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The Effects of Relaxation Exercises on Young Persons with Moderate Asthma

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THE EFFECTS OF RELAXATION EXERCISES ON
YOUNG PERSONS WITH MODERATE ASTHMA

by

Robert Edward Obrecht

A Dissertation
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
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THE EFFECTS OF RELAXATION EXERCISES ON YOUNG PERSONS WITH MODERATE ASTHMA

Robert Edward Obrecht, Ph.D.
Western Michigan University, 1994

This experiment studied the acute and cumulative effects of relaxation exercises on young persons (mean age 11.4 years) with moderate asthma. In order to assess the acute effects of relaxation, treatment group subjects were instructed to perform relaxation exercises immediately before and during methacholine inhalation challenge procedures that produced a 20% reduction in forced expiratory volume in one-second (FEV₁). The control group subjects were not taught the relaxation exercises, but still underwent the methacholine challenges. In order to assess the cumulative effects of the treatment group subjects practicing relaxation exercises twice daily at home for 10-weeks, they were instructed to record peak expiratory flow (PEF) rates, asthma symptoms (wheeze, cough, activity restrictions, and nighttime asthma), and asthma medication use; the control group subjects were only instructed to record these three measures. None of the observed differences (with respect to methacholine sensitivity, daily airflow variability, asthma symptomatology, and asthma medication usage) between the treatment and control groups achieved statistical significance.

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These results suggest that relaxation exercise training and practice, by young persons with moderate asthma, is of questionable clinical utility as a generally prescribed prophylactic treatment adjunct to standard asthma therapy. Intra-subject comparisons, however, suggest that there may be a subgroup of young persons with asthma for whom relaxation exercises are beneficial.
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The effects of relaxation exercises on young persons with moderate asthma

Obrecht, Robert Edward, Ph.D.
Western Michigan University, 1994

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I would like to acknowledge those who were especially important in the successful completion of my dissertation. First and foremost, I want to thank my wife, Gayle, for sharing in the many responsibilities that go into completing a dissertation. Your love and support is invaluable to me. Thank you Gayle, I love you.

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The latter part of mom’s life was not an easy one--even before she had cancer. Her life story will always serve as a source of inspiration for those persons who are personally experiencing, or are observing others struggling to endure, the trials and tribulations of the effects of traumatic brain injury, chronic pain, and/or the acute pain brought on by cancer. Mom has always been, and will continue to be, my best and favorite mentor. "Hey, Mom, I got it done!"

Robert Edward Obrecht

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CHAPTER I

LITERATURE REVIEW

General Introduction

This literature review examines the behavioral treatment of asthma with an emphasis on applications with young persons under the age of 18. In discussing the problem of asthma a helpful perspective is gained by considering epidemiological issues, management goals, pharmacological treatments, and psychological approaches. Epidemiology will be discussed with respect to the definition, prevalence, and socioeconomic impact of asthma. The management of asthma will be discussed in terms of general goals and specific pharmacological and psychological approaches. Three psychological approaches to the management of asthma are differentiated on the basis of an intervention's intended effects. These approaches attempt to reduce anxiety and tension in an effort to directly reduce asthma symptomatology or to provide coping skills. The goals of both pharmacological and psychological treatment are to either reduce symptoms of asthma or to ameliorate the psychological problems related to asthma. Relaxation techniques for reducing anxiety and tension in an effort to impact respiratory functioning are emphasized in this review.
In addition, several limitations in past relaxation training studies are highlighted in the process of addressing the central issue of whether or not this technique is effective. Improving upon these limitations in order to provide some clearer answers about the efficacy of relaxation exercises on young persons with moderate asthma is the impetus for the experiment described herein.

The Problem

Defining Asthma

Agreeing on a consensual definition of asthma has long been a problem for those who study asthma. Several authors have noted the difficulty of defining asthma (Creer, 1982; and Coultas and Samet, 1987). Although Hippocrates made references to the disorder as early as 400 BC, and Aretaeus in the 2nd century provided a detailed description of the physical changes and psychological states involved in asthma, uncertainties still existed well into the twentieth century as to the fundamental disturbance of anatomy or physiology which expresses itself in episodes of asthma (Creer, 1982).

In recent years a better understanding of the airway inflammation-related disease mechanisms involved in asthma has led to the following consensual and operational definition of asthma:
Asthma is a chronic inflammatory disorder of the airways in which many cells play a role, including mast cells and eosinophils. In susceptible individuals this inflammation causes symptoms which are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment, and causes an associated increase in airway responsiveness to a variety of stimuli (National Heart, Lung, and Blood Institute [NHLBI], June 1992a, p. 1).

The specific symptoms and severe consequences are outlined in a more general definition of asthma from the same publication:

Asthma is a chronic, persistent inflammatory disease of the airways characterized by exacerbations of coughing, wheezing, chest tightness, and difficult breathing that are usually reversible, but that can be severe and sometimes fatal (NHLBI, June 1992a, p. xi).

These definitions have two important limitations. First, neither definition includes psychological factors such as worry, excitement and psychic trauma as triggers or exacerbators for asthma symptoms. However, the former operational definition leaves room for these and other possible contributing factors with the ending phrase, "to a variety of stimuli." That is, some psychological factors (e.g., emotional arousal) may be considered to be stimuli that elicit increases in airway responsiveness.

The second limitation is that although the above definition specifies a physiological basis for airways obstruction (inflammation), it does not provide the causal explanation for why some people are susceptible to this inflammatory process while others are not (no current definition of asthma provides such an explanation). It is important make a distinction between the physiological mechanisms underlying asthma and the causes of aberrant
physiological responses, because until the cause-effect relationship is fully understood with respect to why some people have asthma and others do not, the focus of treatment will necessarily remain on the prevention and management of symptom exacerbations rather than on a cure or a reversal of the disease process itself. In order to make such a distinction the following three levels of analysis are suggested: (1) physiological mechanisms; (2) proximal causes, e.g., exposure to allergens, exercise, or physiological changes; and (3) fundamental causes, e.g., biological and genetic factors that render some persons susceptible to asthma while other persons are not.

In spite of this recently derived consensual definition of asthma and better understanding of the disease mechanism underlying asthma, difficulties still remain with respect to the diagnosis of asthma. For example, there is no way to directly and routinely measure airway inflammation, a defining feature of asthma. Instead, a functional correlate of airway inflammation must be used. This currently involves monitoring peak expiratory flow (PEF) rate which is the amount of air expired in the first 0.1 second after maximal inspiration.

Although PEF rate appears to be an objective measure of airways obstruction, the fact that accurate readings depend on patients exerting maximal effort during inspiration and expiration means there are subjective elements that may lead to the underestimation of airway dysfunction.
However, even though PEF rate monitoring may underestimate airways obstruction, it has been shown to correlate sufficiently well with forced expired volume in 1-second (FEV₁) to be useful for serial monitoring of pulmonary function (Bedich, and Olson, 1989).

The Impact of Asthma

The Prevalence of Asthma

All Ages. Approximately 10 million people in the United States have asthma (Evans, Muhally, and Wilson, 1987). The prevalence of asthma increased from 1980 to 1987 by 29 percent. In 1987, 4,360 deaths were attributed to asthma, a 31% increase since 1980. There were 454,000 hospitalizations in 1986 that were directly related to this disease. Most of the approximately 5,000 annual deaths that are expected to occur from asthma are thought to be preventable (Weiss, Gergen, and Hodgson, 1992).

Under 18 Years Old. From 1980 to 1986 three million children under the age of 18 were diagnosed with asthma (Centers for Disease Control, 1990). Of this number, 2 million were thought to suffer activity limitations due to their disease. For example, asthma is one of the leading causes for school absence for illness. Also, hospitalizations and death from asthma increased during the 1980s at more than six percent per year for this age group (Weiss, Gergen, and Hodgson, 1992).
The Economic Impact of Asthma

All Ages. Weiss, et al., (1992) conducted an economic evaluation of asthma in the United States. They calculated that asthma accounted for approximately one percent of all of the health care costs in the United States, eight percent of the health expenditures, and ten percent of indirect costs for diseases of the respiratory system. The health care costs, in 1985 dollars, were equal to two thirds of the dollars spent for all cancers of the lung, bronchus, and trachea.

Under 18 Years Old. The economic evaluation by Weiss et al., (1992) included a breakdown for young persons under the age of 18 years based on 1985 dollars. The cost to parents for ten million lost school days was approximately 900 million dollars. Children were admitted to hospitals 160,371 times for 801,855 days of hospitalization at a cost of 1.2 billion dollars. There were 516,718 emergency room admissions for children at a cost of 148 million dollars. Children made about 1.1 million outpatient visits to the hospital at a cost of 136 million dollars. Hospital inpatient physician services for children were 110 million dollars. Outpatient visits to physicians by children cost 115 million dollars. In summary, the economic impact of asthma in 1990 for those under 18 years of age was about 2.6 billion dollars; and, this figure does not include the cost of medication which was 3.6 billion dollars for persons of all ages.
Asthma Mortality

The most disturbing statistic about the impact of asthma is the increased number of deaths. The asthma mortality data are as follows:

Asthma mortality decreased significantly in the United States during 1968-1977 among people aged 5-34 years. But death rates began to rise again in 1978 and continued at a rate of 6.2% per year until the most recent data collection in 1987. Death rates increased more in children 5-14 years of age than in people 15-34 years of age. Mortality increased to the same degree in whites and blacks, but inner-city black children are disproportionately affected. Asthma deaths were higher in the Northeast and North Central states; Cook County, Illinois, and New York City have the highest rates. Similar data are reported for other developing countries, notably New Zealand and the United Kingdom (Kaliner, Martin, O’Byrne, and Wiedemann, 1992, p. 80).

The factors that may explain the recent increase in deaths, include poor adherence to medications and self-care, disregard of perceived asthma symptoms, family-staff conflict, over-treatment and the effects of drug toxicity, and misdiagnosis and mismanagement (Birkhead, et al., 1989; Miller and Strunk, 1989; Sly, 1988; and Strunk, 1987). Further research is needed to better understand the role of these factors.

Asthma Management

General Treatment Goals and Approaches to Asthma Management

The goals of asthma therapy are to improve the patient’s quality of life by achieving and maintaining control of symptoms; preventing
exacerbations; attaining normal lung function; maintaining normal activity levels, including exercise; and avoiding adverse effects from asthma medications (NHLBI, June 1992a). Since the fundamental defect involving the asthmatic lung is not yet known, asthma cannot be cured (National Jewish Center for Immunology and Respiratory Medicine, 1986). Pharmacological and nonpharmacological treatment approaches are used to meet the objective of managing this disease so that persons can lead a normal life.

Pharmacologic therapy includes establishing medication plans for the chronic comprehensive management of asthma symptoms and avoiding adverse effects from asthma medications. The two main categories of asthma medications to be described in more detail in the next section are anti-inflammatory agents and bronchodilators.

Nonpharmacologic therapy includes patient and family education, environmental control measures, and the role of immunotherapy. Although psychological management is not explicitly mentioned in the Guidelines for the Diagnosis and Management of Asthma (NHLBI, 1991) as an approach to asthma management, there are several references that can be interpreted as "psychological" in nature. For example, there are sections on "Family Understanding and Support" that stress the need for resolving family conflict due to misunderstandings or disagreements about the cause, treatment or prognosis for asthma. There is also a section on "Feelings About Asthma" that discusses asthma related self-image and social stigma.
What is left out of this discussion on nonpharmacologic treatment approaches is a significant portion of the asthma literature that specifically addresses psychological treatment approaches. Three approaches to the psychological treatment of asthma will be discussed after the following examination of pharmacological treatments.

