An pragmatic randomised controlled trial of an asthma nurse i general practic

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Abstrac

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

Desig
A randomised controlled trial with delayed intervention in th control group.

Outcome
Primary outcome measure: the Juniper Asthma Quality of Lif Instrument. Secondary outcome measure: the EQ4D generic qualit of life score

Result
We analyzed data from 55 patients who were invited to attend a Asthma clinic compared with 46 patients who received normal G care. Due to a high drop out rate we were unable to demonstrat significant changes in our outcome measures. However, when w analysed only those patients attending the clinic there wer significant improvements

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

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

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Introductio

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

Eastwoo [2] undertook a systematic review of th published evidence of effectiveness of organisationa methods of asthma management and found little goo published research evaluating different approaches An observational study of 143 practice [3] showe favourable clinical outcomes associated with nurse le asthma clinics but the sample was subject t participant bias and showed an association rather tha causal links. Two prospective and uncontrolled studie have found improvements in morbidit [4] and change that conformed to the British Thoracic Society' guidelines [5] Two randomised controlled studies hav been undertaken. One found successfully self treate episodes of asthma but no difference in symptoms days lost from work or school, and consultation rate [6] The second was unable to identify any differences i d number of outcomes between two matche practices [7]

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

Subject

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

We recruited 101 patients who were randomised int control and intervention groups using compute generated random numbers. The randomisation wa undertaken by our study co-ordinator who was no blinded to patient groups

Interventio

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

Outcome variable

We chose an asthma related quality of life instrumen as the primary outcome measur [8] which was su divided into domains of activity, symptoms, emotion and effect of environment and gave a score o between 1 and 7 (best state). In order to measur

quality of life that encompassed broader domains w
ased the EQ4D (Euroqol) visual analogue scale as
secondary outcome measure [9] This instrumen
measures general health on a scale of between 0 an
100 (best state). Outcome variables were assessed b
post at 0 and 4 months. Non responders received on
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 a
increase of one unit in our primary outcome measure
a change that is likely to give meaningful benefit t
patients. Due to the fact that our primary outcome dat
was not normally distributed, we used the Man
Whitney test for comparison between groups. A
value of <0.05% was considered to be significant
Analysis was on an intention to treat basis using SPS
for Windows

Result

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

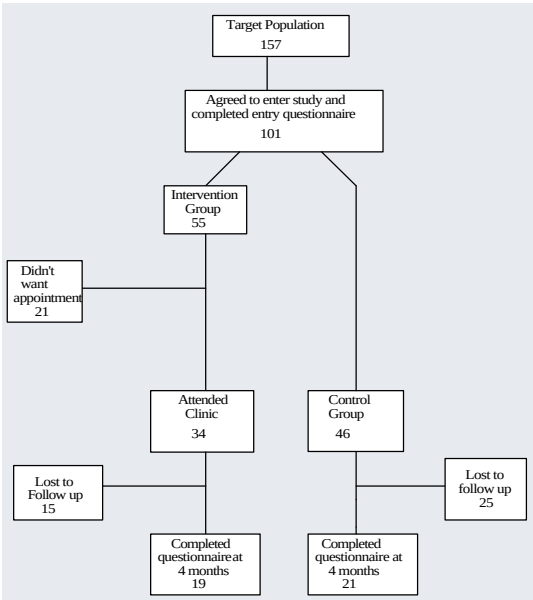

Figure 1 - Asthma Trial Profil

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

The average number of clinic attendances was 2.0
During the four month study period the averag
number of consultations/patient with the GP fo
asthma related problems were 0.3 (intervention group

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

Median (Interquartile ranges)

