

# **Integrated breathing and relaxation training (the Papworth Method) for adults with asthma in primary care: a randomised controlled trial**

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# ABSTRACT

## Background:

An integrated breathing and relaxation technique known as the Papworth Method (PM) has been implemented by physiotherapists since the 1960s for patients with asthma and dysfunctional breathing but no controlled trials have been reported. This study evaluated the effectiveness of the PM by means of a randomised controlled trial.

## Methods:

Eighty-five patients (36 men) were individually randomised to the control group (n=46) or to intervention, receiving five PM sessions of treatment (n=39). Both groups received usual medical care. Assessments were undertaken at baseline, post-treatment (6 months after baseline) and at 12 months. The primary outcome measure was the St George's Respiratory Symptoms Questionnaire (SGRQ). Secondary outcome measures included the Hospital Anxiety and Depression Scale (HADS), the Nijmegen dysfunctional breathing questionnaire and objective measures of respiratory function.

## Results:

Post-treatment and 12-month data were available for 78 and 72 patients respectively. At the post-treatment assessment the mean score on the SGRQ Symptom subscale was 21.8 (SD=18.1) in the intervention group compared with 32.8 (SD=20.1) in the control group (p=0.001 for the difference). At the 12-month follow-up, the corresponding figures were 24.9 (SD=17.9) and 33.5 (SD=15.9) (p=0.007 for the difference). SGRQ Total scores, and HADS and Nijmegen scores were similarly significantly lower in the intervention than control group. The groups did not differ significantly following the treatment on objective measures of respiratory function except for relaxed breathing rate.

## Conclusions:

The Papworth Method appears to ameliorate respiratory symptoms, dysfunctional breathing and adverse mood compared with usual care. Further controlled trials are warranted to confirm this finding, assess the effect in other patient groups and determine whether there is some effect on objective measures of respiratory function.

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## BACKGROUND

There are currently an estimated 5.2 million asthma patients in the UK and 300 million worldwide (1). Management is primarily through medication, though it is recognised that nonpharmacological approaches to reducing symptoms and improving health-related quality of life merit attention (2, 3).

A sequence of integrated breathing and relaxation exercises known as the Papworth Method (PM) was developed in the 1960s (4-7) (See Table 1). This method focuses on problems of dysfunctional breathing including hyperventilation and hyperinflation that are often found in asthma sufferers (3). The cycle of breathlessness and wheezing is frequently accompanied by anxiety and compounded by complex physiological mechanisms (8). It is believed that the PM leads to reduced asthma symptoms, anxiety and symptoms arising from hypocapnia. The present study was designed to investigate this hypothesis.

A Cochrane review on breathing exercises for asthma (9) found seven small-scale, randomised controlled trials (RCTs) satisfying its inclusion criteria. Trends towards improvement were found but no reliable conclusions could be drawn concerning the effectiveness of breathing training for asthma and it was recommended that further trials be undertaken (see also 10). The interventions included in the review were predominantly based on either ancient yoga practices (11, 12) or 'Buteyko techniques' where emphasis is placed on hypoventilation and a reduction in beta2 agonist use (13). To our knowledge no RCTs exist of the PM despite its being in quite widespread clinical use.

## METHODS

### Participants and setting

The study was undertaken in a semi-rural GP practice in Welwyn, Hertfordshire with eight partners and 16,500 patients, with 612 (4%) patients, aged  $\geq 16$  years registered on the practice asthma database. It took place between October 2004 and January 2006.

All 612 adult patients on the asthma register of the practice were initially approached to complete a postal survey about their condition. 359 patients responded. At the conclusion of the survey respondents were invited to attend a physiotherapy-oriented asthma assessment. One-hundred-and-forty-two patients responded positively. One-hundred-and-nine patients actually attended the assessment of whom 85 met the inclusion criteria for the trial (See Figure 1): they had to be between 16-70 years, able to understand, read and write English, with a commitment to participate for possibly 8 attendances, willing to give written informed consent and with no serious co-morbidity. The intention was that as few patients as possible would be excluded so that the sample would be maximally representative of a general practice asthma caseload. One patient in the control group requested withdrawal from the study to be able to receive PM treatment. Six- and 12- month data were available for 78 and 72 patients respectively. The reasons for loss to follow-up were primarily related to logistical or practical difficulties in attending (Figure 1).

Figure 1 about here

## Study design and procedures

This was a two-arm randomised controlled trial comparing an intervention group receiving five PM treatments with a control group receiving no additional treatment. Both groups continued to receive usual asthma care including medication and routine asthma education from a practice nurse. The usual care did not include advice about breathing exercises.

