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A Proof-of-Concept, Randomised, Controlled Cross-Over Study of Palm-seal Method versus Conventional Method using Facemask Chamber with Pressurised Metered-dose-inhaler in Children aged 6 to 36 months old

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Abstract

Introduction: Lack of cooperation in young children posed a great challenge for the delivery of inhaled medication using a valved holding chamber (VHC) with a facemask. Leakage between the face and facemask reduced the delivered dose to the respiratory tract and negatively impacted treatment effectiveness.

Objectives: To prove that palm-seal method (PSM) is the preferred method to deliver inhaled medication using a metered-dose-inhaler (MDI) and facemask VHC for parents with children aged between 6 and 36 months, and that it is associated with a higher successful seal between the facemask and the face.

Methods: In a randomised crossover study with 59 patients newly started on MDI with VHC, the parents were counselled on two different methods to administer inhaled medication, i.e. PSM and CVM, spaced 1 day apart. Parents' preferences for both methods and the ability to ensure a good seal were observed and validated by a clinician.

Results: A total of 59 patients with a mean age of 15.5±6.6 months were recruited. The most common working diagnoses were viral-induced wheeze (50%) and bronchiolitis (29%). Mean duration of hospitalisation was 4.6±3.1 days. More than half (58%) of the patients have a family member who smokes. PSM method was preferred over CVM (73% vs 27%) regardless of whether it was introduced first or later (p=0.211), the patient's gender (p=0.378) and the education level of parents (p=0.878). The reason given was that they found it easier to restrict the child's head movement while ensuring a good seal during drug delivery using PSM when the child was not cooperative. However, PSM was not associated with a significantly higher successful good seal (93%) when compared to the CVM (90%). Within the 3-month follow-up after discharge, the majority (>60%) of the parents switched preference from CVM to PSM, citing the reason as easier to ensure a good seal.

Conclusion: PSM is the preferred method to deliver inhaled medication using MDI with VHC when the child is not cooperative.

INTRODUCTION

The introduction of the valved holding chamber (VHC) with facemask into clinical practice as the standard of care for young children requiring pressurised metered dose inhaler (pMDI) has significantly improved the delivery of inhaled medications to this patient group.[2–4] However, the lack of cooperation in infants and young children presents a challenge for aerosol-based medication delivery.[5] From our clinical experience with young children, we found that many do not cooperate with the facemask chamber (FMC). Despite having an appropriate size and good quality facemask chamber, we still have to try to overcome the challenge of getting it well sealed onto the child's face for an adequate duration to allow at least 8–10 complete and steady breaths. Struggling during inhaler administration, for example, creates a gap between the face and facemask. Studies showed that leaks between the face and

facemask markedly reduce the delivered dose to the respiratory tract.[6–8] And it was proved to be one of the main limiting factors in the treatment effectiveness.[9]

Previous research has focused on improving the valve-holding chamber, designing the ideal facemask and demonstrating the importance of a good seal to ensure effective delivery of inhaled medications to patients.[2, 3, 7, 8, 10–13] However, none of the current standard guidelines recommend a proper method to ensure a good seal between the face and facemask, especially in a non-cooperative child. Some researchers recommend administering the inhaled medication when the child is sleeping or using a distraction method when dealing with less cooperative children.[9, 14] Furthermore, studies also show that medication deposition in the lung is lower in a crying child.[14]

This pilot study was conducted to develop a detailed, effective method to ensure a proper seal during inhaled medication administration via a valved holding chamber (VHC) and facemask in young children. Achieving an effective seal is essential for optimal drug delivery. Data from this initial study will be used to incorporate the developed method into standard patient counselling guides and clinical protocols. Additionally, the findings of this pilot study provide preliminary data for a subsequent, second-phase study, which will investigate a pre-treatment technique aimed at improving the initial acceptance of the facemask chamber among infants and young children.

