Does routine spirometry impact on clinical decisions and patient-related outcome measures of children seen in respiratory clinics: an open-label randomised controlled trial

Wicharn Boonjindasup, Julie M Marchant, Margaret S McElrea, Stephanie T Yerkovich, Ian B Masters, Anne B Chang

ABSTRACT

Introduction There is limited evidence on the efficacy of using spirometry routinely in paediatric practice for improving outcomes.

Objective To determine whether the routine use of spirometry alters clinical decisions and patient-related outcome measures for children managed by respiratory paediatricians.

Methods We undertook a parallel open-label randomised controlled trial involving children aged 4–18 years able to perform spirometry in a specialist children’s hospital in Australia. Children were randomised to either routine use of spirometry (intervention) or clinical review without use of spirometry (control) for one clinic visit. The primary outcomes were the (a) proportion of children with ‘any change in clinical decisions’ and (b) ‘change score’ in clinical decisions. Secondary outcomes were change in patient-related outcome measures assessed by State–Trait Anxiety Inventory (STAI) and Parent-Proxy QoL questionnaire for paediatric chronic cough (PC-QoL).

Results Of 136 eligible children, 106 were randomised. Compared with controls, the intervention group had significantly higher proportion of children with ‘any change in clinical decisions’ (n=54/54 (100%) vs n=34/52 (65.4%), p<0.001) and higher clinical decision ‘change score’ (median=−2 (IQR 1–4) vs 1 (0–2), p<0.001). Also, improvement was significantly greater in the intervention group for overall STAI score (median=−5 (IQR −10 to −2) vs −2.5 (−6.5, 0), p=0.021) and PC-QoL social domain (median=3 (IQR 0 to 5) vs 0 (−1, 1), p=0.017).

Conclusion The routine use of spirometry in children evaluated for respiratory issues at clinical outpatient review is beneficial for optimising clinical management and improving parent psychosocial well-being.

WHAT THIS STUDY ADDS

⇒ Spirometry is recommended as an adjunct test in many respiratory practice guidelines. However, there is a paucity of high-quality evidence to support the routine use of spirometry in children. Only disease-based observational studies reported beneficial outcomes when spirometry was integrated into clinical care and a single randomised controlled trial (RCT) showed that using spirometry in general practice did not result in any significant intergroup difference in asthma-related quality of life.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is limited evidence on the efficacy of using spirometry in improving clinical management and patient-related outcome measures in children seen in a respiratory clinic. Our RCT found that the routine use of spirometry in children being evaluated for respiratory problems, compared with clinical review alone, significantly influenced doctor’s decision (change in diagnosis and/or management) and improved patient-related outcome measures. Both doctors and parent/carer(s) rated the benefits of using spirometry very highly on Likert scales.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ In children evaluated for respiratory issues in outpatients, the routine use of spirometry is beneficial for optimising clinical management and improving parents’ psychosocial well-being. Given the available high-level evidence that we now have, the use of spirometry should be a priority and implemented in routine clinical practice when evaluating children for respiratory illnesses.

INTRODUCTION

In paediatric practice, undertaking spirometry is relatively simple and arguably contributes to clinical practice decisions for diagnosis and management. Spirometry data provide objective information and may identify abnormalities affecting airflow, lung capacity and intra-/extrathoracic obstruction. Unsurprisingly, spirometry is highly recommended in many paediatric clinical...
guidelines including those relating to the management of chronic cough, recurrent wheezing, cystic fibrosis, bronchiectasis and asthma.5–7 Spirometry is often the only objective measurement available in many settings and has been used in multiple studies especially asthma and it is highly accessible.

Although spirometry is widely advocated, it is underused in children, especially in non-pulmonology clinic settings, even in specialist centres.8 One of the main reasons spirometry is under-used is that children may find the manoeuvre difficult to perform, and the success rates in the younger age groups may be low.8 9 A study reported that only 32.4% of children aged 5–8 years with potential asthma had at least one spirometry undertaken either in the year before (6.4%) or the 2 years after (29.7%) the first asthma treatment.10 Moreover, only one-third of children with asthma were referred for spirometry,12 and only half of children hospitalised with asthma underwent spirometry during follow-up.13 Others found that only 10–21% of general practitioners and paediatricians used spirometry consistently in childhood asthma management.14 15

The low utilisation of spirometry on a routine basis is not surprising, likely partly related to limited high-level evidence supporting its benefits. Indeed, the impact of spirometry on clinical outcomes has rarely been studied in children. Our a priori registered systematic review16 followed by an updated search found only one published randomised control trial (RCT) which did not demonstrate improvement in quality of life (QoL) or other clinical endpoints when spirometry was used in the evaluation of children with asthma over a 1-year period.