	Intervention (n=55	Control (n=46	P valu
Ag	35.0 (29.0 - 47.0	37 (27.0 - 50.0	0.94
Sex = femal	24 (44%	31 (67%	
Sex = mal	31 (56%	15 (33%	0.017
Asthma quality of life scor			
Activity domai	6.	5.	0.279
	(5.3-6.8	(4.8-6.3	
Symptom domai	6.	4.	0.042
	(4.9-6.5	(3.8-5.9	
Emotional domai	6.	5.	0.16
	(4.8-6.4	(4.0-6.2	
Environment domai	5.	5.	0.33
	(4.3-6.3	(4.0-6.0	
All domain	**5.**	**5.**	**0.08**
	(5.1-6.4	**(4.1-5.9**	
Euroqol generic quality	80.	75.	0.13
of life scor	(62.0-89.0	(60.0-80.0	
Seen a consultant for asthm	6 (11%	7 (15%	

and 0.5 (control group). These differences were no significant

Figure 2 shows the baseline characteristics of th
intervention and control groups at trial entry. Ther
were significantly more males in the interventio
group and the asthma symptom domain wa
significantly lower in the control group
Figure 3 shows the changes in outcome variables at
months. There were significant improvements in th
intervention group in the activity and emotio
domains of the asthma related quality of life score bu
no change in the overall score or the EQ4D generi
quality of life score. 10 patients improved thei
asthma quality of life score by >0.5 of a uni
compared with 3 in the control group. Of thes
7 patients the number that improved by one unit was
and 1 respectively. These differences were no
significant

Figure 3 - Changes in outcome variables at 4 month

Median (Interquartile ranges

	Intervention (n=55	Control (n=46	P valu
Changes in asthma quality of life scor			
Activity domai	0	0	
	(0.0 - 0.0	(-0.02 - 0.0	0.01
Symptom domai	0	0	
	(0.0 - 0.08	(0.0 - 0.0	0.082
Emotional domai	0	0	
	(0.0 - 0.0	(-0.2 - 0.0	0.01
Environment domai	0	0	
	(0.0 - 0.0	(0.2 - 0.25	0.58
All domain	**0**	**0**	
	(0.0 - 0.09	**(0.0 - 0.012**	**0.09**
Improved asthma quality of life score by >0.	10	3	0.081
Improved asthma quality of life score by >1.	7	1	0.112
Euroqol generic quality of life scor	**0 (0.0 - 1.0**	**0 (0.0 - 0.0**	**0.27**

There were no differences in our primary outcom measure between the 21 patients who had bee randomised to the intervention group but did not tak up an appointment with the clinic and those wh continued with the intervention. Comparing the 3 patients that attended the clinic with the control grou revealed significant changes in asthma quality of lif score and the EQ4D generic quality of life score

Discussio

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

Our study could be criticised in that patients wer recruited from a prevalence rather than an incidenc base. In view of the widespread acceptance of asthm clinics into general medical practice, we felt tha randomising newly diagnosed asthmatics would not b acceptable to patients or GPs. We therefore targete patients who were diagnosed with asthma but had no attended our asthma clinic

Due to our limited resources, short study period an the use of delayed intervention as control we wer restricted in our choice of outcome measurement However, although there may be conceptual an methodological difficulties with the measurement o quality of life, health care research should addres outcomes that are meaningful to patient [1] and th importance of quality of life measures in asthma rathe than surrogate markers such as peak flow has bee emphasised [2]. We therefore restricted our measures t scores reflecting quality of life

Inferential statistics reveal differences between group of subjects rather than changes that are important fo individual patients. Guyat [10] has emphasised the nee to establish health related changes that represen important differences to patients and suggested that moderate differences corresponds to a change of 1 uni in the scale of 1-7 in the instrument we used. 7 patients in the control group achieved thi improvement compared with 1 in the interventio group. These differences were not significant The outcomes of nurse led clinics may be a functio of nurse training and qualification [3]. Ideally questions on health care provision should be answere by large multi centred trials but this is not alway possible and studies themselves have significan resource implications which could otherwise b allocated to direct health care. Research findings ma have more relevance to end users if studies ar undertaken locally and we have satisfied ourselve that our asthma nurse is effective

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

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

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