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Enhancing ventilation in homes of children with asthma:

pragmatic randomised controlled trial

Abstract

Background
Few robust studies have tested whether enhancing housing also improves health.

Aim
To evaluate the effectiveness of installing ventilation systems, and central heating where necessary, in the homes of children with moderate or severe asthma.

Design and setting
Pragmatic randomised controlled trial (RCT) in homes within Wrexham County Borough, Wales, UK.

Method
A pragmatic RCT was carried out, of a tailored package of housing improvements providing adequate ventilation and temperature, following inspection by a housing officer. One hundred and ninety-two children with asthma aged 5 to 14 years, identified from general practice registers, were randomised to receive this package, either immediately or a year after recruitment. At baseline, and after 4 and 12 months, parents reported their child's asthma-specific and generic quality of life, and days off school.

Results
The package improved parent-reported asthma-specific quality of life significantly at both 4 and 12 months. At 12 months, this showed an adjusted mean difference between groups of 7.1 points (95% confidence interval [CI] = 2.8 to 11.4, $P = 0.001$): a moderate standardised effect size of 0.42. The generic quality-of-life scale showed reported physical problems were significantly reduced at 4 months, but not quite at 12 months, when the mean difference was 4.5 (95% CI = −0.2 to 9.1, $P = 0.061$). The improvement in psychosocial quality of life at 12 months was not significant, with a mean difference of 2.2 (95% CI = −1.9 to 6.4, $P = 0.292$). Parent-reported school attendance improved, but not significantly.

Conclusion
This novel and pragmatic trial, with integrated economic evaluation, found that tailored improvement of the housing of children with moderate to severe asthma significantly increases parent-reported asthma-related quality of life and reduces physical problems. Collaborative housing initiatives have potential to improve health.

Keywords
asthma; children; general practice health; housing; quality of life; clinical trials, randomised.

INTRODUCTION

Links between poor housing and health have been well known since the 19th century. However, few rigorous studies have evaluated housing interventions designed to improve health. A recent update of a previous systematic review of the health effects of housing improvements[1,2] identified 39 controlled prospective studies, of which only three had been rigorously randomised, indicating a need for rigorous studies in this field.[3]

In the UK there are 1.1 million children receiving treatment for asthma.[4] Many indoor environmental factors are associated with childhood asthma, including mould,[5,6] house-dust mites, pet allergens, and environmental tobacco smoke.[7] Therefore, there is potential to improve asthma by enhancing the indoor environment.[8] Several environmental modifications have been tried, but most have been ineffective.[9] Nevertheless, ventilation and heating are likely to reduce mould spores, and possibly house-dust mites, pet allergens, and particulate matter.[10] A recent randomised controlled trial (RCT) of home ventilation demonstrated an improvement in evening peak flow readings in adults, and concluded that there may be some merit in considering ventilation in the bedrooms of children with asthma.[11] In short, empirical evidence that investment in housing benefits health is promising but limited.[12–17]

This randomised controlled trial aimed to strengthen this evidence by evaluating the effectiveness and cost-effectiveness of installing ventilation systems, and improving central heating if necessary, in the homes of children with moderate or severe asthma. The primary objective was to test whether these improvements change asthma-specific quality of life. Secondary objectives focused on general quality of life and parent-reported school attendance. The companion economic paper tests whether these improvements change the use of health care, including medication.[18]

This study used a pragmatic trial design to decide whether to invest in ventilation systems, rather than to test scientific hypotheses under laboratory conditions.[19,20] For example, housing officers were encouraged to adapt ventilation systems to individual circumstances. Thus, the study sought to optimise the psychological effects of ventilation systems, rather than to equalise those effects and focus on physiological effects; for example, by installing fake ventilation systems.[11]

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How this fits in

While many studies have found an association between poor housing and ill-health, few robust studies have tested whether enhancing housing also improves health. Although a recent systematic review identified 39 controlled prospective intervention studies, only three had been rigorously randomised. This paper reports that the installation of a ventilation system, and central heating where necessary, in the homes of children with moderate to severe asthma improves their parent-reported respiratory quality of life. Thus, collaborative housing initiatives have the potential to improve health directly.

