence interval was calculated around the mean of these fluctuations within each baby for each incubator group. Data from 36 babies would allow such a confidence interval to be calculated to within ±0.33°C if the actual mean fluctuations are around one degree (i.e. as normally expected) and assuming a two-sided confidence interval. A paired t-test was used to compare values, and p-values were calculated. Each patient served as their own control. The order of incubator type used for each of the two consecutive 24-hour periods of incubator care, was assigned randomly. A Microsoft Excel random number generation system was used to generate random numbers used to assign the arm of the study the infant was assigned (i.e. which incubator type the infant went into for the first 24h before cross-over). Each assignment was placed in an envelope attached to case report form folders already numbered with a continuous series subject number. As secondary endpoints, baseline demographics, then vital signs (i.e. pulse rate, breathing rate and O2% saturation) of the infant, plus set and actual temperature of the incubator were recorded every hour; blood pressure was recorded daily. The type and duration of care activities, duration the portholes or door was open and any adverse events were recorded throughout the 48h each infant spent in the study. Further to these, the time taken to clean each incubator between use was recorded and users were given a questionnaire to complete, regards the usability of the mOm compared to standard incubators. No formal survey was provided to parents, although any comments given were recorded in their infants' case report form.All data were collected, 100% verified by the Sponsor's monitors, and stored in compliance with Good Clinical Practice (GCP) and Data Protection legislation. The CONSORT reporting guidelines were used to provide reporting guidance [7].

Ethics and Regulatory Approvals

This study was initially approved by the London - Harrow Research Ethics Committee (REC), 19 November 2018 (ref: 18/LO/1757). After a delayed start due to the Covid pandemic, MHRA no objection was gained on 22nd October 2021 (ref: CI/2021/0050/GB), Health Research Authority approval on 27th October 2021 and adoption onto the National Institute for Health Research Clinical Research Network portfolio (CPMS ID 38607). The study was conducted in accordance with ISO 14155, Good Clinical Practice and the Declaration of Helsinki for Human Rights.

Results

One hundred patients were screened and identified as eligible for participation in this study over a period from November 2021 until August 2022 at the three study sites. Forty-three infants were enrolled of which three infants were withdrawn, one prior to commencement (moved to a different hospital) and two during the study by neonatal staff (one due nurse wanting to cool infant rapidly after overheating due to too much clothing, one due to staff concern with incubator temperature dropping when alarm not cleared); in both cases the incubator performed correctly. Three infants had no primary endpoint data collected whilst the infants were in the standard incubator so no comparative analysis could be performed; these were excluded from the results reported in this paper. However, the data collection target was reached (i.e. 36 evaluable data sets) with 37 evaluable datasets being available for inclusion in the analyses (Figure 2); see Table 1 for their demographic data. Of the 37 evaluable datasets, 18 (49%) infants were randomised to a mOm incubator -first 24h, then a standard incubator - second 24h, and 19 (51%) infants were randomised to standard - first 24h, then mOm incubator - second 24h (Table 1).

Table 1: Summary of demographics at study inclusion.

Parameter	Analysis Population
N	37
Female Male	20 (54.1%) 17 (45.9%)
Weight (g): Median (IQR)	1323 (1062 to 1415)
Length (cm): Median (IQR)	38 (36 to 40)
Gestational Age (wk + days): Median (IQR)	32+0(30+4 to 33+3)

