

# Improving paediatric asthma outcomes in primary health care: a randomised controlled trial

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Asthma is a major contributor to the burden of illness in children.<sup>1</sup> In addition to specific medical treatments, parents and carers need information and skills to facilitate effective self-management<sup>2</sup> and manage asthma exacerbations in children.<sup>3</sup> Consistent with this, written asthma action plans (WAAPs), patient education and regular review are central components of paediatric asthma management.<sup>4</sup>

However, there is a gap between best practice and clinical care. Fewer than 25% of people with asthma have a WAAP.<sup>5</sup> In Australia, this gap is evident in primary care, where most children with asthma are managed.<sup>1,6–9</sup> The objective of this study was to evaluate the impact of the Practitioner Asthma Communication and Education (PACE) Australia program — an innovative communication and paediatric asthma management program for general practitioners — on asthma management and patient outcomes.

## Methods

A randomised controlled trial was conducted among GPs and their patients. Ethics approval was obtained from the Sydney West Area Health Service Human Research Ethics Committee.

### GP recruitment

We recruited GPs from two regions in metropolitan Sydney between 2006 and 2008. Invitations were sent through the Central and Western Sydney Divisions of General Practice. We contacted GPs who expressed interest by telephone, and then visited them to further explain the study and obtain consent. Initially, the study was designed to recruit one GP per practice. However, due to slow recruitment of GPs, recruitment criteria were changed to allow participation of more than one GP per practice.

### Patient recruitment

Each GP was asked to identify 1–10 children with asthma between the ages of 2 and 14 years in their care. An invitation letter to participate in the

## Abstract

**Objective:** To evaluate the effectiveness of the Practitioner Asthma Communication and Education (PACE) Australia program, an innovative communication and paediatric asthma management program for general practitioners.

**Design:** Randomised controlled trial.

**Setting:** General practices from two regions in metropolitan Sydney.

**Participants:** 150 GPs, who were recruited between 2006 and 2008, and 221 children with asthma in their care.

**Intervention:** GPs in the intervention group participated in two 3-hour workshops, focusing on communication and education strategies to facilitate quality asthma care.

**Main outcome measures:** Patient outcomes included receipt of a written asthma action plan (WAAP), appropriate medication use, parent days away from work, and child days away from school or child care. GP outcomes included frequency of providing a WAAP and patient education, communication and teaching behaviour, and adherence to national asthma guidelines regarding medication use.

**Results:** More patients of GPs in the intervention group reported receipt of a WAAP (difference, 15%; 95% CI, 2% to 28%; adjusted  $P = 0.046$ ). In the intervention group, children with infrequent intermittent asthma symptoms had lower use of inhaled corticosteroids (difference, 24%; 95% CI, –43% to –5%;  $P = 0.03$ ) and long-acting bronchodilators (difference, 19%; 95% CI, –34% to –5%;  $P = 0.02$ ). GPs in the intervention group were more confident when communicating with patients (difference 22%; 95% CI, 3% to 40%;  $P = 0.03$ ). A higher proportion of GPs in the intervention group reported providing a WAAP more than 70% of the time (difference, 23%; 95% CI, 11% to 36%; adjusted  $P = 0.002$ ) and prescribing spacer devices more than 90% of the time (difference, 29%; 95% CI, 16% to 42%; adjusted  $P = 0.02$ ).

**Conclusions:** The PACE Australia program improved GPs' asthma management practices and led to improvements in some important patient outcomes.

**Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12607000067471.

study and an expression of interest form were posted to the parents or carers of these children using the GP's letterhead and signature (limited to one child per family). Parents and carers who returned a signed expression of interest form were contacted by the project officer (ML) and requested to provide oral consent for their child to be enrolled in the study. They were then interviewed using a screening questionnaire. The patient was deemed eligible if the parent or carer had sufficient English language skills to complete the questionnaire and reported that a doctor had diagnosed his or her child with asthma.

