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Minimising Immunisation Pain of childhood vaccines: The MIP pilot study

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Title Page

(i) Minimising Immunisation Pain of childhood vaccines: The MIP Pilot Study

(ii) Original Article

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Conflict of Interest

We declare no conflicts of interest.

Main Text

(i) Abstract

AIM: Pain associated with immunisations can result in distress and/or anxiety for children and parents. We assessed the feasibility and acceptability of two novel devices; Coolsense[®] (cold) and Buzzy[®] (vibration +/- cooling pads) versus standard care to minimise pain during immunisations. **We**

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also evaluated compliance to the devices and parent's perception of the effectiveness of the devices/standard care for minimising pain during immunisation.

DESIGN: Open label, pilot, randomised controlled trial (RCT).

METHODS: 40 children aged 3.5 to 6 years attending an Immunisation Centre at The Royal Children's Hospital in Melbourne, Australia were randomised (1:1:1:1) into four groups: 1) Coolsense® plus standard care; 2) Buzzy® with cold plus standard care; 3) Buzzy® without cold plus standard care; 4) Standard care alone (distraction with bubbles).

RESULTS AND ANALYSIS: Recruitment was completed in 12 days. 70% were compliant with Buzzy® (+/- cold), 82% with Coolsense®, and 60% with standard care. Buzzy® (with cold) was identified as effective by 70% of parents, Coolsense® by 64%, Buzzy® without cold by 50% and standard care by 60%.

CONCLUSIONS: This pilot study demonstrated feasibility. A larger RCT is needed to provide definitive evidence to inform best practice for minimising immunisation pain in young children.

KEYWORDS: Immunisation, General Paediatrics, Pain

What is already known on this topic?

1. The pain associated with routine immunisations can sometimes result in distress and/or anxiety for children and their parents.
2. Distraction techniques such as blowing bubbles are recommended and currently used by many immunisation service providers as their standard of care¹.
3. There is currently no published data on the use of the Buzzy® device without application of the cooling pad (wings) or the Coolsense® device for minimisation of pain during immunisation.

What this paper adds:

1. This study showed that an RCT in the Royal Children's Hospital Immunisation Drop in Centre was feasible.
2. This study provides useful information on the acceptability of the Buzzy® and Coolsense® devices for minimising immunisation pain.
3. A larger RCT is needed to inform best practice for minimising immunisation pain in young children.

(ii) Text

INTRODUCTION:

During their early years, young children receive a number of intramuscular injections as part of their scheduled childhood immunisations. The pain associated with these immunisation procedures can sometimes result in distress and/or anxiety for the children as well as their parents. Longer-term risks of having painful early childhood injections may include fear of needle pain (or needle phobia), non-adherence with routine childhood and adolescent vaccination schedules and avoidance of medical attention². It is therefore imperative that effective pain management interventions are optimised in health care settings where immunisations take place.

Current standard of care for vaccine administration in toddlers and children include holding firmly and using distraction techniques, such as blowing bubbles, which have variable effects on pain minimisation¹. However, other pain reduction strategies are seldom used in health settings in Victoria, Australia where mass immunisations take place³.

A recent systematic review of randomized controlled trials (RCTs) found an insufficient evidence base for many procedural and physical interventions for vaccine injections⁴. Buzzy® is a vibrating handheld device used to help block sharp pain and provide distraction when giving injections to children (<https://buzzyhelps.com/>). A frozen cooling pad (wings) is placed behind Buzzy® before the device is placed on the child's arm (proximal to the injection site). Two trials to date have been published reviewing the effectiveness of using external vibration during immunisation and patient compliance with immunisations^{5 6}. One study used the Buzzy® device with cooling pad (wings)⁵ and

the other used a multifaceted discomfort reducing intervention (including an improvised arm gripper and a vibrating instrument)⁶. Both studies showed some benefit in reducing pain but highlighted a low quality of evidence for the critical outcomes examined overall (pain, fear). One other study demonstrated the efficacy of Buzzy[®] with cooling pad (wings) in reducing injection pain but this study focused particularly on paediatric intravenous access⁷. Although it was a randomised control trial, there were limitations to the study, in particular, the small sample size and the fact that the study was not double-blinded, thus potentially increasing bias.

To date, no studies have been published using the Buzzy[®] device without application of cold (cooling pad (wings)) for pain minimisation during immunisation. **Many community-based immunisation sessions in Australia are run by local councils. These sessions move between different locations, thus making it difficult to easily access a freezer.** Therefore, evidence of the effectiveness of the Buzzy[®] vibration device without the cold pack (wings) for minimising pain and fear associated with immunisations is needed if this device is to be an option for these settings.

