ORIGINAL ARTICLE

A cluster randomised intervention trial of asthma clubs to improve quality of life in primary school children: the School Care and Asthma Management Project (SCAMP)

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Slides of selected material from the workbook are available from the ADC website at <http://www.archdischild.com/supplemental>.

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Aim: To evaluate the effectiveness of a programme of asthma clubs in improving quality of life in primary school children with asthma.

Methods: A cluster randomised intervention trial was undertaken in 22 primary schools within the urban area of south and east Belfast, Northern Ireland. Schools were randomised in pairs to immediate or delayed groups. The study subjects comprised 173 children aged 7–11 years whose parents had notified the school of their asthma diagnosis. Children attended school based weekly clubs over an 8 week period. The main outcome measures were the interview administered Paediatric Quality of Life Questionnaire scores, ranging from 1 (worst) to 7 (best), spirometry, and inhaler technique.

Results: Over 15 weeks, small but non-significant improvements in the overall quality of life score (mean 0.20; 95% confidence interval (CI) –0.20 to 0.61) and in each of its three components, activity limitation (0.20; –0.43 to 0.84), symptoms (0.23; –0.23 to 0.70), and emotional function (0.17; –0.18 to 0.52), were observed in the immediate compared with the delayed group. Inhaler technique at week 16 was markedly better in the immediate group, with 56% having correct technique compared with 15% in the delayed group. No significant effect of the intervention on spirometry results could be demonstrated.

Conclusion: This primary school based asthma education programme resulted in sustained improvements in inhaler technique, but changes in quality of life scores were not significant.

Asthma is the most common chronic disease in children and is responsible for considerable physical and psychological morbidity and school absence. It is more common in the UK than in most European countries,¹ and its prevalence has risen steeply during the past few decades.^{2,3} The aetiology of asthma and the reasons for this increase remain unclear.⁴

A survey of schoolchildren in Northern Ireland aged 13–14 years, using the International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire, showed 17.5% ever having had asthma and 21.8% asthma or treated wheeze,⁵ findings similar to those reported elsewhere in the UK.⁶ A survey in local primary schools revealed that 24% of asthmatic children experienced shyness, teasing, and bullying about using inhalers, and 37% admitted not bringing reliever inhalers to school.⁷

The School Care and Asthma Management Project (SCAMP) was developed in response to these findings. Using a specially developed picture style training pack, the project offered asthma awareness education to school teachers, parents, and community nursing staff within the Trust area. A child held asthma care pathway record incorporating an asthma action plan was also produced in consultation with staff in primary and secondary care to help parents manage their children's asthma. Asthma education for primary level children was also provided, and this paper describes its evaluation.

Meta-analyses of randomised trials of self management teaching programmes in children and adolescents report conflicting results. In one analysis of 11 trials, self management teaching did not significantly reduce school absenteeism, asthma attacks, days in hospital, or visits to the

emergency department.⁸ In contrast, a recent analysis of 32 trials found that such programmes were associated with improved lung function and reductions in school absenteeism, days of restricted activity, and emergency department visits.⁹ However, few studies have examined quality of life. One study reported quality of life improvements, but involved a peer led programme in older children.¹⁰

The aim of this research was to evaluate the effectiveness of a school based education programme of weekly asthma clubs in improving quality of life for primary school children with asthma.

MATERIALS AND METHODS

Participants and protocol

The study was approved by the research ethics committee of Queen's University Belfast. To avoid contamination effects between children within schools, the study design chosen was a cluster randomised intervention trial with schools as the unit of randomisation. Primary schools within the urban area of south and east Belfast that agreed to participate entered the trial between September 2002 and September 2003, and were matched in pairs on socioeconomic characteristics, size, and date of entry. In each pair, the toss of a coin was used to randomise schools to either immediate or delayed intervention. Children in schools allocated to the immediate group attended asthma clubs directly after the preliminary assessment while those in the delayed group

Abbreviations: PRECEDE, Predisposing, Reinforcing, and Enabling Causes in Educational Diagnosis and Evaluation; SCAMP, School Care and Asthma Management Project

Figure 1 Trial profile.

received the same intervention after a 16 week interval (fig 1).