Objectives of the study

The primary aim of this study was to assess the palm-seal method (PSM) when used with a facemask chamber and to determine if it is the preferred approach among parents and caregivers of children aged 6 to 36 months. The secondary aim was to evaluate whether the PSM is linked to a significantly higher rate of a successful seal between the face and the facemask in this group. Additionally, this study sought to estimate the rate of recurrent exacerbation or readmission within three (3) months after discharge in young children hospitalised with acute respiratory illnesses.

METHODS

Study Design and Setting

This was a randomised controlled crossover study conducted over nine months in the general paediatric ward of Hospital Seberang Jaya (HSJ), Penang, Malaysia. A crossover-after-one-day study design was planned to control inter-patient variability, given the small sample size. Arguably, the short washout period was our limitation, as the study was carried out in a real-world setting, and the total time available for intervention and subsequent observation is inherently short, due to our expectation of brief patient hospitalisation for the acute treatment of common paediatric respiratory conditions. The study focused on assessing the effectiveness of the delivery method (pMDI with FMC), ensuring swift and reliable delivery of inhaled medications to unwell young children. Therefore, extending hospitalisation solely for a prolonged washout period was deemed clinically impractical and unethical.

Participants

Eligible participants were children aged 6 to 36 months who were newly started on a pressurised metered-dose inhaler (pMDI) with a facemask chamber during hospital admission, regardless of the underlying diagnosis or indication. Inclusion required that the parent or primary caregiver could communicate in either Malay or English. Patients were excluded if they were neurologically impaired and bedridden, or if their parents or caregivers had previously received counselling from clinicians, nurses or ward pharmacists on the use of pMDI and FMC.

Sample Size

As no prior comparable study existed, the sample size for this proof-of-concept trial was determined according to established guidelines, i.e. the *rules of thumb*[15], whereby each group will consist of 30 patients.

Randomisation and Allocation Concealment

Participants were randomly assigned in a 1:1 ratio to either the conventional method (control) or the palm-seal method (intervention). Randomisation was conducted using permuted block randomisation with two block sizes (4:6) to maintain balance between groups.[16] Strict randomisation of treatment sequence (CVM-PSM vs PSM-CVM) was maintained to ensure that any residual carryover effect, if it exists, is equally distributed between the two groups, preventing systematic bias. The principal investigator retained knowledge of block sizes to ensure allocation concealment and prevent site investigators from predicting treatment assignments.

Intervention Procedures

Parents or caregivers assigned to each group received counselling and practical training in the designated inhalation method – either the conventional or palm-seal method – for using the pMDI with FMC. Each counselling session lasted 20–30 minutes, followed, if necessary, by a 15-minute reinforcement session on the same day in case of difficulties. The effectiveness of the seal and correct device handling was reassessed on the same day by both a clinician and a senior pharmacist. On the second day, participants transitioned to the alternative method. The ward pharmacist provided a 15-minute practical training session, on the alternative method, with an optional 15-minute follow-up if required (*see* Fig. 1). Ward pharmacists conducting counselling and practical guidance adhered to the Medication Counselling Guideline 3rd Edition (2019), issued by the Pharmaceutical Services Programme, Ministry of Health Malaysia.[17] The reassessments by the clinician or senior pharmacist aimed to determine whether each method achieved an adequate seal and to record parental or caregiver preference for either method.

Final Assessment and Definition of Terms

Table 1
below consists of definitions of terms relevant to the study

Terms	Definition and brief descriptions
Reassessment	Done by a clinician or senior pharmacist at the bedside, having the parents/caregivers demonstrate the administration of inhaled medication.
Facemask chamber, FMC	Small volume chamber with an attached facemask; facemask size must be suited for infants and young children
A successful good seal	Complete seal of nose and mouth with facemask for at least 8–10 full breaths (based on flow indicator on the valve holding chamber or abdominal/chest movement) for at least 2 doses of inhaled medication
Failure of a good seal	Unable to ensure a complete seal of nose and mouth with a facemask for at least 8 full breaths (based on flow indicator on valve holding chamber or abdominal/chest movement) after 3 attempts at 5-minute intervals.
Parents/caregiver's preference	Choice by parents/caregivers in deciding which method they ultimately preferred to administer inhaled medication after being counselled on both the methods, and the sustainability of the method over 3 months.