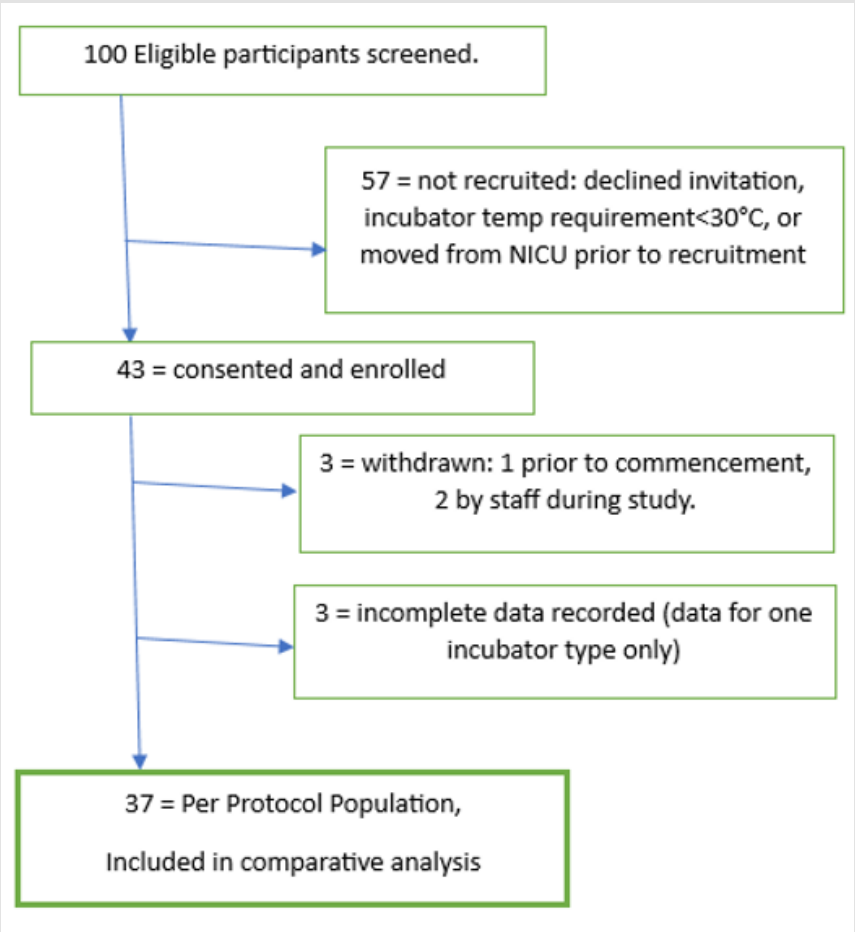

Figure 2: Patient disposition.

Efficacy Outcome

No significant differences were found in the primary endpoint for maintenance of normothermia in infants cared for in either the mOm incubator or the standard incubators. Fluctuations in temperature beyond the normal range were noted and the mean variance compared (Table 2). Figure 3 shows the mean temperatures of the infants recorded in each incubator over the 24-hour period.

Table 2: Analysis of paired data for mean fluctuations from normothermia (°C).

Parameter	mOm Incubator (B) n=37		Standard Incubator (A) n=37		Mean differences of (°C) A-B	
	Skin Temp (°C)	Axilla Temp (°C)	Skin Temp (°C)	Axilla Temp (°C)	Skin Temp (°C)	Axilla Temp (°C)
Mean	-0.13	0.002	-0.06	-0.01		
SD	0.27	0.03	0.11	0.01		
Mean (95% Cl)					0.07 (-0.02, 0.15)	-0.01 (-0.02, 0.01)
SD (95% CI)					0.23(0.21, 0.34)	0.03(0.03, 0.04)
Paired t-test value (p-value)					1.54(p>0.13)	0.398(p>0.30)