The theoretical framework for our intervention was the Predisposing, Reinforcing, and Enabling Causes in Educational Diagnosis and Evaluation (PRECEDE) model.^{11 12} The intervention was designed not to require dedicated staff for implementation but rather to be suitable for delivery by community nurses in eight weekly, lunchtime, child friendly sessions.

Each session began with brief reinforcement of previous training and finished with end of session feedback. The SCAMP club workbook used during the sessions was given to children at prizegiving, along with the child held asthma care pathway record and action plan, all developed as part of the SCAMP project (see supplementary material on the ADC website at <http://www.archdischild.com/supplemental>).

Clubs were piloted in three schools prior to the trial. Following training about asthma and delivery of the programme by the two nurse leaders (EEP and MPB), clubs were run by 19 community nursing staff, usually the named school nurse and health visitor. Sessions on triggers and inhaler technique were assisted by an experienced asthma nurse.

Children aged between 7 and 11 years diagnosed as having asthma and whose parents/guardians had informed the school of their asthma diagnosis were eligible to participate. Invitation letters and consent slips were issued through schools. Children judged either at preliminary examination or subsequently to need immediate medical intervention (forced expiratory volume in one second (FEV₁) <80% of predicted or severe breathlessness, indicated by inability to complete a sentence) were referred to their family doctor or Asthma Clinic.

Table 1 Programme details

Week	Programme	Details
1	Assessment	Spirometry performed, quality of life questionnaire completed, and inhaler technique assessed using placebo and In-Check Dial, with referral for change/modification of therapy if appropriate
2	What is asthma?	Demonstration of asthma characteristics using models, pictures and a parachute team building game
3	What is your inhaler?	Explanation and hands on demonstration of types of inhalers, how they work, and when they should be used
4	The airways	Blowing and sucking games using thick and thin straws to demonstrate airway resistance
5	What makes your asthma worse?	Identification of asthma triggers using model toy kit and accompanying worksheet. Trigger avoidance and prophylactic treatment
6	Managing an asthma attack	Prevention, recognition and management of an attack by rhyme and role play using tailor made story poster, spacer, and placebo inhaler
7	How asthma makes children feel	Interactive session to promote positive attitudes, build self esteem, reduce anxieties, and handle put downs using "What I like about me"
8	Assessment, prize giving	Repeat assessment (as week 1). Prize giving for children and parents/guardians. Presentation of attendance certificates and SCAMP mugs

Table 2 Baseline characteristics of schools and children in the trial

	Immediate	Delayed
Characteristics of schools	n = 11	n = 11
Number of pupils; mean (range)	390 (132 to 1016)	313 (176 to 575)
Receiving free school meals (%); mean (range)	32% (3 to 72%)	22% (3 to 54%)
Characteristics of children	n = 81	n = 92
Demography		
Boys; n (%)	37 (45%)	53 (58%)
Age (years); mean (SD)	9.01 (0.74)	8.99 (0.92)
Height (m); mean (SD)	1.33 (0.07)	1.34 (0.08)
Current therapy		
Regular reliever; n (%)	32 (40%)	37 (40%)
Regular preventer; n (%)	46 (57%)	52 (57%)
Regular preventer (verified); n (%)	24 (30%)	29 (32%)
Reliever in school; n (%)	20 (25%)	45 (49%)
Reliever in school (verified); n (%)	14 (17%)	19 (21%)
Self management plan; n (%)	4 (5%)	8 (9%)
Prescribed peak flow meter; n (%)	10 (12%)	24 (26%)
Paediatric Asthma Quality of Life Questionnaire		
Overall score (range 1–7); mean (SD)	4.9 (1.1)	4.9 (1.1)
Activity limitation score (range 1–7); mean (SD)	4.9 (1.2)	5.1 (1.1)
Symptoms score (range 1–7); mean (SD)	4.8 (1.2)	4.7 (1.3)
Emotional function score (range 1–7); mean (SD)	5.0 (1.2)	5.1 (1.2)
Spirometry		
FEV ₁ % predicted; mean (SD)	99.8 (14.0)	98.1 (13.2)
FVC % predicted; mean (SD)	98.7 (12.1)	98.6 (10.7)
MEF _{25–75} % predicted; mean (SD)	83.9 (23.4)	81.2 (23.4)
FEV ₁ <80% predicted; n (%)	4 (5%)	6 (7%)
Inhaler technique*		
Correct; n (%)	14 (18%)	13 (15%)
Correct and partially correct; n (%)	39 (49%)	35 (40%)