Patient Enrolment and Safety

Eligible patients in the paediatric ward were approached by one of the researchers to obtain written informed consent from their parents or caregivers. The safety of the enrolled patients was prioritised during recruitment. If a patient's clinical condition worsened during the enrolment period, the counselling and recruitment process was put on hold until the paediatric medical team stabilised the patient. Once the patient was stabilised and the inhaled medication was converted back to the pressurised metered-dose inhaler with a facemask chamber (pMDI + FMC), counselling and recruitment continued, with the previously assigned randomised ID remaining applicable. Parents/caregivers were informed that they could withdraw from the study at any point during the hospitalisation. If a parent/caregiver chose to withdraw, the patient continued to receive standard treatment and counselling for their inhaled medication using the method the parent/caregiver was most comfortable with. Withdrawn subjects were not replaced.

Details of Counselling for the Conventional Method Group

Parents/caregivers in this group received standard, step-by-step counselling from paediatric ward pharmacists (details in Appendices) on the correct use of pMDI with FMC (details in Appendices). Parents/caregivers were taught to attach the pMDI to the FMC and then gently press the facemask against the child's face to ensure a good seal during dose administration.

Details of Counselling for Palm-Seal Method (Intervention) Group

Parents/caregivers in the intervention group received the same standard, step-by-step counselling regarding pMDI and FMC use. The intervention aspect focused on teaching parents/caregivers a specialised technique for holding the facemask chamber to ensure an optimal seal. Specifically, they were advised to use their thumb, index and middle fingers to hold the front part of the chamber and facemask, while simultaneously using their palm, ring and little fingers to support the child's chin and cheeks to prevent the facemask from dislodging.

Outcome Measures, Assessment and Follow-up

Primary outcomes included the parents'/caregivers' preference for either one of the methods and the success rate of ensuring a good seal for both methods. The final assessment of parent/caregiver preference and the success or failure in achieving a good seal following each method was conducted independently by a clinician or a senior pharmacist who had no prior contact with the study participants in either group. Sustainability of clinical outcomes was assessed by capturing the number of exacerbations requiring an emergency department visit or re-hospitalisation per patient at 1,2, and 3 months after discharge via a telephone call to the parent/caregiver. The method, i.e. PSM or CVM, reported by the parents/caregivers for administering inhaled medication at home over the past 3 months was used to reflect the sustainability of each method.

Data Collection and Management

Patients' clinical data were collected using an individual Case Report Form, CRF (*see Appendices*). Co-investigators transcribed the data from the CRF into statistical software (IBM® SPSS Version 20). The principal investigator cross-checked all data for accuracy before analysis. All study-related materials, including the CRF, enrolment log, and consent forms, were secured in a locked cabinet in the hospital's Clinical Pharmacy Unit, accessible only by the principal investigator. These forms will be shredded prior to disposal following publication of the study results.

Data Presentation and Statistical Analysis

Descriptive statistics were used to summarise patients' demographic and clinical characteristics. Continuous variables such as age, weight, and length of Hospitalisation were presented as mean and standard deviation, while categorical variables such as race, parents' education level, primary diagnosis, and smoking status of family members were presented as frequencies and not percentages. Children's cooperativeness during facemask chamber administration, rehospitalisation status and receipt of nebulization post 3 months after discharge were also reported as frequencies and percentages.

Parents' preferred method for administering the facemask chamber was assessed using the Chi-square Goodness-of-fit Test. Parents' ability to achieve a satisfactory seal between the child's face and facemask using each method was compared using Fisher's Exact Test. The association between

potential factors affecting parents' preferred method were examined using the Chi-square Test of Independence. The use of inhaled medication and the parents' preference towards PSM and CVM were assessed longitudinally among patients during the 3-month post-discharge period. Differences in preference towards CVM or PSM over 3-month post-discharge were analysed using Cochran's Q Test. A *p*-value < 0.05 was considered statistically significant, and results were presented in tables and figures to illustrate important trends and associations.