The Pharmacological Treatment of Asthma

Pharmacologic therapy is used to treat the reversible airflow hyperresponsiveness and airway obstruction that characterizes asthma. After the two kinds of asthma medicines (anti-inflammatory agents and bronchodilators) are reviewed, the need for psychological interventions as adjunctive treatments to pharmacotherapy is addressed. The following synopsis of asthma medication is adapted from the NHLBI (1991) publication, Guidelines for the Diagnosis and Management of Asthma, and the NHLBI (October 1992b) publication, Teach Your Patients About Asthma: A Clinician’s Guide.

Anti-Inflammatory Agents

Anti-inflammatory agents function by interrupting the development of bronchial inflammation. They reverse and prevent the swelling that causes asthma symptoms. Anti-inflammatory medications include corticosteroids and cromolyn. These medicines are usually prescribed if patients have
symptoms more than twice a week. If the symptoms occur more often, then a bronchodilator is usually prescribed (NHLBI, October 1992b).

**Corticosteroids.** Corticosteroids are anti-inflammatory medicines that prevent and reduce swelling inside the airways and decrease the amount of mucus in the lungs (NHLBI, October 1992b). Corticosteroids can either be inhaled using a metered dose inhaler, swallowed as liquids or pills (oral corticosteroids), or administered by injection. It should be noted that these medicines are not the same as anabolic steroids that some athletes use.

Inhaled corticosteroids are taken using a metered dose inhaler. They are for persons with moderate or severe asthma. They are used prophylactically, and act by reducing the sensitivity of the airways to stimuli that start asthma episodes, and by preventing airway swelling. Side effects include yeast infection in the mouth, irritation of the upper airways, and coughing.

Oral corticosteroids are taken in liquid and tablet form. They are used by persons with moderate or severe asthma. While persons with moderate asthma take oral corticosteroids for a period of days and then stop taking them, persons with severe asthma may consistently take them daily. They are used abortively (i.e., during a severe asthma episodes) and act by reducing airway swelling and preventing the episode from getting worse. The side effects when the medicine is taken on a short term basis (increased appetite, increased weight, fluid retention, facial rounding, mood changes,
and hypertension) will stop when the regimen is discontinued. There are more serious side effects (hypertension, thinning of bones, muscular weakness, slowed growth in children, and cataracts) when the medicine is taken on a long term basis.

**Cromolyn.** Cromolyn is an anti-inflammatory medicine that prevents airways from swelling when they come in contact with an asthma trigger (NHBLI, October 1992b). Cromolyn can be inhaled using a metered dose inhaler, nebulizer, or dry powder inhaler. Cromolyn is used by persons who require a non-steroid anti-inflammatory drug, and acts by keeping asthma episodes from starting; however, it cannot stop an asthma episode once it starts. The only reported side effect is a dry cough upon inhalation.

**Anti-Inflammatory Drugs Under Investigation.** Three medications, nedocromil sodium, antihistamines, and ketotifen are being tested in clinical trials. These drugs appear to have either no or very limited adverse side effects or have a secondary bronchodilator effect.

**Bronchodilators**

Bronchodilators function by relaxing bronchial smooth muscle and dilating the airways. They are used to relieve symptoms of asthma. Bronchodilator medicines include beta₂-agonists, methylxanthines, and anticholinergics. These medicines are usually prescribed if a patient has
symptoms less than once or twice a week. Bronchodilators are usually taken during an asthma episode for symptom relief, and/or before exercising to prevent an episode from beginning (NHLBI, October 1992b).

**Beta₂-Agonists.** Beta₂-agonists are bronchodilator medicines that open airways by relaxing the muscles in and around the airways that tighten during asthma episodes (NHLBI, October 1992b). Beta₂-agonists can be inhaled using a metered dose inhaler or nebulizer, inhaled using a dry-powder inhaler, swallowed as a liquid or tablet, or administered by injection.

Inhaled beta₂-agonists are the preferred form of this medicine because they act quickly (within about 5 minutes) and have fewer side effects than liquids or tablets. Nebulizers are recommended for very young children (under age 5), for patients who have problems using a metered-dose inhaler, or for persons with severe asthma. All beta₂-agonists are only used abortively to relieve symptoms. These medicines cannot reduce or prevent the swelling that causes the symptoms. If beta₂-agonists are used a lot (to relieve symptoms every day or if used more than 3-4 times a day), then this may be a signal that a person’s airways are getting worse and that another kind of medicine (anti-inflammatory agent) is needed. Side effects include nausea, tremors, fast heart beat, and feeling anxious. Rare but more serious side effects include severe nausea, vomiting, dizziness, severe headaches, irregular/fast heart beat, and chest pain.
**Methylxanthines.** Methylxanthines are bronchodilators that open airways by relaxing the muscles in and around the airways that tighten during an asthma episode (NHLBI, October 1992b). Methylxanthines (theophylline is the generic name) can be swallowed in tablet, capsule, or liquid form. This medicine is used by persons who require long-term maintenance therapy for symptom relief. It acts by reducing respiratory muscle fatigue and it may also have anti-inflammatory properties. The potential for the possible side effects (headache, irregular heart beat, muscle cramping, gastrointestinal problems, central nervous system stimulation, seizure activity in adults, and behavioral/learning problems in children) requires routine blood testing to ensure proper drug levels are maintained.

**Anticholinergics.** Anticholinergic agents are bronchodilator medicines that have a delayed onset of action (NHLBI, 1992b). These medicines are typically inhaled using either a metered dose inhalers or a nebulizer. They are used for acute exacerbations of symptoms, however, they can be considered a long-term maintenance technique because acute exacerbations are always being monitored and treated over time. Side effects may include drying of respiratory secretions, blurred vision, and cardiac and central nervous system stimulation. Newer anticholinergic agents such as ipratropium are thought to not have the just-stated side effects of older drugs when used in nebulized form in combination adrenergic agents. The
regular use of anticholinergics as bronchodilators appears to be most effective in persons with chronic obstructive pulmonary disease and partially reversible airflow obstruction.

The Need for Psychological Interventions as Adjunctive Treatments to Pharmacotherapy

Pharmacotherapy is the principal modality of the contemporary management of asthma. Psychological interventions are needed as adjunctive treatments (in addition to drug therapy) for any of several reasons including: (a) to reduce the need for costly asthma medications that can also have dangerous side effects (Rainwater and Alexander, 1982); (b) to deal with behavioral factors that may contribute to the poor medical management of asthma which in turn may be responsible for increased mortality from asthma (Lehrer, Sargunaraj, and Hochron, 1992); and (c) to deal with psychological variables in asthma that pharmacotherapy does not address (Ellis, 1983; and LeBaron and Zeltzer, 1983).

The latter psychological variables include any of the following: (a) the various emotional states that have been identified as precipitants or aggravating factors (Tal, and Miklich, 1976); (b) the psychological attitudes that influence adherence to therapeutic regimens (Zifferblatt, 1975); (c) the psychological disturbances that may partially or totally account for the subtype of asthma called "intrinsic asthma" where no allergic factors appear
to be involved in the manifestation of the disease (Purcell, Bernstein, and Bukantz, 1961; and Block et al., 1964); (d) the stress, both emotional and financial, that can cause major disturbances within the family of a chronically ill asthmatic child (Ellis, 1983); and (e) the way the coping-response (with respect to panic-fear) to an asthma episode may affect the over- or under-utilization of physician services (Kinsman et al., 1977).

Because traditional psychotherapy is not cost-effective and has a questionable ability to modify the primary disease process, a variety of behavioral approaches have been used effectively to improve self-image, deal with manipulative behavior, reduce the anxiety level associated with asthma episodes, and improve adherence to medical regimens (Creer, Weinberg, and Molk, 1974; Yorkston et al., 1974; Miklich et al., 1977; Richards et al., 1981). Issues related to the psychological treatment of asthma are discussed in greater detail in the following section.

The Psychological Treatment of Asthma

Although the medical community appears to have reached agreement on a definition of asthma that emphasizes physiological mechanisms, there is still much interest in identifying psychological precipitants of asthma and psychological interventions that may lessen the severity of asthma. There are three psychological treatment approaches which have been proposed for persons with asthma (Creer, 1982). These approaches can be differentiated
on the basis of the rationale for using psychological interventions. The first
approach places little emphasis on etiology, and uses psychological
interventions to treat problematic behavior that accompanies asthma
episodes. The second approach uses psychological interventions
(psychoaanalysis) to treat asthma while assuming asthma is a psychological
problem. The third approach assumes there is a physiological basis for
asthma but still uses psychological interventions to treat asthma symptoms.

**Treating Problematic Behavior That Accompanies Asthma Episodes**

The focus of the psychological interventions to be discussed in this
section is on the management of asthma-related behaviors by employing
operant techniques instead of attempting to alter in a direct way pulmonary
function variables or asthma symptomatology (Creer, 1982; and Cluss,
1986). Little or no emphasis is placed on the etiology of asthma; however,
Creer (1982) states that changes in asthma-related behavior, if effected,
may affect a person’s asthma. The goal is to strengthen behavior that
makes asthma episodes less likely, and/or to make them less aversive for
the patient and caretaker. The general approaches that will be discussed
are "symptom discrimination" and "modifying attack behaviors."

**Symptom Discrimination.** Symptom discrimination refers to the ability
of the patient to discriminate the onset of an asthma episode and react
appropriately (Creer, 1982). If asthma attacks can be anticipated, then parents and their children can act sooner to prevent a full-blown asthma episode which might require more potent medication or the need for hospitalization.

One strategy for helping young persons detect asthma symptoms is to train them how to use a portable peak flow meter which measures a person's ability to breathe-out quickly. A second strategy, applicable in the absence of a peak flow meter, involves the training of more accurate discriminations of the initial stages of an asthma episode. This training can be achieved by: (a) having the child correlate their subjective feelings of asthma with objective indexes (via peak flow meter recordings) of airflow functioning; or (b) teaching parents to use behavioral and physical cues that accompany the start of an asthma episode to tell when medical treatment should begin. Studies using these strategies found that children and their parents were able to more accurately predict and prepare for asthma episodes that were imminent. Learning to discriminate asthmatic symptoms earlier made it easier to abort serious asthma attacks and reduce emergency room visits and longer hospital stays. (Creer, Renne, and Chai, 1982).

**Modifying Attack Behavior That Accompanies Asthma Episodes**

Creer (1982) used the term "attack behaviors" to refer to behavior that accompany asthma episodes which may interact with physical events
to exacerbate the episode. Behavior that occurs at the same time as an asthma episode that may interfere with the medical management of asthma include: panic; use of emergency respiratory equipment; and overuse of hospital facilities. Behavioral techniques such as breathing exercises to reduce hyperventilation, relabeling of bodily symptoms to deal with thoughts of dying, and relaxation exercises have been used to prevent incipient panic attacks (Creer, 1974 and 1979). The goal is symptom management and the avoidance of full-blown panic attacks.