More recently another device, Coolsense[®] has been trialled in the Royal Children's Hospital departments of Medical Imaging and Anaesthetic. A prospective observational audit of 100 children aged 6 to 18 years found Coolsense[®] to be safe and a useful tool during intravenous (IV) cannulation for minimising pain⁸. Coolsense[®] is fully registered by the Therapeutics Goods Administration (2013) as a reusable, non-invasive hand-held device that immediately cools and numbs the skin at the site of an injection⁹. It has been used for providing topical anaesthesia for painful procedures of the skin such as IV cannulation, venous blood tests and blood glucose testing¹⁰. Coolsense[®] has also been studied for minimising pain during finger prick blood glucose monitoring in adults¹⁰. There is currently no published data on the use of the Coolsense[®] device for minimisation of pain during immunisation.

A number of developmentally appropriate self-reporting tools can be used to measure pain in children and adolescents¹¹ such as Wong-Baker Faces[®] Pain Rating Scale¹¹, and the Visual Analogue Scale (VAS). Most children from the age of 4 years are able to appropriately provide a meaningful assessment of their pain¹² using the Faces Pain scale. From 8 years of age the validated VAS tool can be utilised to accurately measure pain intensity.

The Child Fear Scale (CFS) can be a useful tool for measuring fear in children before, during and after painful procedures^{6,13}. The CFS is a visual scale consisting of five cartoon faces where a neutral expression represents no anxiety and sits at zero, and a frightened expression is at the other end of the scale, representing significant anxiety and a score of four. Measurement of the efficacy of the devices in relation to pain and fear will be performed using Wong Baker Faces Scale (for self-report), and the VAS and CFS (for nurse and parent-report).

The Royal Children's Hospital Immunisation Drop-In Centre provides opportunistic vaccinations to patients, siblings and parents. In 2015/16 the centre vaccinated 9399 patients and their family members, an increase of 15% from the previous year. This number includes drop in patients, siblings and/or parents of the patient as well as outpatients directed to the centre. With such a high volume of patients, particularly pre-school aged children, attending the Royal Children's Hospital Immunisation Drop-In Centre, it is imperative that pain minimisation strategies are optimised for this age-group and if shown to be effective routinely offered to these children and their families.

OBJECTIVES:

This pilot study aimed to determine feasibility of the study design, in terms of recruitment and consent by parents of children attending the Royal Children's Hospital (RCH) Immunisation Drop-in Centre, as well as to provide data to inform sample size calculations for a future large RCT to evaluate the efficacy of Coolsense®, Buzzy® with wings, in addition to standard care versus standard care alone in minimising immunisation pain (by child report, parent report and nurse immuniser observer of pain) and child's fear (by parent and nurse immuniser report). Secondary objectives were to measure pain, compliance to pain minimising devices/standard care and parent's perception of effectiveness and usefulness of the devices/standard care.

METHODS

Design and Setting

The Minimising Immunisation Pain (MIP) study was a low risk, non-invasive, non-drug, four-armed pilot RCT set up to be conducted at the Immunisation Drop-in Centre at the RCH. It was estimated it would take approximately 3 months to recruit the required number of children for the study based on 75% uptake of those that met the inclusion criteria.

The study received ethical approval from the **RCH Melbourne** Human Research Ethics Committee (HREC 37041).

Participants:

Children

All children aged 3.5 to 6 years of age inclusive presenting with a parent/guardian to the **RCH** Immunisation Drop-in Centre for a **single** immunisation were eligible to participate in the study. Children with a significant needle phobia, haemophilia or bleeding disorder, skin damage (such as eczema) at the injection site were excluded from the study. After study commencement, an additional exclusion criterion was added: diagnosed intellectual, developmental, or behavioural disorder (which prevented them from being able to complete a visual pain scale).

Sample Size Estimation

The sample size for this pilot study was chosen to be 40 children (10 each arm) since 40 children can be recruited over a fairly short period of time (**approximately 3 months**) and would provide data on the feasibility and to inform on sample size for the future study.