SD, standard deviation; FEV₁, forced expiratory volume in one second; FVC, forced vital capacity; MEF_{25–75}, mid-expiratory flow rate. *Excludes six children (two in the immediate group, four in the delayed) not regularly using inhalers.

Assessments

The primary outcome was overall quality of life measured using the Paediatric Quality of Life Questionnaire,¹³ a 23 item questionnaire with three domains (symptoms, activities, and emotions) designed to assess quality of life among asthmatic children in the age range 7–17 years. Questions were read to children in a standard form by one of two observers (EEP, MPB) and the seven possible responses, ranging from 1 (extremely bothered) to 7 (not bothered), were presented on a card for children to select the appropriate response. The questionnaire has good reproducibility, and gives results that correlate with conventional asthma indices.¹³

Spirometry was conducted using the MicroLab SuperSpiro (Micro Medical, Rochester, MN, USA) which features a child friendly visual incentive. Height was measured at each assessment using the Leicester Height Measure (Invicta, Leicester, UK). Children performed up to eight forced expirations until two technically satisfactory manoeuvres were obtained. Percentage of predicted FEV₁, forced vital capacity (FVC) and mid-expiratory flow rate (MEF_{25–75}) related to children's height and sex were derived from the best manoeuvre.

Inhaler technique was investigated using placebo inhalers at each assessment (except the preliminary assessment in the delayed group). Results were recorded on a three point scale (correct, partially correct, or poor) based on those criteria relevant to the child's usual device: removal of cover, priming of device, vigorous shaking before each actuation, expiration before actuation, inspiration rate within device's recommended range as judged by In-Check Dial (Clement Clarke, Harlow, Essex, UK), and holding breath after inspiration. Correct technique was recorded when children met all relevant criteria and inspiratory flow rate was within the recommended range. Partially correct technique was recorded when there were errors in technique, but it was thought that children would receive some medication. Poor inhaler

technique was recorded when it was considered unlikely that any medication would be inhaled. Interassessor agreement was checked during the trial by independent assessment of 50 children by the two assessors and found to be excellent, with discrepancy for only three children (linearly weighted kappa = 0.91).

Start of club assessments were performed at week 1 in the immediate group and week 16 in the delayed group (fig 1). End of club assessments took place 7 weeks later and follow up assessments after a further 8 weeks. Additionally, a preliminary assessment (excluding inhaler technique) was performed at week 1 in the delayed group.