Renne and Creer (1976) also trained patients how to use inhalation therapy equipment in order to increase the benefits of pharmacological treatment and to decrease the incidence of hospitalization due to inadequate treatment. These researchers successfully used a reinforcement program to train requisite behaviors for effective equipment use by both adults and children. This skill is especially important for children who must be prepared for those times when adults are: (a) not around to supervise the equipment use, or (b) temporarily unable to respond effectively due to their own feelings of panic and uncertainty upon witnessing their child having an asthma episode.

Hochstadt, Shepard, and Lulla (1980) successfully used a time out procedure and contingent positive reinforcement for appropriate behavior to significantly decrease the number of days of hospitalization per year for seven children with asthma who had a history of "over-using" inpatient
hospital services. The time-out procedures included removing comic books, and TV from the child's room, and decreasing opportunities for socializing.

Neisworth and Moore (1972) used a similar approach when they successfully taught parents to use extinction (ignoring "sick" behavior at bedtime) procedures and differential reinforcement of desirable behavior to reduce the duration of their child's nighttime asthma symptoms. Some might question the wisdom and ethics of such strategies, however, because they might teach children to under-report asthma symptoms.

Creer (1982) reached three conclusions about the treatment of asthma-related behaviors: (1) asthma-related behaviors have proven to be amenable to change with behavioral techniques, meaning they no longer intensify ongoing attacks or interfere with medical management; (2) altering asthma-related behaviors can directly affect measures of asthma per se; and (3) the techniques for altering asthma-related behavior can be combined with educational components to create asthma self-management systems.

_Treating Psychological Problems Using Psychological Interventions_

French and Alexander (1941) reviewed the psychoanalytic literature with respect to persons with asthma undergoing psychoanalysis. The basic conclusion of their review was that persons with asthma are psychologically abnormal (Creer, 1982). This attitude, according to Creer, has had a lasting negative impact on the perceptions and psychological treatment of
asthmatics. French and Alexander (1941) purported that asthma results from unresolved maternal dependency conflicts. This notion was based on the hypothesis that asthma is a suppressed cry where children with asthma cry less than children without asthma especially during critical periods of separation conflict. King (1980) noted that the notion that asthmatic children cry less than nonasthmatic children has never been formally tested. Purcell (1963) suggested that if children with asthma do cry less it is to avoid crying-induced asthma episodes. Crying is viewed as another stimulus event, like laughing and coughing that can provoke an asthma episode.

Several researchers have questioned the notion that asthma is related to maternal dependency and separation conflicts. For example, Purcell et al (1969) found that certain children with asthma tend to improve when separated from their parents. Furthermore, Gauthier (1977), analyzed the relationships between children and their mothers, and found that children were developing in age-appropriate manners, appeared autonomous, independent and had adequate coping skills for the types of demands in their environments. Thus, French and Alexander's (1941) psychoanalytic theory of asthma appears to be outdated and lacking in empirical evidence (King, 1980; and Creer, 1982).

Creer noted that the belief that persons with asthma are psychologically abnormal has placed a burden on persons with asthma and their family members. While not explicitly stated, this is probably the
"social stigma" that is referred to in the NHLBI's (1991) Guidelines for the Diagnosis and Management of Asthma.

Even when the mechanisms of asthma were less certain in the early 1980s, researchers refrained from hypothesizing that the cause was due to psychological factors (Wadden and Anderton, 1982). Other authors concluded that the routine referral to a psychiatrist or psychologist for treatment of underlying psychiatric abnormalities was unnecessary (Mclean and Ching, 1973), and a waste of time, effort, and money (Creer, 1978).

It must be carefully pointed out, however, that the criticism of French’s and Alexander’s (1941) conclusions, does not negate the widespread belief that (a) psychological factors may precipitate, exacerbate, or increase susceptibility to asthma episodes (Hock, Rodgers, Reddi, and Kennard, 1978; Wadden and Anderton, 1982; Conners, 1983; and Lask, 1991), or (b) a person suffering from asthma may sometimes require assistance for psychologic or behavioral problems many of which may be a direct consequence of their asthma (Creer, 1978). Creer (1982) also wrote that "the person's adjustment with his or her asthma should be the primary deciding factor as whether or not the child is referred for psychiatric or psychological treatment (p. 920)." Thus, there is a substantial difference between purporting that a person's asthma is caused by psychiatric problems and, according to Creer, recognizing that asthma may lead to problems in living that require behavioral intervention. This difference deals
primarily with the emphasis on the etiological factors—psychological versus physiological. The following section examines the point of view that psychological interventions impact a disease that is physiological in origin.

**Treating Physiological Disease Using Psychological Interventions**

Researchers have used numerous psychological interventions under the assumption that they can directly affect the physiological process of asthma. One popular theory is that if anxiety makes asthma worse, then reducing anxiety should make it better (Kinsman, Jerald, Jones, and Dahlem, 1980). Anxiety reduction is thought to lead to bronchial muscle relaxation and in turn to a reduction of bronchospasm and wheezing and to an increase in peak expiratory flow rates (Knapp and Wells, 1978). Clinical observations of the role of anxiety and other strong emotions in the precipitation and exacerbation of asthma episodes led to the use of relaxation techniques to reduce the physiological arousal which characterizes anxiety (Cluss, 1986).

Support for the relationship between anxiety, relaxation, and asthma comes from a variety of other sources. For example, the adverse effect of emotional arousal on pulmonary functioning was first shown by Faulkner (1941) who used a bronchoscope to observe bronchial widening and narrowing in response to suggested positive and negative emotions in a nonasthmatic subject. Likewise, Tal and Miklich (1976) found that vividly
remembered incidents of intense anger and similarly recalled fear resulted in decreases in pulmonary flow rates in children with asthma. The pulmonary flow rates then increased with relaxation. They concluded that emotional arousal can cause bronchoconstriction with anger having a greater effect than fear. They added the caveat that their findings did not mean that emotional arousal was the proximal cause of asthma. They also distinguished between arousal as a psychological event and bronchoconstriction as a physiological event, and postulated that there must be at least one intervening psychophysiological chain of events that leads to the precipitation of bronchoconstriction soon after emotional arousal.

The essence of the psychological treatment of asthma is to help reduce anxiety and tension and to provide coping skills (Lask, 1991). Many methods have been used to reduce anxiety such as psychoanalysis (Alexander, 1950), family therapy (Gustafsson, Kjellman, and Cederblad, 1986), group therapy (Deter and Allert, 1983), hypnosis (Maher-Loughnan and Kinsley, 1968; Aronoff, Aronoff, and Peck, 1975; and Morrison, 1988), yoga (Goyeche, Abo, and Ikemi, 1982), cognitive therapy, (Yorkston, McHugh, Brady, Serber, and Sergeant, 1974) and behavior therapy (Khan, Staerke, and Bonk, 1973; and Lukeman, 1975; and Cluss, 1986), and electroconvulsive therapy (ECT) (Purcell and Weiss, 1970). Purcell and Weiss noted there have been claims of success for these approaches except for ECT.
Behavioral treatment procedures are finding wide application as an adjunct to the medical management of symptoms of disease (Masek, Fentress, and Spirito, 1984). A recent review of behavioral interventions as adjunctive treatments for chronic asthma specifically studied relaxation training, biofeedback, and systematic desensitization (Cluss, 1986).

**Relaxation Training.** Relaxation techniques were among the first behavioral methods used as treatments for asthma (Cluss, 1986). The goal of this technique is to counteract anxiety which purportedly can precipitate and exacerbate asthma episodes (Alexander, 1972; and Hock et al., 1978).

Most relaxation exercises are based on Jacobson's (1938) progressive muscle relaxation technique. It involves progressively tightening and relaxing individual muscle groups such as arms, hands, and biceps, face and neck, chest, shoulders, back and abdomen, and upper leg, calf, and foot. Each of the 12 relaxation studies that Cluss (1986) reviewed used a different variation of this relaxation technique that was sometimes supplemented with biofeedback, breathing exercises, or imagery. Cluss summarized the relaxation training research findings as:

The evidence for efficacy of [relaxation] treatment for asthma is less than substantial. Only five [of 12] studies demonstrated statistically significant improvement in lung function for relaxation-trained subjects. Of these, only two groups of subjects showed results which were clinically significant. Poor research design, including lack of adequate control groups and small sample sizes, and inadequate statistical analyses are possible contributing factors to the lack of positive results in this area of research (p. 141).
Despite recognition of methodological problems (Creer, 1982), and speculation that physiological relaxation may be counter-therapeutic in asthma (Alexander, Cropp, and Chai, 1979), relaxation is still recommended (NHLBI, 1991 & June 1992a), and researchers still study the relationship between anxiety, relaxation, and asthma (Weiner, 1987).

Support for the use of relaxation comes from the findings of several research studies (Alexander, 1972; Alexander et al., 1972; and Philipp, Wilde, and Day, 1972). These researchers taught relaxation techniques to persons with asthma and compared the outcome with that of a control group. Although relaxation training produced statistically significant increases in pulmonary functions as compared to the control group, it is doubtful these improvements were clinically significant (King, 1980).

Alexander et al., (1979) stated that the most optimistic appraisal of relaxation training is that its effect is of little or no clinical significance even if real. The three reasons given below help explain why researchers continue to study the effects of relaxation techniques on asthma symptoms despite a negative appraisal. The first reason deals with the importance of small effects. Kotses, Hindi-Alexander, and Creer (1989) stated:

Airways changes due to relaxation or stress in asthmatics may, respectively, attenuate or potentiate the effects of asthma on the airways...such effects are small but could be important. Because of the manner in which bronchomotor changes due to relaxation and stress interact with asthma, individuals may, over a period of time, learn to approach relaxing situations and avoid stress (p. 61).
Cluss (1986) also makes an appealing argument for the continued use of relaxation techniques, despite small effects, with the following speculation:

Perhaps for adjunctive treatments, however, which are meant to be used in addition to asthma medication, interventions can be considered clinically useful even if they result in less than a 15% improvement in pulmonary function. A behavioral treatment which produces a 10% increase in peak expiratory flow rate, for example, when used in addition to a bronchodilator drug which itself effects a clinical improvement, may provide just enough added relief to allow a patient to resume or maintain activities without disruption (p. 153).

Second, researchers are also still interested in investigating relaxation techniques that use a supplemented approach to produce subjective and objective improvement in asthma symptoms (Erskine-Milliss and Schonell, 1981). Biofeedback has been found to be a useful adjunct to relaxation training and to autogenic training used in systematic desensitization. Biofeedback and systematic desensitization are discussed below.

And third, methodological limitations with relaxation studies need to be resolved. Cluss (1986) stopped short of concluding that relaxation should not be used. Rather than switching to new research areas, Cluss suggested:

Some evidence for the limited effectiveness of relaxation training has been demonstrated...It cannot be said, however, that the results reported represent the definitive statement regarding the usefulness of these interventions, due to the lack of methodological sophistication evident in this body of research. Behavioral investigators currently interested in this area have the opportunity to design and implement research strategies which attend to sound methodological considerations and which may present a clearer demonstration of the efficacy of the adjunctive behavioral treatments which have been used with asthma patients for the past several decades (p. 156).
Biofeedback. There are two fundamental strategies for using biofeedback as a behavioral intervention for asthma. First, EMG equipment is used to provide feedback on skeletal muscle tension to facilitate the effects of relaxation training, or to study the interaction between muscle tension and pulmonary function in the absence of relaxation training (Kotses and Glaus, 1981). The use of EMG-assisted progressive muscle relaxation training is based on the theory that objective information about muscle tension level enhances the general state of relaxation during relaxation practice. Biofeedback also can provide direct feedback of respiratory function in persons with asthma in order to increase a person's ability to increase ventilation of the lungs (Kotses and Glaus, 1981).