Randomisation was undertaken by a computer-generated number sequence assigning consecutive subject ID numbers either a 1 or 2 to denote intervention or control condition. Masking/blinding of patients and therapist was obviously not possible: patients had to sign an informed consent and it is obvious whether they are receiving the treatment or not. Whereas it might in principle have been possible for the follow-up assessments to have been undertaken by an assessor blind to the randomisation, resources did not permit this.

The primary outcome measure was the St George's Respiratory Questionnaire (SGRQ) (14). This assesses impaired respiratory symptoms and quality of life relating to these. It has good repeatability and is sensitive to changes in disease activity (15). A change in SGRQ Total score of 4 points is regarded as clinically significant (15). The questionnaire yields three subscale scores relating to 1) experience of symptoms, 2) their impact and 3) impairment in levels of activity. It also yields a total score. Secondary self-report measures were: the Hospital Anxiety and Depression Scale (HADS) yielding separate scores for anxiety and depression (16), and the Nijmegen questionnaire (17, 18) to assess hypocapnic symptoms (breathlessness accompanied by dysfunctional breathing in the form of hyperventilation) (19, 20). A portable capnograph (Better Physiology) was used to measure end-tidal carbon dioxide (ETCO<sub>2</sub>) and relaxed breathing rate over a 10-minute period and standard spirometric parameters were also assessed (Micromedical Microloop). Each assessment session took approximately one hour. Assessments took place at baseline, post-treatment (approximately 6 months after baseline) and at 12 months. Ethical approval was obtained from the local research ethics committee.

## Intervention – the Papworth Method

Between the baseline and post-treatment assessment the intervention group received five PM, 60-minute individual treatments from a respiratory physiotherapist, as summarised in Table 1. Ideally the PM is taught to patients in periods of remission in order that the techniques may be integrated into daily life activities and implemented at the first sign of symptoms (7).

**Table 1: Summary of the Papworth Method of treatment**

The PM integrates five components the principal one being specific breathing training:

- Breathing training, including teaching of appropriate minute and tidal volume and the development of a pattern of breathing suitable to current metabolic activity. Elimination of dysfunctional breathing, including hyperinflation and hyperventilation patterns is discussed. A specific PM diaphragmatic breathing technique is taught to replace the use of inappropriate accessory muscles of respiration.(5, 22) Emphasis, when relaxed, is placed on calm, slow nasal expiration. Patients are encouraged to ‘nose-‘ rather than ‘mouth-breathe’ and eradication or reduction of habits such as yawning, sighing etc is taught and practised.
- Education, with the emphasis on the recognition and physical management of stress responses and specifically the interaction with breathing patterns.
- Relaxation training, specific and general.
- Integration of ‘appropriate’ breathing and relaxation techniques into daily living activities. Initially the techniques are taught in a semi-recumbant position progressing to sitting, then standing and during daily living activities. Finally, the integration of breathing and relaxation techniques into speech is taught and practised.
- Home exercises with an audio-tape or CD containing reminders of the breathing and relaxation techniques are supplied at the third treatment. Encouragement is given to practise at least once a day with the tape.

### **Sample size and power calculation**

The sample size was calculated on the basis of a difference between intervention and control groups in the primary outcome measure (SGRQ, Total score) of 12 units at post-treatment assessments, as found in a pilot study, and a standard deviation of the difference between baseline and post-treatment assessment of 14 units (21). With these parameters 23 patients in each group would yield 80% power at the  $\alpha = 0.05$  level, 2-tailed. To take account of attrition rates of the order found in similar interventions (e.g. 10) we initially aimed to recruit 28 patients to each arm of the trial. In the event, a larger number of volunteers came forward from the recruitment process and to avoid wasting the opportunity, these were included. The original randomisation process had generated sufficient numbers to include the extra participants.

### **Data analysis**

Analyses were undertaken with SPSS v11.5. Analysis of covariance (ANCOVA) was used to compare the control and intervention groups on primary and secondary outcomes at post-treatment and 12-month assessments, controlling for baseline scores. The outcome variables were normally distributed apart from two SGRQ domain scores (‘activities’ and ‘impact’) which had a positive skew which was not judged to be so great as to invalidate the use of an analysis of covariance with this sample size.

Analysis was undertaken on a ‘per protocol’ basis rather than ‘intention to treat’. Intention to treat analysis is more common in RCTs but in this case it was expected that loss to follow-up would not have been correlated with lack of improvement, but rather due to practical or logistic issues and neither would it differ between the

intervention and control conditions. Moreover no satisfactory method could be found for imputing a value for those patients lost to follow up. If it turned out that loss to follow-up was high or different in the two study groups, this would undermine the interpretability of the findings.