Procedures/Interventions:

Children attending the **RCH Melbourne** Immunisation Service Drop-in Centre were assessed for eligibility by an Immunisation Nurse. **The child's parents or legal guardians were then approached to explain the pilot study and written informed consent was obtained prior to recruitment.**

Once enrolled, participants were randomised using Redcap Software Version 6013.3 ©2016 Vanderbilt University. Randomisation was to 1) Coolsense® + Standard care, 2) Buzzy® with wings+ Standard care, 3) Buzzy® without wings Standard care or 4) Standard care (distraction with bubbles)

with an allocation ratio of 1:1:1:1, using a web-based randomisation procedure. The randomisation schedule and web-based service was provided by an independent statistician from the Clinical Epidemiology and Biostatistics Unit (CEBU) at the Murdoch Children's Research Institute. Randomisation was in randomly permuted blocks of variable length.

All children received standard care which involved administering of the vaccine into the non-dominant arm and distraction with the blowing of bubbles. Blowing bubbles was used in addition to the other treatment interventions. The immunisation nurse or child blew the bubbles immediately prior to administering the vaccine. For the standard care group this was the only intervention they received.

Children randomised to the Coolsense® group, had the Coolsense® device placed on the site of injection for a count of 10 seconds prior to the vaccine being administered. The Buzzy® device either with or without wings, was placed at the site for injection and held in place for 30 seconds and then moved up the arm so that it was placed proximal to where the injection would be given. The use of the Buzzy® device was based on the manufacturer's recommendations and was the agreed practice by all immunisation staff involved in the study¹⁴. All immunisation staff involved in the study were given information and practical training in the use of both the Buzzy device and Coolsense® device prior to contact with participants.

All data collected was entered in RedCap Software.

MEASURES:

In order to determine feasibility of study design, we collected the following; 1) the number of participants who were approached; 2) the number of participants who agreed to be in the study; 3) the number of participants who refused to be in the study; 4) the number of participants who fully complied with the device/standard care; 5) the number of participants who withdrew from the study early.

Outcome measures to gather preliminary information about efficacy included: nurse and parental report of the child's level of fear/anxiety pre and post procedure using the Children Fear Scale (CFS); nurse and parental report of child's pain using the Visual Analogue Scale (VAS); Child's self-report of

pain using Wong Baker Faces Scale^{©11} immediately post injection. The CFS is a visual scale consisting of five cartoon faces where a neutral expression represents no anxiety and sits at zero, and a frightened expression is at the other end of the scale, representing significant anxiety and a score of four⁶. The VAS is a 10cm pain rating scale with 0cm representing no pain and 10cm at the other end of the scale representing the worst pain¹¹. The Wong Baker Faces Scale[©] is a visual tool consisting of six cartoon faces placed on a numerical linear scale, with faces ranging from happy at zero to crying at ten.

Compliance with allocated intervention was rated by the Immunisation nurse administering the immunisation to the participant. They rated each participant as either fully compliant, somewhat compliant or not compliant. A participant was rated as fully compliant if they allowed the device to be held in place for the required time as recommended by the manufacturer. A participant was rated as somewhat compliant if they allowed the device to be placed at the injection site but requested the device be withdrawn earlier than the required time. A participant was rated not compliant when they refused to have the device placed at the injection site at all. Assessment was standardised through training of immunisation nurses providing immunisations to the participant.

Effectiveness of the intervention/technique was rated by the participant's parent or guardian as less painful, more painful, or no effect. In addition, they were asked if they would consider the technique/intervention for their child with future immunisations by responding with a yes, no or uncertain.

ANALYSIS

Baseline characteristics of the children were presented separately by arms using means and standard deviations for continuous data and proportions for categorical data [Table 1]. Absolute frequencies of patients who were approached regarding the study, who agreed to be in the study, and who refused were summarised. Absolute and relative frequencies of participants who fully complied with the device/standard care, who withdrew from the study, who early withdrew the device/standard care were calculated and reported by arm. Means and SDs of the child WONG Baker Faces Scale[©] score, parent and nurse immuniser VAS and CFS Scores were calculated and reported by arm [Figure 2].

Nurse Immuniser rating compliance to the device/standard care were reported by arm [Figure 3].