Cluss (1986) reviewed 15 published articles on the use of biofeedback as an adjunctive treatment for persons with chronic asthma, and she summarized the results of this review as follows:

Overall, of the 15 studies cited, 11 showed statistically significant differences between the experimental and control groups; only two of these interventions, however, can be said to demonstrate clinically meaningful improvements in pulmonary function after biofeedback training. . . This body of research appears to include better attention to design characteristics including larger groups of subjects and inclusion of appropriate controls, than does the group studies investigating relaxation interventions. The large proportion of studies with statistically significant results is encouraging, but lack of clinical significance of the outcome engenders doubt as to the technique's usefulness with clinical populations (pp. 148-149).

Specific findings from Clauss' review included the observation that frontalis muscle feedback was most effective in altering pulmonary function
when biofeedback techniques are used. These results were supported by Kotses, Harver, Segreto, Glaus, Creer, and Young (1991) who studied the effects of EMG biofeedback on measures of asthma severity in children. Based on the improvements observed in pulmonary function, attitude, and anxiety measures, they concluded that biofeedback training for facial relaxation contributes to the self-control of asthma and may be a valuable addition to self-management programs.

**Systematic Desensitization.** The rationale of using systematic desensitization is to reduce psychological sensitivity to any stimuli that have a history of eliciting asthma episodes. Subjects are trained initially in progressive muscle relaxation techniques, and are then exposed in a step-by-step manner to weak and then successively stronger asthma-related, anxiety-producing stimuli while maintaining a relaxed state. These stimuli are typically not allergens but stimuli associated with increased anxiety. As exposure to these stimuli is repeated, the stimuli should progressively lose the ability to elicit anxiety and should, therefore, result in a decrease in anxiety-related asthma symptoms. This process is also known as reciprocal inhibition, the theory that it is impossible for states of anxiety and states of relaxation to co-exist. Systematic desensitization is thus another way of inducing relaxation with the goal of eliminating anxiety and affecting bronchoconstriction (Yorkston, et al., 1974; Cluss, 1986; and Lask, 1991).
Cluss (1986) reviewed four studies which used systematic desensitization as adjunctive treatments for asthma (Moore, 1965; Miklich et al., 1977; Yorkston et al., 1974; and Yorkston et al., 1979). Three of these studies achieved statistically significant results, and for two of the studies, the significance was clinically meaningful (a 15% improvement in pulmonary function (Itkin, 1967)). It was noted that further investigation with inclusion of appropriate control groups is necessary before unqualified statements about treatment effectiveness can be made.

The same overall conclusion has been reached by several extensive reviews of behavioral interventions used for chronic asthma: there is little evidence for the effectiveness of progressive muscle relaxation training when used alone, and more substantial evidence for the use of biofeedback and systematic desensitization (Cluss, 1986; Conners, 1983; LeBaron & Zeltzer, 1983; Erskine et al., 1981; Kotses & Glaus; 1981; King, 1980; Blanchard and Ahles, 1979; and Surwit & Keefe, 1978). These studies mention methodological problems commonly encountered in this area of research—especially related to relaxation training. These problems include lack of adequate control groups, lack of attention to how subjects were assigned to groups (e.g., inclusion of both adults and children in the same sample, and having homogenous groups with respect to asthma severity), small sample sizes, and inadequate statistical analyses (Cluss, 1986).
General Summary

The management of asthma can be broken down into pharmacological and nonpharmacological treatment approaches. Psychological interventions can be used in addition to pharmacological treatment. Despite a considerable literature base, psychological treatments for asthma have received little attention from the medical community as evidenced by the lack of consideration in recent major publications by the NHLBI.

Summary of Findings

Interventions primarily directed at asthma related behaviors have been found to be effective at teaching persons with asthma to discriminate the onset of asthma episodes and to follow standard medical procedures sooner and more effectively with the result of aborting severe asthma episodes and reducing hospitalizations. Interventions directed at resolving psychodynamic conflict, that purportedly lead to asthma, are considered out of date and lack empirical support; however, an unfortunate legacy of this approach has been to stigmatize persons with asthma as being psychologically abnormal.

Behavioral interventions directed at treating asthma as a physiological problem have been found to have equivocal results. Biofeedback and systematic desensitization treatments produced statistically significant results, whereas there was only limited evidence for the effectiveness of
relaxation training. The clinical usefulness of these behavioral interventions remains open to question. Methodological flaws with relaxation studies prevent definitive statements from being made about the efficacy of these treatments. Some researchers have chosen to improve the methodology to provide some clearer answers about the efficacy of relaxation training.

The Rationale for Studying Relaxation Exercises

The rationale for studying relaxation exercises as an adjunctive treatment for asthma is twofold. The first relates to the goal of young asthmatics performing relaxation exercises to reduce emotional/physical arousal to facilitate bronchodilation. The second relates to the goal of relaxation exercises being used to reduce fear/panic responses that interfere with the timely performance of coping skills during an asthma episode. There has been much debate about the former and little about the latter.

It is likely that the true effects of relaxation on pulmonary mechanics have been obscured by the lack of methodological sophistication in this body of research. While it is doubtful that all asthmatics can benefit from the likely small effects of relaxation, additional research is needed to determine if there are subgroups of asthmatics for whom relaxation may be beneficial. Before this can be determined for certain much research needs to be conducted that takes into consideration experimental design issues, subject variables (regarding asthma subtypes and individual characteristics),
independent variables (with respect to relaxation techniques and possibly levels of relaxation), and dependent variables (with respect to outcome measures that can best detect the relaxation effect).

The Purpose of the Current Experiment

The purpose of this experiment is to answer research questions created by specific limitations with past relaxation studies. The answers to these research questions will help to fill-in the gaps about what is not known about the effects of relaxation on airways sensitivity with respect to children/adolescents, and the ways by which the effects of relaxation can best be detected. These limitations are discussed in more detail below with respect to the specific objectives and hypotheses of the current experiment.

Objective One: To Determine the Effects of Relaxation During an Asthma Episode

The first of the three experimental objectives is to determine the effects of relaxation exercises on airways sensitivity to methacholine. This objective is important because it addresses the question, "Are the effects of relaxation helpful or harmful during an asthma episode?" This issue is raised by case study observations that it helps to be calm during an acute asthma attack to decrease wheezing severity, and contradictory evidence that deep relaxation is countertherapeutic for persons with asthma.
(Alexander et al., 1979; and Weiner, 1987). The latter evidence is based on a theory that deep relaxation leads to over-activation of the parasympathetic division of the autonomic nervous system (via vagus nerves) which leads to the subsequent release of circulating acetylcholine which causes large airway constriction (Weiner, 1987; Morse and Furst, 1979; and Alexander et al., 1979). One might expect relaxation to have beneficial effects during an asthma attack since Lehrer et al (1986) found that subjects with predominant large-airway (versus small-airway) obstruction who received relaxation training improved on a methacholine challenge. Thus, there is an inconsistency in the literature that leaves unanswered the question concerning the efficacy of relaxation during asthma episodes.

The first objective is also of importance because it addresses the issue of making predictions about relaxation treatment response. The Lehrer et al., (1986) study, described briefly above, helped to differentiate subpopulations of asthmatics for whom relaxation exercises are and are not beneficial by examining the type (large or small) of airway obstruction. However, it is unclear whether similar results would be obtained if the subject population consisted of children/adolescents because Lehrer et al used an adult subject population the mean age of which was 44.3 years.

In addition, Philipp et al (1972) reported that relaxation training improved methacholine tolerance in subjects from age 14 to 49; but, they did not discuss their results in terms of the subjects’ age. Attention to the
age is necessary because inclusion of both children and adults in a sample may confound the interpretation of results due to potential differences in pathogenesis, manifestation, and prognosis of asthma in children versus adults (Cluss, 1986; and Richter and Dahme, 1982). A systematic replication would determine if results similar to Lehrer et al (1986) can be achieved with a pediatric population. The hypothesis is as follows.

**Experimental Hypothesis One (Methacholine Sensitivity).** Hypothesis one states that there will be differences in methacholine sensitivity between treatment group subjects who practice relaxation exercises and control group subjects who do not. Specifically, it is predicted that the treatment group subjects who are taught relaxation exercise and are instructed to practice these exercises for 10-weeks thereafter, and then are instructed to perform them before and during a post-training methacholine challenge, will show a greater tolerance to a methacholine challenge than the control group subjects who do not receive such training and instruction.

**Objective Two: To Determine the Effects of Relaxation on Daily Peak Flow Variability**

The second experimental objective was to determine the effects of relaxation exercises on daily measures of peak expiratory flow (PEF) rate variability. This objective is of importance because of the manner in which previous researchers have used infrequent assessments of daily variability
of PEF rate as an outcome measure. The current review of relaxation studies found no instances where day-to-day variation in PEF rate was measured on either a short- or long-term basis. Instead, comparisons of pre-to post-relaxation treatment session peak expiratory flow rate changes were most frequently reported. This is unfortunate because daily variability of PEF rate provides a reasonable index of asthma stability/severity over time (NHLBI, June 1992a). The hypothesis tested is as follows.

**Experimental Hypothesis Two (Peak Flow Variability).** Hypothesis two states that there will be a difference in daily measures of airflow variability between treatment group subjects who practice relaxation exercises and control group subjects who do not. Specifically, it is predicted that treatment group subjects who are taught relaxation exercises and are instructed to practice these exercises for 10-weeks thereafter, will show less day-to-day peak expiratory flow (PEF) rate variability during the 10-week period than control group subjects who are not.

**Objective Three: To Determine the Effects of Relaxation on Asthma Symptoms and Medication Use**

The third experimental objective was to determine the effects of relaxation exercises on subjective measures of asthma (self-report of asthma symptom severity) that may or may not correspond with the effects on more objective measures of asthma (self-report of asthma medication use).
This objective is important because it addresses the question, "Does relaxation differentially affect commonly used indices of the clinical course of asthma?" It is unclear whether relaxation can decrease asthma symptoms or medication use since declines in these indices have not been confirmed statistically in previous studies by Kotses et al (1991), and Lehrer et al (1986). Thus, a systematic replication is needed to determine if a more definitive answer can be achieved. The hypotheses are as follows.

**Experimental Hypothesis Three (Asthma Symptoms).** Hypothesis three states that there will be a difference in asthma symptom ratings between treatment group subjects who practice relaxation exercises and control group subjects who do not. Specifically, it is predicted that treatment group subjects who are taught relaxation exercises and are instructed to practice these exercises for 10-weeks thereafter will report asthma symptoms of less severity than control group subjects who are not.

**Experimental Hypothesis Four (Asthma Medication Use).** Hypothesis four states that there will be a difference in medication usage between treatment group subjects who practice relaxation exercises and control group subjects who do not. Specifically, it is predicted that treatment group subjects who are taught relaxation exercises and are instructed to practice these exercises for 10-weeks thereafter, will use less asthma medications than control group subjects who are not.
CHAPTER II

METHOD

Subjects

The subject sample consisted of 14 moderate asthma patients who were recruited from a group of over 322 active pediatric asthma patients who had comprehensive medical documentation available from the outpatient asthma clinic at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS), Midtown Medical Center. All subjects were patients that had been seen by, and were under the continual medical care of a pediatric pulmonologist, Douglas N. Homnick, M.D.