### Randomisation, concealment and blinding

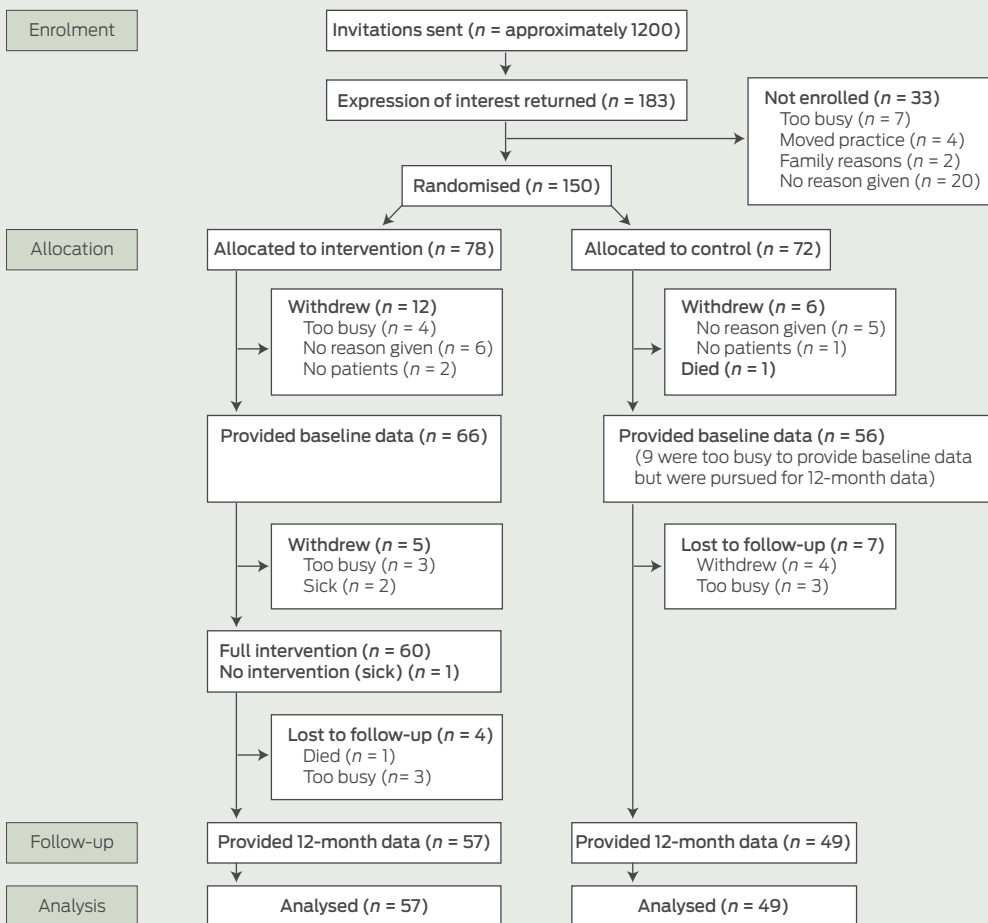
GPs were randomly allocated to the intervention or control group by mini-

randomisation within the strata of sex and Fellowship of the Royal Australian College of General Practitioners using a computer-generated algorithm. Concealment of randomisation was maintained until GP characteristics were entered into a database and a randomisation code was generated. If more than one

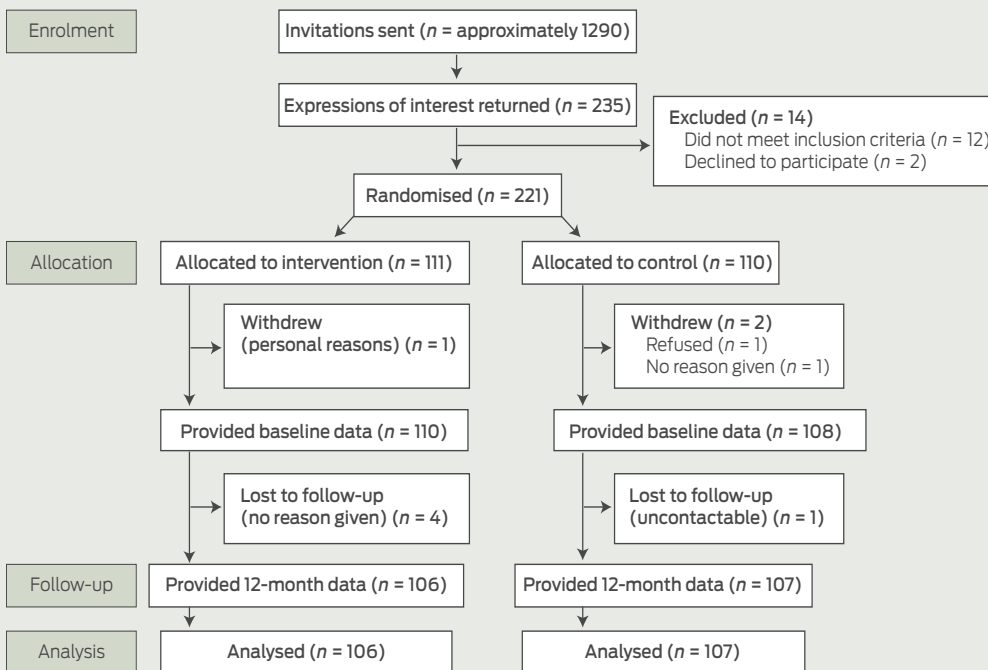
GP was recruited at a practice, the first to be recruited was randomly allocated and others in the practice were allocated to the same group.