RESULTS

The MIP Study was commenced in July 2017, which coincided with the peak of the Australian Influenza season, hence a busy immunisation Drop-In centre. Recruitment of participants was completed within 12 days of commencement. Forty-six patients presenting to the RCH Immunisation Drop in Centre were screened for eligibility. There was 100% uptake of willingness to be in the study from parents and guardians approached and no withdrawals from the study. Of the forty-six patients screened, five patients were excluded (two were less than 3.5 years, one was unable to communicate effectively, one child needed more than one vaccine, and one related to incomplete randomisation) [Figure 1]. The remaining forty-one participants were randomised for the study. One of the first patients screened and randomised was found post procedure to have a behavioural and developmental disorder, affecting their ability to accurately utilise the Wong Baker Pain Faces scale. All other post-procedural scores as reported by the child's parent, and the nurse had been recorded and this data was analysed. An additional exclusion criterion was added to the study protocol following this such that children diagnosed with an intellectual, developmental, or behavioural disorder (which prevents them from being able to complete a visual pain scale) were excluded. The Standard Care group had one participant who refused to point to a face on the Wong Baker Pain Faces scale, despite verbalising their understanding of each face on the scale. All other data had been collected for this participant and has been analysed and reported in the tables below.

FIGURE 1 – CONSORT Diagram

Of the 41 children who participated in the pilot study, including 18 females (44%) and 23 males (56%), 34 (83%) received the vaccine in their left arm (Table 1).

The majority of vaccines administered were Influenza vaccines (63%), with the scheduled 4-year old Infanrix IPV given to 29% of children. There were three children that received 'Other' vaccines: one

child each received a Varilrix and a Pneumovax 23 in the Coolsense[®] group. The child in the Buzzy[®] WITHOUT wings group received a Priorix (MMR) vaccine.

TABLE 1 – BASELINE AND DEMOGRAPHICS

FIGURE 2 – PAIN AND FEAR OUTCOMES

Based on observational assessment by the immunisation nurse, full patient compliance with the immunisation procedure was 82% in the Coolsense[®] group, 70% in the two groups receiving the Buzzy[®] device and 60% in the standard care group [Figure 2].

FIGURE 3 – PATIENT COMPLIANCE

Based on parent report, intervention technique effectiveness for pain minimisation was 70% in the Buzzy[®] with wings groups, 64% in the Coolsense[®] group, 60% in the Standard Care group, and 50% in Buzzy[®] without wings [Figure 3].

FIGURE 4 – TECHNIQUE EFFECTIVENESS (AS PER PARENTS)

DISCUSSION

The MIP pilot was primarily set up to assess feasibility and acceptability of study design so that a larger randomised controlled trial could be conducted to determine the efficacy of these two novel devices (Coolsense[®] and Buzzy[®]) to minimise immunisation pain. The study design was acceptable to children, parents and nurses with all parents approached about the study consenting to recruitment. Feasibility of study design was demonstrated with the recruitment of 40 children within twelve days, despite three months being initially estimated for recruitment. The Coolsense[®] device and Buzzy[®]

device with wings were perceived to be the most effective by parents. It does not appear that parents thought the Buzzy® device without wings was as effective as the other two devices. This therefore may not be a useful alternative for community immunisation service providers who don't have access to portable freezers. This was an important consideration leading into the larger RCTs and it was decided that only the Buzzy® device with wings would be included in the trials.

There were some key lessons learned from conducting this pilot study that provided valuable knowledge and data for setting up the larger RCTs. As previously discussed, we initially included a patient that had an intellectual, developmental, or behavioural disorder which prevented them from being able to complete a visual pain scale. The reason for not excluding this participant from the analysis was that there was no ground for doing so, since they were not in violation of any of the entry criteria in place at the time of their randomisation.

This pilot study was successful in providing the information that the study protocol was not feasible for participants with an intellectual, developmental, or behavioural disorder as they were unable to complete the visual pain scale. Fortunately, this lack of feasibility was revealed early on in the first group of patients and the protocol was amended immediately. In error, we also randomised an additional participant, so we report on 41 participants in this study. A further limitation of this pilot study was not stratifying randomisation based on vaccine type administered. As some vaccines can be more painful than others on administration, the potential differences between administration of subcutaneous and intramuscular vaccines will be considered for the larger RCTs.

Both the pain measurement scales and fear scales used were validated tools and were appropriately selected for the ages of the populations studied. Whilst definitive conclusions cannot be drawn from the preliminary pain and fear results, it was important to confirm the appropriateness of these measurement tools prior to commencing the larger RCTs.

The measurements of compliance and technique effectiveness, although subjectively assessed, supported the study design. Although non-validated tools were used, the parents' perception of effectiveness and nurses' opinion of compliance were important in assessing feasibility of study design and acceptability of the novel devices prior to commencing two larger RCTs in younger and older children.

Overall this was a well-designed study which offers the first reported information on the feasibility and acceptability of two novel devices, and preliminary data on the compliance and parent reported effectiveness of Coolsense® and Buzzy® devices to minimise immunisation pain in pre-school aged children.

