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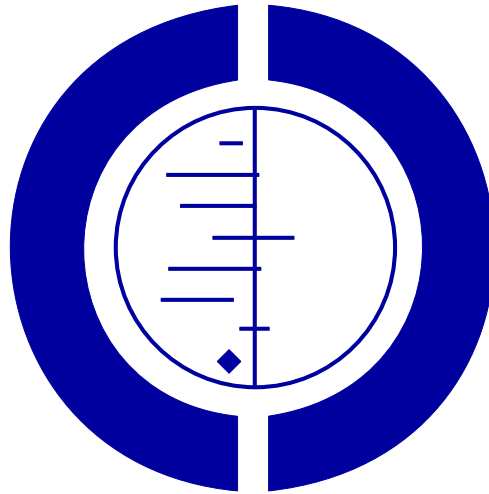
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# Psychotherapeutic interventions for adults with asthma (Review)

Fleming SL, Pagliari C, Churchill R, McKean M, Shuldham CM



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## ABSTRACT

### Background

Many people have asthma, and for some their symptoms may be triggered by psychological factors. In addition compliance with medical therapy may have a psychological dimension. Therefore, psychological interventions aim to reduce the burden of symptoms and improve management of the disease.

### Objectives

To assess the effectiveness of psychological interventions for adults with asthma.

### Search strategy

The Cochrane Airways Group specialised register and PsycINFO were searched with pre-defined terms until September 2003.

### Selection criteria

Randomised controlled trials published in any language assessing the effects of a psychological intervention compared with a form of control in adult participants were included in the review.

### Data collection and analysis

Two reviewers assessed the relevance of abstracts identified by electronic searching and retrieved agreed studies for further scrutiny. The studies that met the inclusion criteria were assembled and data extracted.

### Main results

Twelve studies were included in the review, however study quality was poor and sample sizes were frequently small. No meta-analysis could be performed due to the diversity of interventions and the outcomes assessed. Findings between studies were conflicting. This may have been due to the different types of interventions used and the deficiencies in trial design.

### Authors' conclusions

This review was unable to draw firm conclusions for the role of psychological interventions in asthma due to the absence of an adequate evidence base. Large, well-conducted and reported randomised trials are required in this area, in order to determine the effects of these techniques in the treatment of asthma in adults.

## SYNOPSIS

There is not enough evidence to determine whether psychological interventions for adults with asthma help to improve symptoms and mental health; more research is required.

It is thought by some that psychological interventions can help people with asthma. Systematically, we searched the literature on psychological interventions to find valid studies that looked at the effects of providing mainly psychological interventions for adults with asthma. The studies found examined many different therapies and measured different physical and psychological outcomes; for

these reasons, their results could not be easily combined. Furthermore, the available studies were completed with small numbers of people and the way the studies were conducted could be improved. More research with large numbers of people and improved design needs to be done before it is known whether psychological interventions are effective in making adults with asthma feel better.

## BACKGROUND

Asthma is a condition, which is characterised by recurrent or chronic variable airflow obstruction due to inflammation of the airways resulting in airway smooth muscle contraction in response to a number of chemical, physical and emotional stimuli. It is often divided into two types- allergic or extrinsic asthma and non-allergic or intrinsic asthma. However, many asthmatics can have symptoms from both allergic and non-allergic stimuli.

With few exceptions, there is no cure for asthma. Treatment is aimed at controlling chronic and acute symptoms and maintaining lung function to as near normal as possible. Modern treatment methods rely on reducing airway inflammation and smooth muscle contraction. Drugs are titrated according to symptoms, lung function and side effects.

An estimated 5.1 million people in the UK have asthma (including 1.4 million children). Asthma is expensive, resulting in an estimated cost to the NHS in England of £850 million a year. There are also indirect costs to the economy as over 18 million working days are lost due to the disease each year. People with asthma also incur costs for medication, travel to GP surgeries and medical equipment (NAC 2001). The high frequency of the disease, and its attendant costs, have prompted the production of guidelines for the management of asthma (BTS 2003). These guidelines include medication management as well as recommendations to improve patients' self-management skills in the form of Asthma Action Plans. Most patients with asthma are treated in primary care and outpatient settings and the overall success of treatment relies on the contribution to effective management that the patient can bring to bear. This includes factors such as compliance with medical therapy, effective inhaler technique and the ability to manage psychological elements. Asthma has a psychological component, including emotion (Lehrer 1993), so the treatment of asthma increasingly needs to focus on the whole person, taking account of psychological as well as physiological elements. This means that evidence to support clinical staff in deciding upon the type, format and frequency of psychological techniques is needed. The aim of these strategies is to help reduce panic or fear, improve breathing and respiratory function and impact positively on general health and quality of life.

Literature is growing on the relationship between psychosocial factors and asthma. Bosley 1996 found in their review of studies on asthma deaths and near fatal asthma attacks that asthma deaths are related to lack of prompt medical treatment and lack of prompt action by patients and their relatives. They also suggested that there

may be an association between psychiatric and asthma morbidity and that a near fatal attack may increase denial or psychiatric problems. Patient's attitudes to their illness may affect their coping skills and compliance with treatment. Because of the psychosocial effects of asthma, strategies such as cognitive-behavioural therapy (Kotses 1995), and group and individual counseling (Bailey 1990) are now integrated with educational packages about the self-management of asthma in order to improve health outcomes. Other psychotherapies that have been used are autogenic therapy (Henry 1993) and relaxation therapy (Lehrer 1994).

There is a growing body of work using review methodologies to assess the impact of a range of psychosocial interventions in asthma. For example, Devine 1996 showed that psychoeducational programmes involving relaxation and behavioural techniques improved health outcomes for adults with asthma. Reviews have been undertaken on self-management education for asthmatic adults (Gibson 2002a), limited asthma education for adults (Gibson 2002b) and family therapy for asthma in children (Panton 2002). Gibson 2002a concluded that training in asthma self-management, which involves self-monitoring by peak flow or symptoms, coupled with regular medical review and a written plan, appears to improve health outcomes for adults with asthma. Training programmes, which enable people to adjust their medication, also appeared to be more effective than other forms of self-management. In contrast limited asthma education, meaning information only, did not appear to improve health outcomes in adults with asthma, although perceived symptoms might improve (Gibson 2002b). Reviews led to the conclusion that more work is needed to elucidate the effect of providing information in the emergency department for adults (Gibson 2002b) and children (Haby 2002). Panton 2002 in their review of the only two trials on family therapy in asthma found some indication that this is a useful adjunct to medication for children with asthma.

Khateeb 1995 suggested that psychotherapy appears to have a role in the treatment of asthma. Hypnosis in asthma has also been the subject of research over many years to assess its impact but it is suggested that it is premature to conclude that hypnosis is unequivocally effective (Hackman 2000). With regard to relaxation as a therapeutic technique in asthma, Ritz 2001 proposed that more work was needed before a convincing case could be made. A similar conclusion was reached in the latest systematic review of relaxation therapies; there it was also suggested that there is limited evidence to suggest that muscular relaxation may warrant further investigation (Huntley 2002).

These reviews do not answer questions specifically about psycho-

logical interventions and therefore a systematic review of the effectiveness of psychological interventions for adults with asthma is also required. When managing patients, clinical staff need to have reliable information on whether psychological techniques work, and if so which are the most effective, for which patients. It is also important to know whether interventions work best alone or in combination with each other, and whether it is better that patients are taught individually or in groups. If possible it would also be useful for staff and patients to know what benefits may be expected, and whether they are short-lived or last in the longer term.

## OBJECTIVES

The purpose of this study was to conduct a systematic review of randomised controlled trials and a meta-analysis of all randomised trials where the efficacy of psychological interventions in modifying health and behavioural outcomes for adults with asthma was investigated.

The specific objectives were:

1. To assess the overall efficacy of psychological interventions compared with usual treatment in improving health and behavioural outcomes for adults with asthma.
2. To assess the comparative efficacy of different types of psychotherapy for adults with asthma.
3. To assess the comparative efficacy of individual and group formats of psychotherapy for adults with asthma.

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

Randomised controlled trials (RCTs) comparing the effects of psychological interventions for adults with asthma.

In the original protocol it was stated that this review would examine CCTs (case-controlled trials) on this subject as well, however as RCTs provide the stronger level of evidence, it was decided to concentrate on these only and a search strategy was designed to include RCTs.

### Types of participants

Adults, both male and female, over 16 years of age with asthma who have been physician diagnosed or have been diagnosed using internationally established criteria (e.g. BTS guidelines).

Treatments in both in and out patient settings were included.

### Types of intervention

Any type of psychological intervention used in the treatment of asthma in adults was considered for this review. Psychological interventions have a long history and have been defined as the

procedure by which a therapist purposively and systematically attempts to influence a patient by psychological means so that the patients' symptoms decrease or there is a positive change in behaviour (Barendregt 1957). These interventions will be delivered by a trained practitioner or in consultation or supervision by a trained practitioner.

Psychotherapy models were categorised according to their theoretical base as follows:

1. Cognitive behavioural therapy (incorporating core elements of both behavioural and cognitive models)

Using behavioural techniques to change negative thoughts mediating health behaviour. In asthma, this may address incorrect symptom attributions (over- or under-playing their significance) giving rise to suboptimal medication use, or may use systematic relaxation techniques to extinguish fear responses associated with psychosocial triggers.

2. Cognitive therapy

Identification and constructive management of damaging thoughts, such as perceptions of helplessness or inappropriate fear of asthma attack that can trigger episodes. Information (e.g. about the relationship between anxiety and bronchoconstriction) also targets cognitions.

3. Behavioural therapy

Concerned with identifying the processes by which behaviour has been learned via association, reward or observation and modifying behaviour using methods such as systematic desensitization, selective reinforcement and positive modelling. The behaviour itself, rather than underlying motivations, is the focus of behavioural interventions.

4. Relaxation therapy with or without biofeedback

Designed to control stress & anxiety. In asthma, may reduce panic or fear & improve breathing and respiratory function. Approaches include progressive relaxation (systematically creating tension and release in different parts of the body and/or via guided mental imagery), autogenic training (focuses on attending to bodily feelings and mentally controlling them), hypnosis (deep relaxation that may be induced using mental imagery, often accompanied by autosuggestion to create positive thoughts & feelings), and biofeedback (feedback of biological indicators), which the subject must control via relaxation. May also be considered a behavioural intervention since the feedback can act as a reinforcer.