METHOD

Protocol

The CHARISMA randomised controlled trial (Children's Health in Asthma: Research to Improve Status by Modifying Accommodation) was undertaken by the CHARISMA study group, a multidisciplinary team comprising local authority, NHS, and academic representatives. The trial was conducted according to the registered protocol.[21]

Study population

Twenty of the 23 general medical practices within Wrexham, North Wales participated in the trial. Of the three others, one was refurbishing, one was concerned about confidentiality, and one was in an affluent ward. Children were eligible to take part if they were aged between 5 and 14 years, resident in Wrexham (in any type of housing), and registered with a participating general practice; and had received three or more prescriptions for corticosteroid inhalers (*British National Formulary* category 3.2) in the preceding year. Participating practices identified eligible children and invited their parents to take part. Children entered the study if their parents consented to randomisation, completion of questionnaires, and access to medical records. If more than one sibling was eligible in a family, one was chosen at random as the index child for analysis.

Intervention

The intervention was a tailored package of housing improvements designed to provide adequate ventilation and heating, and thus reduce mould spores. Children allocated to the intervention group received their housing improvements immediately, while those allocated to the control group received them 12 months later, after completing follow-up. Thus, 'waiting list controls' were used to overcome the problem of 'resentful demoralisation' suffered by trials that use 'treatment as usual' as the control.[22]

Before randomisation, a local authority housing officer visited each child's household and used a standardised housing-condition survey to assess the improvements needed. At the randomly allocated time, the local authority installed in the roof space of each house a Vent-Axia® HR200XL ventilation system. This comprises two insulated flexible pipes: one delivers fresh air from outside the house through a cleaning filter to first-floor bedrooms; the other removes stale air from the house, and warms the fresh air. This process stabilises humidity and temperature, as moist air is rapidly replaced by fresh air. The system has a heat-recovery efficiency of up to 70%, and running costs are about £15 a year. If necessary, contractors also improved or replaced central heating systems to bring them to the standard defined by the housing officer. Families did not pay for these improvements.

Outcome measures

The main outcome measure was the parent-completed asthma-specific module of PedsQL™, a validated and widely used quality-of-life measure in children.[23–25] The asthma module has four subscales: symptoms (11 items); treatment (11 items); worry (3 items); and communication (3 items). The PedsQL generic module was also used; this assesses physical health on one subscale (8 items), and psychosocial health on three subscales: emotional (5 items); social (5 items); and school (5 items). The PedsQL asks how much of a problem each item has been for the child during the previous month, on a 5-point fixed-response Likert scale. Each scale combines the relevant item responses into a score between 0 (worst problems) and 100 (no problems). Parents were also asked to recall their child's days off school over the study period, and about pets and smoking in the household.

Sample size

The study sought to recruit a total of 200 children, to yield 80% power to detect, at a 5% significance level, a change in asthma-specific quality of life of at least 0.4 of the standard deviation (SD) of the asthma-specific PedsQL. Data from a pilot practice suggested that, if all 23 practices within Wrexham could be recruited, the study would identify about 400 eligible children; if

half consented, a sample of 200 would be achieved. The observed baseline SD was about 17 PedsQL points from a range of 100. Thus 0.4 SD is equivalent to a 7-point change in PedsQL, which is generally regarded clinically relevant.[23–25]

Randomisation

After the baseline visit, consented children were randomised to either immediate or delayed intervention. Researchers emailed children's stratifying variables — practice, age, sex, type of housing, smoking in the household, and whether central heating needed improvement — in batches to the randomisation service at the North Wales Organisation for Randomised Trials in Health (NWORTH) in Bangor, Wales. To prevent subversion, NWORTH used contemporaneous dynamic randomisation,[26] emailed the resulting allocation, and updated the independent randomisation database.