Patient Consent

In general, the study protocol was designed to be a randomised prospective crossover trial involving young children. Hence, a detailed protocol, patient information sheet and consent form were submitted for review by the Ministry of Health Medical Research Ethics Committee. Written informed consent was obtained from the parents / legal caregivers of all participants before enrolment. Participation was entirely voluntary, and confidentiality of patient information was maintained throughout the study. Personal identifiers were removed from all study documents and data analysis.

Ethical Considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and the Malaysian Good Clinical Practice Guidelines (2018). Ethical approval was obtained from the Medical Research Ethics Committee (MREC), Ministry of Health Malaysia (research registration no. NMRR-20-631-54325; approval reference no. KKM/NIHSEC/P20-771(12)), and institutional permission was granted by Hospital Seberang Jaya, Penang, before study initiation.

RESULTS

A total of 59 patients aged 6 to 36 months were enrolled in this crossover study. The mean age was 15.5 (±6.61) months. The majority of participants were male (n=39, 66%) and Malay children (n=54, 91.5%). Viral-induced wheeze (n=30, 51%) and acute bronchiolitis (n=17, 29%) were the most common primary diagnoses. A large proportion of the enrolled children (75% with the PSM method vs 81% with the CVM method) were classified as non-cooperative during the intervention. We summarised the demographic data in *Table 1*.

Table 1 Demographic Characteristics

	Demographics	*Mean*	*SD*
	Age in months	15.5	6.61
	Weight in kg, *N=56*	8.9	1.68
	Length of Hospitalisation, days	4.6	3.10
	Demographics	n	%
Sex	Male	39	66
	Female	20	34
Race	Malay	54	91.5
	Chinese	2	3.4
	Indian	3	5.1
Education Level of parents/caregivers	Primary	2	3.4
	Secondary	28	47.5
	Tertiary	29	49.2
Primary Diagnosis	Viral-induced wheeze	30	50.8
	Acute bronchiolitis	17	28.8
	Pneumonia	12	20.4
Family member smoking	Yes	34	57.6
	No	25	42.4
Non-cooperative children	When using PSM	44	74.6
	When using CVM	48	81.4
Re-hospitalisation within 3 months after discharge		3	5.1
Nebulisation at a health clinic or ED within 3 months after discharge		1	1.7

Footnote:

Total number of sample, N = 59 if not otherwise specified; CVM, Conventional method; PSM, Palm-seal method; SD, Standard deviation; n = number of sample; ED, emergency department

From our study findings (*see Table 2*), the successful seal rate was 93% for the Palm-seal method (PSM) and 90% for the Conventional Method (CVM). There was no statistically significant difference in the successful seal rate between the two methods (*p=0.351*). Based on the final assessment done by the clinician and the senior pharmacist, parents'/caregivers' preference towards PSM was significantly higher compared to CVM, with 73% of them preferring PSM versus 27% preferring CVM (p<0.001).

General feedback recorded from the parents/caregivers was that PSM was easier to seal the mask to the face and restrict head movement (*see Table 3*).

Table 2 Outcomes & Potential Factors Affecting Outcomes

Outcomes		%	*p-value*[a]
Successful Seal	Palm-seal method, PSM	93	*0.351*[b]
	Conventional method, CVM	90	
Parents/Caregiver Preference	Palm-seal method, PSM	73	*< 0.001*[b]
	Conventional method, CVM	27	
Potential factors affecting parents' preferences towards PSM		n (%)	*p-value*[a]
Initial assignment	To CVM	24 (80)	*0.211*[c]
	To PSM	19 (66)	
Sex of children	Male	27 (69)	*0.378*[c]
	Female	16 (80)	
Education level	Primary	2 (100)	*0.878*[d]
	Secondary	21 (75)	
	Tertiary	20 (69)	
Primary diagnosis	Viral-induced wheeze	21 (70)	*0.133*[d]
	Acute bronchiolitis	14 (82)	
	Partially-treated pneumonia	5 (100)	
	Bronchopneumonia	3 (43)	