5. 'Supportive' counselling

Counselling involves talking over problems with a health professional. In supportive counselling, the counsellor simply aims to be a good listener and provide emotional support, rather than offering a more targeted psychotherapeutic intervention. It generally focuses on problems in the here and now and has a short-term duration.

6. Hypnosis

Conceptualizations of hypnosis vary. At the broadest it can be regarded as a form of deep relaxation induced by guided mental imagery. In this sense it may be placed with other types of relaxation therapy. Hypnosis is also thought to induce a state of suggestibility,

facilitating both patients' insight into their unconscious motives or anxieties and the absorption of therapeutic messages.

#### 7. Individual and group format

Some therapies can be delivered to groups of individuals as well as single patients. Social interaction within a supportive non-judgmental peer group may increase self-esteem and encourage disclosure, both of which may (under appropriate circumstances) facilitate therapy.

Patient education programmes were only included where psychotherapy formed the major part of the intervention. Breathing retraining, yoga and massage therapies were not included in this review as these therapies were not considered to be primarily psychological in nature.

### Types of outcome measures

The types of outcome measures that might be expected are:

1. Level of severity of asthma symptoms
2. Medication usage
3. Lung function (e.g. Peak expiratory flow (PEF), forced volume capacity (FVC), spirometry)
4. Immune function
5. Health service utilisation (e.g. hospitalisation, GP visits)
6. Asthma knowledge questionnaires
7. Psychological questionnaires (e.g. coping skills, anxiety, asthma related behaviour scales, locus of control, self esteem, quality of life, psychological status)
8. Change of behaviour scales
9. Absenteeism from school or work

For the purposes of the review the primary outcomes include physical and psychological outcomes, namely:

1. Frequency, severity and duration of asthma symptoms  
Although these encompass three measures of asthma symptoms, the diversity with which these outcomes were recorded prompted us to group these together.
2. Psychological health status (e.g. anxiety, locus of control, self-esteem and quality of life) These encompass several measures of psychological well-being, but again, there was much diversity in the reporting of these outcomes, hence they are pooled as a group.

The secondary outcomes are:

1. Treatment: e.g. doses of reliever per time period, daily dose of inhaled corticosteroid
2. Health service utilisation: e.g. A&E visits, hospitalisation, GP visits
3. Absenteeism from work or school
4. Lung function
5. Markers of inflammation
6. Patient satisfaction.

## SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Airways Group search strategy

The Cochrane airways group register of controlled trials was used to identify randomised controlled trials, see Airways Group search strategy. The register includes references from MEDLINE, EMBASE, CINAHL, hand searched respiratory journals, meeting abstracts, and from searching the bibliographies of all trials. The Airways Asthma database was searched using the following terms:

Psychotherap\* or group Psychotherap\*

An advanced search of the CENTRAL Cochrane Controlled Trials Register (CCTR) was also completed using the above search strategy. A search for relevant trials used the search terms asthm\$ or wheez\$ and the exploded term Psychotherapy.

An extensive search was also made of the electronic register PsycINFO using the following search strategy-

Asthm\$ OR Wheez\$ AND psychotherap\$ OR psychol\$

Bibliographies of each identified trial were also searched for additional papers that might contain relevant trials.

Searches were updated annually; studies found up to the end of September 2003 were included.

Authors of all studies included in the review were contacted and asked to identify further published or unpublished work. In addition researchers known by the reviewers to have conducted a relevant study and to know the subject of the review were approached to identify other possible studies.

## METHODS OF THE REVIEW

### Study selection

The literature search identified eighty-five possibly relevant studies. Two independent reviewers (SF & CS) established whether each study met the inclusion criteria as an RCT of a psychological intervention for adults with asthma according to the above inclusion criteria. Disagreements were resolved by discussion. Twelve RCTs were appropriate for inclusion in this review (see Included Studies table).

### Methodological quality

The methodological quality of the studies (allocation concealment) was independently assessed by two reviewers (SF & CS) using the following criteria for allocation concealment:

Grade A: adequate concealment

Grade B: uncertain

Grade C: clearly inadequate concealment

Grade D: not used

There were no disagreements on ratings given to studies.

Each study was also assessed using a modified 0 to 5 scale developed by Jadad 1996 and summarised as follows:

1. Was the study described as randomised (1=yes;0=no)?
2. Was the outcome assessment blinded (1=yes;0=no)?
3. Was there a description of withdrawals and dropouts (1=yes;0=no)?
4. Was the method of randomisation well described and appropriate (1=yes;0=no)?
5. Was the method of blinding well described and appropriate (1=yes;0=no)?
6. Deduct one point if methods for randomisation or blinding were inappropriate.

Modification of this scale was essential as, due to the nature of the psychological interventions, it would be difficult to conduct double-blinded trials. Therefore in step 2 and 5 'double-blind' has been changed to 'blind'.

There was one disagreement on assessments between reviewers (SF & CS) and this was resolved by discussion.

The methodological quality of the studies was poor with only two studies rated Grade A (adequate) for allocation concealment (Ewer 1986; Mussell 1988), the remainder being rated Grade B, C or D. One RCT (Put 2003) had a rating of 4 on the Jadad scale, two had a rating of 3 (Ewer 1986; Loew 2001) with the remainder scored 2 or 1. Where allocation concealment or the randomisation process was unclear, letters were sent to authors asking for this information. However, as most of these studies were completed some time ago, correspondence from only two authors (Ewer 1986; Sommaruga 1995) was received (apart from information that authors had died or moved away).

#### Data analysis

Data from the twelve RCTs could not be entered into RevMan 4.1 for statistical analysis for the following reasons-

The studies were assessing different psychological interventions and even though several used relaxation therapy, the interventions were so diverse, it was not possible to pool results. Also, the studies either used different outcomes to measure the effectiveness of the intervention, or if the same outcomes were used- the data was presented in a method that could not be used (e.g. in graphical form). Authors were contacted to ask for data from these studies but this met with no response.

Therefore, outcome data could not be combined by meta-analysis in this review but are discussed descriptively. Where means and standard deviations were reported, 95% confidence intervals of the mean difference were calculated by an author (SF).

## DESCRIPTION OF STUDIES

### Study Design

See Included Studies table. Twelve studies were included in the review, with two publications from one study reporting different outcomes (Henry 1993). All were randomised and were conducted over a variety of durations (3 days to 12 months). Ten studies (Deter 1983; Erskine 1979; Ewer 1986; Henry 1993; Lehrer 1994; Lehrer 1997; Payette 1977; Put 2003; Sommaruga 1995; Wagaman 2000) were of parallel design and two (Loew 2001; Mussell 1988) were of cross-over design.

### Interventions used

Five types of intervention were also diverse. Eight studies used some form of relaxation technique as their intervention (Deter 1983; Erskine 1979; Ewer 1986; Henry 1993; Lehrer 1994; Lehrer 1997; Loew 2001; Payette 1977) however techniques used ranged from autogenic therapy to hypnosis and progressive muscle relaxation. Different placebo formats or different therapies were also used as controls. The other three studies used tracheal noise biofeedback (Mussell 1988), cognitive behavioural therapy combined with rehabilitation (Sommaruga 1995) a psycho-educational programme which included behavioural and cognitive techniques (Put 2003) and hypnotic suggestions to improve immune function and symptom relief (Wagaman 2000). Details of the interventions used are described in the included studies table.

It should be pointed out that single methods are seldom used and most practicing therapists use an eclectic approach employing different combinations of therapies to suit the individual circumstances (e.g. presumed mechanism of influence, patient characteristics, therapist preferences). There is also considerable overlap between methods; for example, relaxation techniques are part of the armoury of tools used for behaviour modification. In asthma, all of these techniques are used in combination with drug therapies.

## METHODOLOGICAL QUALITY

Overall the methodological quality of the studies was poor, with several weaknesses in experimental design. Jadad scores varied between 1 and 4 with only one study rated at 4 (Put 2003) and two studies rated at 3 (Ewer 1986; Loew 2001). The studies by Erskine 1979, Lehrer 1994, Mussell 1988; Sommaruga 1995 and Wagaman 2000 were accorded 2 points while the rest (Deter 1983; Henry 1993; Lehrer 1997; Payette 1977) received 1 point.

Only two studies rated Grade A (adequate) for allocation concealment (Ewer 1986; Mussell 1988) the remainder being rated Grade B (unclear) (Deter 1983; Erskine 1979; Henry 1993; Lehrer 1994; Loew 2001; Put 2003; Sommaruga 1995); Grade C (inadequate) (Wagaman 2000) or D (not used) (Lehrer 1997; Payette 1977).

### Study Participants

The studies were generally small with only one having more than a hundred people included (Lehrer 1994 recruited 106 people). The smallest (Erskine 1979) had 12 and the largest of the rest



(Sommaruga 1995) 40 people. A power calculation to determine sample size was only done in one study (Lehrer 1994). Four studies included details about how many people were approached to join the research: Deter 1983 where 90 people were invited and 27 declined to join and 34 agreed (no information is given about the other 29 people), Lehrer 1994 where 47 more people were screened than actually participated in the study. Put 2003 invited 101 and 25 agreed and Wagaman 2000 where 90 people attended an initial interview resulting in 30 joining the research. No further data are provided from the other studies.

In some studies a description of withdrawals was not given (Henry 1993; Mussell 1988; Payette 1977; Sommaruga 1995). Erskine 1979; Ewer 1986; Lehrer 1997 and Wagaman 2000 gave the numbers who withdrew but no details of their characteristics. Deter 1983 did not mention withdrawals but eleven people appear not to have completed the study and it is difficult to see what happened to patients, as the numbers do not tally. Lehrer 1994 referred to patients who had dropped out, but also seemed to have a group who completed the treatment but for whom there are no measurements. Loew 2001 excluded patients (n = five) from some of the measures when they did not experience bronchoconstriction. Although Put 2003 commented on missing data there was no other discussion about missing data and the potential impact this might have had on the findings. In no study was there a clear plan enabling the reader to track easily the progress of patients approached or included in the trial and there was no discussion about missing data and the potential impact this might have had on the findings.

The severity of asthma varied from mild to severe, however not all studies reported this. Participants with co-morbidity were excluded from the studies.