Data collection and timing of questionnaires

During the initial visit, the housing officer also ensured that the child's carer completed the baseline questionnaire. Children randomised to the control group were paired with a child from the intervention group, and allocated a 'shadow installation time' with the same gap between baseline and installation as that of the paired child. Children allocated to the intervention who missed it because of change of mind or circumstances were allocated a 'shadow installation time' calculated from the average time from baseline to completed works for other intervention children. Since Wrexham is a small county borough, this use of 'shadow installation times' ensured that each pair of children (one experimental, one control)

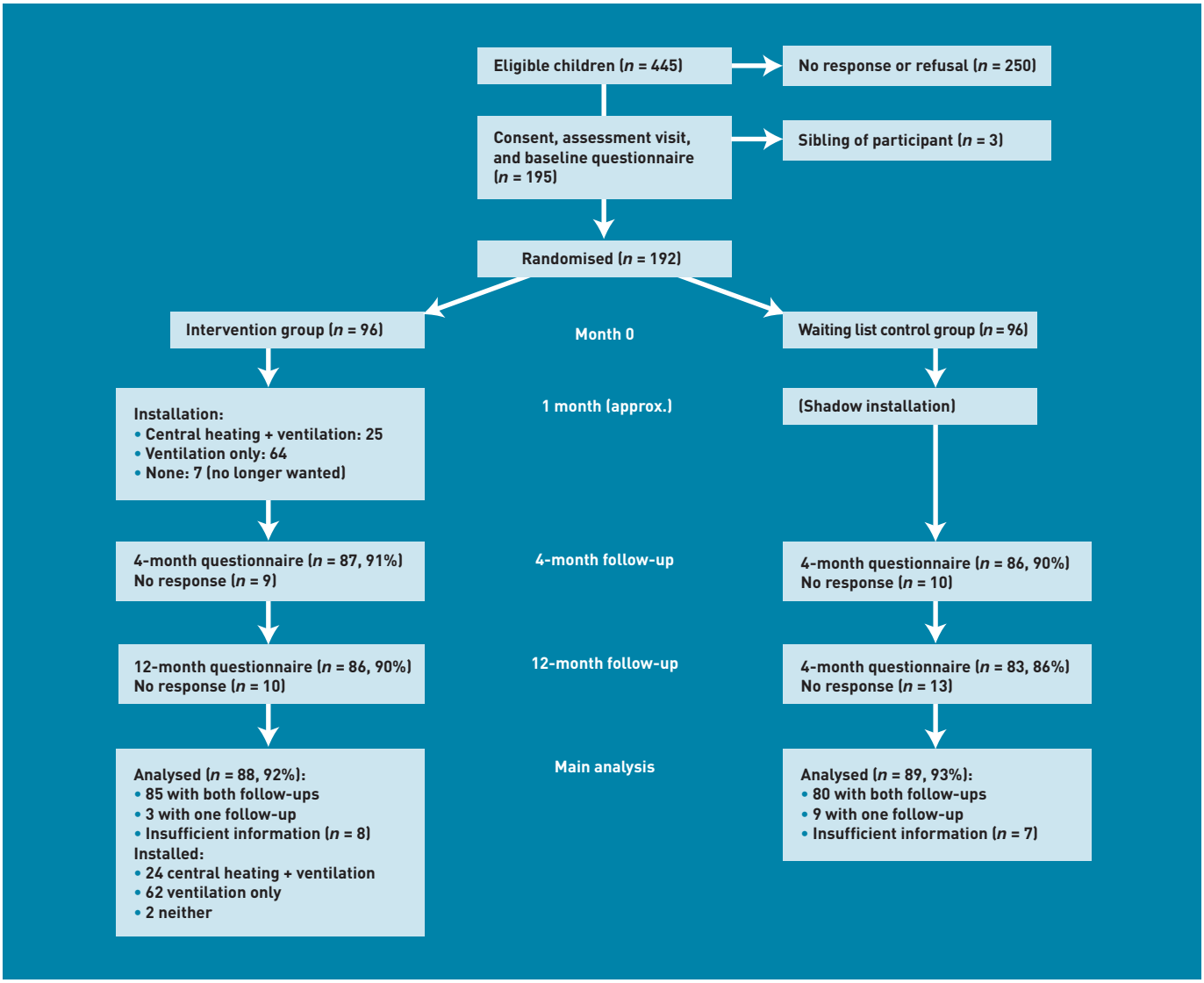

Figure 1. Progress of children through the trial.

experienced the same temperature and weather, thus avoiding seasonal bias.