Subject Recruitment Procedure

Subject recruitment was conducted so parents and their children could decline to participate without any investigator knowledge. A research nurse, employed by MSU/KCMS but not affiliated with the current research, reviewed 322 patient files. She then telephoned the parents of 38 patients who met the inclusion criteria (see below). The parents of 14 patients expressed an interest in the study and were then scheduled to attend an informed consent/assent meeting. Subjects' parents signed informed consent.
consent forms (Appendix A), and subjects signed informed assent forms (Appendix B), as approved by the human subjects institutional review boards of Western Michigan University, and Bronson Hospital (Appendix C).

Inclusion Criteria

Subjects were included if after a review of medical records the following criteria were met: (a) meet the NHLBI 1991 guidelines for moderate asthma (Appendix D); (b) be between the ages of 8 and 14 years; (c) be willing to sign a behavioral contract stating she or he (the child) will be willing to practice relaxation twice daily, and record information related to asthma on a daily, weekly, and monthly basis (Appendix E); (d) be within 10% of age-predicted FEV₁ (forced expired volume in 1-second) spirometric readings; (e) be able to understand and sign the assent form (Appendix B); (f) both parents or legal guardians (or parent or guardian with full custody) able to understand and sign the consent form (Appendix A)—but only after their child understands and signs the assent form.

Exclusion Criteria

Subjects were screened out of the study if any of the following criteria were met: (a) the use of oral corticosteroids within one month of the start of study; (b) a history of viral or other infectious processes immediately prior to the start of study; (c) a diagnosis of mild or severe
asthma (see Appendix D); or (d) a physical condition that contraindicates the systematic tensing and relaxing of muscle groups. Although all subjects were required to continue their usual medication regimen, the methacholine challenge protocol required that they be able to withhold asthma medications for up to 72-hours before the challenge.

**Subject Characteristics**

Age and sex characteristics of the subjects are given in Table 1.

**Table 1**

<table>
<thead>
<tr>
<th>Subject characteristics</th>
<th>Experimental Groups</th>
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<tbody>
<tr>
<td></td>
<td>Relaxation</td>
<td>Control</td>
<td></td>
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<tr>
<td>Number of males</td>
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<td>5</td>
<td></td>
</tr>
<tr>
<td>Number of females</td>
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<tr>
<td>Age range</td>
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<td>8.3-14 years</td>
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<tr>
<td>Age mean ± s.d.</td>
<td>9.9 ± 1.3 years</td>
<td>11.2 ± 2.2 years</td>
<td></td>
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</tbody>
</table>

**Setting**

Subjects were taught how to use peak flow meters and how to fill-out Asthma Weekly Recording Sheets (Appendix F) at the medical center where they went for their regular asthma check-ups. The methacholine
inhalation challenges were performed in the pulmonary function laboratory at Bronson Hospital, Kalamazoo, Michigan according to this hospital’s standardized methacholine inhalation challenge protocol. Subjects were also taught relaxation exercises in this laboratory. Subjects were instructed to listen to a 10-minute relaxation exercise tape in a quiet setting in their homes and to complete their Asthma Weekly Recording Sheets daily.

Apparatus and Dependent Measures

**Spirometric Measurement**

The respiratory therapist recorded serial spirometry measures (spirograms) during the methacholine inhalation challenges using a Puritan-Bennett PB 900 Diagnostic Spirometer (265 Ballardvale St., Wilmington, MA, 01887). The respiratory therapist coached each subject throughout the spirometry procedure encouraging each to exhale with maximal force (blow hard!) until a valid reading was graphically displayed on a computer monitor connected to the spirometer. These measures are reported in the forced expiratory volume (measured in liters) in one second (FEV₁), and are indices of change in pulmonary function due to repeated administrations of methacholine. The spirometric measurements allowed the respiratory therapist and pediatric pulmonologist to determine the inhalation dose of methacholine necessary to cause a 20 percent drop in FEV₁. This inhalation
dose was converted to methacholine breath units according to the procedure detailed in Appendix G. The results of the first methacholine challenge, reported in methacholine breath units, served as a baseline against which to make inter- and intra-group comparisons with the second methacholine challenge 10-weeks later.

**Frontalis EMG Measurement**

The principal researcher recorded electrical activity of frontalis muscle using a portable EMG module (J&J EMG Model M-52, Bio-Medical Instruments, 2387 E. Eight Mile Rd., Warren, MI, 48091). Silver chloride disposable surface electrodes are placed symmetrically across each subject’s frontalis area, approximately 1-inch above the eyebrow. The J&J Dual Digital Integrator D-200 quantified the physiological activity monitored by the J&J M-52. The principal researcher sampled and recorded EMG readings (in microvolts) every 15-seconds for 5-minutes before and after the challenges, as well as before and after the relaxation training sessions. The EMG readings were used to assess acquisition of relaxation exercise skills.

**Peak Expiratory Flow (PEF) Rate Measurement**

Subjects measured their peak expiratory flow rates using HealthScan Assess Peak Flow Meters (HealthScan Products Inc., Cedar Grove, NJ, 07009-1292). This portable, light, plastic instrument consists of two
detachable parts, a mouth piece and a metered component. The principal researcher instructed subjects how to correctly use the peak flow meter. The proper use requires connecting the two parts, making sure the measuring piston is at the lowest meter setting, and blowing as hard as one can into the mouthpiece. The force of the blow raises the piston, and the level it attains provides information on pulmonary functioning in liters per second. If the airways are obstructed in some way then fewer liters of exhalant per second are measured by the peak flow meter. If the airways are less obstructed then more liters of exhalant per second are measured by the peak flow meter.

Subjects took three successive readings in the morning and evening, before taking their asthma medication, and recorded the results on their Asthma Weekly Recording Sheets. At the end of each week subjects (or their parents) mailed the recording sheets to the principal researcher who then calculated peak expiratory flow (PEF) rate daily variability scores according to the following formula (NHLBI, June 1992a):

\[
\text{Daily Variability} = \frac{\text{Highest PEF} - \text{Lowest PEF}}{\text{Highest PEF}} \times 100
\]

This measure (daily variability) was used to assess the long-term effects of relaxation after the principal researcher taught the treatment subjects the exercises and instructed them to practice twice daily for 10-weeks.
Relaxation Exercises Cassette Tape

The principal researcher produced a 10-minute relaxation exercise audio cassette tape and gave each subject a copy (see Appendix H for the transcription). There are four types of relaxation exercises on the tape: (1) diaphragmatic (belly) breathing exercises with the focus/meditative statement "I am...relaxed;" (2) Jacobsonian progressive muscle relaxation of the face, shoulder, arm and leg muscles; (3) mental imagery exercises; and (4) self-affirmation statement exercises. At the beginning of the tape the subject is asked to rate his or her current level of relaxation on a scale from 0 to 10 where 0 coincides with being completely relaxed, and 10 coincides with being completely tense. At the end of the tape the subject is again asked to rate his or her level of relaxation--after completing the relaxation exercises. Subjects recorded these ratings on their Asthma Weekly Recording Sheets. These ratings were intended to help the subjects in the treatment attend to differences in their relaxation level before and after listening to the tape. These ratings also functioned as indicators that the subjects listened to the tape as instructed.

Asthma Weekly Recording Sheet and Asthma Symptom and Medication Use Measurement

The principal researcher instructed subjects how to record their subjective ratings of four asthma symptoms (e.g., wheeze, cough, activity
restriction, and nighttime asthma symptoms) on their Asthma Weekly Recording Sheets. The asthma symptom ratings are based on a (Likert) scale from 0 to 10: 0 coincided with the absence of symptoms and 10 coincided with the most severe level of the symptom. Illustrative scales were printed on the back of each Asthma Weekly Recording Sheet to assist subjects in their ratings. The principal researcher also instructed subjects and their parents how to record the type and frequency of asthma medication on the Asthma Weekly Recording Sheets. Asthma symptom rating scores, and frequency of asthma medication use were used to assess the effects of relaxation exercises on change in airways functioning.

General Procedure

Experimental Design

A stratified, randomized case control design was used.

Group Assignment

An attempt was made to establish fairly homogeneous treatment and control groups by matching subjects into 7 pairs according to the results of the first methacholine challenge (described below). The members of these 7 pairs were then randomly assigned, using a random digits table (Hopkins and Glass, 1978), to either the treatment or control groups. Subjects in the
treatment group were taught and subsequently practiced relaxation exercises while subjects in the control group did not. The principal researcher taught the relaxation exercises to, and gave the 10-minute relaxation audio tape to, the control group subjects after the study.

Hypothesis one was tested based on a total of 9 subjects, with 4 in the treatment group and 5 in the control group. Hypotheses two, three, and four were tested based on a total of 14 subjects, with 7 per group. This discrepancy exists because two subjects failed to complete the first challenge and three other subjects failed to complete the second challenge. Subjects' lung functioning indices were too low on the day of the challenge to safely go through the procedure in all but one of these failures. With respect to the other failure, the subject experienced asthma symptoms (before the first dose of methacholine was completely administered) that required immediate therapeutic breathing treatments. It was still possible to have 7 subjects per group to test hypotheses two, three, and four by pairing the two subjects who didn't complete the first challenge and then randomly assigning them to either the treatment group or control group.

Pre-Relaxation Training Methacholine Sensitivity Assessment Session

A licensed respiratory therapist (RT) administered the methacholine challenges under the supervision of the pediatric pulmonologist in a pulmonary functions hospital laboratory. The RT took spirometry readings
between each progressively larger dose of methacholine (administered by nebulizer) to determine when lung functioning decreased by 20 percent—the point after which drug administration stopped, recovery time was monitored, and breathing treatments (administered by nebulizer) began. The standard hospital protocol for this methacholine inhalation challenge procedure is documented in Appendix I. The principal researcher gave no special instructions to subjects in either experimental group other than to follow the directions of the respiratory therapist during the challenge procedure. The principal researcher recorded the frontalis EMG levels of all subjects every 15-seconds during the following time periods: (a) five minutes before the challenge; and (b) five minutes after the challenge.

Baseline Conditions

The baseline condition consisted of the time period from when the principal researcher taught all of the subjects how to use a peak flow meter and how/what to record on the Weekly Asthma Recording Form, to when the relaxation treatment group learned and immediately began practicing the relaxation exercises. The principal researcher gave the following verbal and written instructions to all of the subjects/parents about what to do during the baseline conditions: (a) take and record peak expiratory flow rates, before taking asthma medications, three consecutive times in the morning and three consecutive times in the evening; (b) upon waking-up in the
morning record the rating for the severity of the nighttime symptom that they experienced; (c) record before bedtime the ratings for the severity of daily asthma symptoms (wheezing, coughing, and restrictions); and (d) record before bedtime the asthma medication that they took during the day.

Subjects and the parents from both groups also signed an agreement that specified that each subject would receive weekly credits toward a monetary incentive (paid after the study) if they mailed the Weekly Asthma Record Form to the principal researcher in a timely manner. The specific terms of the agreement stayed in effect for the duration of the experiment.