#### Method of randomisation

Studies were randomised with patients allocated to control and experimental groups, however authors tended not to be clear as to whether all the patients who were eligible for the study were approached. Frequently the method of randomisation was not mentioned (Deter 1983; Erskine 1979; Henry 1993; Lehrer 1994; Lehrer 1997; Mussell 1988; Payette 1977; Wagaman 2000). Put 2003 had a system of drawing from unmarked envelopes. Loew 2001 used a computerised randomisation scheme to determine the sequence of the tests. Ewer 1986 reported that the outpatient department sister, who had no other involvement in the study, was responsible for the randomisation and on correspondence confirmed randomisation was done by computer. Sommaruga 1995 also confirmed on correspondence that randomisation was done by computer. Therefore it is difficult in all the studies to gauge whether the method of randomisation was appropriate. This is reflected in the Jadad scores.

Sometimes a researcher blinded to the participants group assessed the outcomes. Put 2003 used independent researchers who were unaware of the patient's treatment allocation. Ewer 1986 involved the outpatient department sister who was blind to the patient's

group and although the author conducted the intervention, they are clear that the challenge test was conducted with a researcher who was blinded. Mussell 1988 used placebo treatments and referred to the study being double blind as to the treatment order. Loew 2001 refer to their study as being single-blind but are not clear whether the researcher or the subject was blinded. As they used a placebo relaxation technique, the subjects may have been blinded to the active treatment. Assessment of outcome in Payette 1977 was not blinded and in Lehrer 1997, the same person undertook the treatment intervention and measurement. Wagaman 2000 stated that assessments and medical assessments were blinded, but the investigator performed the interventions and delivered the psychometric assessments. All other authors failed to mention whether the assessment of outcomes was blinded or not.

In general therefore, the conclusion reached about the quality of the studies reflects the comment made by Ritz 2001:653, in his overlapping systematic review, that 'most of the few available studies suffer from inadequacies in experimental design, instrumentation, procedures and/or reporting of results'.

#### Outcomes

A wide variety of outcomes were used. These included objective measures of lung function such as FEV1, FVC and peak flow (Erskine 1979; Ewer 1986; Henry 1993; Lehrer 1994; Lehrer 1997; Loew 2001; Mussell 1988; Payette 1977; Put 2003; Wagaman 2000) or medication usage (Deter 1983). Asthma symptoms were measured (Erskine 1979; Ewer 1986; Lehrer 1994; Lehrer 1997; Put 2003; Sommaruga 1995; Wagaman 2000). In contrast some researchers measured psychological traits such as anxiety (Deter 1983; Ewer 1986; Sommaruga 1995; Wagaman 2000), fear (Deter 1983) or health locus of control (Sommaruga 1995). Health service utilisation was measured by Deter 1983; Sommaruga 1995 and Wagaman 2000.

## RESULTS

### Primary outcomes

#### Frequency, severity and duration of asthma symptoms

This was measured by seven studies (Erskine 1979; Ewer 1986; Lehrer 1994; Lehrer 1997; Put 2003; Sommaruga 1995; Wagaman 2000). Put 2003 used the McMaster Asthma Quality of Life Questionnaire (Juniper 1992) and the Asthma Symptom Checklist (Kinsman 1973). Measurements were taken at baseline for both groups. For the experimental group they were taken again immediately after the intervention (which lasted three months) and three months thereafter. The waiting list controls had measurements at three and six months after baseline. There were significant differences in symptoms ( $p < 0.05$ ) between groups. Analysis of variance showed differences in obstruction ( $F(2,42)=3.3, p < 0.05$ ), fatigue ( $F(2,42)=7.9, p=0.001$ ) and irritation ( $F(2,42)=3.8, p < 0.05$ ), with

the treatment group reporting a decrease in symptoms. There were no significant differences for dyspnoea and hyperventilation.

The findings for the between group analyses for the rest of the studies were not significant, however some significant results were found on within or whole group analysis.

One study (Sommaruga 1995) of an asthma rehabilitation programme including cognitive behavioural therapy resulted in both the intervention group and the control group having less asthma attacks (data to support this are not provided, apart from  $p < 0.05$ ).

Nocturnal symptoms i.e. sleep, and wheeze, activity, cough and phlegm were reported in one study (Ewer 1986). They examined the impact of hypnosis on people with a history of mild to moderate asthma. Patients were separated as to whether they scored high or low on a scale to measure their susceptibility to hypnosis (Stanford hypnotic clinical scale). Daily symptom scores, the rating scale is not given, were averaged for the first two and the last two weeks of the treatment period. In the high susceptibility group who received the hypnosis intervention, the subjective scores for nocturnal symptoms, wheeze and activity limitations improved after treatment. Mean percentage change in symptom scores was -62 ( $p < 0.05$ ) for sleep, -53 ( $p < 0.001$ ) for wheeze and -58 ( $p < 0.01$ ) for activity. No significant change was found in either the low susceptibility treatment or control groups.

Bronchoconstriction, hyperventilation, panic-fear, irritability and fatigue were measured in a study by Lehrer 1997. Within group differences, before and after treatment, were not significant for bronchoconstriction and hyperventilation and no differences were found for the other three outcomes. Between group differences were not reported and it is assumed that these were not significant.

Hyperventilation severity ( $F=3.97$ ,  $df=2,106$ ,  $p < 0.04$ ) and frequency ( $F=4.82$ ,  $df=2,106$ ,  $p < 0.02$ ) using an asthma symptom checklist (Lehrer 1994) showed within group differences over the course of treatment with relaxation and music therapies but there was no significant differences between groups.

Subjective symptoms before and after hypnosis sessions were measured by Wagaman 2000 using the Asthma Symptom Checklist (Kinsman 1973). The groups were too small to allow statistical analysis to test for differences, however the whole sample had a decrease in overall symptoms post intervention when compared to pre-intervention measurement, however no usable data were presented. Frequency of acute attacks as measured by patient diaries were unable to be assessed statistically due to the small sample and the infrequency of these attacks.

Psychological Health Status- Anxiety, Locus of Control, Self-esteem, Quality of Life

Anxiety was used as an outcome measure in five studies (Deter 1983; Ewer 1986; Put 2003; Sommaruga 1995; Wagaman 2000). Health locus of control was examined in Sommaruga 1995 and

psychological symptoms in one (Erskine 1979). Anxiety was measured using the State-trait Anxiety Inventory (Spielberger 1970) in Ewer 1986- but no data are presented. There were no significant differences between groups for psychological health status, but there were some within group differences.

Trait anxiety was measured by Sommaruga 1995. Patients were treated in an Asthma Rehabilitation Group involving education and a cognitive behavioural intervention. There were significant differences between baseline and one year follow up in those who received the intervention, in respect of trait anxiety (data at enrolment (t0) showed a mean 43.2 (SD10.0) and at 1 year (t1) 36.7 (9.1),  $p < 0.0005$ ), psychophysiological disorder (t0 48.7 (9.3) t1 45.1 (9.4),  $p < 0.02$ ) and depressive symptoms (t0 5.8 (3.7) t1 3.6 (3.0),  $p < 0.006$ ), but not for psychophysiological disorder in the control group. There are other outcomes studying optimism, negative staff regard, internal awareness, external control, psychological stigma and authoritarian attitude from a Respiratory Illness Questionnaire (Staudenmayer 1978). Within group analyses showed significant decreases for external control (data at enrolment (t0) showed a mean 10.1 (SD3.8) and at 1 year (t1) 8.4 (3.5),  $p < 0.05$ ) and psychological stigma (t0 9.0 (3.8), t1 7.5 (3.8),  $p < 0.03$ ) in the intervention group and psychological stigma (t0 10.2(5.6) t1 7.8 (3.8)  $p < 0.03$ ) in the control group.

Anxiety, using the MMPI (Minnesota Multiphasic Personality Inventory) showed an increase for the intervention as compared to the control group which is referred to as 'a tendency to react positively' although the implication of a higher score may be of worse anxiety. The magnitude was small with an increase or decrease of one point only, which is unlikely to have either clinical or statistical significance (Deter 1983). Anxiety is a sub-scale on the asthma symptom checklist used by Put 2003. No significant differences between groups were found.

State anxiety was assessed in Wagaman 2000. The groups were too small to allow statistical analysis to test for differences between the two intervention groups and the control group, however the whole sample had a significant decrease in anxiety post intervention (at one year follow up) when compared to pre-intervention measurement (mean change -12.09;  $t=4.13$ ;  $p < 0.01$ ). The same study assessed neuroticism, extraversion and lying (Eysenck Personality Inventory), repressive coping (Marlowe Crowne Social Desirability Scale (Crowne 1960)), self-control methods to the solution of behavioural problems (Self-Control Schedule (Rosenbaum 1980)), and catastrophising (Dysfunctional Cognition Inventory (Zocco 1985)). There were no significant differences found.

Health locus of control, including internal beliefs, and external control through powerful others and chance was measured using the Health Locus of Control Scale (Wallston 1976) in an Italian version in a study by Sommaruga 1995. There were no significant differences between baseline and one year follow-up except an increase in beliefs about 'external chance' in the control group.

'External chance' on the Health Locus of Control Scale measures the belief that health depends on casual factors and luck (t0 9.9 (3.5) t1 11.5(3.0)  $p < 0.03$ ).

Panic/fear and fatigue using an asthma symptom checklist (Lehrer 1994) showed differences over the course of treatment with relaxation and music therapies in an RCT. They report no significant differences between groups, but panic/fear severity did decrease for the whole sample ( $F = 3.34$ ,  $df = 2, 104$ ,  $p < 0.02$ ). Wagaman 2000 also included panic/fear and fatigue but did not present usable data.

Psychological symptoms were examined in a RCT of relaxation therapy, using a self-report weekly symptom questionnaire incorporating a five-point severity rating scale (Erskine 1979). Data showed no difference between the two groups (muscular relaxation, and mental and muscular relaxation) and patients overall did not show any significant reduction in symptoms and signs.

Psychological elements were examined in a trial of autogenic therapy (Henry 1993) with measures of the patient's state- 'vegetative', emotional, behavioural, cognitive and reactivity to stress with no significant differences between baseline and follow up in either group, with the exception of 'vegetative' state in the experimental group (mean difference (SD) 1.83(2.69)  $p < 0.05$ ). A Negative Emotionality Scale, which incorporates measures of negative affectivity as a personality trait, including irritability, nervousness and emotional instability was used by Put 2003. People in the experimental group had a decrease in scores, suggesting improvement, and there were significant differences between experimental and control groups ( $F(2,42) = 10.8$ ,  $p = 0.0002$ ).