Most installations were completed about a month after randomisation. The first follow-up was 3 months after installation or shadow installation, approximately 4 months after randomisation. The final follow-up was 11 months after (shadow) installation, approximately 12 months after randomisation.

Follow-up questionnaires were sent with business reply envelopes. Non-responders were reminded after 2 weeks by postcard; after 4 weeks by telephone; and after 6 weeks by letter and duplicate questionnaire. Completed questionnaires were scanned electronically by Teleform and imported directly into SPSS. Data management included checks for scanning errors. Finally, data were collected from general practice records, on all consultations, prescriptions, and hospital attendances during the year of the study and the previous year. These results are reported in the companion paper.[18]

Table 1. Baseline characteristics at entry by group

	Intervention (*n* = 96)	Control (*n* = 96)
Person filling in baseline questionnaire, *n* (%)		
Mother	83 (86)	84 (88)
Father	12 (12)	12 (12)
Other	1 (1)	0 (0)
Age parent left full-time education, years, *n* (%)		
≤16 or under	49 (51)	54 (56)
17–19	34 (35)	21 (22)
≥20, or still in full-time education	13 (14)	21 (22)
Housing type, *n* (%)		
Council	25 (26)	23 (24)
Owner occupier	63 (66)	68 (71)
Housing association or private landlord	8 (8)	5 (5)
Number of household members who smoke, *n* (%)		
None	58 (60)	59 (62)
One	29 (30)	26 (27)
More than one	9 (9)	11 (12)
Dog or cat in household? Yes, *n* (%)	47 (49)	45 (47)
Central heating needed? Yes, *n* (%)	20 (21)	20 (21)
Child		
Age, mean years (SD)	9.59 (2.95)	9.57 (2.95)
Sex, female *n* (%)	42 (44)	43 (45)
Parent-reported days off school in last 3 months, mean (SD); median, minimum, maximum		
Total[a]	5.5 (5.6); 3, 0, 23	7.3 (8.7); 5, 0, 50
Due to asthma[b]	3.6 (4.8); 2, 0, 23	4.9 (8.0); 2, 0, 50
Baseline PedsQL™, mean (SD)[c]		
Asthma subscales symptoms	51.5 (20.0)	50.6 (20.2)
Treatment	76.8 (18.1)	74.1 (19.1)
Worry	78.7 (22.8)	73.5 (26.2)
Communication	72.0 (28.2)	75.2 (27.4)
Overall asthma scale	66.6 (16.4)	64.9 (17.5)
Physical scale	69.3 (18.6)	67.0 (22.0)
Emotional	66.8 (22.5)	61.4 (26.1)
Social[d]	79.3 (20.7)	71.3 (24.8)
School	65.9 (22.4)	61.8 (23.9)
Overall psychosocial scale	70.7 (18.4)	64.8 (21.8)

[a]Seven non-responders (six intervention, one control). [b]Three non-responders (two intervention, one control). [c]All scale scores run from 0 (worst) to 100 (best). [d]Significant difference between intervention and control (P = 0.016).

Statistical analysis

To minimise bias, the researchers who undertook analysis were blind to children's allocation. In keeping with the pragmatic nature of this trial, they analysed all participants by 'intention to treat': to infer whether ventilation systems are effective in practice, they included children in analysis whether or not they took up their allocated intervention. They imputed missing data by regression where possible, but also undertook a sensitivity analysis on children with complete data. Non-response to both follow-up questionnaires resulted in exclusion from the main PedsQL analysis. SPSS (versions 12–15) was used to analyse changes between baseline and 4 or 12 months, by general linear models, independent sample *t*-test, and Mann–Whitney *U* tests as appropriate, with associated confidence intervals (CIs).