The GPs enrolled in the study, the parents and carers of patients enrolled in the study, and the project officer administering the parent questionnaire interviews were blinded to group allocation. GPs were informed that the study would involve completion of two questionnaires and participation in two

1 Flow diagram of general practitioners through each stage of the study



2 Flow diagram of patients through each stage of the study



workshops within 3 years. GPs in the control group were offered the PACE workshops at the end of the study period.

**Intervention**

The PACE Australia program is made up of two structured, 3-hour, interactive small-group workshops (up to 10 GPs per workshop), held 1 week apart. The workshops were adapted for Australia from the original PACE program in the United States.<sup>10</sup> A respiratory paediatrician and community physician led the topic discussions. A GP presenter discussed the Asthma Cycle of Care, which reimburses GPs for two asthma-related consultations within 12 months.<sup>11</sup> The content of the workshops was based on five themes: assessment of the pattern of asthma; appropriate use of medications; provision of a WAAP; doctor-patient communication; and patient education. A video demonstrating 10 communication<sup>12</sup> and asthma education strategies was shown.

**GP and patient outcomes**

Outcome data for the GPs and patients were assessed via the questionnaires used in the PACE USA trial,<sup>13</sup> which measured communication and asthma management behaviour. GPs completed a self-administered questionnaire and the parents and carers of patients completed a telephone questionnaire (administered by an external research organisation) at baseline and 12 months after intervention or, if in the control group, 12 months after enrolment.

The primary outcome was the proportion of patients who were provided with a WAAP, as reported by their parent or carer. Secondary outcomes for patients were appropriateness of medication use related to the pattern of asthma (indicated by decreased use of inhaled corticosteroids and long-acting β-agonists for those with infrequent intermittent symptoms, and increased use of these medications for those with persistent symptoms), parent or carer days off work, and patient days missed from school or child care because of asthma. Secondary outcomes for GPs were improvement in communication and teaching behaviour, appropriate

### 3 Characteristics of study participants

General practitioner characteristics	Intervention group (n = 66)	Control group (n = 56)
Men	27/63 (43%)	17/49 (35%)
Graduated before 1989	49/62 (79%)	41/50 (82%)
Country of graduation (Australia)	31/63 (49%)	31/51 (61%)
FRACGP	35/63 (56%)	30/51 (59%)
< 20 years working as GP	32/61 (52%)	30/50 (60%)
Solo practice	9/62 (15%)	7/51 (14%)
Family and household characteristics	Intervention group (n = 110)	Control group (n = 107)
<b>Parent or carer</b>		
Born before 1969	74/110 (67%)	69/107 (64%)
School or college (ie, non-university) education	61/110 (55%)	51/107 (48%)
Employed full time or part time	59/108 (55%)	76/107 (71%)
<b>Child</b>		
Mean age in months (SD)	35 (26)	30 (22)
Born overseas	5/110 (5%)	7/107 (7%)
<b>Pattern of asthma symptoms</b>		
Infrequent intermittent	48/106 (45%)	47/107 (44%)
Frequent intermittent	46/106 (43%)	51/107 (48%)
Persistent	12/106 (11%)	9/107 (8%)
<b>Household</b>		
Only English spoken at home	87/110 (79%)	104/107 (97%)
Person in household smokes	26/110 (24%)	12/107 (11%)
Total household income < \$60 000/year	38/108 (35%)	29/103 (28%)

FRACGP = Fellow of the Royal Australian College of General Practitioners. \* Data are number/denominator (%) unless otherwise specified; denominators vary due to missing data. ◆

prescribing of medication, and proportion of children who participated in the Asthma Cycle of Care.