Temperament was studied in Payette 1977 using the Taylor-Johnson Temperament Analysis (Taylor 1974) with no significant differences found between a group receiving biofeedback training and a control group.

Lehrer 1994 included measures of the most relaxed and tense moment in a session using a 9-point Likert scale. They found a significant treatment effect for relaxation during the training session, with the waiting list group being less relaxed (mean 4.2 (SD 1.5)) than the progressive relaxation groups (2.8 (1.4)) during their eighth session ( $p < 0.05$ , 95% CI 0.6 to 2.2).

Henry 1993 found no significant differences between groups when measuring reactivity to stress. Reactivity to stress is the extent to which the body reacts to stressors. It can be assessed by comparing physiological measures in a resting state (baseline or relaxation) to those in the presence of a physical or psychological stressor. Psychological outcome measures may also be used.

## Secondary Outcomes

### Treatment

Four studies examined intervention effects on treatment (Deter 1983; Ewer 1986; Lehrer 1997; Wagaman 2000). Each trial used

a different method of measuring this outcome so effects could not be pooled. Deter 1983 found a significant difference in the numbers of people in the experimental group ( $n = 4$ ) who required less bronchodilators when compared to the control ( $n = 0$ ;  $p < 0.05$ ). For the sub-group of people with a high susceptibility to hypnosis, Ewer 1986 found the treatment group had significantly less bronchodilator use after treatment (mean 34.0 puffs/day (SD 7.8)) when compared to before treatment (46.0 (7.2),  $p < 0.05$ ). Lehrer 1997 found no significant differences when measuring amounts of inhaled or oral steroids taken at 6 weeks post intervention. Wagaman 2000 found significant decreases in medication requirements in both of the experimental groups and a significant increase in the control group at one year after hypnotic suggestions were given. No usable data was presented to demonstrate this.

### Health Service Utilisation

Three studies (Deter 1983; Sommaruga 1995; Wagaman 2000) examined this outcome and there were no significant differences between experimental and control groups. Each study measured this outcome using different methods so data could not be pooled. Sommaruga 1995 found numbers of hospitalisation days and number of emergency visits were decreased for both the intervention group (an asthma rehabilitation programme) and the control group (data to support this are not provided, apart from  $p < 0.05$ ). Numbers were too small in the Wagaman 2000 study on hypnosis to test for statistical differences for this outcome.

### Absenteeism from work or school

Two studies examined this outcome by using patient diaries (Wagaman 2000) and recording the number of work/school absences (Sommaruga 1995). Work/school absences were significantly decreased post-intervention for both the asthma rehabilitation group and the control group (data to support this are not provided, apart from  $p < 0.05$ ). Numbers were too small in each group to test for statistical differences in the Wagaman 2000 study.

### Lung Function

Eleven RCTs (Deter 1983; Erskine 1979; Ewer 1986; Henry 1993; Lehrer 1994; Lehrer 1997; Loew 2001; Mussell 1988; Payette 1977; Put 2003; Wagaman 2000) used lung function as an outcome to measure the effectiveness of their intervention. Of these, two used a hypnotic technique to relax subjects (Ewer 1986) and to improve immune function (Wagaman 2000), seven trials used relaxation therapy (Deter 1983; Erskine 1979; Henry 1993; Lehrer 1994; Loew 2001) two including biofeedback training (Lehrer 1997; Payette 1977), and another used tracheal noise biofeedback training to reduce bronchoconstriction (Mussell 1988). The final one (Put 2003) used a psychoeducational intervention, which included behavioural and cognitive techniques. Data could not be pooled in Metaview as the interventions used were too diverse. Data could not be pooled in Metaview as the interventions used were too diverse. In some studies, data was often presented in a format that could not be analysed (e.g. graphically). There was no

response from authors of these studies on written request for raw data.

#### Methacholine challenge test.

A methacholine challenge test to detect improvement of asthma following intervention was used in two RCTs. One adopted a hypnotic technique to relax subjects (Ewer 1986) and the other study used relaxation training (Lehrer 1994). No significant treatment effects were shown in the RCT using relaxation training. In the trial using a hypnotic technique the most important finding was a significant improvement in bronchial hyper-responsiveness for patients with a high susceptibility for hypnosis. The data using mean PC20 (SEM) were 9.09 (1.71) before treatment and 15.9 (2.79) after treatment ( $P=0.008$ ), where PC20 is the provocation concentration of methacholine that caused a 20% fall in FEV1.

#### Spirometry

Spirometry was used in nine RCTs, however only three studies used the full range of spirometric tests as outcomes (Ewer 1986; Henry 1993; Lehrer 1994). Two RCTs, one using relaxation and the other biofeedback training (Erskine 1979; Mussell 1988) used FEV1 (forced expiratory volume in one second) only. Another, (Put 2003), measured Peak Expiratory Flow Rate (PEFR). Significant differences were found for day ( $F(2,40)=3.8, p=0.02$ ) and night ( $F(2,40)=3.3, p<0.05$ ) PEFR with the experimental patients faring best. The remaining three studies used a variety of measures (Loew 2001; Payette 1977; Wagaman 2000). There were no significant differences between groups for spirometry measures, however there were some within group improvements.

Ewer 1986 found significant improvement in FVC (forced vital capacity) for both intervention (6.9%) and control groups (5.03%)  $p<0.002$ , PEF (peak expiratory flow) and MEF (mid expiratory flow) (50%) for the treatment group after hypnosis of 11.7% ( $p<0.002$ ) and 14.7% ( $p<0.05$ ) respectively when compared to baseline measurements. Henry 1993 found significant improvements in spirometric measures for the treatment group after autogenic therapy when compared to baseline measurements. These were- FVC (mean difference 0.31 (SD 0.24)  $p<0.001$ , % of predicted value of FVC (14.3 (8.39)  $p<0.001$ , FEV1 (0.35 (0.36)  $p<0.01$ ), % of predicted value of FEV1 (16.3 (12.4)  $p<0.001$ ), FEF25-75 (middle half of forced expiratory flow) (0.44 (0.58)  $p<0.5$ ), % of predicted value of FEF25-75 (12.1 (15.5)  $p<0.05$ ) and % of predicted value for MEF50 (13.6 (19.9),  $p<0.05$ ).

Lehrer 1994 found no significant differences between groups for any of the spirometry measures after relaxation therapy. However significant decreases pre-test to post-test occurred for a subgroup of people (37) from the whole sample for PEF [ $F(1,49) = 8.12, p<0.007$ ] and FEF50 [ $F(1,49) = 12.29, p<0.001$ ]. Significant pre-test to post decreases also occurred for the whole sample for FEV1 [ $F(1,87) = 21.56, p<0.001$ ] and FEV1/FVC [ $F(1,87) = 13.64, p<0.0005$ ]. Loew 2001 showed significant improvement for the functional relaxation group for FEV1 (mean difference of

%values -1 (SD 7),  $p<0.05$ ), PEF (-1 (14),  $p<0.05$ ), MEF50 (0 (10),  $p<0.01$ ) and MEF75 (-3 (10),  $p<0.01$ ) when compared to baseline measures. Payette 1977 found no significant differences between groups for FVC, FEV1, FEV1/FVC (ratio of FEV1 and FVC) after EMG biofeedback training. Wagaman 2000 also found no significant differences between groups for FEV1, FEF 25-75, and PEF after hypnotic suggestion. Erskine 1979 and Mussell 1988 also reported no significant differences between groups for FEV1 measurements.

#### Airways resistance

Airways resistance was measured in three RCTs (Deter 1983; Lehrer 1997; Loew 2001). There was no significant difference between groups for airways resistance, however Lehrer 1997 showed significantly decreased airways resistance for the RSA biofeedback group ( $F(4,21) + 2.91, p<0.05$ ) compared to pre-test measures. Loew 2001 also showed significant improvement for the functional relaxation group for airways resistance (Mean difference pre to post treatment 38% (SD 63)  $p<0.01$ ) and specific airways resistance (Mean difference pre to post treatment 53% (SD 85)  $p<0.01$ ) when compared to baseline measures. There were no significant differences for the control group. Data was presented for airways resistance (Mean 4.78 (SD 3.22)) and conductance (0.083 (0.48)) for the intervention group only in Deter 1983 with no significant differences found.

#### Markers of Inflammation

Immunoglobulins (IgE, IgA, IgM, IgG) were measured in Deter 1983 and showed that 82% ( $n=19$ ) of patients had a raised IgE, 8% ( $n=2$ ) raised IgM values and 4% ( $n=1$ ) raised IgE. There was much missing data and immunoglobulins were not used as an outcome measure.

#### Patient Satisfaction

Patient satisfaction with the intervention, and a report on its effectiveness, were mentioned by Lehrer 1994 but no data are presented and no further comment was made about these measures.

## DISCUSSION

This systematic review evaluated twelve trials of varied psychological interventions for adults with asthma and found that generally these interventions do not decrease frequency, severity and duration of asthma symptoms or decrease health service utilisation. However, there were some positive effects found in some studies. Put 2003, describing one of the better designed trials, showed significant differences between experimental and control patients on a range of outcomes. These include symptoms such as obstruction, fatigue and irritation, as well as an aspect of lung function and psychological state. Another trial (Deter 1983) evaluating autogenic therapy found a significant decrease in the amount of bronchodilators taken for the intervention group, however another

three trials which tested different interventions but evaluated this outcome reported no significant differences (Ewer 1986; Lehrer 1997; Wagaman 2000). Lehrer 1994 found that progressive relaxation resulted in the intervention group being significantly more relaxed, but no further significant differences were found between groups for psychological health status. With the exception of Put 2003, there were no significant differences in lung function between intervention and control groups for any of the interventions but there were some within group improvements. However, these improvements should be viewed with caution as the within group outcomes reported are not covered by the randomisation process and are reported in this review for comprehensiveness only.

Trials evaluating hypnosis (Ewer 1986), autogenic therapy (Henry 1993) and functional relaxation (Loew 2001) found lung function improved for the intervention group from baseline measurement to post-intervention measures. However a trial of progressive muscle relaxation (Lehrer 1994) found significant decreases in lung function for the intervention group from pre to post-session measures. Improvement of airways resistance was found for the intervention group after a trial of functional relaxation therapy (Loew 2001) and another trial evaluating biofeedback training (Lehrer 1997).