Analysis of covariance was used to adjust reported outcomes, notably for any differences between groups in corresponding scores at baseline. Demographic variables (practice, age, sex, type of housing, smoking in household, and heating in need of improvement) were also investigated, and all other variables at baseline were investigated as possible covariates. As they did not improve the statistical model, these analyses are not reported.

RESULTS

Eligible families were recruited from March 2004 to February 2005. General practices identified 445 eligible children, and invited all to take part. Of 192 (43%) whose parents completed the baseline questionnaire, 96 were allocated to the intervention group and 96 to the control group (Figure 1). Response rates after 4 and 12 months were 90% (173/192) and 88% (169/192) respectively. General practice data were extracted on all but one child. After approval and funding, there were no changes in protocol.

Baseline characteristics

Table 1 shows the baseline characteristics of the children. Most lived in owner-occupied properties; most parents had left full-time education at 16 years or earlier; and most children came from non-smoking families.

Questionnaire completion

Of the 192 randomised children (96 intervention, 96 control), 165 (85 intervention, 80 control) completed both

Table 2. PedsQL™ summary scores at 4 and 12 months after randomisation by group[a]

	4 months			12 months		
Outcome measure[b]	Unadjusted mean difference	Mean difference adjusted for baseline (95% CI)	Standardised effect size[a]	Unadjusted mean difference	Mean difference adjusted for baseline (95% CI)	Standardised effect size[c]
Asthma subscales						
Symptoms	9.2	9.0 (3.8 to 14.3)	0.45[d]	9.6	9.4 (4.0 to 14.9)	0.47[d]
Treatment	6.4	4.4 (0.4 to 8.4)	0.24[e]	6.6	4.7 (0.2 to 9.2)	0.25[e]
Worry	8.6	6.6 (–0.3 to 13.4)	0.27	8.0	6.2 (–0.5 to 12.9)	0.25
Communication	0.6	2.1 (–6.0 to 10.2)	0.08	8.3	10.1 (2.2 to 18.0)	0.36[e]
Overall asthma scale	7.2	6.3 (2.1 to 10.4)	0.37[d]	8.0	7.1 (2.8 to 11.4)	0.42[d]
Physical scale	9.3	7.2 (2.6 to 11.8)	0.35[d]	6.4	4.5 (–0.2 to 9.1)	0.22
Psychosocial subscales						
Emotional	8.5	5.8 (0.6 to 11.0)	0.24[e]	6.5	3.6 (–1.5 to 8.8)	0.15
Social	6.6	1.2 (–4.0 to 6.5)	0.05	7.9	2.5 (–2.5 to 7.6))	0.11
School	4.3	2.3 (–2.7 to 7.4)	0.10	3.4	1.8 (–3.2 to 6.7)	0.08
Overall psychosocial scale	6.9	3.0 (–1.3 to 7.2)	0.13	6.2	2.2 (–1.9 to 6.4)	0.11

[a]Analysis of covariance was used to adjust differences after 4 and 12 months for differences in the corresponding scores at baseline. [b]All scale scores run from 0 (worst) to 100 (best); thus positive differences represent better results in the intervention group. [c]Standardised effect sizes relative to baseline standard deviation of relevant scale or subscale. [d]Significant at P<0.01. [e]Significant at P<0.05.

follow up questionnaires; eight (two intervention, six control) completed only the 4-month follow-up; and four (one intervention, three control) completed only the 12-month follow-up. From this main analysis, the 15 otherwise similar children (eight intervention, seven control) without either follow-up questionnaire were excluded. Thus, the main analysis of Table 2 uses (partially imputed) data from 177 children.

Main findings

Parents of children in the intervention group reported significantly better asthma-specific quality of life at both follow-ups, and significantly better physical functioning at 4 months, compared with the control group (Table 2). Reported psychosocial scores were also better, but not significantly so.