#### Sample size

The study was powered for the proportion of patients provided with a WAAP. We estimated an event rate, at 12-months, of 40% for the control group<sup>14</sup> and 70% for the intervention group. To provide adequate statistical power (power, 80%;  $P < 0.05$ ) to demonstrate a between-groups difference of 30% in the primary outcome at 12 months, we set out to enrol 60 GPs per group, expecting that 45 per group would complete the study. With an average of four

patients per GP, we estimated that this would provide a sample size of 240 patients per group and that 180 patients per group would complete the study.

#### Data analysis

Data were analysed using the intention-to-treat principle, with GP data analysed in the group to which the GP was allocated and patient data analysed in the group to which the patient's GP was allocated. For GP communication style and teaching behaviour, 10 items for confidence, helpfulness and frequency domains were each summed; GPs who had a higher score at 12 months than at baseline were consid-

ered to have improved their communication skills. The impact of the intervention at 12 months was assessed using continuity-corrected  $\chi^2$  tests. To adjust outcomes at 12 months for baseline values, logistic regression was used for binary variables and linear regression for continuous variables. For binary variables with a significant difference between groups, number needed to treat (NNT) was calculated — for example, the number of GPs who need to receive training for one GP to change their communication style or for one patient to receive a change in asthma care. We also adjusted for clustering of GPs by prac-

### 4 General practitioner-reported measures of asthma management

Outcome (in past 12 months)	Baseline*		12 months*		Between-group difference at 12 months (95% CI)	NNT	$\beta$ coefficient	Adjusted $P$ value <sup>†</sup>
	Intervention	Control	Intervention	Control				
Provides WAAP more than 70% of time	30/66 (45%)	25/56 (45%)	42/55 (76%)	25/47 (53%)	23% (11% to 36%)	5	0.67 <sup>‡</sup>	0.002
Asks parent or carer to demonstrate use of asthma device very often or always	18/65 (28%)	9/55 (16%)	28/56 (50%)	18/46 (39%)	11% (-2% to 24%)	9	0.39 <sup>§</sup>	0.03
Prescribes spacer devices more than 90% of time	31/66 (47%)	30/56 (54%)	38/55 (69%)	19/47 (40%)	29% (16% to 42%)	4	0.43 <sup>‡</sup>	0.02
Increased use of Asthma Cycle of Care	—	—	31/56 (55%)	12/47 (26%)	29% (17% to 43%)	3	—	—

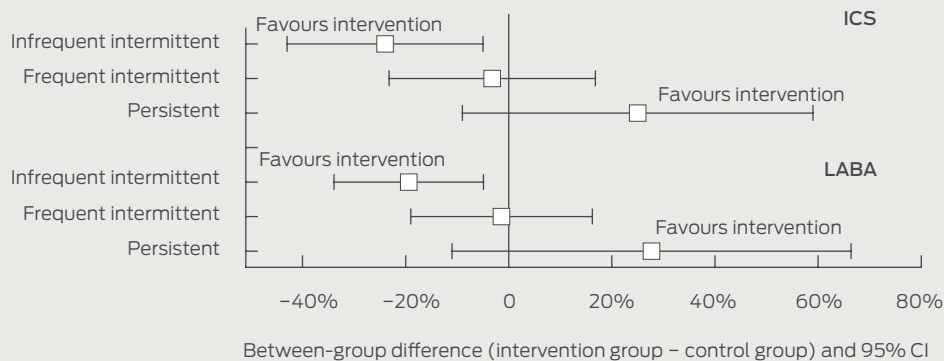
NNT = number needed to treat. WAAP = written asthma action plan. \* Data are number/denominator (%) unless otherwise specified; denominators vary due to missing data. † Adjusted for clustering. ‡  $\beta$  coefficient determined using an 11-point scale in 10% increments (0% to 100%). §  $\beta$  coefficient determined using a 6-point scale (never to always). ◆