There is a general view that asthma is connected with psychological elements in the person (Lehrer 1993). This may involve a cause and effect relationship and because psychology and emotion are involved it is thought that psychological techniques may have a positive effect on patient outcomes. Psychological techniques may be effective in improving patients asthma symptoms, however there is no suggestion that these techniques could act on their own, rather as a supplement to medical treatment. There is a large worldwide literature base supporting these ideas but this review shows that questions of effectiveness have not yet been answered. It is clearly a difficult area to investigate and presents challenges for the design of good RCTs. Researchers have to recruit sufficient numbers of subjects to show an effect if there is one, ensure appropriate randomisation and blinding techniques and follow up subjects for a reasonable period.

RCTs evaluating this area are diverse. They study a mixed group of psychological techniques, which are difficult to classify due to the different methods used to deliver the intervention. This resulted in heterogeneous interventions even when the technique was given the same classification by study authors. It was then impossible to analyse any of these interventions collectively.

The diversity of the interventions was also complicated by a multiplicity of outcomes and the tools used to measure these. There is no consensus on which outcomes a psychological intervention might influence and the conceptual link between them. The most common outcome used in the studies reviewed was lung function; eleven of the studies evaluated this. However, whilst lung function was widely assessed, different measurements were taken, for example % predicted FEV1 and PEF L/min. Health care util-

isation is increasingly being used as a primary outcome in drug trials and other studies on patients with asthma. This being the case, the primary outcome of this review may need to change as being hospitalised or being ill enough to visit the GP may be the most important outcome for the patient, however few trials included in this review have used this outcome. It is assumed that self-report measures were used, and these may not give accurate data.

The psychological outcomes used were even more numerous and diverse and there seems to be no consensus as to which psychological outcomes are conceptually linked to asthma or to the psychological interventions being studied.

An added complication was that two of the studies (Loew 2001; Mussell 1988) used a cross over design. This may not be an appropriate design to evaluate psychological interventions, as the influence of a treatment might continue after the intervention has been stopped. No account was taken for this potential carry-over effect in the analyses. This should be considered in the design of future studies.

It is apparent that this body of work does not seem to have a clear direction where current work is influenced by previous studies. Most of these small studies were done by trialists who, with the exception of Lehrer's team, did only one study. This has resulted in diverse studies looking at diverse interventions reporting on large numbers of different outcomes.

## AUTHORS' CONCLUSIONS

### Implications for practice

Because of the poor methodological quality and small sample sizes of the trials included, this review can draw no conclusions as to the effectiveness of psychological techniques for adults with asthma. The results from current RCTs in the field do not allow us to answer any of our original objectives. This review cannot therefore provide guidance for clinical practice.

### Implications for research

Larger RCTs with good methodological quality are needed. There are a limited number of rigorous trials in this area and comparisons are frustrated by diversity of outcomes and poor results reporting. All pertinent results such as means and standard deviations should be reported to aid comparisons.

As asthma is a complex multi-factorial illness, the inclusion criteria used to select patients for research is important. Interventions should be targeted at groups of patients who are most likely to benefit from them, not broadly for 'patients with a confirmed diagnosis of asthma' as most RCTs have done in this review. For example, cognitive behavioural therapy to reduce emotional exacerbation of asthma will not be effective if the patient is not suffering acute stress or anxiety due to their asthma. This was

addressed by only one study, Put 2003 where only participants with 'reported asthma symptomatology and impairment despite adequate medical treatment' were recruited.

There does not seem to be a developed programme of research for evaluating psychological interventions for adults with asthma, with many research teams doing just one study. Researchers in the field should agree common interventions, taxonomy and outcome indicators. There is a question over how appropriate it is to conduct RCTs of psychological interventions at all. This mainly has to do with the fact that, in practice, isolated therapies are seldom used and treatment plans are individualised to patients as complex self-management plans.

Evaluation using an RCT in the clinical setting may mean that the intervention is so tightly controlled that even if effectiveness were proven it might be difficult to transfer the intervention into routine clinical practice. Research funding should target a range of good quality research, including well designed rigorous RCTs, to determine the effectiveness and cost effectiveness of psychological techniques that have a sound theoretical base, with common taxonomy and outcome indicators and which can be used in the real world with individual patients who have differing needs and get better at different speeds.

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## POTENTIAL CONFLICT OF INTEREST

None known.

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\* Indicates the major publication for the study

## TABLES

### Characteristics of included studies

Study	Deter 1983
Methods	RCT (parallel design). Method of randomisation: randomised into 3 groups, method not described. Outcome assessment: method not described. Withdrawals and dropouts: not described. Jadad score 1.
Participants	90 eligible for inclusion. 31 randomised, 23 completed. Intervention 1-7. Intervention 2-8. Control- 8. Age range given in categories: <30=7, 30-50=14, >50=10. Mean age: 43.5 years. Sex: Male 14, female 17. Asthma diagnosis by physicians using Scadding's (1976) criteria for clinical and body plethysmographic examinations. Severity of asthma: Light (10), medium (9), Severe (12). Hospital clinic setting (Germany). Inclusion criteria: Clinic patients with asthma but not had group therapy. Exclusion criteria: patients who had received group therapy in the past.
Interventions	Intervention 1: Exchange of information, discussion sessions and autogenic training (7) Intervention 2: Exchange of information, discussion sessions and functional relaxation (8) Control: waiting group offered intervention after one year (8). 40 sessions delivered over 12 months. Intervention delivered by physicians (internists and psychosomatics).

### Characteristics of included studies (Continued)

Outcomes	Use of bronchodilators; use of steroids; use of inhalation sprays; pulmonary function (resistance and conductance); psychological state and anxiety (MMPI fear index), patients' observation of their own bodies; GP visits; hospitalisation (number of days). Measured at baseline and 12 months.
Notes	Comparison between functional relaxation and control only. Data presented as change scores between groups with no SD. No sample size calculation.
Allocation concealment	B

#### Study Erskine 1979

Methods	RCT (parallel design). Randomisation method: Patients matched in pairs according to age, sex, FEV1, and severity of asthma, then randomly allocated to one of the 2 intervention groups. Method of randomisation not described. Withdrawals and dropouts: 2 patients withdrawn, characteristics not described. Jadad score 2.
Participants	Number eligible not stated. 12 randomised, 10 completed. Intervention 1- 5. Intervention 2- 5. Age: 16-46 years, mean age 30. Sex: not stated. Physician diagnosed asthma using ATS criteria. Severity: Moderate or severe, numbers not stated. Setting not stated (authors from Australia). Inclusion criteria: moderate and severe asthma. Exclusion criteria not stated.
Interventions	Intervention 1: Muscular and mental relaxation techniques. Intervention 2: muscular relaxation techniques. No control group Intervention given once a week for 4 weeks. Intervention delivered by 'the therapist'.
Outcomes	FEV1, weekly symptom questionnaire (Kinsman et al. 1973), daily symptom questionnaire (locally designed), subjective severity rating (5 point scale); Self report measurements - psychological, physical and bronchoconstriction; Post treatment questionnaire: expectations of treatment, success of the treatment, frequency of relaxation performed at home. Outcomes measured once a week for 3 weeks pre-treatment, during treatment and 6 weeks after (13 weeks in total).
Notes	No imputable data in this trial. Results are reported as means without standard deviations. FEV1 data is graphical only. No sample size calculation.
Allocation concealment	B

#### Study Ewer 1986

Methods	RCT (parallel design). Randomisation method: Not clear in paper but used computerised randomisation tables, allocation concealed (from correspondence with TE). Outcome assessment blinded. Withdrawals and dropouts described. Jadad score: 3.
Participants	Number eligible not stated. 44 randomised, 39 completed. Intervention (low susceptibility to hypnosis)- 10. Intervention (high susceptibility to hypnosis)- 12. Control (low susceptibility to hypnosis)- 7. Control (high susceptibility to hypnosis)- 10. Age: 18-45.

## Characteristics of included studies (Continued)

	<p>Sex: Male 15, female, 24.          Physician diagnosed asthma.          Severity: mild to moderate, numbers not stated.          Setting: asthma clinic, patients recruited from the local community (New Zealand).          Inclusion criteria: History of mild to moderate asthma. Exclusion criteria: a reduction of less than 20% in the ratio of forced expiratory volume in one second to forced vital capacity with the maximum concentration of methacholine, a history of severe asthma, concurrent systemic steroid treatment, pregnancy, history of psychosis or relevant medical illness.</p>
Interventions	<p>Intervention: Hypnotic induction with progressive relaxation, progression of guided imageries, ego enhancement, self hypnosis. Half hour sessions over six weeks.          Intervention delivered by physician (project leader).          Control: half hour sessions with asthma nurse over 6 weeks.</p>
Outcomes	<p>FVC, FEV1, FEV1/FVC (%), PEF, MEF at 50% VC. FRC, RV and airways resistance measured by Collins Plethysmograph, bronchial responsiveness, subjective sensitivity. Diary recordings of PEF twice daily, daily use of drugs, symptoms related to asthma (cough, activity limitation, wheeze, phlegm, nocturnal symptoms), psychological profile using STAI (Spielberger et al 1970), Zung's self rating depression scale (Zung 1965) and Pilowsky's illness behaviour questionnaire (Pilowsky et al 1969).          Outcomes measured before and one week after treatment for lung function, methacholine challenge test, and psychological profiles.</p>
Notes	<p>Psychological profile results reported in another paper (not published).          No sample size calculation.          (author delivered intervention but outcome assessment was blinded).</p>
Allocation concealment	A

Study	Henry 1993
Methods	<p>RCT (parallel design).          Randomisation method: not stated. Outcome assessment method: not stated.          Withdrawals and dropouts: not described.          Jadad score 1.</p>
Participants	<p>Number eligible not stated. 24 randomised, Intervention 12, Placebo 12. Dropout rate not stated.          Age: 18-58 years (mean 39.66).          Sex: Male 3, female 21.          Physician diagnosed chronic asthma. Severity: moderate to severe. Numbers not stated.          Setting: Hospital clinic in Spain.          Inclusion criteria: presence of psychopathological disorders or psychosocial factors associated with the asthmatic disorder requiring treatment as well as imperfect control of asthma with conventional medical treatment; Spirometric evidence of bronchial asthma; age between 18 and 60 years.          Exclusion criteria: severe disorders; mental retardation or other contraindications for autogenic therapy.</p>
Interventions	<p>Intervention: Autogenic therapy.          Placebo: supportive group psychotherapy including an educational component.          Intervention and placebo group sessions one hour a week over eight months.          Delivered by 'the therapist'.</p>
Outcomes	<p>FVC, FVC % predicted, FEV1, FEV1 % predicted, FEF 25-75, FEF 25-75 % predicted, MEF 50, MEF 50 % predicted.          Measured at pre-treatment and post treatment, exact measurement points not stated.          Psychological outcomes (reported in separate spanish publication): 'reactivity to stress' measured by questionnaire with four sub scales vegetative, emotional, cognitive and behavioural (Gonzalez de Rivera, 1983).          Measured before and after treatment (exact time not given).</p>

## Characteristics of included studies (Continued)

Notes Within group differences reported for all lung function outcomes. Between and within group differences reported for psychological outcomes.  
No sample size calculation.