At the final 12-month follow-up, after adjusting for baseline differences, there was an estimated mean difference of 7.1 between groups in the primary outcome measure, the PedsQL asthma summary score (95% CI = 2.8 to 11.4, $P = 0.001$, standardised effect size = 0.42). Three of the four individual subscales of the asthma summary score were significantly better in the intervention group, with adjusted mean differences of 9.4, 4.7, and 10.1 in symptoms, treatment, and communication respectively.

The parents of children in the intervention group reported significantly better physical functioning at 4 months, with an adjusted mean difference of 7.2 (95% CI = 2.6 to 11.8, $P = 0.002$); the corresponding adjusted effect at 12 months just failed to reach significance. They also reported improved psychosocial functioning, with a mean adjusted difference of 2.2, but after allowing for baseline differences, this effect was not significant (95% CI = –1.9 to 6.4, $P = 0.292$). The individual psychosocial subscales (emotional, school functioning, and social functioning) were also higher, but not significantly higher, in the intervention group. No 'serious adverse events' were reported.

A sensitivity analysis of 12-month results without eight imputed cases gave substantially similar results; the effect on reported physical functioning became just significant ($P = 0.050$).

Parent-reported school attendance over 12 months was better in the intervention than the control group (Figure 2), but not significantly so (Mann–Whitney U tests: $P = 0.091$ for all-cause absence, $P = 0.053$ for asthma-related absence). The intervention group had a mean of 9.2 days absent (median 7, range 0–48), compared with a mean of 13.2 days (median 9, range 0–101) in the control group. Mean number of asthma-related days of absence was 3.9 (median 0, range 0–38) in the intervention group and 6.4 (median 2, range 0–91) in the control group.

Of the 177 households in the primary analysis, 38 (19 intervention, 19 control) needed both ventilation and central heating; the rest needed only ventilation (Figure 1). There was no significant difference in outcome ($P = 0.80$) or in the effect of the intervention ($P = 0.82$) between those needing and not needing heating improvements, though the observed effect was slightly higher in the former (Table 3). Two of the 177 households allocated to