**Table 2: Baseline demographic and clinical data**

	Control group (n = 46)	Intervention group (n = 39)
N (%) male	18 (39)	18 (46)
Mean (SD) age in years	49.3 (14.2)	50.2 (14.0)
N (%) married/cohabiting:	36 (78)	34 (87)
N (%) Employment status:		
N (%) full time	20 (44)	16 (41)
N (%) retired	10 (22)	11 (28)
<b>Asthma impact factors:</b>		
Mean (SD) years since asthma diagnosed	27 (17.7)	23 (15.2)
Mean (SD) years since first prescribed reliever medication	20 (13.6)	17 (13.0)
N (%) ex-smokers	14 (30)	14 (36)
N (%) current smokers	2 (4)	6 (15)
<b>Spirometry % predicted:</b>	(n=42)	(n=38)
Mean (SD) FEV1 (l)	91.67 (18.43)	87.24 (19.36)
N (%) *FEV1 <80% predicted	8 (17)	6 (15)
Mean (SD) FVC (l)	96.76 (13.58)	90.55 (18.34)
Mean (SD) PEF (l/min)	93.62 (21.31)	89.53 (21.80)

FEV1 = forced expiratory volume in one second; FVC = forced vital capacity; PEF = peak expiratory flow

\*BTS interpretation guidelines

## RESULTS

**Table 3: Effects on symptoms of five PM treatments compared with usual asthma care only**

	Baseline mean (sd)		Post-treatment (6-month post baseline) mean (sd)			12 months post-baseline mean (sd)		
	Control (n=46)	PM (n=39)	Control (n=45)	PM (n=33)	<sup>†</sup> p	Control (n=40)	PM (n=32)	<sup>†</sup> p
<b>SGRQ</b>	35.1	42.9	32.8	21.8	0.001	33.5	24.9	0.007
<b>Symptoms</b>	(12.9)	(21.3)	(20.1)	(18.1)		(15.9)	(17.9)	
<b>SGRQ</b>	20.2	27.8	17.0	20.4	0.984	18.4	19.0	0.16
<b>Activities</b>	(17.4)	(21.3)	(17.5)	(18.8)		(18.93)	(15.69)	
<b>SGRQ</b>	14.7	18.2	10.8	11.5	0.818	10.4	10.0	0.393
<b>Impacts</b>	(11.53)	(14.8)	(11.0)	(11.5)		(10.7)	(10.1)	
<b>SGRQ</b>	19.7	25.2	16.3	15.9	0.186	16.7	15.2	0.05
<b>Total</b>	(11.3)	(16.1)	(12.2)	(14.0)		(11.6)	(10.9)	
<b>Nijmegen</b>	17.8	19.2	15.0	11.0	<0.001	14.2	11.9	0.015
<b>Total score</b>	(9.1)	(11.0)	(9.5)	(9.7)		(9.2)	(8.6)	
<b>HADS</b>	6.2	6.3	6.2	4.7	0.002	5.9	4.4	0.006
<b>Anxiety</b>	(3.8)	(3.5)	(3.7)	(3.1)		(4.1)	(2.7)	
<b>HADS</b>	2.2	3.3	2.4	2.2	0.075	2.6	2.1	0.03
<b>Depression</b>	(1.8)	(2.5)	(2.4)	(2.3)		(2.7)	(2.2)	
<b>ETCO<sub>2</sub></b>	39.0	38.3	39.4	39.9	0.375	39.2	39.3	0.772
<b>mmHg.</b>	(3.7)	(5.5)	(4.4)	(4.6)		(3.4)	(6.0)	
<b>Relaxed</b>	15.1	15.0	15.3	10	<0.001	15.3	9.6	<0.001
<b>breathing</b>	(2.5)	(3.3)	(2.4)	(3.0)		(2.7)	(3.7)	
<b>rate over 10 min</b>								

<sup>†</sup>From analysis of covariance comparing PM and control groups controlling for baseline scores

SGRQ – St George's Respiratory Questionnaire scores. Range 0-100 (best-worst)

Nijmegen scores – higher scores indicate increased severity in symptoms from hypocapnia. Range 0-64 (best-worst)

HADS - Hospital Anxiety and Depression Scale. Range 0-21 (best-worst)