Allocation concealment B

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### Study **Lehrer 1994**

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Methods RCT (parallel design).  
Randomisation method: not stated. Outcome measurement method: described but not stated if blinded.  
Withdrawals and dropouts: described.  
Jadad score 2.

Participants 153 eligible after telephone screening. 106 randomised after further screening. 72 completed. Intervention 1- 25, Intervention 2- 26, Control- 21.  
Age: 18-65 years.  
Sex: Male 51, female 55.  
Physician confirmed diagnosis of asthma.  
Severity: mild to moderate (on average), numbers not stated.  
Setting: Not clear but may have been hospital clinic in USA, may have several centres.  
Inclusion criteria: Physician diagnosed asthma by history, physical examination, measurement of diffusion capacity and spirometry; Bronchial hyperreactivity to methacholine challenge test.  
Exclusion criteria: Gross psychopathology, psychoactive medications, smokers, pregnant women, prior exposure to any form of relaxation therapy, asthma triggered only by exposure to specific easily avoided allergens, pulmonary disease other than asthma.

Interventions Intervention 1: Progressive muscle relaxation.  
Intervention 2 : listening to relaxing music.  
Control (waiting list).  
8 sessions with one hour a day at home (of intervention) in between sessions. Length of programme not given.  
Interventions delivered by 'relaxation therapist'.

Outcomes Methacholine challenge test results, FEV1, FVC, Peak flow, FEF50, asthma symptom checklist (Kinsman et al 1973), relaxation questionnaire (9 point Likert scale), daily medication consumption and symptoms as reported in a log, Semantic differential rating (Osgood, 1957) of treatment and relationship with relaxation therapist and respiratory physician.  
Outcomes for intervention groups measured at baseline and after each session. Control group had three measurement points (time not stated).

Notes Lung function outcomes presented graphically.  
Sample size calculation done.

Allocation concealment B

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### Study **Lehrer 1997**

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Methods RCT (parallel design).  
Randomisation method: not stated. Outcome measurement method: described but not blinded.  
Withdrawals and dropouts: numbers given but not described.  
Jadad score: 1.

Participants Number eligible not stated. 17 randomised, 15 completed.  
Intervention 1-5, Intervention 2-6, Control-4.  
Age: 18-65 years (mean 37.8).  
Sex: Males 5, females 12.  
Asthma diagnosis by respiratory physician.  
Severity: not stated.

## Characteristics of included studies (Continued)

	<p>Setting: not clear but may be hospital asthma clinic.</p> <p>Inclusion criteria: History of recurrent asthma in the prior 12 months, wheeze that responds to B2 aerosol therapy OR positive methacholine challenge test in the last 12 months OR bronchodilator response on the laboratory of <math>\geq 20\%</math> in FEV1; abnormal spirometry (FEV1 &lt; 80% or FEF50% &lt; 60%) in prior 12 months.</p> <p>Exclusion criteria: Chronic bronchitis or sinusitis, emphysema or non-asthma respiratory disease, smoker, previous experience of a relaxation procedure, cardiovascular or neurological disease, psychiatric disorder requiring psychoactive medication or which might interfere with understanding of treatment procedures and/or co-operation with them.</p>
Interventions	<p>Intervention 1: Respiratory Sinus Arrhythmia Biofeedback. RSA biofeedback given, then instruction given to increase amplitude of respiratory sinus rhythms. No relaxation or autogenic instructions were used.</p> <p>Intervention 2: EMG Biofeedback. Instruction given to relax shoulder muscles and breathe automatically. Electrodes measured thoracic muscle activity. Autogenic and progressive muscle relaxation methods used with incentive spirometry and EMG feedback.</p> <p>Control (waiting list): Three testing sessions at two week intervals where participants were told to relax with eyes open.</p> <p>6 intervention sessions given at weekly intervals (30 minutes each).</p> <p>Training and testing done by same person (co-author), Profession not stated.</p>
Outcomes	<p>Respiratory impedance (ri); end tidal CO<sub>2</sub>; thoracic and abdominal breathing; peak respiratory flow; minute volume; heart "period" (R-R) intervals and amplitude, sensations of relaxation by Relaxation Inventory (Crist et al, 1989), Asthma symptoms (frequency of symptoms in previous week), Medication consumption</p> <p>Outcomes measured at one, four and six weeks.</p>
Notes	No sample size calculation.
Allocation concealment	D

Study	Loew 2001
Methods	<p>RCT (cross-over).</p> <p>Method of randomisation: computerised randomisation to two medical institutions and to three treatments.</p> <p>Outcome measurement: described and blinded.</p> <p>Withdrawals and dropouts: described.</p> <p>Jadad score: 3.</p>
Participants	<p>Number eligible not stated.</p> <p>21 adults randomised, 16 completed.</p> <p>Intervention 1 (eFR): 18, Intervention 2 (IT): 19, Placebo (PRT): 21.</p> <p>Age: 23-74 years (mean 48.9).</p> <p>Sex: Males 7, females 14.</p> <p>Asthma diagnosed by history of asthma with current manifestation of reversible reduction in airway resistance.</p> <p>Severity: not stated.</p> <p>Setting: Outpatients clinic at two medical institutions in Germany.</p> <p>Inclusion criteria: History of asthma with current reversible reduction in airways resistance; no oral corticosteroids for duration of trial.</p> <p>Exclusion criteria: acute dyspnoea, sputum production, fever, chronic bronchitis, no bronchoconstriction on a treatment day (this meant patient was withdrawn from study).</p>
Interventions	<p>Intervention 1: Functional relaxation (eFR). Instruction given while patient sitting in the cabin of the body plethysmograph. The patients then practiced these instruction while measurements were taken. Intervention 2: Inhaled terbutaline (IT). 1x0.5mg dose of terbutaline given. Pulmonary function tests were carried out after 5 minutes.</p> <p>Placebo relaxation technique (PRT).</p> <p>Based on isotonic exercises of one hand in conditions comparable to the eFR intervention.</p> <p>Instructions given for minutes. All three therapies received in course of 3 consecutive days.</p> <p>Training delivered by trained therapist, same therapist supervised administration of terbutaline.</p>

## Characteristics of included studies (Continued)

	No analysis for carry over effects.
Outcomes	Airways resistance (Raw); specific airways resistance (sRaw), FEV1, PEF, MEF 50, MEF 75. Outcomes measured before and after each therapy. Responder analysis also done. Responders defined as achieving a decrease of at least 20% in sRaw and increase in FEV1.
Notes	No sample size calculation. Each person had each intervention on different days except 2 missed IT and 3 missed eFR as they had no bronchoconstriction that day.
Allocation concealment	B

<b>Study</b>	<b>Mussell 1988</b>
Methods	RCT (cross-over). Method of randomisation: not described. Outcome assessment: described, but confusing as not stated who performed assessments- study described as double blind. Withdrawals and dropouts: not described. Jadad score: 2.
Participants	Number eligible not stated. 16 adults randomised to exercise challenge or hyperventilation challenge, then half of each group randomised to biofeedback training. Dropout rate not stated. Age: 22-44 years. Sex: Males 11, females 5. Asthma diagnosis confirmed by a testing if FEV1 would fall by at least 20% following a standardised hyperventilation challenge. Severity: not stated. Setting: not stated, ? Chest clinic in UK. Inclusion criteria: A fall in FEV1 of at least 20% after a standardised hyperventilation challenge. All subjects refrained from using their anti-asthma medication for at least 12 hours before visiting the laboratory. Exclusion criteria: History of cardiopulmonary disorders other than asthma.
Interventions	After randomisation into two groups of 8 for exercise or hyperventilation challenge tests, half of each of these two groups were randomly assigned to biofeedback training or control. The others were untrained. Subjects then given 5 randomly ordered interventions- 1) active bronchodilator 2) placebo bronchodilator 3) correct biofeedback (using tracheal noise and feedback on FEV1 changes) 4) wrong biofeedback (wrong information is fed back to the subject) 5) no treatment. A second challenge test was administered 40 minutes after the first challenge to observe for refractory effects. All interventions (or control) were given double blind over 5 visits. Length of study not stated. Person delivering interventions not stated. No analysis for carry over effects.
Outcomes	FEV1 measured at baseline, 1,4, and 8 minutes after the challenge, then at 2 minutes and every 5 minutes after treatment (given at 10 minutes) until lung function back to within 10% of baseline values. Eysenck personality inventory: extraversion and neuroticism sub scales measured after the final test session in order to correlate personality type with recovery rates.
Notes	No sample size calculation. All FEV1 data presented graphically.
Allocation concealment	A

<b>Study</b>	<b>Payette 1977</b>
Methods	RCT (parallel design). Method of randomisation: not stated. Outcome assessment described but not blinded. Withdrawals and dropouts not described. Jadad score 1.
Participants	Number eligible not stated. 18 adults randomised.