Statistical methods

Without knowledge of the intracluster variation in quality of life score changes and of the effectiveness of the matching, it was not possible to definitively estimate power prior to the start of the trial.¹⁴ However, the variability in quality of life score changes in a similar population was reported in a pilot study to be 1.3 units.¹⁵ To have 90% power to detect a statistically significant ($p < 0.05$; two tailed) difference of 1 unit in mean change between groups over the first 15 weeks would require 36 children per group in a trial of conventional design. Incorporating a design effect adjustment to take account of intracluster correlation requires an inflation factor of $1 + (m-1)r$, where m is the average cluster size and r the intracluster correlation in quality of life score changes. With a predicted average cluster size of eight children ($m = 8$) and a planned total study size of 160 children (20 schools), the study had adequate power provided the intracluster correlation, r , was no larger than 0.175. Comparisons of preintervention and post-intervention results were obtained using regression analysis with correction for intraschool correlation. Comparisons of changes in outcomes between groups were obtained using random effects meta analysis,¹⁶ which takes account of the cluster randomised design by weighting and combining

Figure 2 Changes in mean quality of life scores by treatment group during the trial. (A), activity limitation; (B) symptoms; (C) emotional functioning; (D) overall.

estimates of the effect of intervention from each pair of schools. Analyses were performed using Stata software (release 8; Stata Corporation, College Station, TX, USA).

RESULTS

Of 102 eligible children in the schools randomised to the immediate group, consent to participate was obtained for 84 (82%). Corresponding numbers in the delayed group were 126 eligible and 92 consented (73%). Most common reasons for non-participation were non-response after three attempts ($n = 27$), outgrown asthma ($n = 13$), change of school ($n = 4$), and did not wish to attend ($n = 3$). Three children in the immediate group did not complete the trial (fig 1).

Average attendance at the eight clubs was 92% in both immediate and delayed groups.

Characteristics of schools and children that participated are summarised in table 2. Staff from three schools in the immediate group and four in the delayed group had received asthma awareness education prior to the trial. The majority (92%) of children were aged between 8 and 10 years. Although 57% of parents claimed their children used preventers regularly, only 54% of these claims were verified by the children during their assessments. Similarly, parents exaggerated the availability of relievers in school. For only 7% of children did parents claim that self management plans existed, although 20% of parents reported that their children

Table 3 Group comparisons of quality of life score and spirometry changes from week 1 to week 16 and of inhaler technique at week 16

	Immediate, n = 81; mean (SD) or n (%)	Delayed, n = 92; mean (SD) or n (%)	Weighted difference (95% CI)	p
Quality of life score change (week 16 minus week 1)				
Overall	0.30 (1.19)	0.23 (0.98)	0.20 (−0.20 to 0.61)	0.32
Activity limitation	0.27 (1.45)	0.11 (1.25)	0.20 (−0.43 to 0.84)	0.53
Symptoms	0.32 (1.39)	0.28 (1.12)	0.23 (−0.23 to 0.70)	0.33
Emotional function	0.29 (1.31)	0.23 (1.16)	0.17 (−0.18 to 0.52)	0.35
Spirometry changes (week 16 minus week 1)				
FEV ₁ (% predicted)	−1.7 (8.3)	−1.2 (10.6)	−0.4 (−2.8 to 2.0)	0.74
FVC (% predicted)	−0.5 (8.6)	0.1 (9.3)	0.0 (−2.8 to 2.7)	0.98
MEF _{25–75} (% predicted)	−3.0 (14.4)	−1.9 (19.6)	−0.5 (−6.1 to 5.0)	0.85
Inhaler technique (week 16)†				
Correct	44 (56%)*	13 (15%)*	41% (29% to 54%)	<0.001
Correct and partially correct	66 (84%)*	35 (40%)*	49% (24% to 73%)	<0.001

*n (%). †Excludes 6 children (2 immediate, 4 delayed) not regularly using inhalers. FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; MEF_{25–75}, mid-expiratory flow rate.

Figure 3 Random effects meta-analysis of changes over 15 weeks (week 16 minus week 1) in overall quality of life scores for 173 participants in 11 pairs of schools.