Footnote:

Total number of sample, N=59 if not otherwise specified; CVM, Conventional method; PSM, Palm-seal method; [a] *Test statistical significance level at p-value<0.05;* [b] *Chi-Square Goodness-of-Fit;* [c] *Chi-Square test for independence;* [d] *Fisher's exact test*

To address the issue of potential sequence bias in our short crossover period, we demonstrated that the proportion of preferring PSM between the initial assignment method, i.e. PSM first or CVM first, was not significantly different (*p=0.211*). The Palm-seal method was preferred over the conventional method (73% vs 27%) regardless of whether it was introduced first or later, the patient's sex and the education level of parents/caregivers (*see Table 2*).

Table 3 General feedback from parents/caregivers

Feedback (parents/caregivers' own words)	
With PSM	Easier maneuverability to ensure a good seal and restrict head movement
	Easier to ensure a good seal with PSM when the child was not cooperative
	Able to administer inhaled medication without a helper
	Fingers too short for PSM
	The child became less cooperative, switched back to PSM
With CVM	Required assistance to hold down the child and restrict the head movement
	Need to swaddle the patient most of the time
	Still able to ensure a good seal with some restrictions
	Child already got used to FMC and can cooperate, switched back to CVM
	Only administer when the child is sleeping.

Footnote:

PSM, Palm-seal method; CVM, Conventional method; Frequency not defined.

Patients were followed up via telephone call by a pharmacist at 1, 2, and 3 months after discharge to assess the sustained use of the preferred method. The rate of patients maintaining the preferred method was 73% for PSM and 54% for CVM. However, only 11 patients reported using inhaled medication regularly on a PRN basis during the 3-month post-discharge follow-up because there was a marked reduction in the number of patients reported to use inhaled medication from the 1st month (n=26, 44%) up to the 3rd month (n=16, 27%) post-discharge. There was no evidence of a difference in parents' preference towards PSM and CVM over time at 1-, 2-, and 3-month post-discharge (Cochran's Q test, p=0.925). Besides, a higher percentage of children using CVM required swaddling (CVM, 41% vs PSM, 31%), and parents needed assistance to restrict the patient's head when using CVM. Among the patients initially preferred PSM, 27% switched to CVM at home because they claimed that their child had adapted to the facemask and had become more cooperative. In addition, we found that only 3 patients (5.1%) were re-hospitalised within 3 months, reported by parents as viral wheeze, rapid breathing, and shortness of breath.

DISCUSSIONS

In this study, caregivers demonstrated a strong and statistically significant preference for the Palm-Seal Method (PSM) over the Conventional Method (CVM), with 73% favouring PSM compared with 27% favouring CVM ($p < 0.001$). Notably, this preference was sustained at the 3-month follow-up, with the

same proportion of caregivers (73%) continuing to use PSM for medication administration at home. Caregivers consistently reported that PSM was easier to manoeuvre, required less physical effort, and allowed a single adult to administer medication independently without the need for an additional person to restrain the child. The ability to limit head turning while simultaneously supporting the cheeks and chin was perceived as a key practical advantage, particularly in non-cooperative or actively struggling children – an issue observed in 75–81% of administration attempts. These subjective advantages are clinically meaningful, as reducing caregiver stress and workload may enhance long-term treatment adherence, especially in situations that require frequent medication administration during acute exacerbations.

Despite these clear subjective advantages, the primary objective outcome—successful mask seal—did not differ significantly between PSM and CVM, with effective sealing achieved in 93% and 90% of administrations, respectively ($p = 0.351$). Both techniques, therefore, demonstrated high seal success rates. In routine clinical practice, facemask leaks commonly occur when children cry or resist treatment; however, the intensive one-to-one bedside training, structured demonstration, and immediate reassessment by experienced clinicians and pharmacists in this study likely contributed to the uniformly high seal success observed in both groups. These findings suggest that, when supported by comprehensive counselling and supervised practice, caregivers can achieve an effective mask seal regardless of the technique used. They also point to a potential ceiling effect, whereby optimal training conditions reduce observable differences between methods, limiting the ability to detect any inherent superiority of PSM in objective outcomes.