## Characteristics of included studies (Continued)

	<p>Intervention: 11, Control: 7  Dropout rate not stated.  Age: 22-67 years.  Sex: 5 males, 13 females.  Asthma diagnosis by medical diagnosis.  Severity of asthma not stated.  Setting: Asthma and allergy outpatient clinic at Tucson Medical Center, Arizona, USA.  Inclusion criteria: Primary medical diagnosis of asthma, in adequate health to complete the study, over age of 18, patient of the asthma clinic.</p>
Interventions	<p>Intervention: EMG biofeedback training-surface electrodes applied to lower frontalis muscle, subjects told to relax using biofeedback auditory and visual signals from frontalis muscle area. Told by lowering tone and microvolt setting they were relaxing.  Control: Instructions to relax as best they could while reclining in comfortable recliner chair.  12 treatment sessions given over 20 minutes.  Length of study not stated.  Intervention given by investigator.</p>
Outcomes	<p>Blood pressure; Pulmonary function tests- FVC, FEV1, %FEV1/FVC; Schedule of Recent Experiences (SRE); Taylor-Johnson Temperament Analysis (Taylor et al 1974).  Outcomes measured at baseline. Blood pressure and pulmonary function tests measured before and after each session. At 2 post-baseline sessions after the treatment sessions the SRE and The Taylor-Johnson Temperament Analysis were administered. All outcomes were also measured at 30 days following the last session.</p>
Notes	<p>No sample size calculation.  Results presented graphically and by statistical tables, mean scores not presented.</p>
Allocation concealment	D

Study	Put 2003
Methods	<p>RCT (parallel design).  Method of randomisation: drawing of envelopes.  Outcome assessment: performed by independent researchers unaware of treatment allocation.  Withdrawals and dropouts: described.  Jadad score 4</p>
Participants	<p>Number eligible 101. 25 adults randomised with one drop out from each group.  Intervention: 12.  Waiting list control: 11.  Age: mean 43 years in intervention group, mean 48 years in control group.  Sex: males 11, females 12.  Asthma diagnosis by ATS criteria at least 6 months earlier.  Severity: Mild 7, Moderate 15, Severe 1.  Setting: University hospital outpatient pulmonary clinic, Belgium.  Inclusion criteria: Asthma diagnosis using ATS criteria at least 6 months earlier. Experience of asthma complaints and impairment despite adequate medical treatment.  Exclusion criteria: Aged less than 18 or over 65 years, occupational asthma, nicotine, drug or alcohol abuse, absence of asthma symptoms during the last 6 months, brittle asthma, previous participation in an educational or other asthma programme.</p>
Interventions	<p>Intervention: Psycho-educational programme where the patients' personal illness representations, or their cognitions regarding origin, symptoms, course and therapy of their illness were identified. Information about the pathophysiology of asthma, mechanisms of medication, eliciting factors etc. was provided in an interactive way. Behavioural techniques such as self-monitoring/self observation, stimulus control, and response control were also taught. Certain parts of the programme were elaborated upon according to individual need.</p>

## Characteristics of included studies (Continued)

	Control: waiting list. Programme delivered by two independent researchers. Profession not stated. Delivered over 3 months in 6 one hour individual sessions.
Outcomes	Health related limitations in quality of life during the past 2 weeks assessed by McMaster Asthma Quality of Life Questionnaire (Juniper et al, 1992), Subjective symptomatology of asthma measured by Asthma Symptom checklist (Kinsman et al 1973), Negative affectivity as a personality trait including negative emotional conditions (irritability, nervousness, emotional instability was measured by Negative Emotionality Scale (Tellegen et al, 1988). Frequency of non-adherent behavior was measured by The Adherent Scale (Brooks et al, 1994). Patients' knowledge regarding asthma, attitude towards the illness, and self-efficacy regarding perceived ability to control the disorder was measured by The Knowledge, Attitude, and Self-efficacy Asthma Questionnaire (KASE-AQ) (Wigal et al, 1993). Outcome measurement was done at baseline, 3 months and 6 months for the control group; baseline, immediately after the treatment interventions and 3 months later for the intervention group. Assessment done by researchers blind to the treatment allocation. PEF was measured by the subjects at home twice daily during 14 consecutive days.
Notes	No sample size calculation. Randomisation method is unclear, states done by sealed envelopes but no description of method is given. Between group analysis done by repeated measures analysis of variance.
Allocation concealment	B

Study	Sommaruga 1995
Methods	RCT (parallel design). Method of randomisation: Not clear in paper but used computerised randomisation tables (from correspondence with MS). Outcome measurement: described but not stated as blinded. Withdrawals and dropouts: not described. Jadad score: 2.
Participants	Number eligible not stated. 40 randomised, 36 completed. Intervention- 20, control-16. Age: mean 48.0 range not reported. Sex: Males 21, females 19. Asthma diagnosis according to ATS criteria (1987). Severity: not stated, all using drug therapy. In-patients with asthma. Setting: Hospital Respiratory Department in Italy (inpatients). Inclusion criteria: Asthma diagnosed according to ATS guidelines. Exclusion criteria not stated.
Interventions	Intervention: Asthma Rehabilitation group involving education and cognitive behavioural intervention with medical treatment following international guidelines. Control: Medical treatment following international guidelines. Education programme was delivered by physician, physiotherapist and psychologist twice during admission and quarterly for 12 months. Cognitive behavioural intervention delivered by psychologist during 3 individual meetings.
Outcomes	Trait anxiety measured by STAI (Spielberger et al. 1970); Depression, assessed by QD questionnaire; Psychophysiological disorders, assessed by QPF from Cognitive behavioural assessment questionnaire (Sanavio et al. 1986); emotional reactions to asthmatic crises, assessed by Asthma Symptom Checklist (Kinsman et al. 1973) in Italian version; Optimism, negative staff regard, specific internal awareness, external control psychological stigma, authoritarian attitude, assessed by Respiratory Illness Opinion Survey (Staudenmayer et al. 1978); Internal beliefs, external powerful others and external chance assessed by Health Locus of Control Scale (Wallston et al. 1976) (Italian Version). Outcomes measured at baseline and at one year.
Notes	No sample size calculation, Within group analysis only.

## Characteristics of included studies (Continued)

Allocation concealment B

Study	Wagaman 2000
Methods	<p>RCT (parallel design).</p> <p>Method of randomisation: Following hypnotic susceptibility and psychometric testing, participants were stratified according to hypnotic susceptibility (large representation (46%) of highly hypnotisable subjects). Randomised to three groups. Randomisation method not described.</p> <p>Outcome assessment: Assessments and medical examinations blinded, but investigator performed interventions and delivered psychometric assessments.</p> <p>Withdrawals and dropouts: 9 withdrawals, no description given.</p> <p>Jadad score: 2.</p>
Participants	<p>Number eligible: 90. 45 met inclusion criteria after interview.</p> <p>30 adults randomised, 21 completed.</p> <p>Intervention 1: hypnotic control group- symptom control (7), Intervention 2: Hypnotic suggestion group-immune function and airway relaxation (7), Placebo control (7).</p> <p>Age: 19-65 years (mean 41.0)</p> <p>Sex: Males 3, Females 18.</p> <p>Asthma diagnosed by physicians.</p> <p>Severity of asthma: Moderate to moderately severe- classified using National Institute of Health Guidelines.</p> <p>Setting: Allergy and Immunology private practice.</p> <p>Inclusion criteria: Full time local residents, non-smokers at present, inexperience with hypnosis and other similar techniques, not receiving immunotherapy.</p> <p>Exclusion criteria: History of past or present psychiatric disorders, past or present psychotropic drug use, significant secondary gain, significant psychosocial problems, recent major loss (death, job, divorce).</p>
Interventions	<p>Intervention 1: Hypnotic control group with taped hypnotic sessions directed at symptom relief through ability to relax smooth airway muscle. Intervention 2: Hypnotic suggestion group, taped hypnotic sessions directed at improvement of immune function, resolution of inflammation and biochemical relief of bronchospasm.</p> <p>Control: Non hypnotic placebo group, taped session of neurophonic tones- told may or may not contain subliminal suggestions pertaining to asthma care and control.</p> <p>6 sessions for each group delivered by hypnosis therapist (author), 3 one week apart, 3 reinforcement sessions delivered at 3 month intervals. Tapes used by participants daily and for symptom relief.</p>
Outcomes	<p>Daily patient diaries of PEF, asthma symptom score, frequency of use of PRN medication, work/school absences, private doctor visits, emergency room visits, and hospitalisations. Recorded for 3 to 4 months before sessions commenced and for one year afterwards.</p> <p>Initial and final interview done.</p> <p>Clinical assessments done every 3 months by physicians blind to group allocation- FEV1, FEF 25-75%, PEF.</p> <p>Psychometric testing done by author at baseline and one year follow up. Eysenck Personality Inventory to measure neuroticism, extraversion, and lying. Marlowe-Crowne Social Desirability Scale (Crowne &amp; Marlowe 1960) to measure repressive coping. STAI (Spielberger et al. 1970) to measure anxiety. Self-control schedule (Rosenbaum 1980) to measure the solution of behavioural problems. Dysfunctional Cognition Inventory (Zocco 1984)- catastrophizing scale, Asthma Symptom Checklist (Kinsman et al. 1973).</p>
Notes	<p>No sample size calculation.</p> <p>Data presented in graphical form.</p> <p>Mainly within group analysis.</p>

Allocation concealment C

### Abbreviations-

ATS American Thoracic Society, EMG- Electro-myogram, FEF- Forced expiratory flow, FEV1- Forced expiratory volume over one second, FEV1/FVC- ratio of FEV1 and FVC, FRC- Functional residual capacity, FVC- Forced vital capacity, MEF- Mid expiratory

### Characteristics of included studies (Continued)

flow, PEF- Peak expiratory flow, RCT- Randomised controlled trial, RV- Residual volume, SD- Standard Deviation, STAI- State-Trait Anxiety Inventory, VC- Vital capacity.

