A pragmatic randomised controlled trial of an asthma nurse in general practice

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Abstract

Aim
To measure the impact of a nurse led asthma clinic on the quality of life of patients with asthma.

Design
A randomised controlled trial with delayed intervention in the control group.

Outcomes
Primary outcome measure: the Juniper Asthma Quality of Life Instrument. Secondary outcome measure: the EQ4D generic quality of life score.

Results
We analyzed data from 55 patients who were invited to attend an asthma clinic compared with 46 patients who received normal GP care. Due to a high drop out rate we were unable to demonstrate significant changes in our outcome measures. However, when we analysed only those patients attending the clinic there were significant improvements

Conclusion
Our trial was small and limited to one practice. Due to the high dropout rate we were unable to demonstrate a positive benefit of the intervention of an asthma nurse on the quality of life of asthma sufferers using an intention to treat analysis. This study illustrates the difficulties of undertaking trials on interventions that are well established.

Key words: asthma nurse, primary care, number needed to treat

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Introduction
Asthma represents a substantial burden in terms of both quality of life and socio-economic impact on both sufferers and their families.[1] Since the introduction of the 1990 GP Contract, there has been a rapid expansion of nurse run asthma clinics in general practice but the evidence for their effectiveness and cost effectiveness remains limited and often equivocal. No studies have sought to identify an impact on the quality of life of suffers and we are unaware of any randomised controlled trials that have shown a benefit from the intervention of an asthma nurse.

Eastwood[2] undertook a systematic review of the published evidence of effectiveness of organisational methods of asthma management and found little good published research evaluating different approaches. An observational study of 143 practices[3] showed favourable clinical outcomes associated with nurse led asthma clinics but the sample was subject to participant bias and showed an association rather than causal links. Two prospective and uncontrolled studies have found improvements in morbidity[4] and changes that conformed to the British Thoracic Society's guidelines.[5] Two randomised controlled studies have been undertaken. One found successfully self treated episodes of asthma but no difference in symptoms, days lost from work or school, and consultation rates[6] The second was unable to identify any differences in a number of outcomes between two matched practices.[7]

In view of the circumstantial evidence to support the benefits of asthma clinics and their wide spread acceptance into practice, we felt that it would be unethical to enter patients into a trial following a new diagnosis of asthma. We targeted patients that were known to have asthma but who had not seen our asthma nurse and undertook a randomised controlled trial to assess the impact of an nurse led clinic on the quality of life of suffers. The cost implications of the intervention were also considered from a limited economic perspective.

Subjects
The study took place at St Thomas' Health Centre, a practice of 9 GPs. Our inclusion criteria were patients between the ages of 18 and 55 years who were registered on our practice asthma data base but who had not been seen in our asthma clinic. As we sought to undertake a pragmatic trial, no further diagnostic confirmation was sought.

We recruited 101 patients who were randomised into control and intervention groups using computer generated random numbers. The randomisation was undertaken by our study co-ordinator who was not blinded to patient groups.

Intervention
The patients in the intervention group received a written invitation from their GP to attend the asthma clinic where they received assessment, education and management from one of our practice nurses over a period of four months. She had received structured training in asthma care and followed the British Thoracic Society's guidelines. Doctors signed prescriptions for her recommendations provided they conformed to the recommended guidelines. Control patients received routine GP care and were then invited to attend the clinic at the end of the study period.

Outcome variables
We chose an asthma related quality of life instrument as the primary outcome measure[8] which was sub divided into domains of activity, symptoms, emotions and effect of environment and gave a score of between 1 and 7 (best state). In order to measure

quality of life that encompassed broader domains we used the EQ4D (Euroqol) visual analogue scale as a secondary outcome measure.[9] This instrument measures general health on a scale of between 0 and 100 (best state). Outcome variables were assessed by post at 0 and 4 months. Non responders received one follow up reminder by post.

Analysis

In order to achieve 80% power and 5% significance, providing there was no change in the control group, we would need 22 patients in each group to detect an increase of one unit in our primary outcome measure - a change that is likely to give meaningful benefit to patients. Due to the fact that our primary outcome data was not normally distributed, we used the Mann Whitney test for comparison between groups. A p value of <0.05% was considered to be significant. Analysis was on an intention to treat basis using SPSS for Windows.

Results

408 patients in our target age range had been seen in the asthma clinic. 157 patients were identified who had not attended the clinic of whom 101 agreed to enter the study. We made no attempt to ascertain why patients did not wish to take up our invitation. There were no differences in age or sex of those who did not respond and in those who did. Figure 1 shows the trial profile.

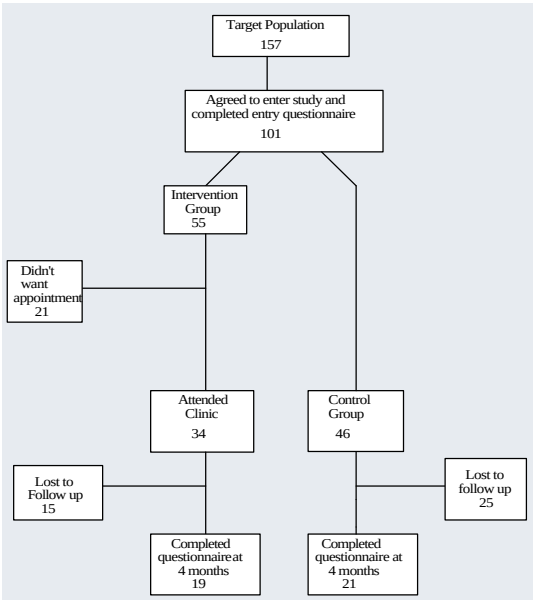

Figure 1 - Asthma Trial Profile

There were 46 patients in the control group and 55 in the intervention group, 21 had agreed to participate but did not make an appointment for the clinic. 25 and 15 patients were lost to follow up in the control and intervention groups respectively. These were patients that did not respond to a questionnaire following two reminders.