Although most caregivers preferred PSM, a minority were unable to adopt it consistently or reverted to CVM during home use. Reported barriers included small hand size or short fingers, insufficient strength to maintain steady palm pressure, concern about applying excessive force to the child's face, and reduced confidence when the child was highly distressed. These observations highlight that while PSM offers advantages for many families, it may not be universally applicable, with caregiver hand anthropometry, dexterity, and physical comfort influencing its feasibility.

The low preference for CVM was largely attributable to its practical and emotional challenges. CVM often requires two individuals—one to hold the chamber and mask and another to restrain the child – or relies heavily on swaddling. Many caregivers expressed discomfort with immobilising their child, describing the experience as distressing for both the caregiver and the child. Although swaddling is sometimes recommended, it may restrict chest and abdominal movement, potentially reducing tidal volume and aerosol delivery, and may contribute to negative treatment-associated experiences. Caregivers also frequently reported applying excessive mask pressure to counteract head turning, which can distort mask geometry and paradoxically increase leakage or discomfort. In contrast, PSM allows simultaneous support of the mask, cheeks, and chin, enabling caregivers to follow head movements more naturally and maintain a stable seal, even in highly uncooperative children.

A small proportion of caregivers transitioned from PSM back to CVM during the 1–3 months follow-up period because they claimed that their child had adapted to the facemask and had become cooperative. Besides, there could also be other potential contributing factors for the PSM to CVM switch. The practicality of using CVM may be more prominent when a second caregiver is available to assist. In multi-caregiver households, particularly those involving grandparents, inconsistent familiarity with PSM also may lead to a preference for the more established CVM. During episodes of severe distress or tantrums, some caregivers felt unable to maintain the gentle, controlled pressure required for PSM and temporarily reverted to CVM. These findings illustrate that the feasibility of each technique may change over time in response to child behaviour, caregiver capacity, and household dynamics.

Taken together, these findings underscore an important distinction: caregiver preference and perceived ease of use do not necessarily translate into superior objective seal performance under optimised training conditions. Nevertheless, caregiver preference remains highly relevant in real-world practice, where ease of use, independence, and reduced caregiver stress may strongly influence adherence. Future studies incorporating more sensitive leak quantification, direct measurements of aerosol delivery, and evaluations conducted under less controlled home conditions are warranted to determine whether the practical advantages of PSM translate into meaningful improvements in clinical outcomes.

In this cohort, children managed with palm-seal method (PSM) had shorter duration (4 ± 1.86 days vs 5.2 ± 3.96 days) of hospitalisation than those managed with the conventional method (CVM), which may suggest an association between PSM use and reduced hospitalisation. However, length of stay is multifactorial and influenced by disease severity, comorbidities, and institutional practices, which should be considered when interpreting comparisons across studies. When contextualised with published data, reported mean or median hospital stays for paediatric viral respiratory infections range from approximately 3.5 to 5 days[18], which is similar to our study findings.

Limitations of study

A potential limitation of the PSM is the caregiver's ability to accurately observe the recommended 8–10 breaths if the VHC does not come with a visual indicator that moves with every inhalation. The hand position required to maintain an effective palm seal and stable mask placement may partially obstruct visualisation of the infant's chest or abdomen, making confirmation of effective breathing challenging, particularly given the naturally subtle chest expansion in infants. This difficulty is further compounded when the flow indicator on the valved holding chamber is unreliable, necessitating reliance on visual cues alone, which may be obscured by the caregiver's hands, the mask, or the device itself. When either PSM or CVM is concerned, other factors such as caregivers misunderstanding the 8–10 breaths as a count of 8–10, suboptimal lighting, awkward positioning of the child, and the need to prioritise seal integrity may further impair accurate breath counting. Despite these challenges, observation of gentle, visible chest or abdominal rise and fall remains the most practical method for confirming effective breaths when flow indicators cannot be relied upon, provided caregivers consciously maintain a clear line of sight.