**Relaxation Training Sessions**

The relaxation training sessions were conducted individually with the treatment group subjects within one week of the first methacholine challenge. After the principal researcher explained, modeled, and coached the relaxation exercises, subjects listened to the 10-minute audio cassette tape and performed the exercises. Frontalis EMG readings were recorded every 15-seconds for 5 minutes before and after relaxation training sessions to determine if the subjects had relaxed—operationally defined as a decrement in pre versus post mean EMG (microvolt) readings. Additional relaxation training sessions were scheduled until there a pre-post decrement in averaged EMG readings for each relaxation treatment group subject.
Relaxation Practice

The relaxation practice phase of the experiment was the 10-week period from the last relaxation training session to the last experimental session involving the second methacholine challenge. During this time period, subjects in the relaxation treatment group were instructed to: (a) practice their relaxation exercises twice each day, in the morning and in the evening; (b) record their peak expiratory flow rates on the Weekly Asthma Recording Sheets; and (c) record their asthma symptoms, and asthma medication usage on the Weekly Asthma Recording Sheets. Subjects in the control group were not given any instructions in addition to those previously given during baseline conditions. All subjects received a weekly credit towards a monetary incentive (payable at the end of the study) if they mailed the Weekly Asthma Record Form to the principal researcher in a timely manner.

Follow-up Methacholine Sensitivity Assessment Session

The final experimental session involved subjects from both the control and treatment groups undergoing the follow-up methacholine sensitivity assessment challenge. The same standard protocol that was used for the first methacholine challenge (described above) was used for the second methacholine challenge.
The principal researcher gave no special instructions to subjects in the no-treatment control group other than to follow the respiratory therapist's directions during the challenge procedure. The principal researcher recorded frontalis EMG levels of the control group subjects every 15-seconds during the following time periods: (a) 5-minutes before the challenge; (b) during the challenge; and (c) 5 minutes after the challenge.

The principal researcher instructed subjects in the treatment group to listen to the 10-minute relaxation exercise tape immediately before the second challenge while sitting in the pulmonary function hospital laboratory. Thereafter, subjects in the treatment group were instructed to follow the directions of the respiratory therapist during the challenge procedure. Subjects were also encouraged to perform the relaxation exercises whenever possible during the challenge procedure itself. The principal researcher recorded frontalis EMG levels of the treatment group subjects every 15-seconds for 5-minutes during the following periods: (a) before listening to the relaxation exercise audio tape; (b) while listening to the relaxation exercises; (c) after listening to the tape (immediately before the challenge); (d) during the challenge; and (e) 5-minutes after the challenge.
CHAPTER III

RESULTS

Study Overview

This experiment studied the acute and cumulative effects of relaxation exercises on young persons with moderate asthma. A methacholine inhalation challenge procedure was used to determine the effects of relaxation on airflow obstruction during an asthma episode. Peak expiratory flow rate readings were taken twice daily to determine if relaxation had prophylactic effects on asthma symptoms. Such effects might also be reflected in the reduced use of asthma medication.

Hypothesis One: Methacholine Sensitivity

Hypothesis one stated there would be differences in methacholine sensitivity between treatment group subjects who learned and practiced relaxation exercises and control group subjects who did not. It was predicted that treatment group subjects who practiced relaxation exercises for 10-weeks and then performed them before and during the post-methacholine sensitivity assessment would show greater methacholine tolerance during the second challenge than control group subjects.
With respect to this hypothesis, the results are based on 4 subjects in the treatment group and 5 subjects in the control group (instead of 7 subjects in each group) because 2 subjects were too asthmatic to start or complete the procedure on the day of the first challenge, as were 3 subjects on the day of the second challenge.

**Inter- and Intra-Group Comparisons of Methacholine Sensitivity**

Figure 1 shows the difference in airway sensitivity to methacholine between the relaxation treatment and no-treatment control groups. The unit of measure is the cumulative number of methacholine units required to reduce lung function by 20 percent. Higher numbers along the y-axis correspond with greater tolerance or decreased sensitivity. Lower numbers along the y-axis corresponds with lesser tolerance or increased sensitivity.

Inspection of Figure 1 reveals that treatment group subjects were more sensitive to methacholine than control group subjects--before the relaxation exercises training and 10-week practice period. However, the data analysis on which this figure is based indicates this difference did not achieve statistical significance ($t_{obtained} = 0.30 < t_{critical} = 2.37$; 2-tailed probability value = 0.771).

Inspection of Figure 1 also reveals that treatment group subjects who received relaxation exercise training and were instructed to practice these exercises for 10-weeks, and listened to a 10-minute relaxation exercise
Figure 1. The Mean Number of Cumulative Methacholine Breath Units Recorded During the Methacholine Sensitivity Assessment Sessions Which Were Conducted (1) Before Relaxation Training Instructions Were Given to the Relaxation Group Subjects and (2) After the 10-Week Period During Which the Relaxation Group Subjects Were Instructed to Practice the Relaxation Exercises.

NOTE: Although the Control Group Subjects Were Not Provided Relaxation Training (Until After the Study) PRE- and POST-MSAS Distinctions Were Made in This Figure, With Respect to the Control Group, Only to Allow for Inter-Group Comparisons Based on Similar Time Periods.
tape immediately before (and were instructed to do the exercises during) the second methacholine challenge, were more tolerant to methacholine than the control group subjects with no such history of training and practice. However, the data analysis on which this figure is based indicates that this difference did not achieve statistical significance ($t_{\text{obtained}} = 0.77 < t_{\text{critical}} = 2.37$; 2-tailed probability value = 0.466).

**Inter- and Intra-Subject Comparisons of Change in Methacholine Sensitivity**

Figure 2 shows how airway sensitivity to methacholine changed from the first to the second methacholine challenge for subjects from both groups who underwent both challenges. Increased methacholine tolerance is indicated when the white bar (coinciding with the second challenge) is higher than the dark bar (coinciding with the first challenge). Inspection of Figure 2 reveals that for the relaxation group, one subject (11R) became more tolerant, one subject became less tolerant (04R), and two subjects (10R and 13R) retained the same tolerance to methacholine. For the control group, one subject (06C) became more tolerant, two subjects (02C and 12C) became less tolerant, and two subjects (05C and 07C) retained the same tolerance to methacholine. Much of the change in group mean for the control group is attributable to a remarkable decrease in tolerance for subjects 02C and 12C.
INTER- AND INTRA-SUBJECT COMPARISON OF CHANGE IN METHACHOLINE SENSITIVITY

Figure 2. Subjects' Change in Methacholine Sensitivity.

NOTE: The Following Treatment and Control Group Subjects Are Matched Pairs: 10R and 02C; 11R and 06C; and 13R and 05C. Subject 04R's Matched Pair, 14C, Did Not Undergo Either of the Methacholine Challenges.
EMG-Activity Levels Before and After the Relaxation-Training Session

The testing of hypothesis one rests on the assumption that relaxation exercises have an effect on the treatment group's methacholine tolerance. The validity of the results rests on the notion that the treatment group subjects relaxed as a result of doing the relaxation exercises. Thus, it is important to be certain that the treatment group subjects achieved an acceptable level of relaxation. To this end, Figure 3 shows the difference in mean EMG-activity levels before and after the treatment group subjects' relaxation-training sessions. Subjects 01R and 10R underwent a second relaxation-training session because their first pre-post relaxation EMG-activity levels did not show a decrement. Inspection of Figure 3 reveals that despite relaxation training there were no large percentage decreases in EMG-activity level for any of the treatment group subjects. Also of note is the substantial variability in the mean EMG-activity levels for subject 01R from the first to the second relaxation-training session. Subject 11R, who had the lowest pre-relaxation training EMG-activity level also was the only treatment group subject who showed a decreased sensitivity to methacholine as revealed in Figure 2. No treatment group subject achieved a mean EMG-activity levels from 0.5 to 3.0 microvolts which is the range researchers have used as the criterion for being relaxed (Budzynski and Stoyva, 1969; and M. Edwards, personal communication, August 6, 1993).
Figure 3. The Mean EMG-Activity Levels Achieved by Treatment Group Subjects Before and After the Relaxation Training Sessions.
This section reflects a continuation of the attempt to evaluate the extent to which the treatment group subjects actually achieved an adequate level of relaxation prior to the final methacholine sensitivity assessment session. The results of this analysis will provide information about any practice effects (as a result of being instructed to practice the exercises twice daily for 10-weeks). To these ends, Figure 4 shows the difference in mean EMG-activity levels for treatment and control group subjects before, during, and after the post methacholine sensitivity assessment session.

Figure 4 also shows the treatment group subjects' mean EMG-activity levels before and during the relaxation exercises which they were instructed to do immediately before the methacholine assessment session. When comparing EMG-activity before (pre-relax) and after (relax) the relaxation exercises, inspection of Figure 4 reveals that 2 treatment group subjects (04R and 13R) did relax before the methacholine sensitivity assessment (if 3.0 microvolts is considered the criterion level for "being relaxed"). However, neither subject showed a desired decrease in methacholine sensitivity as revealed in Figure 2. Conversely, the one treatment group subject who did show a decrease in methacholine sensitivity, had EMG-activity levels which were higher after performing the relaxation exercises. Thus, there is no predictable relationship between EMG-activity levels,
REPEATED ASSESSMENTS OF EMG LEVELS DURING THE FOLLOW-UP METHACHOLINE SENSITIVITY ASSESSMENT SESSION (POST-MSAS)

<table>
<thead>
<tr>
<th></th>
<th>BEFORE RLX EXERCISES</th>
<th>DURING RLX EXERCISES</th>
<th>BEFORE POST-MSAS</th>
<th>DURING POST-MSAS</th>
<th>AFTER POST-MSAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUBJECTS' ID CODES</td>
<td>R-RELAXATION GROUP; C-CONTROL GROUP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 4. Follow-Up Assessment of EMG Activity Levels.

NOTE: EMG Activity Levels Were Assessed: (1) Before Treatment Group Subjects Were Instructed to Practice Relaxation Exercises Prior to the Post-MSAS [BEFORE RLX EXERCISES], (2) During the Relaxation Exercises Which the Treatment Group Subjects Were Instructed to Practice Prior to the Post-MSAS [DURING RLX EXERCISES] Treatment Group Subjects During Relaxation Exercises, (3) Immediately Before the Post-MSAS for the Control and Treatment Group Subjects (Which Was Also After the Treatment Group Subjects Finished Practicing the Relaxation Exercises) [BEFORE POST-MSAS], (4) During the Post-MSAS for the Control and Treatment Group Subjects [DURING POST-MSAS], and (5) After the Post-MSAS for the Control and Treatment Group Subjects [AFTER POST-MSAS].

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supposedly indicative of a state of relaxation, and outcome on the methacholine sensitivity assessment. In addition, there was no large percentage increase in EMG-activity level during the methacholine sensitivity assessment sessions for any of the subjects in either group.

Inspection of Figure 4 also reveals that the treatment group subjects’ EMG-activity levels were lower before, during, and after the second challenge (see Figure 4), as compared to their mean EMG-activity levels during the relaxation training sessions (see Figure 3).