5 Family-reported measures of asthma management and patient outcomes

Outcome (in past 12 months)	Baseline*		12 months*		Between-group difference at 12 months (95% CI)	NNT	β coefficient or OR	Adjusted P value†
	Intervention	Control	Intervention	Control				
Received WAAP one or more times	46/105 (44%)	37/105 (35%)	62/101 (61%)	48/104 (46%)	15% (2% to 28%)	7	2.06‡	0.046
One or more parent days away from work because of patient's asthma	33/110 (30%)	45/108 (42%)	26/101 (26%)	37/104 (36%)	-10% (-22% to 2%)	—	0.46§	0.55
One or more patient days away from school or child care because of asthma	73/110 (66%)	89/108 (82%)	61/101 (60%)	68/106 (64%)	-4% (-17% to 8%)	—	0.02¶	0.98
One or more visits to hospital for urgent asthma care	30/110 (27%)	34/108 (31%)	18/101 (18%)	13/106 (12%)	6% (-4% to 15%)	—	0.17**	0.12

NNT = number needed to treat. OR = odds ratio. WAAP = written asthma action plan. \* Data are number/denominator (%) unless otherwise specified; denominators vary due to missing data. † Adjusted for clustering. ‡ OR determined using binary variables (did or did not receive WAAP one or more times). § β coefficient determined using the following variables: < 1 day away from work per month, 2–4 days away from work per month, > 4 days away from work per month. ¶ β coefficient determined using number of days away from school or child care. \*\* β coefficient determined using the number of hospital visits.

6 Change in family-reported use of inhaled corticosteroids (ICS) and long-acting β-agonists (LABA) at 12 months by pattern of asthma symptoms\*



\* Data represent 95 patients with infrequent intermittent symptoms, 97 with frequent intermittent symptoms and 21 with persistent symptoms.

Outcomes and estimation

GP outcomes

At 12 months, GPs in the intervention group reported 20% improvement, compared with GPs in the control group, in how confident they were in using the 10 communication strategies, how helpful they thought the strategies were and how frequently they used the strategies. GPs in the intervention group were more confident when communicating with patients (difference 22%; 95% CI, 3% to 40%; NNT, 5;  $P=0.03$ ).

The self-reported GP outcomes (Box 4) — which reflect the national asthma guidelines<sup>16</sup> and PACE Australia objectives — show that the frequency of providing a WAAP increased in both groups over the study period, more so in the intervention group. At 12 months, there was a 23% between-group difference in self-reported provision of a WAAP more than 70% of the time. GPs in the intervention group also had a higher rate of asking the parent or carer to demonstrate how they would use the asthma device and a higher rate of prescribing spacer devices more than 90% of the time. Data on use of the Asthma Cycle of Care was not collected at baseline, but there was a 29% higher rate of increased use of this item in the intervention group compared with the control group at 12 months, which was statistically significant ( $P<0.001$ ); this translates to three GPs needing to attend the training workshops for one extra child to complete the Asthma Cycle of Care.

Patient outcomes

In the intervention group, 15% more children received a WAAP than in the control group at 12 months, a statistically significant difference ( $P=0.046$  after adjusting for clustering) (Box 5).

tice and patients by GP. Within-cluster intra-class correlation coefficients were computed and used to adjust Wald and  $t$  values.<sup>15</sup> Analyses were performed using SPSS version 15.0 (SPSS Inc, Chicago, Ill, USA).

Results

We recruited 150 GPs from 109 practices. In the intervention group, 66 GPs provided baseline data, 60 participated in the workshops and 57 provided 12-month follow-up data. In the control group, 56 provided baseline data and 49 provided 12-month follow-up data (Box 1). A total of 221 patients were enrolled; baseline data were provided for 218 patients, 12-month follow-up data were provided for 213 patients (96%) (Box 2). One hundred and sixty-six patients (75%) attended the same GP throughout the study. The patients who no longer saw the same GP were included in the analysis and attended other GPs for asthma care.

There was an average of 1.5 (122/80) GPs per practice and 1.8 (218/122) patients per GP at baseline, and adjustments for clustering did not alter results.

GP and family characteristics

GP and family characteristics were mostly balanced across the control and intervention groups (Box 3). More GPs in the control group graduated overseas, but this characteristic did not have a significant univariate association with any of the outcome variables ( $P>0.1$  for all associations). For families, there were differences in language other than English spoken at home and person in household who smokes, but these variables were not found to be significant univariate predictors of the primary outcomes ( $P>0.1$  for all associations). Asthma symptoms (as defined in the national asthma guidelines<sup>16</sup>) were infrequent intermittent for 45% of children, frequent intermittent for 46%, and persistent for 10%.