Furthermore, this study did not investigate and address the impact of children being non-cooperative during drug administration and the brand of VHC used to deliver inhaled medication. Studies have claimed that crying during inhaled drug administration markedly reduces drug deposition and absorption in the lungs.[19, 20] Recent guidelines also did not elaborate on the importance of calming the child and providing instructions on the administration of inhaled medication in non-cooperative young children.[21, 22] In general, all our patients clinically improved and were discharged home after 4 ± 3 days of hospitalisation.

Practical Implementation

As securing a tight face-to-mask seal is critical for successful drug delivery, guidelines could benefit from more elaborate instructions on inhaled drug administration using VHC in young children. In our local practice, we encourage a more gradual and positive introductory measure, perceiving it as a possible effective approach in helping young children adapt to MDI use with a VHC. Caregivers may first allow the child to explore the device without medication, followed by brief mask placement for a few seconds at a time with reassurance or positive reinforcement. Mask contact duration can be progressively increased while keeping sessions short and calm. Once tolerated, practising normal tidal breathing with the chamber attached reinforces steady breathing, and demonstrating valve movement may improve engagement. The inhaler actuation can then be introduced and incorporated into a predictable routine, with caregivers modelling the technique when appropriate. Practising in different settings, maintaining a clear line of sight to observe breathing, and reinforcing technique through hands-on training or refresher education further support successful use.

In the context of an acute exacerbation of airway disease upon admission, timely administration of inhaled medication via a facemask and VHC is essential for effective bronchodilation. In young children, distress and lack of cooperation are common. In this situation, waiting for full cooperation may delay treatment and risk clinical deterioration. Consequently, controlled application of the facemask may be required to ensure delivery of inhaled medication. The standard approach should be undertaken using CVM with swaddling or assisted by nursing staff, or the PSM can be offered to parents, empowering them with the capacity to manage inhaled drug therapy in the ward with confidence, requiring minimal assistance.

Abbreviations

CVM
conventional method
ED
emergency department
FMC
facemask chamber
MREC

Medical Research Ethics Committee
NMRR
National Medical Research Registry
pMDI
pressurised metered dose inhaler
PSM
palm-seal method
SD
standard deviation
VHC
valved holding chamber

Declarations

AUTHORS' CONTRIBUTIONS

Conceptualisation and design : Tang Kai Lun and Balamurugan

Registration of clinical trial : Balamurugan.S

Data acquisition: Tang Kai Lun, Dr Teo Zhi Qi, Balamurugan, Foo Jia Zhi, Lau Pei Xin,

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DISCLOSURE

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Conflict of Interest : All authors have no conflicts of interest to disclose

Contents Summary:

Administering inhaled medications via a facemask chamber to young children can be very challenging, and we attempted to demonstrate that the palm-seal method is a more effective way to deliver inhaled medications using a facemask chamber.

Guideline Used for Reporting:

Consolidated Standards of Reporting Trials (CONSORT) with Extension for Randomised Cross-over Trial[1]

Registration of Research : NMRR-20-631-54325

Ethical Approval: MREC approval reference no. KKM/NIHSEC/P20-771(12)