What is already known on this topic

- Childhood asthma is a common problem that adversely affects quality of life
- A meta-analysis of previous educational interventions in children reported improvement in lung function and reduction in indicators of asthma attacks
- Few studies have considered quality of life measures other than symptoms in children of primary school age

owned peak flow meters. Quality of life scores and spirometry results were similar in the groups. Although mean FEV₁ and FVC results were close to predicted, MEF₂₅₋₇₅ rates in both groups were considerably lower, with 76 (44%) of the 173 children having results less than 80% of predicted. Only 27 (16%) of the 167 children who regularly used inhalers were assessed as having correct technique at the start of club, this figure increasing to 74 (44%) if children whose technique was partially correct were included.

As can be seen from fig 2, the delayed group experienced improvements in quality of life scores between week 1 and week 16 (that is, prior to receiving the asthma club programme), so the effect of intervention is most reliably assessed by comparing changes from week 1 to week 16 between groups as shown in table 3. The weighted differences in table 3 were obtained by pooling the 11 intraschool pair differences, as illustrated for overall quality of life in fig 3. Small but non-significant improvements in quality of life were observed in the immediate group relative to the delayed group. Inhaler technique at week 16 was markedly better in the immediate group, 59 (73%) of whom had been recommended at the start of club assessment to see their family doctor or asthma nurse to obtain a spacer, to change to a more suitable device, to standardise treatment where multiple devices were being used, to consider add on therapy, or to reinforce regular therapy. Spirometry changes were similar in both groups.

DISCUSSION

In contrast to other studies^{17 18} that have indicated that education programmes can improve asthma management and reduce symptoms in this age group, we were unable to demonstrate significant improvements in symptom scores. One recent study reported improved daytime symptoms but worsening night time symptoms over a 2 year period.¹⁹ We

What this study adds

- A primary school based educational programme resulted in improved inhaler technique
- Intervention resulted in small but non-significant improvements in symptomatic and non-symptomatic quality of life scores

were unable to demonstrate significant improvements in overall quality of life, or its three component domains, or in spirometry results. However, our intervention resulted in a significant improvement in inhaler technique, an important aspect of asthma management behaviour.

Reasons for the improvements in preintervention quality of life scores in the delayed group are unclear, but could be due to seasonal influences or questionnaire familiarisation. Raising children's awareness of activity limitations, symptoms, and emotions might be expected to result in worse rather than improved quality of life at subsequent assessments, although it could also have prompted improved treatment compliance.

At the start of club the majority of children had poor technique and were therefore unlikely to inhale any medication. At the follow up assessment 15 weeks later, this figure had reduced to 13%. Inefficient inhaler use in asthmatic children has long been recognised,²⁰ and, in keeping with previous studies,^{18 21} we have demonstrated that instruction and advice on inhaler use results in sustained improvement in technique, which should result in improved future treatment compliance. Schools provide an ideal environment for inhaler education and training with frequent reinforcement. A trained school nurse with dedicated time could achieve this efficiently.

There are other interesting findings from our study. At the start of the study 57% of parents claimed that their children were on regular preventive therapy, but this was later verified on open questioning by only 52% of these children. Similarly, only 19% of children, approximately half the number reported by parents, were found to have a reliever available in school. Although 20% of children had been prescribed peak flow meters, only 7% of parents reported that their child had a self management plan.

Although we attained our target recruitment, the 1 unit difference between groups in quality of life score change that we planned to detect may have been unrealistically large,

given the “ceiling” effect arising from the inclusion of large numbers of children with mild asthma in our study. In contrast to the small and non-significant effect of intervention in the full trial (table 3, fig 2) we found a larger, significant effect of intervention (0.53 (95% confidence interval 0.06 to 1.00), $p=0.03$) in a subgroup analysis of the 88 children (41 immediate, 47 delayed group) with initial overall quality of life score <5 . However, this finding must be interpreted cautiously as it was not planned in advance of the trial. Possible dilution of the intervention could also have resulted from our requirement that children assessed as needing immediate medical intervention were referred. Six children in the delayed group were referred at their preliminary assessment, four of whom attended their family doctor or asthma nurse prior to the start of intervention.

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