**Treatment Group Subjects’ Spirometric Measures Before and After the Methacholine Sensitivity Assessment Sessions**

The data presented in this section represent the results of a retrospective attempt to find measures that could be used as predictors of treatment response. To this end, Tables 2 and 3 show the treatment group subjects’ spirometric measures before and after the two methacholine sensitivity assessment sessions. The spirometer is limited to measuring only those volumes that can be expelled from the lung. The following spirometric measures were used: FEV$_1$ and FEF$_{25-75}$. The FEV$_1$ is the volume of air forcefully expired during the first second after a full breath and normally comprises greater than 75% of the vital capacity which is the maximum volume of air that can be expired slowly and completely after a full inspiratory effort. The FEV$_1$ is the single best measure of
Table 2
Spirometric Measures Before & After the Pre-Relaxation Training Methacholine Sensitivity Assessment Session (MSAS)

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Percent Predicted FEV₁ Pre-MSAS</th>
<th>Percent Predicted FEV₁ Post-MSAS</th>
<th>Percent Predicted FEF₂₅-₇₅ Pre-MSAS</th>
<th>Percent Predicted FEF₂₅-₇₅ Post-MSAS</th>
<th>Methacholine Sensitivity Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>04R</td>
<td>111</td>
<td>98</td>
<td>95</td>
<td>71*</td>
<td>increased sensitivity</td>
</tr>
<tr>
<td>10R</td>
<td>81</td>
<td>69*</td>
<td>61*</td>
<td>42*</td>
<td>same sensitivity</td>
</tr>
<tr>
<td>11R</td>
<td>79*</td>
<td>66*</td>
<td>56*</td>
<td>33*</td>
<td>decreased sensitivity</td>
</tr>
<tr>
<td>13R</td>
<td>109</td>
<td>93</td>
<td>102</td>
<td>67*</td>
<td>same sensitivity</td>
</tr>
</tbody>
</table>

R = Relaxation Treatment Group
FEV₁ = Forced Expired Volume (liters) in 1-Second
FEF₂₅-₇₅ = Mean Forced Expiratory Flow During the Middle of Forced Vital Capacity
* = Outside Normal Range

Table 3
Spirometric Measures Before & After the Follow-up Methacholine Sensitivity Assessment Session

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Percent Predicted FEV₁ Pre-MSAS</th>
<th>Percent Predicted FEV₁ Post-MSAS</th>
<th>Percent Predicted FEF₂₅-₇₅ Pre-MSAS</th>
<th>Percent Predicted FEF₂₅-₇₅ Post-MSAS</th>
<th>Methacholine Sensitivity Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>04R</td>
<td>94</td>
<td>106</td>
<td>61*</td>
<td>96</td>
<td>increased sensitivity</td>
</tr>
<tr>
<td>10R</td>
<td>81</td>
<td>85</td>
<td>61*</td>
<td>72*</td>
<td>same sensitivity</td>
</tr>
<tr>
<td>11R</td>
<td>73*</td>
<td>81</td>
<td>42*</td>
<td>56*</td>
<td>decreased sensitivity</td>
</tr>
<tr>
<td>13R</td>
<td>111</td>
<td>110</td>
<td>94</td>
<td>100</td>
<td>same sensitivity</td>
</tr>
</tbody>
</table>

R = Relaxation Treatment Group
FEV₁ = Forced Expired Volume (liters) in 1-Second
FEF₂₅-₇₅ = Mean Forced Expiratory Flow During the Middle of Forced Vital Capacity
* = Outside Normal Range

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pulmonary function for assessing severity (NHLBI, 1991). The FEF_{25-75} is the mean forced expiratory flow during the middle of forced vital capacity; and, forced vital capacity is the volume of air that can be expired utilizing a maximal forceful expiration. The FEF_{25-75} is less effort-dependent than is the FEV₁ and is a more sensitive indicator of early airways obstruction (NHLBI, 1991).

Tables 2 and 3 also indicate treatment group subjects’ outcome with respect to the results of the methacholine sensitivity assessment sessions (Figure 2). Inspection of Tables 2 and 3, and Figure 2, reveals that the only treatment subject (11R) who had a decrease in methacholine sensitivity also had the lowest percent predicted spirometric measures.

**Summary**

The results of the data analysis on which Figure 1 is based indicate that although there were differences in methacholine sensitivity between treatment group subjects who learned and practiced relaxation exercises and control group subjects who did not, the observed differences did not achieve statistical significance. Thus, hypothesis one was not confirmed.

**Hypothesis Two: Daily Variability of PEF Rate**

Hypothesis two stated that there would be a difference in daily measures of airflow variability between treatment group subjects who
INTER-GROUP COMPARISON OF DAILY VARIABILITY IN MEAN PEAK EXPIRATORY FLOW (PEF) RATES

Figure 5. The Mean Daily Variability Percentage of Peak Expiratory Flow (PEF) Rate for Treatment and Control Group Subjects.

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INTER-GROUP COMPARISON OF THE INDICATOR THAT ASTHMA WAS WORSENING OVER TIME

Figure 6. The Number of Days the Mean Percent Daily Variability in Peak Expiratory Flow (PEF) Rate Exceeded 15 Percent for Treatment and Control Group Subjects.
learned and practiced relaxation exercises and control group subjects who did not. It was predicted treatment group subjects would show less day-to-day airflow variability during a 10-week period than control group subjects.

Figure 5 shows the difference in daily variability of peak expiratory flow (PEF) rate between the relaxation group and the control group. Higher numbers along the y-axis correspond with increased variability and increased sensitivity to stimuli that start asthma episodes. Inspection of Figure 5 reveals the mean percent daily variability was less for the relaxation group and higher for the control group. However, the data analysis on which this figure is based indicates this difference did not achieve statistical significance ($t_{\text{obtained}} = 1.5 < t_{\text{critical}} = 2.18$; 2-tailed $p$-value = 0.16).

Figure 6 shows the difference between the relaxation and control groups with respect to an indicator that asthma was getting worse for the 10-week period during which subjects in the treatment group were instructed to listen to the relaxation exercise tape twice daily. The indicator that asthma was getting worse was "any variation in peak expiratory flow rate greater than 15 percent" (NHLBI, June 1992, p. 20). Inspection of Figure 6 reveals that the mean number of days with daily variability above 15% was fewer for the relaxation group as compared to the control group. However, the data analysis on which this figure is based indicates that this difference did not achieve statistical significance ($t_{\text{obtained}} = 1.38 < t_{\text{critical}} = 2.18$; 2-tailed probability value = 0.194).
In summary, the results of the data analysis on which Figures 5 and 6 are based indicate that although the measures of day-to-day peak expiratory flow variability were lower for the treatment group than for the control group, the observed differences did not achieve statistical significance. Thus, hypothesis two was not confirmed.

**Hypothesis Three: Asthma Symptomatology**

Hypothesis three stated that there would be a difference in asthma symptom ratings between treatment group subjects who learned and practiced relaxation exercises and control group subjects who did not. Specifically, it was predicted that the treatment group subjects would report asthma symptoms of less severity than the control group subjects.

Figure 7 shows the difference in overall asthma symptom ratings between the relaxation group and the control group. The unit of measure is the average rating of symptom severity on a scale from 0 to 10, where 0 corresponded this no symptoms and 10 corresponded with the most severe case of the symptom. The data represent asthma symptom ratings recorded for the 10-week between the relaxation exercise training and the second methacholine challenge. Inspection of Figure 7 reveals low mean scores for all four types of asthma symptom ratings, i.e., all of the means were below a severity rating of "2". Inspection of Figure 7 also reveals that with respect to the mean number of ratings for the 10-weeks prior to the
Figure 7. The Overall Mean Asthma Symptom Ratings for the Treatment and Control Group Subjects.
second methacholine challenge, the treatment group had fewer wheeze and cough ratings, more activity restriction ratings, and more nighttime symptom ratings. Inspection of Figure 7 reveals that with respect to the number of ratings per week at or above "5" (this experiment's operational definition of an asthma episode), the treatment group had fewer wheeze ratings, the same number of cough ratings, more activity restriction ratings, more nighttime symptom ratings, and fewer combined asthma symptoms than the control group. However, the data analysis on which this figure is based indicates that the observed differences did not achieve statistical significance (For Wheeze, $t_{obtained} = -0.122 < t_{critical} = 2.18$, 2-tailed probability value = 0.905; For Cough, $t_{obtained} = -0.133 < t_{critical} = 2.18$, 2-tailed probability value = 0.896; For Activity Restrictions, $t_{obtained} = 0.274 < t_{critical} = 2.18$, 2-tailed prob value = 0.79; For Nighttime Asthma Symptoms, $t_{obtained} = 0.18 < t_{critical} = 2.18$, 2-tailed prob value = 0.101).

Figure 7 shows there were low mean scores for all four types of asthma symptom ratings by subjects in either group. This figure does not adequately reflect the fact that subjects in both groups occasionally reported more severe asthma symptoms--indicative of a moderate to severe asthma episode, defined in this experiment as a asthma symptom rating at or above 5. Figure 8 more adequately depicts the frequency with which subjects in both groups reported more severe asthma symptoms. Figure 8 shows the difference in the mean number of moderate-to-severe asthma 1
Figure 8. The Mean Number of Asthma Symptom Ratings Per Week at or Above a Severity Score of Five for Treatment and Control Group Subjects.
symptom ratings per week between both groups. The unit of measure is the number of ratings per week in the 5-to-10 range. The maximum weekly score is 7 and the minimum score per week is 0. Ratings from 5 to 10 are defined herein as a moderate to severe asthma.

Inspection of Figure 8 reveals that: (a) subjects in the relaxation group reported fewer moderate-to-severe wheezing episodes per week; (b) subjects in both groups reported the same mean number of moderate-to-severe coughing episodes per week; (c) subjects in the relaxation group reported more moderate-to-severe activity restrictions and nighttime asthma symptoms per week; and (d) subjects in the relaxation group reported more moderate-to-severe asthma symptoms of all types combined. However, the data analysis on which Figure 8 is based indicates that the observed differences did not achieve statistical significance (for wheeze, $t_{obtained} = 1 < t_{critical} = 2.18$, 2-tailed $p$-value = 0.3; for cough, $t_{obtained} = -0.1 < t_{critical} = 2.18$, 2-tailed $p$-value = 0.95; for activity restrictions, $t_{obtained} = 0.7 < t_{critical} = 2.18$, 2-tailed $p$-value = 0.5; for nighttime asthma symptoms, $t_{obtained} = 0.6 < t_{critical} = 2.18$, 2-tailed $p$-value = 0.6; and for all symptoms combined, $t_{obtained} = -0.1 < t_{critical} = 2.18$, 2-tailed $p$-value = 0.94).

In summary, the results of the data analysis, on which Figures 7 and 8 are based, show that although there were differences between the groups regarding to ratings of asthma symptoms, none of the observed differences achieved statistical significance. Thus, hypothesis three was not confirmed.
Hypothesis Four: Asthma Medication Use

Hypothesis four stated there would be a difference in medication use between subjects who learned and practiced relaxation exercises and subjects who did not. It was predicted that treatment group subjects would use fewer doses of asthma medication than control group subjects.

Figure 9 shows the differences in asthma medication use between the relaxation and control groups. The unit of measure is the number of doses per week for five types of asthma medication. The data represent asthma medication use recorded for 10-weeks after treatment group subjects were instructed to practice the relaxation exercises. Weekly means for each group and each medication type are shown.