Between-group differences in asthma-related parent days away from work and child days away from school or child care were not statistically significant at 12 months, although the proportions of 1 or more days of each were lower in the intervention group. There was no significant difference in frequency of hospital visits for urgent asthma care between groups at 12 months. The frequency of discussing patient fears “very often or always” increased by 20% in the intervention group and 26% in the control group ( $P=0.56$ ).

Favourable changes in family-reported use of inhaled corticosteroids and long-acting  $\beta$ -agonists were associated with the intervention at 12 months (Box 6). Children in the intervention group who had infrequent intermittent asthma symptoms had lower use of inhaled corticosteroids (difference, 24%; 95% CI, -43% to -5%;  $P=0.03$ ) and long-acting  $\beta$ -agonists (difference, 19%; 95% CI, -34% to -5%;  $P=0.02$ ). Conversely, children in the intervention group who had persistent asthma symptoms had higher use of inhaled corticosteroids (difference, 25%; 95% CI, -9% to 59%;  $P=0.4$ ) and long-acting  $\beta$ -agonists (difference, 28%; 95% CI, -11% to 66%;  $P=0.4$ ), although the confidence intervals were wide and the differences not statistically significant. In children who had frequent intermittent asthma symptoms, there was little difference between groups in the use of inhaled corticosteroids (difference, 3%; 95% CI, -23% to 17%;  $P=0.9$ ) or long-acting  $\beta$ -agonists (difference, -1%; 95% CI, -19% to 16%;  $P=1.0$ ).

## Discussion

Significantly more children received WAAPs, as reported by GPs as well as parents and carers, in the intervention arm of our study. Prescribed medications also more closely reflected the child's clinical pattern of asthma (in line with asthma guidelines<sup>16</sup>) and there was greater prescription of spacer devices. The intervention also resulted in significant improvements in GPs' self-reported confidence when communicating with patients. The NNT values for many of the clinically important outcomes were low — ranging from 3 to 9 — suggesting that the PACE Australia program is both effective and efficient.

The PACE workshops aimed to change GP behaviour and specifically focused on improving communication

skills. Appropriate prescription of inhaled corticosteroids and long-acting  $\beta$ -agonists according to the pattern of asthma was another key issue discussed. Another Australian small-group trial of GP education did not show any effect on providing WAAPs.<sup>17</sup> We believe the workshops in our study were effective because they included a combination of training in communication skills plus best-practice asthma management in a supportive learning environment.<sup>10</sup>

In comparison with the PACE USA trial, we found similar-sized increases in the proportion of doctors who provided written instructions about asthma therapy.<sup>13</sup> Although we used the framework of the PACE USA intervention, the workshops in our study included more specific teaching about matching medication to pattern of asthma, the importance of providing WAAPs, and assessing device competency. GPs in the intervention group of our study improved their practice in each of these domains. Unlike the PACE USA trial, we did not find significant differences in GPs addressing fears about asthma medications. This may reflect differences in the participants (GPs rather than primary care paediatricians), the severity of asthma (“mild to moderate” in our study compared with “more severe” in the US study), or treatment concerns (possibly more anxiety about inhaled corticosteroid use in the US).

A limitation of our study was the use of data that were self-reported by participating GPs. However, the use of parent-reported outcomes (eg, receipt of a WAAP) provided strong validation of GP-reported outcomes. In addition, the length of the questionnaires, which were based on those used in the PACE USA trial,<sup>13</sup> may have reduced the questionnaire response rate at 12 months. A potential limitation of our study was slow recruitment, which led to a need to recruit more than one GP per practice. However, this clustering had a negligible effect on the results.

Despite our success in recruiting GPs, we were only able to recruit 221 families with a child with asthma in the study period. While some GPs did not have paediatric asthma patients, a major barrier was that we were only able to contact parents who had replied to their GP's invitation, a well recognised challenge.<sup>18</sup>

Our results provide robust evidence that the PACE Australia intervention

improved evidence-based asthma management practices of GPs and improved important patient outcomes. Further research is needed to test the efficacy of extending the intervention to other age groups of patients and other health professionals, such as practice nurses and pharmacists.

**Competing interests:** No relevant disclosures.

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