Given the paucity of data, we undertook this RCT to formally evaluate the benefits of using spirometry in a single outpatient visit. Our primary aim was to determine whether the routine use of spirometry alters the treating doctor’s clinical decisions for children with respiratory problems being managed by respiratory paediatricians in outpatient clinics. Our secondary aims were to (1) determine whether the routine use of spirometry impacts on diagnostic certainty and patient-related outcome measures (PROMs), and (2) quantify the benefits of routinely using spirometry in clinical practice assessed by 10-point Likert scales.17 Our hypothesis is that the integration of spirometry into the consultation alters clinical decision-making, improves diagnosis certainty and improves PROM(s), specifically in emotional and social domains (evaluated by State–Trait Anxiety Inventory (STAI))18 19 and/or Parent-Proxy QoL questionnaire for paediatric chronic cough (PC-QoL)).20 21

METHODS
Study design
Our single-centre open-label RCT protocol has been published.22 Briefly, our RCT with concealed (1:1) allocation was undertaken at the Department of Respiratory and Sleep Medicine at the Queensland Children’s Hospital, Brisbane, Australia. The study was registered; Australian New Zealand Clinical Trials Registry (ACTRN12619001686190).

Patient and public involvement
Patients were first involved in this study at the stage of study design as the study was partially based on the experience and preferences from parents/ grandparents of children attending our respiratory clinics. As spirometry is not a routine evaluation when they see doctors at non-specialty settings, they questioned the necessity of undertaking spirometry and how it could have an effect on patient’s care. They were not involved in the conduct of the study. We did not assess the burden of participating in this study, but the patients were able to report any burden and could withdraw at any time. Our outcomes included appropriate PROMs. We plan to disseminate the study outcomes to study participants during their follow-up clinical reviews through a leaflet with a summary of what our study found. We will disseminate study results to the wider community through this publication, future workshops and education sessions to health professionals, to highlight the utilisation of spirometry.

Participants
In our centre, spirometry in accordance with standard guidelines23 24 is undertaken in all age-appropriate children at each clinic visit, calculated and interpreted using standard references.25 26 All spirometry was performed using Vyaire Pneumo or Masterscreen spirometers (Vyaire Medical, Mettawa, Illinois). All spirometry and bronchodilator responsiveness tests were conducted by paediatric trained respiratory scientists who are graduates and accredited in lung function testing (detailed further in online supplemental material). Eligible participants were approached by an investigator in the outpatient clinic before they saw the doctor.

Inclusion criteria were (1) children with parent/guardian in attendance and able to provide written consent, (2) children aged 4–18 years able to perform reliable spirometry and (3) parent/guardian able to complete the study questionnaires. Written informed consent was obtained from the child’s parent/carer. Exclusion criteria were (1) previously enrolled or (2) contraindication for spirometry including presence of acute dyspnoea, pneumothorax, haemoptysis, vital signs instability, lung cyst/bleb and recent thoracic/ophthalmic surgery.

Randomisation and allocation
Children were randomised to either routine use of spirometry (intervention) or delayed use of spirometry (control) using a computer-generated permuted block sequence (sizes of 2–6) generated by an external statistician. The randomisation was stratified by consultation type (new patient/review patient) and chronic cough
(present/absent). The group allocation was concealed in sequentially numbered envelopes until the participant was recruited. However, blinding was not feasible due to obvious difference in availability of spirometry data between groups.

**Study arms**

The study is outlined in figure 1. Before seeing the doctor, parents in both groups completed baseline PROM questionnaires (timepoint-1, T1). All parents completed the STAI, while only those whose child had a current chronic cough also completed the PC-QoL. These questionnaires are summarised in online supplemental material.