### Characteristics of excluded studies

Ago 1976	CCT of teaching patients about the mind-body relationship
Allen 1995	RCT of a self-management programme
Anon 1968	RCT of hypnosis in adults and children. Unable to separate data
Bailey 1990	RCT of a self-management programme. Intervention was mainly education with a small element of counseling
Barendregt 1957	CCT of Group psychotherapy
Ben-Zvi 1982	Before and after study of hypnosis
Boulet 1995	CCT of an education only programme
Cambach 1997	RCT of pulmonary rehabilitation including asthma and chronic obstructive pulmonary disease (COPD) patients
Ciurluini 1993	CCT of psychotherapy techniques
Clark 1997	Review of self-management education programmes
Coen 1996	RCT of relaxation. Study includes adults and children. Unable to separate data
Conte 1981	Review of psychotherapy for medically ill patients
Cox 1991	CCT of rehabilitation. Study includes asthma and COPD patients. Unable to separate data
Deter 1983a	Cost effectiveness study based on data of included study (Deter 1983)
Devine 1996	Meta-analysis of psychoeducational care
Erskine-Milliss 1987	Two studies of biofeedback in adults and children (before and after study)
Franco 1982	CCT of hypnosis
Fujii 1997	Case study of step-down management of asthma
Ghosh 1998	RCT of self-management without psychotherapy in adults and children
Groen 1960	Clinical study, not controlled or randomised
Grover 2002	CCT of Cognitive Behavioural Therapy
Hackman 2000	Review of hypnosis in adults and children with asthma
Haire-Joshu 1993	Survey, focus groups and interview to assess patients' attitudes according to clinical setting
Hajjar 1999	Review of behavioural interventions in asthma
Harding 1982	CCT Of biofeedback training
Hashizume 1996	Psychosomatic therapies in a before and after study
Hirokawa 1992	CCT of biofeedback apparatus
Huntley 2002	Review of relaxation therapies for asthma
Jonckheere 1997	Review of psychosomatic issues in a range of diseases
Kang 1993	Before and after study of the impact of psychological factors in adolescents.
Kaptein 1987	Review (COPD)
Kern-Buell 2000	Adults and children included in RCT on relaxation
Khateeb 1995	Meta-analysis of psychotherapy
Klingelhofer 1988	Review of asthma self-management programmes
Kolbe 1996	Knowledge of self-management outcome measure validity study
Kotses 1991	CCT of self-management without psychotherapy

**Characteristics of excluded studies (Continued)**

Kotses 1995	RCT of self-management without psychotherapy
Kotses 1996	RCT of self-management, primarily education although some received a relaxation tape
Lahdensuo 1996	RCT of a self-management programme
Laidlaw 1994	Before and after study of hypnosis
Lehrer 1986	CCT of relaxation and biofeedback
Lehrer 1992	Review of psychological approaches in asthma
Lehrer 1993	Review of the relationship between emotion and asthma
Lehrer 1997a	Analysis of data from 1994 study (included) to study the physiological relationship between pulmonary function and autonomic control of the heart.
Levendel 1980	Narrative review of the biofeedback method
Lewith 1996	Review of complementary therapies in asthma
Linden 1994	Review of autogenic training in a range of diseases
Loew 1996	Before and after study of functional relaxation
Maes 1988	CCT of an education and behaviour modification intervention
Matts 1973	Review of the treatment of bronchospasm (including psychological)
Moore 1965	CCT of behavioural therapy. Adults and children included in study
Murphy 1989	CCT of hypnotic susceptibility and relaxation
Nagata 1995	Before and after study of a psychosomatic treatment
Negley-Parker 1986	Case report of hypnotherapy of families of children with chronic illness
Peper 1992	CCT of behavioural and desensitization programme using biofeedback
Richter 1982	Review of psychosomatic aspects of asthma
Richter 1987	Review of behavioural therapy and relaxation
Ringsberg 1990	RCT of self-management without psychotherapy
Ritz 2001	Systematic review of relaxation therapies for asthma
Sachs 1993	CCT of relaxation training
Sauer 1978	CCT of autogenic training
Schaeffer 1975	CCT of self-training
Sclare 1957	CCT of group therapy
Snyder 1987	RCT of self-management without psychotherapy
Spiess 1988	RCT of education intervention (non-randomised sub group received relaxation therapy)
Stepans 2000	RCT of patients with asthma and COPD. Unable to separate data.
Step toe 1981	CCT of biofeedback, non asthmatic volunteers included
Stout 1997	RCT of breathing retraining only
Stuhr 1996	Review of psychosomatic and psychotherapy research
Vedanthan 1998	Yoga RCT
Vickers 1997	Survey and review of complementary therapies
Wilson 1975	Cross-over study of transcendental meditation
Wilson 1993	RCT of self-management without psychotherapy

## Characteristics of excluded studies (Continued)

### Characteristics of ongoing studies

Study	Harrison
Trial name or title	The Coping with Asthma Study: A randomised controlled trial and economic evaluation of a home-based coping skills training programme for high risk asthma sufferers.
Participants	92 patients aged 15-66 (mean 36.46) recruited mainly from 5 hospital respiratory departments in Norfolk and Suffolk with a small number recruited from general practice. The setting for the study is the community (patient's homes) with the intervention co-ordinated via the lead hospital. Patients are recruited on the basis that they have severe asthma as indicated by them being on British Thoracic Society Step 4/5 treatment and/or having had previous admissions for asthma. The patients are also deemed to be at risk of future adverse asthma outcomes due to failure to attend clinic appointments or comply with their asthma management in other ways (e.g. non-compliance with medication or changes in medication, failure to keep peak flow records when asked)
Interventions	Four fortnightly home visits of approximately one hour in length conducted by an asthma nurse for two months, supplemented by phone calls between visits and monthly for four months after the last visit, making a 6 month intervention in total. Patients are also able to phone the asthma nurse throughout and after the duration of the intervention. The nurse provides asthma education, self-management and coping skills training and, with clinical supervision from a general practitioner with psychiatric training and Health Psychologist, aims to address co-existing psychosocial problems which compromise effective asthma management. The intervention takes a cognitive behavioural approach and involves liaison with/referral to other medical, psychological or social services as necessary. The control group continues with routine care comprising usual use of primary, secondary and emergency health services which varies to some degree across the hospitals involved.
Outcomes	Primary outcome: Asthma control assessed via a score from a brief questionnaire asking about asthma symptoms in the past month (questionnaire based on recommendations from Royal College of Physicians Asthma Outcomes seminar 1999, used in previous local studies, reliability and validity work being undertaken). Secondary outcomes: Quality of life assessed via the Living with Asthma Questionnaire (Hyland) and Short Form 36 (Ware et al). Economic evaluation will also involve assessment of direct health care, social service and patient costs and indirect costs. Additional/explanatory outcomes: Psychiatric morbidity assessed via the General Health Questionnaire 12 and Hospital Anxiety & Depression Scale, attack and everyday coping assessed via the Asthma Coping Questionnaire (Maes & Schlosser), perceived control assessed via the Perceived Control of Asthma Questionnaire (Katz et al), attack management and compliance assessed via 2 subscales of the Revised Asthma Problem Behavior Checklist (Creer et al) and compliance scale of Moriskey, readiness to change asthma self management behaviour assessed via an Asthma Stage of Change Questionnaire developed for the study and supplemented with additional questions on performance of self management behaviours (trigger avoidance, peak flow

## Characteristics of ongoing studies (Continued)

	monitoring, smoking, exercise etc.) Outcomes are assessed via self administered questionnaires completed by patients during interviews in their home conducted at baseline and 2, 6 and 12 months after entry into the study. The primary endpoint is 6 months (the end of the intervention for those receiving the nurse programme).
Starting date	September 1999
Contact information	Study researcher: Jane Smith, School of Medicine, Health Policy & Practice, University of East Anglia, Norwich, NR4 7TJ, UK. Email: j.r.smith@uea.ac.uk, Phone: 01603 593584 Principal investigator: Dr Brian Harrison, Department of Respiratory Medicine, Norfolk & Norwich University Hospital NHS Trust, Colney Lane, Norwich, NR4 7UY, UK. Email: brian.harrison@norfolk-norwich.thenhs.com, Phone: 01603 289642.
Notes	Expected completion early 2003 Funded by the British Lung Foundation with sponsorship from the Community Fund (formerly National Lottery Charities Board)

## ADDITIONAL TABLES

**Table 01. Description of Psychotherapeutic Techniques**

Technique	Description
Behavioural therapies	Concerned with identifying the processes by which behaviour has been learned via association, reward or observation and modifying behaviour using methods such as systematic desensitization, selective reinforcement and positive modelling. The behaviour itself, rather than underlying motivations, is the focus of behavioural interventions.
Cognitive therapies	Identification and constructive management of damaging thoughts, such as perceptions of helplessness or inappropriate fear of asthma attack that can trigger episodes. Information (e.g. about the relationship between anxiety and bronchoconstriction) also targets cognitions.
Cognitive behaviour therapy	Using behavioural techniques to change negative thoughts mediating health behaviour. In asthma may address incorrect symptom attributions (over- or under-playing their significance) giving rise to suboptimal medication use, or may use systematic relaxation techniques to extinguish fear responses associated with psychosocial triggers.
Relaxation techniques	Designed to control stress & anxiety. In asthma, may reduce panic or fear & improve breathing and respiratory function. Approaches include progressive relaxation (systematically creating tension and release in different parts of the body and/or via guided mental imagery), autogenic training (focuses on attending to bodily feelings and mentally controlling them), hypnotherapy (deep relaxation that may be induced using mental imagery, often accompanied by autosuggestion to create positive thoughts & feelings), and biofeedback (feedback of biological indicators, such as tracheal noise, which the subject must control via relaxation. May also be considered a behavioural intervention since the feedback can act as a reinforcer).

This review has no graphs.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Adult; Asthma [psychology]; Health Services Needs and Demand [utilization]; Psychotherapy; Randomized Controlled Trials

**Medical MeSH check words**

Humans

**COVER SHEET**

<b>Title</b>	Psychotherapeutic interventions for adults with asthma
<b>Authors</b>	Fleming SL, Pagliari C, Churchill R, McKean M, Shuldham CM
<b>Contribution of author(s)</b>	SF and CS developed the protocol and assessed abstracts for potential inclusion in the review. CP offered input on the types of psychological interventions used in the reviews and wrote the description of the psychotherapeutic interventions. RC helped with methodological aspects of the protocol and review. SF and CS analysed the results and wrote up the findings and discussion. MM gave editorial support and guidance throughout.
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<b>Date new studies found but not yet included/excluded</b>	Information not supplied by author
<b>Date new studies found and included/excluded</b>	Information not supplied by author
<b>Date authors' conclusions section amended</b>	Information not supplied by author
<b>Contact address</b>	Ms Sharon Fleming Head of Nursing Research Department of Nursing and Quality Royal Brompton and Harefield NHS Trust Sydney Street London SW3 6NP UK Telephone: +44 020 7351 8841 E-mail: s.fleming@rbh.nthames.nhs.uk Facsimile: +44 020 7351 8836
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