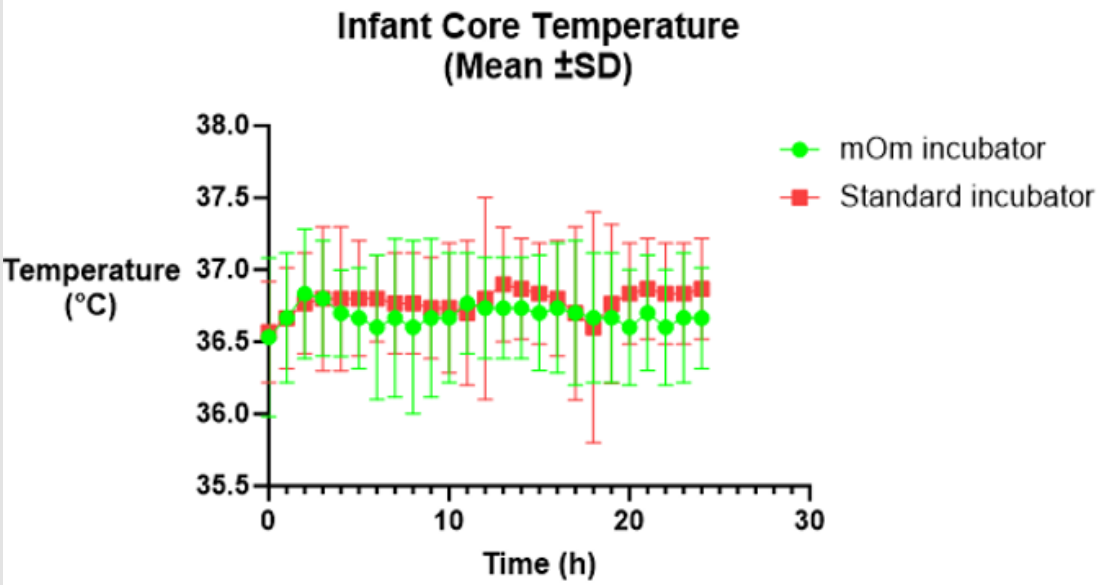

Figure 3: Comparison of Infant Temperature Maintenance.

Secondary Endpoints

Clinical Stability: There were no statistical differences in heart rate, respiratory rate, oxygen saturations, or blood pressure between mOm and standard incubator groups (Table 3).

Table 3: Vital signs

Incubator	mOm	standard	mOm	standard	mOm	standard	mOm	standard
Measure	Respiration rate (breaths/minute)		Pulse rate (beats/minute)		Oxygen saturation (%)		Blood pressure mean (mmHg)	
Median	50	50	155	155	96	97	47	46
IQR	44-58	44-57	145-164	144-164	95-98	95-98	42-52	41-52
t-test p-value	0.387		0.3482		0.6192		0.2597	
Significant difference (p <0.05)?	No		No		No		No	

Incubator Performance: Standard incubators used in the study included a variety of Draeger (Lubeck, Germany) models (90.2%) and GE (Chicago, IL) Giraffes (7.3%). Both incubator groups demonstrated temperature differences between set and actual temperature (as displayed on the incubators interfaces) which were within the permitted limits of the BS EN 60601-2-19 Standard [7]. Both had the same median difference of 0.03°C. The overall mean (standard deviation; SD) difference was 0.04°C (±0.06°C) for the mOm, compared to 0.03°C (±0.03°C) for the standard incubator group. The mean length of time the infants underwent care activities with the portholes and/or door open was similar in both incubator groups with no significant difference (Table 4). Both incubator groups had a median of 10 minutes for care activities with similar interquartile ranges (IQR) of 5.5-20 minutes for the mOm group and 7.0-20 minutes for the standard incubator group.

Cleaning of Incubators (Table 4): Cleaning times were recorded on 44 (69%) occasions for the mOm incubator compared to 20 (31%) occasions for the standard incubators. Median (IQR) cleaning time was significantly shorter for the mOm incubator compared to the standard incubator; 25 (15-30) vs. 45 (30-45), p <0.001) (Table 4).

Table 4: Activities and Incubator Cleaning Times.

Incubator	mOm	Standard	mOm	Standard
Measure	Care Activities (time in minutes portholes/door open)		Deep Cleaning incubator (time in minutes)	
Median	10	10	25	40
IQR	5.5-20.0	7.0-20.0	15-30	30-45
t-test p-value	0.6483		<0.0001	
Significant difference (p <0.05)?	No		Yes	

Adverse Events (AEs): Seven AEs were reported (3 hyperthermia, 1 hypothermia, 1 skin irritation, and 2 oxygen desaturations) of which none were considered causally related to either type of incubator. No serious AEs or device-related AEs were reported.

Usability: Thirty-two clinical staff, of whom the majority 27(84%) were nursing staff and the rest consultants, and 10 non-clinical staff (healthcare support workers), completed responses. 85% found the device intuitive to use and all respondents said they would be happy to allow their own baby to be managed in the mOm incubator. The majority of clinical staff felt the incubator may be useful for interdepartmental transfers (78%), home use (66%), ward use (e.g. transitional care, postnatal wards (63%)), delivery suite (56%) or for low infrastructure countries. There were positive comments about the size and cleanability of the mOm ("less invasive looking for parents", "easy to transfer" [referring to interdepartmental transfer]). Eight (80%) of the non-clinical respondents who commented, thought that the cleaning, disassembling, and setting up the mOm incubator was 'Easier' or of 'Similar Difficulty', when compared to a standard incubator. Negative comments included the self-closing porthole doors (feature now removed), and about accessibility for complex babies with multiple intravenous (IV) lines (four IV ports currently provided), or during an emergency. Suggestions included additional portholes for access. Clinical staff also did not like the lack of a height adjustable trolley (now available).