CONCLUSIONS

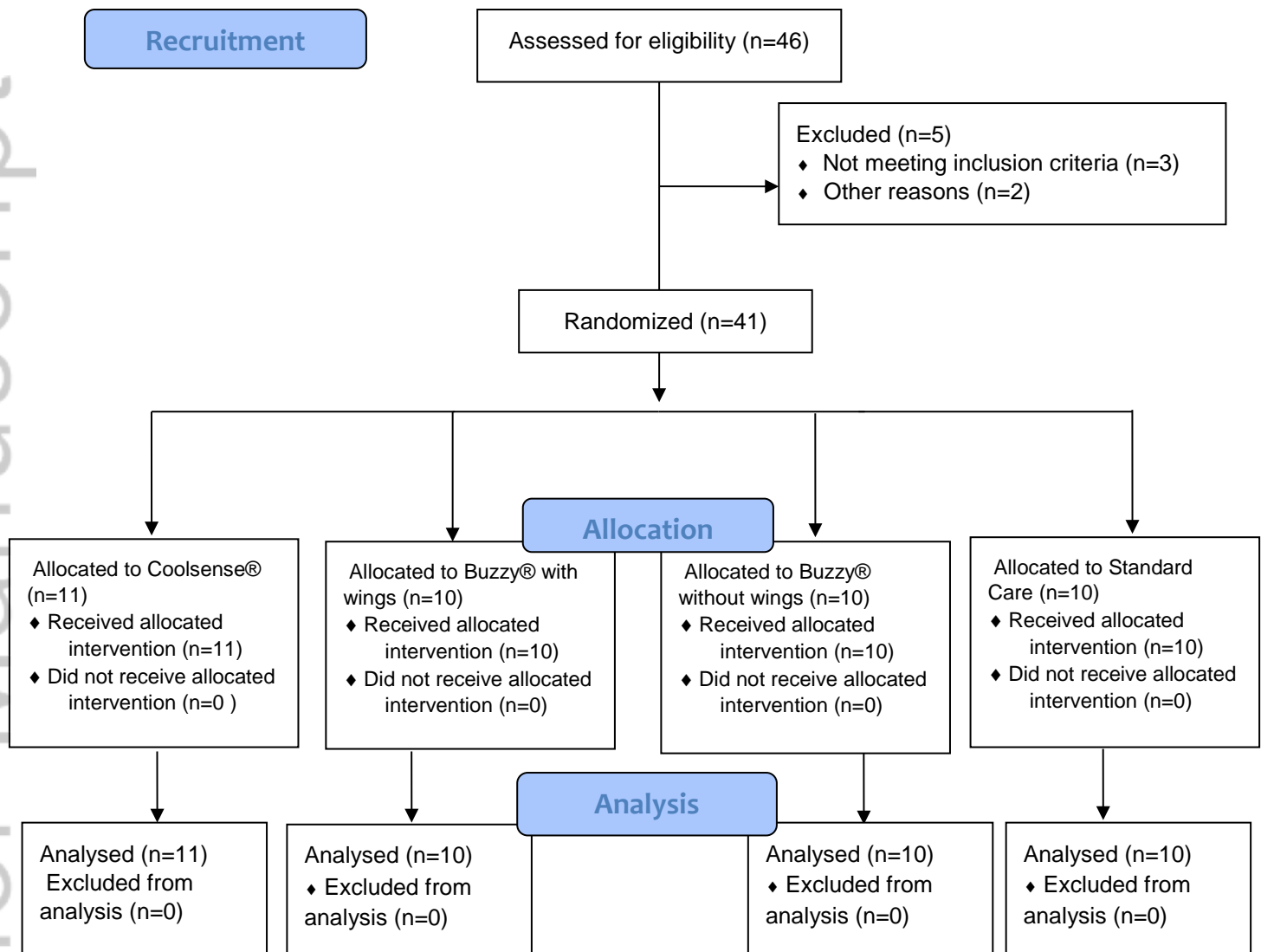
This pilot study demonstrated feasibility and acceptability of the two novel devices to minimize pain during immunisation. Larger RCTs assessing the efficacy of Coolsense® and Buzzy® compared to standard care in younger (3.5 to 9 years inclusive) and older (10 to 17 years inclusive) children are now underway^{15,16}. These RCTs are expected to provide definitive results which will directly inform clinical practice to enable immunisation providers to optimally minimize pain and fear of immunisations in childhood.

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Figure 1



Title Page

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