Following this, the intervention group had a consultation with their doctor with spirometry results, while the control group had an initial consultation without spirometry results. The doctor interpreted the spirometry, using the respiratory scientist’s comments, flow–volume curve, volume–time curve, lung function parameters (FEV1, FVC and FEV1/FVC) and changes in these parameters post-bronchodilator (when done) in accordance with standard recommendations. Spirometry data were used with clinical review to inform the doctor’s clinical decisions for the individual child’s management and, when appropriate (for the new patients), the diagnosis as well. After the consultation (timepoint-2, T2), all parents/guardians completed the same questionnaires for a second time, and the doctor completed data collection sheets which captured changes in diagnosis, and management after spirometry results were reviewed compared with T2.

At the completion of the consultation with spirometry results (ie, T2 for intervention group and T3 for control group), the parents scored on a 10-point Likert scale “how much did the spirometry help with this visit?” Using the Likert scale, the doctors also scored three aspects of using spirometry for the clinical review; “How much did the spirometry: (i) contribute to general management; (ii) increase confidence in clinical practice; and (iii) aid education/counselling with each patient?”. The unipolar scale (1 to 10) is anchored by increasing degree of agreement, with 1 being ‘not at all’, 5 being ‘somewhat’ and 10 being ‘very much so’.

**Outcomes**

Our primary outcomes were intergroup differences at T2 for the (a) proportion of children with ‘any change in clinical decision making’ (diagnosis and/or management) and (b) ‘change score’ (figure 1). This score consisted of an a priori list including any change decisions in diagnosis based on two categories ((i) disease, a new diagnosis made or changed from the former one and (ii) severity, change in severity classification or disease status) and management based on four categories ((i) change in medications prescribed, (ii) change in additional investigations needed, (iii) change in follow-up schedule from regular or previous interval and (iv) change in patient education or new education provided). The change in each category was dichotomised as ‘yes’ or ‘no’. Each ‘yes’ scored 1 point, so the possible range in ‘change score’ ranged from 0 to 6 (2 points for change in diagnosis and 4 points for change in management). If there was a change in clinical decision, the doctor also indicated what was changed in the category.

Our secondary outcomes were (a) change of PROM scores (STAI and PC-QoL score) from baseline (T1) assessed at T2 (T2−T1), (b) degree of diagnosis certainty as ‘definite’ or ‘probable/doubtful’ (c) parent and doctor opinions on the value of spirometry being part of the consultation using a 10-point Likert scale. STAI and PC-QoL are further described in online supplemental material.

**Sample size**

To determine our sample size, we assumed that the proportion of children with any change in clinical decision in the population was 30% (Ho: p=0.30). We required a total of 106 children for 90% power to detect 15% difference in the proportion (alternative p=0.45) between groups at 5% significance (α=0.05, two-sided).
Statistical analysis
A statistical analysis plan was approved by the research team prior to data analysis. We analysed the data using intention-to-treat on the STATA software (V.15). The main analyses focused on outcomes between groups (intervention vs controls) at T2. The difference of categorical data, including the proportion of children with change in each clinical decision, and children with ‘definite’ certainty of diagnosis, were examined using χ² test. The difference of continuous data, including change in clinical decision calculated as score, and change of PROM scores (T2−T1) were examined using t-test or Mann-Whitney U test depending on normality of the data. If there was any imbalance between groups at baseline, we planned to adjust the results for these factors in a sensitivity analysis, using logistic regression for categorical data or linear regression for continuous data.

In addition to our main analyses, we analysed outcomes in the control group to compare data before and after spirometry inclusion in the consultation (T2 vs T3), although our study was not powered for this analysis. Continuous data including change in clinical decisions (calculated as ‘change score’) as well as change of PROM scores (T3−T2) were both examined using Wilcoxon signed-rank test.

RESULTS
Children were recruited from 17 March 2020 to 17 February 2022. Of the 136 eligible children approached over the recruitment period, 110 parents consented, and 106 children were randomised (four excluded for non-acceptable spirometry on review of spirometry data) (figure 2). No participants dropped out of the study.

The groups were similar in most, but not all, the characteristics at baseline (T1) (table 1). In both groups, 50–52% of the children had asthma, and approximately 30–33% of the children had chronic suppurative lung disease (protracted bacterial bronchitis or bronchiectasis). Most of the children were not new patients and were being reviewed at the visit for cough or dyspnoea. Although the diagnostic profiles were similar, the intervention group had slightly lower mean spirometry values although still in the normal range. More children in the intervention group (20.4%) had significant bronchodilator reversibility compared with the control group (7.7%).