Parents: Parents commented that they liked the compact size of the mOm incubator, as it seemed "right sized" for their baby. Parents said it was easier to see the baby and that the "baby looked perfect size in [mOm] incubator". Parents also said they liked the display of their baby's temperature. No comments were recorded for the standard incubators.

Discussion

There were no significant differences in the maintenance of normothermia between infants cared for in the mOm and the standard incubators. Similarly, there were no differences in recorded physiological measurements. The performance of the incubator was within expected values; the differences noted between set and actual values are within the permissible safety and performance criteria of the BS EN 60601-2-19 Standard [8]. There were no device-related adverse incidents. The mOm incubator was designed by James Roberts, at the time a Design Engineering student at Loughborough University, winning the Sir James Dyson Global Prize for Innovation in 2014. Originally known as an "inflatable incubator", it has been refined and re-designed, whilst maintaining the original aims of being portable and space-saving, able to operate from a variety of power sources and to be more cost-effective than standard incubators. This study is the first report of its clinical use, paving the way for further evaluations in different settings. The aim for medical equipment to be cost-effective, or designed for lower resource settings, does not mean that functionality, safety or usability should not be evaluated and meet the standards required in higher-resource environments.

A recent review examined currently available warming devices suitable for low-resource settings [9]. These included radiant warmers, incubators, warming mattresses and phase-change materials. Devices were generally effective although it was noted that radiant warmers increased insensible water losses. Some require consumables which may add additional costs, and phase-change materials have a relatively short duration of action before replacement is needed. Considerations such as servicing, parts and power availability, and means of disposal, should also be considered. A randomised controlled study of a prototype cardboard incubator [10] demonstrated non-inferiority in a low-resource setting with high ambient temperatures (25°C) and humidity (50%); 1:1 nursing was provided for the study duration (48h).

During our study trial period, 60% of babies with parental consent did not participate in the study, and trial recruitment was slower than anticipated. The overwhelming reason for this was due to a requirement for a lower incubator temperature than the mOm incubator could provide. Stable neonatal patients often require a set incubator temperature of 28-29°C. The standard incubators could provide this, however, the operating range of the mOm incubator used in the study was 30-37°C. The mOm incubator has since been adjusted to provide a wider range of 28-37°C, demonstrating the value of clinical evaluation. The mOm incubator was designed for use in a broad range of settings, including emergency ones where environments would be expected to be less favourable and staff less experienced. Assessment of usability was important in order to understand the attitudes of staff to a medical device which does not have the features associated with more expensive, conventional devices. The positive feedback from users was reassuring that use in a busy high resource setting was acceptable, with all respondent clinical staff (consultants and nurses) and non-clinical staff (healthcare support workers) saying they would allow their own baby to be cared for in a mOm Essential incubator.

Study Limitations

This was a small-scale pilot study, which although demonstrating compliance to the safety and performance incubator standards [8], was not powered to show non-inferiority against one particular standard incubator, instead hospitals used standard practice which included the use of a range of different 'standard' incubators.

Conclusion

In this pilot study, performance of the mOm Essential Incubator showed no significant differences in maintaining thermal stability compared with the standard incubators in infants ≤6Kg, who did not require humidification, and no incubator-related adverse events were observed. In a busy high resource setting, the mOm incubator matches the performance of standard incubators in the maintenance of temperature and may provide the additional benefit of shorter cleaning time.

Acknowledgments

We sincerely thank all the parents who allowed their babies to participate in this study. We particularly thank the clinical research nurses at the recruiting sites who helped with recruitment, training, and data collection, the healthcare support workers who cleaned the incubators between use and the neonatal intensive care nurses who collected all the data required by the study protocol.

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