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Figures

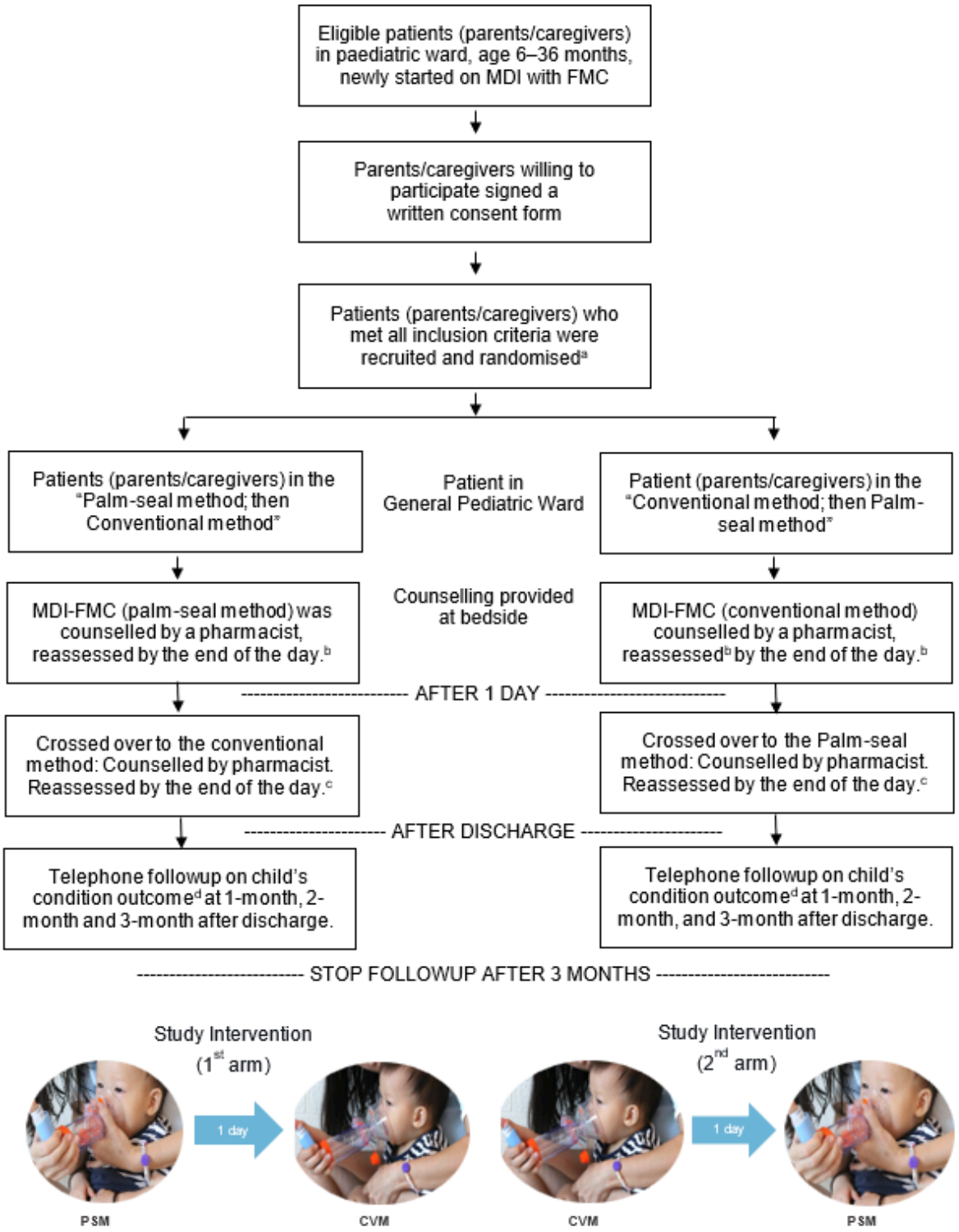


Figure 1

Flow-chart. (a) Randomised into two groups (i.e. conventional method and palm-seal method) using permuted block randomisation with 2 block sizes (4:6). Site investigators will recruit the patients and will be assigned to either one of the groups by the principal investigator. The block sizes will be kept confidential by the principal investigator to ensure that treatment allocation is not predictable by site investigators towards the end of a block, thereby ensuring complete randomisation. (b) Reassessed to

determine if the method successfully ensure good seal. (c) Reassessed to determine if the alternative method successfully ensure good seal and parents' ultimate preference towards any one method. (d)Outcome as in the number of exacerbations (per month) which require a visit to the ED or hospitalisation.

Supplementary Files

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