All children in the intervention group, compared with around two-thirds of children in the control group, had at least one change in doctor’s clinical decision. The proportion of children with any change in doctors’ clinical decisions at T2 and the clinical decision ‘change score’ were significantly higher in the intervention group (both p<0.001), that is, when spirometry was part of the consultation (table 2). The differences were primarily in change in ‘follow-up schedule’ and ‘education’. These outcomes remained significant when data were adjusted for FEV₁ and bronchodilator reversibility. There were no differences between groups in other specific changes in diagnosis or management.

At T2, when doctors had spirometry available in their clinical review (intervention group, n=54), using the spirometry results led to the following change in clinical decisions:

► For respiratory disease diagnosed: 6 children had a new diagnosis made, and 8 children had diagnosis changed (3 from asthma to others, 5 from others to either asthma or obstructive lung disease).
► For severity classification: 8 children had improved, and 9 children had deteriorated.
► For medications prescribed: 14 children had their medications increased or a new medication added, and 5 children had their medications decreased or ceased.
► For additional investigations: 5 children were sent to radiology for either chest X-ray or CT chest, 3 children were booked for advanced respiratory function testing and 2 children were booked for sleep tests.
► For follow-up schedule: 7 children had an earlier review, 5 children had a later review, 2 children were discharged from the respiratory clinic and 1 child was withheld from discharging.
► For patient education: 26 children received reassurance due to normal lung function, 20 children received further explanation about the respiratory disease and 7 children received further discussion of management illustrated using the lung function.

Regarding the change in PROM scores, the improvement at T2 from baseline (table 2) in the intervention group was significantly greater than that in the control group, although both groups improved. The improvement in the overall STAI score was predominantly related to the state anxiety component. The total PC-QoL score also improved in both groups and was significantly better in the intervention group, predominantly in the social domain. However, with statistical
adjustment for FEV₁ and bronchodilator reversibility imbalance, the total PC-QoL improvement between groups was no longer significant, but the social domain remained significantly better in the intervention group. The adjustment did not alter the significance of other PROMs.
The control group was evaluated again after the delayed presentation of spirometry to the doctor (T3). Additional analyses to compare between before and after spirometry inclusion in the consultation for the control group are presented and discussed in online supplemental material.

The scores of parents and doctors rating the routine use of spirometry in clinical practice on Likert scales were very high (Table 3), with the median ranging between 8 and 9.

**Table 2** Change in clinical decision, clinical decision ‘change score’, degree of diagnosis certainty and change of STAI and PC-QoL scores from baseline (T1) of both groups at post-consultation (T2)

<table>
<thead>
<tr>
<th>Reported by doctor at T2:</th>
<th>Intervention (N=54)</th>
<th>Control (N=52)</th>
<th>p Value</th>
<th>Adjusted p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in any clinical decision</td>
<td>54 (100%)</td>
<td>34 (65.4%)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>14 (25.9%)</td>
<td>12 (23.1%)</td>
<td>0.823</td>
<td>0.528</td>
</tr>
<tr>
<td>Severe</td>
<td>17 (31.5%)</td>
<td>13 (25%)</td>
<td>0.521</td>
<td>0.666</td>
</tr>
<tr>
<td>Change in management, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>19 (35.2%)</td>
<td>11 (21.2%)</td>
<td>0.133</td>
<td>0.243</td>
</tr>
<tr>
<td>Investigation</td>
<td>15 (27.8%)</td>
<td>12 (23.1%)</td>
<td>0.658</td>
<td>0.636</td>
</tr>
<tr>
<td>Follow-up schedule</td>
<td>15 (27.8%)</td>
<td>4 (7.7%)</td>
<td>0.006</td>
<td>0.009</td>
</tr>
<tr>
<td>Education</td>
<td>53 (98.2%)</td>
<td>21 (40.4%)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Clinical decision change score, median (IQR)</td>
<td>2 (1–4)</td>
<td>1 (0–2)</td>
<td>&lt;0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Diagnosis certainty, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Definite</td>
<td>37 (68.5%)</td>
<td>38 (73.1%)</td>
<td>0.672</td>
<td>0.495</td>
</tr>
<tr>
<td>Probable/doubtful</td>
<td>17 (31.5%)</td>
<td>14 (26.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T2–T1 scores:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in STAI scores, median (IQR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>State anxiety</td>
<td>−5 (−10 to −2)</td>
<td>−2.5 (−8.5, 0)</td>
<td>0.021</td>
<td>0.032</td>
</tr>
<tr>
<td>Trait anxiety</td>
<td>3.5 (−9, −2)</td>
<td>−1 (−4.5, 1)</td>
<td>0.003</td>
<td>0.007</td>
</tr>
<tr>
<td>Change in PC-QoL scores, median (IQR) (intervention N=19, control N=18)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychological domain</td>
<td>10 (1, 20)</td>
<td>3 (−2.5)</td>
<td>0.037</td>
<td>0.153</td>
</tr>
<tr>
<td>Physical domain</td>
<td>4 (1, 9)</td>
<td>0.5 (−1, 4)</td>
<td>0.080</td>
<td>0.422</td>
</tr>
<tr>
<td>Social domain</td>
<td>3 (−1, 12)</td>
<td>1 (−1, 4)</td>
<td>0.211</td>
<td>0.292</td>
</tr>
<tr>
<td></td>
<td>3 (0, 5)</td>
<td>0 (−1, 1)</td>
<td>0.010</td>
<td>0.047</td>
</tr>
</tbody>
</table>