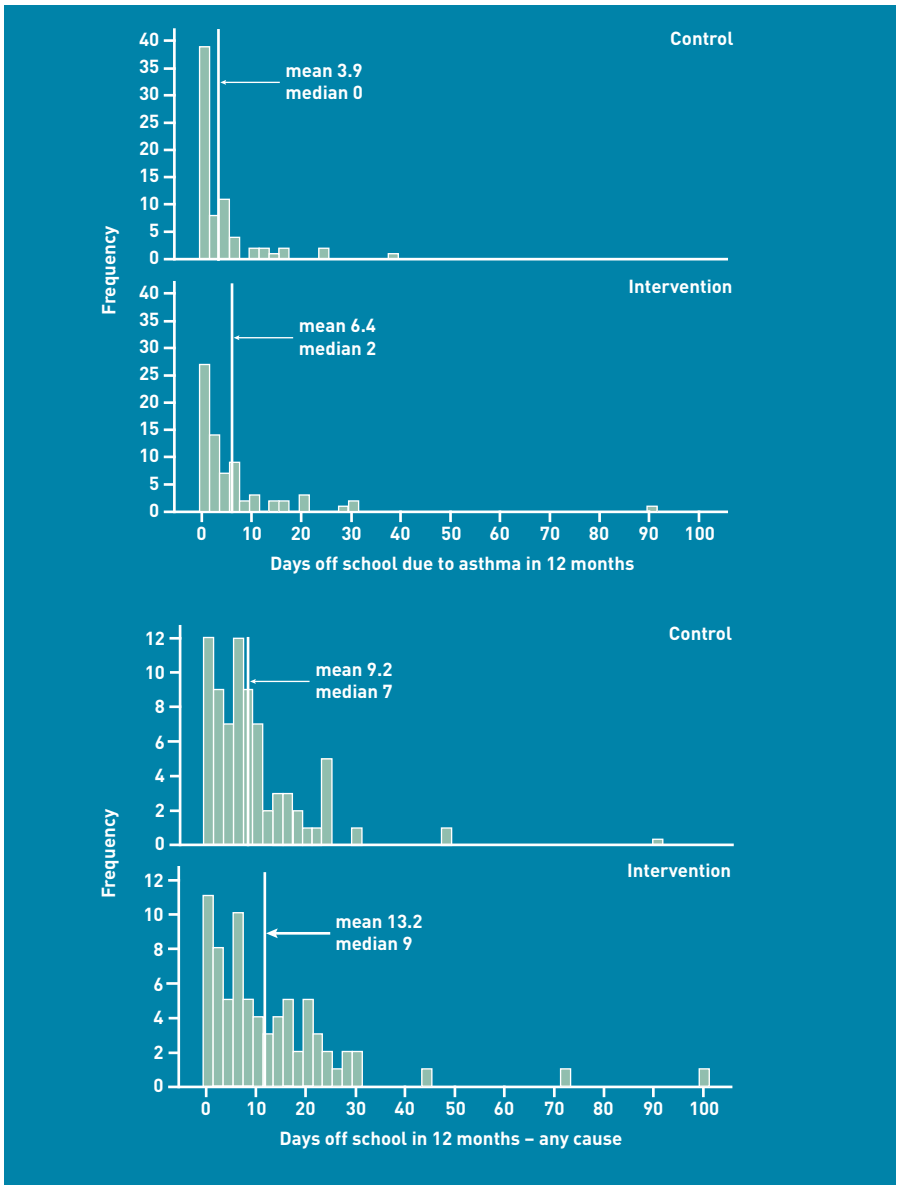

Figure 2. Patient-reported school absence in 12 months from randomisation to final follow-up (Mann–Whitney U tests: P = 0.091 for all-cause absence, P = 0.053 for asthma-related absence.

intervention and later analysed did not receive housing improvements (Figure 1). Five of the eight intervention households excluded from analysis did not receive improvements: three withdrew explicitly and two implicitly. In contrast, six households assessed as needing only ventilation received central heating when their existing system proved deficient.

Table 3. PedsQL™ summary scores 12 months after randomisation by type of housing improvement needed

Outcome measure	Intervention mean	Control mean	Unadjusted mean difference	Mean difference adjusted for baseline (95% CI)	Standardised effect size
Ventilation only (*n* = 69 + 70)					
Overall asthma scale	75.1	67.8	7.2	6.8 (2.1 to 11.5)[a]	0.44
Physical scale	74.4	69.6	4.8	3.7 (–1.8 to 9.1)	0.18
Overall psychosocial scale	74.6	68.3	6.3	2.7 (–1.8 to 7.2)	0.13
Ventilation and central heating (*n* = 19 + 19)					
Overall asthma scale	75.9	65.1	10.8	9.3 (–1.9 to 20.6)	0.55
Physical scale	77.1	64.8	12.2	10.3 (–1.7 to 22.4)	0.51
Overall psychosocial scale	73.1	67.0	6.1	0.6 (–10.1 to 11.3)	0.01

[a]*Significant at P<0.01.*

DISCUSSION

Summary

The CHARISMA randomised controlled trial has shown that the installation of ventilation, and central heating where necessary, achieves a significant improvement of moderate size over at least 12 months in parent-reported asthma-specific quality of life in children. It also improves children's physical functioning initially, but that effect is not quite significant at 12 months. Parent-reported school

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Ethical approval

North East Wales Research Ethics Committee approved the study on 30 July 2003.

Trial registration

ISRCTN 13912429.