ETCO<sub>2</sub> – End tidal carbon dioxide



**Table 4: Effects on spirometric parameters of five PM treatments compared with usual asthma care only**

	Baseline mean (sd)		Post-treatment (6 month post baseline) mean (sd)			12 months post baseline mean (sd)		
	Control (n=42)	PM (n=38)	Control (n=41)	PM (n=32)	<sup>†</sup> p	Control (n=37)	PM (n=30)	<sup>†</sup> p
<b>VC (l)</b>	3.6 (1.0)	3.4 (1.0)	3.6 (1.0)	3.6 (0.9)	0.687	3.6 (1.0)	3.6 (0.8)	0.804
<b>FEV1 (l)</b>	2.8 (0.9)	2.7 (0.9)	2.8 (0.9)	2.9 (0.8)	0.974	2.7 (0.8)	2.8 (0.7)	0.583
<b>FVC (l)</b>	3.5 (1.0)	3.4 (1.1)	3.5 (0.9)	3.6 (0.9)	0.151	3.4 (0.9)	3.6 (0.9)	0.345
<b>PEF (l/s)</b>	413.4 (130.1)	408.5 (141.7)	425.9 (120.0)	439.5 (113.2)	0.745	407.9 (119.4)	439.3 (109.1)	0.375

<sup>†</sup> From analysis of covariance comparing PM and control groups controlling for baseline scores

SGRQ – St George's Respiratory Questionnaire scores. Range 0-100 (best-worst).

VC - vital capacity, FEV1 - forced expiratory flow, FVC - forced vital capacity, PEF – peak expiratory flow

No significant differences were found between groups at baseline (Tables 2, 3 and 4).

SGRQ Symptom mean scores were lower in the PM group compared with the control at post-treatment, and at 12 months (Table 3). The post-treatment and 12-month SGRQ Total scores were also significantly lower in the intervention group (Table 3).

Nijmegen and HADS scores were also significantly lower following the intervention in this group than in the control group (Table 3). Objective respiratory measures did not differ significantly across the groups apart from breathing rate (Table 4).

No adverse events were reported by patients or GPs.

## DISCUSSION

These results supported the hypothesis that the PM would ameliorate respiratory symptoms and improve quality of life in a general practice population of patients diagnosed with asthma. The effect was observed with reported symptoms and mood but no significant effect was observed on objective measures of lung function. To our knowledge this is the first evidence from a controlled trial to demonstrate the effectiveness of the PM.

The effect sizes on symptoms were clinically significant. A reduction of  $\geq 7$  points in SGRQ domains in the intervention group is approximately double the change considered to be clinically relevant. Anxiety and depression scores were also reduced to a clinically meaningful degree. Significant reductions in Nijmegen scores together with a reduction in breathing rate in the PM group suggested an improved ability to control breathing rate consistent with metabolic requirements.

The fact that no significant change was observed in objective measures of lung function suggests that the PM does not improve the chronic underlying physiological causes of asthma, but rather their manifestation in acute episodes.

There was no observable effect on patients' reports of the extent to which their activities were affected by their condition. However, in such a group with mild to

moderate asthma, the level of impairment at baseline was small and there was limited scope for differential improvement in the intervention and control conditions.

A limitation of the study is lack of detailed information on pharmacological treatment and changes in this over time during the trial. It would in principle be worthwhile examining how far, if at all, the intervention led to a reduction in medication usage or better adherence to medication regimens but this would have been complicated by changes in prescribing practices while the study was going on and would have been difficult to interpret.

The PM is a multi-component programme and we could not determine what element or elements contributed to its effect or even whether the elements combined synergistically. Because the comparison condition was usual care, we could not determine whether the PM is more effective than other active treatment options that might be adopted over and above usual care. It may be noted, however, that patients in the control group received considerably more attention than would have been the case in usual care because of the repeated assessments. It seems unlikely, therefore that the effects observed were simply due to increased attention.

The majority of patients had either mild asthma or symptoms well controlled with medication. It remains to be seen whether the PM would benefit patients with more severe asthma. Asthma and COPD are part of the same family of disorder, often co-exist and are difficult to differentiate. It would therefore be of interest to determine whether the PM could help patients diagnosed predominantly with the latter condition.

The most important limitation of the present study was that the same individual delivered the intervention and undertook the assessments. Although this is commonplace in studies of clinical/behavioural interventions, there is always the risk of patients responding to what they perceive as the expectations of the researcher. Such a bias may be expected to influence self-report measures across the board and so the fact that there was a marked improvement particularly in symptom scores suggests specific efficacy of the intervention. However, having obtained this positive finding better funded studies are warranted that would enable independent assessments to be carried out.

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## COMPETING INTERESTS:

RW undertakes research and consultancy for developers and manufacturers of smoking cessation treatments such as nicotine replacement products.

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## CONTRIBUTIONS OF AUTHORS

EH conceived and undertook this study with advice from RW. RW advised and participated in the analysis and interpretation. EH and RW wrote the manuscript. EH will act as guarantor.

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**Figure 1: The CONSORT flowchart of patient withdrawals**