*Sensitivity analysis adjusted for FEV1, z-score and bronchodilator reversibility.
PC-QoL, Parent–Proxy QoL questionnaire for paediatric chronic cough; STAI, State–Trait Anxiety Inventory.

**DISCUSSION**

In this open-label RCT, we examined the impact of the routine use of spirometry on doctors’ clinical decisions and PROMs, compared with non-use of spirometry, at paediatric respiratory clinics. We found that using spirometry with clinical review, compared with controls, significantly increased (1) the proportion of children whose doctors altered their clinical decision during the review and (2) ‘change score’ in clinical decision. Spirometry also contributed to significant improvement in PROMs, including overall STAI with state anxiety, and the PC-QoL social domain. Both patients and doctors rated the benefits of using spirometry in clinical practice highly on Likert scales.

To use, or not to use, spirometry routinely for children with respiratory problems is a long-standing question; hence, our study attempted to find an answer. Our study is important as this is the first high-level evidence informing the role of spirometry in paediatric respiratory practice. Despite the importance of spirometry for clinical practice, there is marked paucity of Level 1 evidence. We undertook the RCT by concealed allocation to strengthen our findings, although blinding was not possible. Given that spirometry data is a measure used for a single point in time for clinical decisions, we evaluated the outcomes of spirometry integration at a single clinic visit. Our study’s endpoints, assessed from both doctor and patient perspectives, provided clear evidence of the benefits of incorporating spirometry into regular clinical review.
The impact of spirometry on diagnosis and management in children has previously been reported in few observational asthma studies. One study of 367 children with asthma described that spirometry results changed treatment decisions in 15% of outpatient visits, independent of the patient’s age, disease severity, symptom control or clinical findings. In another community-clinic-based study involving 56 children with an asthma exacerbation, nearly one-third of the children had their original treatment plans changed after doctors viewed their spirometry results. Similar to these previous studies, we found that spirometry changed clinical decisions in medication use for approximately one-third of the children. However, most subgroups of clinical decision changes (including diagnosis certainty or severity, or medication or investigation) were not significantly different between groups. This is likely because the majority of our participants were review cases in the tertiary centre who already had a definitive diagnosis and established management regimes and our sample size was not powered for subgroup analysis. However, despite the lack of statistical significance, we still believe that the contribution of spirometry is substantial for each individual as it is important to correct or confirm the diagnosis and management, as recommended by several guidelines.

Our findings of spirometry contributing to clinical decision-making especially in their follow-up schedule and education are not surprising. Although there are currently no such data on the role of spirometry in such management, it is intuitive that spirometry is helpful as it provides objective evidence pertinent to aid discussion and improve parent understanding of their child’s medical condition. The benefits of spirometry are also reflected in the high Likert scale scores rated by parents and doctors.