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

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absence also improves, although not significantly. However, there is no evidence of effect on psychosocial quality of life or health-service use.[18]

The PedsQL asthma scale sums 28 items, each on a 5-point Likert scale, and converts that sum to a score between 0 and 100; thus, the observed mean difference of 7.1 points represents a change of 1 Likert-scale point (for example, from 'often' to 'sometimes' experiencing problems) on about 8 of the 28 items. However, even relatively small shifts in mean score can have a large effect on the proportion of a population with 'serious' problems. PedsQL is not generally used to diagnose asthma, or to distinguish between moderate and severe forms. Thus, there is no recognised threshold that distinguishes 'moderate' from 'severe' asthma. However, in a population of children with the same range of scores at baseline, increasing each child's score by 7.1 would decrease the proportion of children scoring below 50 points (an average response of 'sometimes' to all 28 items) by more than one-third: from 18.1% to 10.7%.

It was found that demographic variables such as parental smoking and pets, which are known to influence the prevalence and severity of asthma, had no significant effect on these results. Although the power to detect such differences is limited, there is no evidence that the effect of the intervention varied according to the severity of children's asthma.

Strengths and limitations

This study exploited real collaboration between the local authority, NHS, and academia to develop and evaluate the effectiveness of a complex environmental intervention based on the literature.[10–13] The controls contributed to the excellent response rate, while waiting a year for their ventilation systems. Rigorous methods were used to reduce possible bias. Randomisation occurred after the first baseline assessment, so that parents were initially unaware of their allocation. However, as a placebo arm was neither feasible in the real world nor desirable in a pragmatic trial, it was not possible to blind participants to the intervention. While the authors accept that participants may have overestimated the intervention's effect out of gratitude to Wrexham County Borough Council, no evidence of this was found, for example in parental response rates or supplementary comments. Furthermore, interviewer bias was avoided by using parent-completed questionnaires, and analytical bias was avoided by blinding the analysts to whether participants were in the intervention or control group.

The merit of objective outcome measures is recognised. However, the need for them to be valid, reliable, and responsive also greatly restricts the candidate measures. For example, a portfolio of respiratory function tests would have been intrusive, repetitive, and very expensive, with little chance of achieving validity. In contrast, PedsQL has an impressive psychometric underpinning.[23–25] In particular, it was decided not to measure peak flow because of diurnal variation in readings, with the result that even a large sample size might not detect a difference.[15,17] To count mould spores in children's bedrooms, or to measure their sensitisation to such spores, was also beyond the scope of this pragmatic study.

Comparison with existing literature

There is allergenic evidence to suggest that enhancing the indoor environment can improve asthma.[10,11] The results of CHARISMA strengthen the generally positive findings of six recent randomised trials of interventions to enhance the indoor environment — one in the US,[12] three in the UK,[11,14,15] and two in New Zealand.[16,17] Although the six interventions were heterogeneous, all sought to enhance ventilation, or housing, or both. Informal meta-analysis suggests that the cumulative evidence in favour of enhancing ventilation and heating is now strong, not least in improving school attendance.

Implications for practice and research

Although the study findings stem from parental reports, validated measures were used in rigorous fashion, so these findings should inform policy at both national and local level. Improving the health and wellbeing of children is a key national and local priority. Results of this trial are timely, given policies to stimulate joint working to improve public health. Since its formation in 1999, the Welsh Assembly Government has encouraged multi-agency working to improve public health, especially through its Health, Social Care and Well-being Strategy. The present study provides a model for collaboration between the local authority, NHS, and academic researchers to improve public health through environmental interventions, and to evaluate the outcomes.

The companion economic analysis evaluates whether the intervention is cost-effective as well as effective.[18] Further

research could usefully extend the trial to other regions, lengthen the follow-up period, and consider effects on parents and other members of the household.

Few households needed improved central heating. Hence the study did not have the power to test whether ventilation had the same effect in houses with or without adequate central heating. Thus, future research could usefully 'dismantle' the complex intervention that this study has shown to be effective, to estimate the relative contributions of ventilation and heating improvements.

In conclusion, the installation of a ventilation system, and central heating where necessary, in the homes of children with moderate to severe asthma improves their parent-reported respiratory health and quality of life. Collaborative housing initiatives have the potential to improve health.

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