The average number of clinic attendances was 2.0. During the four month study period the average number of consultations/patient with the GP for asthma related problems were 0.3 (intervention group) and 0.5 (control group). These differences were not significant.

Figure 2 - Characteristics of intervention and control groups at trial entry

Median (Interquartile ranges)

	Intervention (n=55)	Control (n=46)	P value
Age	35.0 (29.0 - 47.0)	37 (27.0 - 50.0)	0.943
Sex = female	24 (44%)	31 (67%)	
Sex = male	31 (56%)	15 (33%)	0.017
Asthma quality of life score			
Activity domain	6.1 (5.3-6.8)	5.5 (4.8-6.3)	0.279
Symptom domain	5.6 (4.9-6.5)	4.8 (3.8-5.9)	0.042
Emotional domain	6.0 (4.8-6.4)	5.1 (4.0-6.2)	0.164
Environment domain	5.3 (4.3-6.3)	5.1 (4.0-6.0)	0.338
All domains	**5.7 (5.1-6.4)**	**5.1 (4.1-5.9)**	**0.080**
Euroqol generic quality of life score	80.0 (62.0-89.0)	75.0 (60.0-80.0)	0.136
Seen a consultant for asthma	6 (11%)	7 (15%)	

Figure 2 shows the baseline characteristics of the intervention and control groups at trial entry. There were significantly more males in the intervention group and the asthma symptom domain was significantly lower in the control group.
Figure 3 shows the changes in outcome variables at 4 months. There were significant improvements in the intervention group in the activity and emotion domains of the asthma related quality of life score but no change in the overall score or the EQ4D generic quality of life score. 10 patients improved their asthma quality of life score by >0.5 of a unit compared with 3 in the control group. Of these patients the number that improved by one unit was 7 and 1 respectively. These differences were not significant.

Figure 3 - Changes in outcome variables at 4 months

Median (Interquartile ranges)

	Intervention (n=55)	Control (n=46)	P value
Changes in asthma quality of life score			
Activity domain	0 (0.0 - 0.0)	0 (-0.02 - 0.0)	0.018
Symptom domain	0 (0.0 - 0.08)	0 (0.0 - 0.0)	0.082
Emotional domain	0 (0.0 - 0.0)	0 (-0.2 - 0.0)	0.011
Environment domain	0 (0.0 - 0.0)	0 (0.2 - 0.25)	0.589
All domains	**0 (0.0 - 0.09)**	**0 (0.0 - 0.012)**	**0.097**
Improved asthma quality of life score by >0.5	10	3	0.0812
Improved asthma quality of life score by >1.0	7	1	0.1124
Euroqol generic quality of life score	**0 (0.0 - 1.0)**	**0 (0.0 - 0.0)**	**0.275**

There were no differences in our primary outcome measure between the 21 patients who had been randomised to the intervention group but did not take up an appointment with the clinic and those who continued with the intervention. Comparing the 34 patients that attended the clinic with the control group revealed significant changes in asthma quality of life score and the EQ4D generic quality of life score.

Discussion

We experienced a high drop out rate and due to our relatively small sample size we were unable to demonstrate significant improvements for our patients using an intention to treat analysis. The reason for our high drop out is unknown but it is likely to be due to the fact that many of our target population had already rejected an invitation to the clinic.

Our study could be criticised in that patients were recruited from a prevalence rather than an incidence base. In view of the widespread acceptance of asthma clinics into general medical practice, we felt that randomising newly diagnosed asthmatics would not be acceptable to patients or GPs. We therefore targeted patients who were diagnosed with asthma but had not attended our asthma clinic.

Due to our limited resources, short study period and the use of delayed intervention as control we were restricted in our choice of outcome measurement. However, although there may be conceptual and methodological difficulties with the measurement of quality of life, health care research should address outcomes that are meaningful to patients[11] and the importance of quality of life measures in asthma rather than surrogate markers such as peak flow has been emphasised.[12] We therefore restricted our measures to scores reflecting quality of life.

Inferential statistics reveal differences between groups of subjects rather than changes that are important for individual patients. Guyatt[10] has emphasised the need to establish health related changes that represent important differences to patients and suggested that a moderate differences corresponds to a change of 1 unit in the scale of 1-7 in the instrument we used. 7 patients in the control group achieved this improvement compared with 1 in the intervention group. These differences were not significant. The outcomes of nurse led clinics may be a function of nurse training and qualification.[13] Ideally, questions on health care provision should be answered by large multi centred trials but this is not always possible and studies themselves have significant resource implications which could otherwise be allocated to direct health care. Research findings may have more relevance to end users if studies are undertaken locally and we have satisfied ourselves that our asthma nurse is effective.

Due to the high drop out rate we were unable to rigorously demonstrate a benefit from our asthma clinic but analysing only those who attended the clinic inferred that benefit had been obtained by a significant number of patients.

This study demonstrates the problems of formally testing an intervention that is already well established in practice but could form the basis for a wider multi-centred study. ■

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