PROMs are now considered important in clinical studies as they focus on patient’s perspective. We used STAI and PC-QoL as they have demonstrated validity and reliability. Our findings were consistent with our hypothesis as we found that the integration of spirometry into a consultation had significantly improved state anxiety, and social domain of PC-QoL relating to respiratory diseases, compared with controls. After consultation with the doctor, both groups had improved PROM scores, but there was a greater improvement in those whose consultation included spirometry. Our findings were in contrast to cluster general practice-based RCTs which reported that QoL scores (Pediatric Asthma Impact Scale or Pediatric Asthma QoL Questionnaire) were not significantly impacted by spirometry. Several differences in study design between this study and our study can explain the contrast in findings; the intervention of the cluster RCTs was either 3-monthly spirometry reports sent to general practices or spirometry used at general practices after 2–6 hours of training for local staff, while our RCT intervention used spirometry operated by experienced lung function scientists and interpreted by respiratory paediatricians. In addition, PROMs in the former study were reported at baseline and 12 months, while we assessed change of PROMs at a single visit that spirometry was performed.

While our findings on the important role of spirometry in paediatric respiratory practice are novel, there are some limitations. First, this is a non-blinded study with its systematic biases. Although debatable, we had considered that it was unethical to withhold spirometry data for the entire outpatient appointment as spirometry is routine practice in our centre. Second, because this RCT was undertaken in a specialist children hospital, data may not be applicable in other settings where children are less likely to have respiratory problems. Also, in settings with resource constraints, the effect size would likely be diminished. For spirometry to be beneficial, it needs to be undertaken in accordance with standard guidelines and requires correct interpretation. Thus, outside of respiratory practice, it is likely that additional training for users is required. In addition, our findings are limited to a single timepoint assessment, and we could not determine long-term outcomes, especially physical outcomes that require regular assessment such as symptom control, and cardiopulmonary capacity. Third, many participants scored PROMs near the upper limit and a ceiling effect was likely to occur, making it difficult to get an accurate measure of the spirometry effect. Fourth, our study was limited to children older than 4 years who were able to reliably perform spirometry. A study in younger children using alternative measurements is required to confirm the benefits (or otherwise) of other routine lung function tests. Lastly, our study was designed to evaluate the routine use of spirometry in outpatient setting as an adjunct to clinical review. A study design that evaluates the benefits of spirometry specifically for the (a) diagnosis, (b) monitoring of different respiratory diseases and/or (c) in settings where spirometry is not routinely used would likely have provided higher-level evidence for the benefits (or otherwise) of spirometry in clinical practice.

CONCLUSION

The routine use of spirometry in children at outpatient clinics significantly influenced the doctor’s clinical decision and improved parents’ psychosocial QoL. Both doctors and parents reported that they were markedly satisfied with spirometry use in clinical practice and its contribution to general management, strengthened confidence in decisions, and that it aided education of parents and children. Spirometry should be routine in healthcare system when evaluating children with suspected or known respiratory disease. RCTs involving multiple centres, including primary care settings, to determine the role of spirometry with extended study duration are warranted to confirm our findings.

Author affiliations

1 Child Health Division, Menzies School of Health Research, Casuarina, Northern Territory, Australia
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Contributors ABC conceptualised the study and designed the study with IBM. WB, JMM, and MSM co-designed the methodology. ABC and WB were project administrators. WB involved in investigation, data curation and formal analysis under supervision of ABC, JMM, MSM and STY. All authors validated the data and analysis. The first draft of manuscript was written by WB. All authors reviewed and approved the final manuscript. WB had full access to the data in the study and takes responsibility for the content of the manuscript, including the integrity and accuracy of the data and analysis.

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Competing interests No competing interests to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and ethical clearance was granted by the Human Research Ethics Committee of the Queensland Children’s Hospital (HREC/19/QCHQ/5872). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review In the study before taking part.

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Provenance and peer review

Data availability statement Data are available on reasonable request. Only individual data underlying published results, after de-identification, will be shared, ending 3 years following the publication. Data are available on reasonable request only for researchers who provide a methodologically sound proposal and obtain an approval from the Human Research Ethics Committee.

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ORCID iDs

Wicharn Boonjindasup http://orcid.org/0000-0003-2942-9380
Margaret S McElrea http://orcid.org/0000-0001-9078-2357
Anne B Chang http://orcid.org/0000-0002-1331-3706

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