Inspection of Figure 9 reveals that treatment group subjects used less inhaled corticosteroids (ICS), inhaled beta₂-agonists (IBA), and cromolyn (CRO) per week, and more oral methylxanthines (OMT) and anticholinergics (ANC) per week than control group subjects. The data analysis on which Figure 9 is based indicates these difference did not achieve statistical significance (for ICS, \( t_{\text{obtained}} = 0.3 < t_{\text{critical}} = 2.4; 2\text{-tailed p-value} = 0.8 \); for IBA, \( t_{\text{obtained}} = 0.3 < t_{\text{critical}} = 2.3; 2\text{-tailed p-value} = 0.8 \); for CRO, \( t_{\text{obtained}} = 0.3 < t_{\text{critical}} = 2.4; 2\text{-tailed p-value} = 0.9 \); for OMT, \( t_{\text{obtained}} = 0.3 < t_{\text{critical}} = 2.4; 2\text{-tailed p-value} = 0.8 \); for ANC, \( t_{\text{obtained}} = 0.3 < t_{\text{critical}} = 2.4; 2\text{-tailed p-value} = 0.8 \)). Thus, hypothesis four was not confirmed.
Figure 9. The Mean Number of Doses of Asthma Medication (Inhaled Corticosteroids [ICS], Inhaled Beta₂-Agonists [IBA], Cromolyn [CRO], Oral Methylxanthines [OMT], and Anticholinergics [ANC]) Taken Per Week by Treatment and Control Group Subjects.

NOTE: These Comparisons Are Based on the 10-Week Time Period During Which the Treatment Group Subjects Were Instructed to Practice Relaxation Exercises.
CHAPTER IV

DISCUSSION

Overview of the Current Experiment

This experiment reports the acute and cumulative effects of relaxation exercises on young persons with moderate asthma. The acute effects are defined as the effects of relaxation immediately before or during an asthma episode. The cumulative effects refer to the effects of relaxation between asthma episodes. A methacholine inhalation challenge procedure was used to determine the effects of relaxation on airflow obstruction during an asthma episode. Peak expiratory flow rate readings were taken twice daily for 10-weeks to measure daily variability and to determine if relaxation had prophylactic effects on reducing the incidence or severity of asthma. Self-report measures of asthma symptom severity and asthma medication were analyzed to determine if practicing relaxation exercises twice daily for 10-weeks reduces symptom severity or the need for asthma medication.

It was predicted that subjects who were taught relaxation exercises, instructed to practice these exercises for 10-weeks thereafter, and instructed to perform them before and during the post-training methacholine challenge, would show a greater tolerance to methacholine during the
second challenge than control group subjects who received no such training or instructions. It was also predicted that subjects would have lower daily PEF rate variability, fewer asthma symptoms, and reduced asthma medication use than control group subjects. Confirmation of these predictions would lend support to the contention that relaxation exercises have an preventative effect on asthma episodes in young persons.

Discussion of the Experimental Hypotheses

Hypothesis One: Methacholine Sensitivity

It was predicted that treatment group subjects who were taught relaxation exercises, instructed to practice these exercises for 10-weeks, and instructed to perform them before and during the post-training methacholine challenge, would show greater methacholine tolerance during the second challenge than the control group subjects. The results indicated that there was a comparable number of treatment and control group subjects whose methacholine tolerance increased, decreased, or stayed the same. Hypothesis one was not confirmed because the observed differences between the groups as a whole did not achieve statistical significance.

The non-confirmation of hypothesis one would seem to support the belief that relaxation does not directly affect pulmonary mechanics. This belief was originally suggested by Alexander, Cropp, and Chai (1979) who
studied the effects of a modified form of progressive relaxation training on pulmonary mechanics in severely asthmatic children, and found the effects to be consistently unremarkable (pp. 32-33). The current findings represent a minor expansion of their conclusion by adding that relaxation apparently has little or no beneficial effect on the pulmonary mechanics of young persons with "moderate" asthma. It may be premature, however, to say that there was no effect because the small sample size used in the current group study may have made it statistically impossible to detect an effect—even if one actually existed—especially if the size of the effect was small. The small sample size was further reduced because five subjects were too asthmatic to safely undergo the procedure on the scheduled day.

A criticism of group studies is that individual variation is often obscured by the averaging of the data. An inter-subject comparison of the four treatment group subjects revealed that only one subject (11R) showed an increase in methacholine tolerance. Even so, the absolute increase in tolerance was low in comparison with the other subjects in the treatment group. In addition, the increase in tolerance for subject 11R is similar in kind but less in degree to the increase in tolerance for the control group subject 6C (11R’s matched pair); and, both increases may simply reflect chance variation. Thus, the examination of the individual variation within the current data would seem to further support the belief that relaxation does not directly affect pulmonary mechanics.
Hypothesis Two: Daily Variability of PEF Rate

It was predicted that treatment group subjects, who were taught relaxation exercises and instructed to practice these exercises for 10-weeks thereafter, would have less daily PEF rate variability than control group subjects. The results reported herein indicated that in comparison to the control subjects, treatment subjects had lower daily PEF rate variability and fewer days where PEF rate worsened. Unfortunately, hypothesis two could not be confirmed, however, because the observed differences between the groups did not achieve statistical significance.

The non-confirmation of hypothesis two questions the strategy of using relaxation exercises to lower a person's overall arousal level in order to keep a person's asthma from getting worse over time. This strategy may only be effective with persons whose asthma is primarily related to emotional factors. Lehrer et al (1986) found that relaxation therapy has its greatest effect on asthma that is mediated by emotional factors. The current findings may have been due to treatment subjects having a type of asthma that is not primarily mediated by emotional factors. A replication study, with larger groups, may be warranted to elucidate the role of high scores on pre-training assessments of emotional behavior (laughing, crying, anger, over excitement, and anxiety), or self-reports of emotional triggers, as predictors of beneficial response to relaxation-based interventions.
Hypotheses Three and Four: Asthma Symptoms and Medication Use

With respect to hypothesis three, it was predicted that the treatment group subjects, who were taught relaxation exercises and instructed to practice these exercises for 10-weeks thereafter, would have fewer asthma symptoms than control group subjects. The results indicated that with respect to the number of ratings per week at or above "5", the treatment group had lower wheeze ratings, the same number of cough ratings, more activity restriction ratings, and more nighttime symptom ratings than the control group. The finding for "wheeze" was the only symptom where the observed difference was in the necessary direction to confirm hypothesis three. However, hypothesis three could not be confirmed because the observed differences failed to achieve statistical significance, and because of the inconsistent effects on symptoms.

These results are based on subjective ratings of asthma symptoms, the adequacy of which is a function of the subjects' accurate and consistent self-observation and self-recording (Creer, Kotses, and Wigal, 1992). Although parents assisted subjects with their ratings, a lack of sufficient symptom detection and reporting skills may have been a mitigating factor in this study with respect to the non-confirmation of hypothesis three.

With respect to hypothesis four, it was predicted that treatment group subjects would use fewer asthma medications than control group
subjects. The results indicated that with respect to the mean number of doses per week, the treatment group used less inhaled corticosteroid (ICS), inhaled beta\textsubscript{2}-agonists (IBA), and cromolyn (CRO), but more oral methylxanthines (OMT) and anticholinergics (ANC) than the control group. The findings for ICS, IBA and CRO were the only asthma medication types where the observed differences were in the necessary direction to confirm hypothesis four. However, hypothesis four could not be confirmed because these observed differences failed to achieve statistical significance.

Whereas the dependent measures related to hypothesis two assessed the general severity of asthma over time, the dependent measures related to hypotheses three and four provided a clinical index of the manner in which asthma changed over time. The observed differences may have failed to achieve statistical significance due to a variety of factors including the effect of a small sample size (discussed below in "limitations" section), the type of relaxation exercise actually used, the lack of any relationship between relaxation and indices related to pulmonary functioning, or controlling factors not related to the actual asthma symptoms.

Rejection of relaxation exercises would be premature at this time because previous research suggests that response to treatment may be a function of the type of relaxation used (Lehrer and Woolfolk, 1984). Lehrer et al (1986) suggested that cognitive relaxation components produce observable decreases in self-report of asthmatic symptoms. Because it is
not clear what relaxation technique is the most effective, the current study's relaxation exercises were comprised of several techniques—including cognitive relaxation components.

The level of relaxation achieved by a particular relaxation exercise is an important variable to study because although treatment subjects in this study were instructed to listen to and practice the relaxation exercises, it is unclear whether they used one subtype to the exclusion of another. It is possible that subjects did not use the more cognitively oriented (and more verbally sophisticated) relaxation techniques on the tape, and instead exclusively used the progressive muscle relaxation and/or diaphragmatic breathing techniques. One can speculate that they may have done so because the latter techniques are better defined with respect to task demands, and may produce more immediately noticeable effects with less effort.

The type of relaxation exercise employed may have an indirect effect on self-report of asthma medication use because reductions in self-reports of symptoms may lead to a concomitant reduction in the use of asthma medication—especially "PRN" medications. Thus, before relaxation can be rejected as a treatment adjunct, future research is needed to determine if different levels of relaxation achieved by particular relaxation exercises differentially effect direct and/or indirect pulmonary indices of asthma.
Limitations of the Current Experiment

Number of Subjects

The most serious limitation in this study is the small sample size. Every attempt was made to recruit as many subjects as possible, but due to various parental objections only 14 subjects could be recruited from the available subject pool. The resultant 7 subjects per group, although less than desirable, is fairly consistent with many of the published relaxation studies (Cluss, 1986). Further confounding the problem associated with small sample size, only 9 of the subjects completed both methacholine challenges as scheduled, due to unpredictable changes in subjects’ asthma and/or general health. Although not an excuse for a small sample size, subject attrition is common in this line of research (Lehrer et al., 1986).

The small sample size was dealt with by conducting an analysis based on intra-subject comparisons (Figure 2) in addition to inter-subject comparisons (Figure 1). Intra-subject comparisons proved to be useful in this study because they revealed how tolerance to methacholine changed for each of the treatment group subjects. This information was then used in combination with pre-training dependent measures to determine if there were any reasonable predictors of treatment response.

Still, the results of this study must be considered tentative until replicated using larger samples. A larger sample would increase the
probability of finding statistical evidence in support of relaxation's usefulness—given this effect does exist. However, the use of more subjects may only result in a proportional increase regarding the number of treatment group subjects whose methacholine tolerance either increased, decreased, or stayed the same. Furthermore, even with a larger groups, it is still necessary to look at responders and non-responders to relaxation as few interventions produce consistent effects across all subjects.

Level of Relaxation

Another limitation concerns the possibility that treatment group subjects may not have achieved a sufficient level of relaxation to effect changes in their pulmonary mechanics. This limitation is important because it would be premature to conclude that relaxation has no or minimal effects if there is a question about whether subjects relaxed. The treatment group as a whole had lower mean microvolt levels before, during, and after the second methacholine challenge than the control group; however, these observed differences failed to achieve statistical significance. Even if the differences achieved statistical significance, this may not have assured that the difference would have been clinically meaningful. That is, lower EMG activity may be necessary but insufficient to produce a treatment effect.

The insufficiency of the treatment group subjects' relaxation level is suggested by an intra-subject comparison of their mean microvolt levels
before, during, and after the second methacholine challenge (Figure 4). The analysis of the treatment subjects’ microvolt levels before the second challenge includes examining the mean microvolt levels before and during their performance of the relaxation exercises. The treatment subjects’ EMG-activity levels were lower before, during, and after the second challenge (see Figure 4), as compared to their mean EMG-activity levels during the relaxation training sessions (see Figure 3). Despite this desired decrease in EMG-activity, suggesting the achievement of more relaxed states, the mean EMG-activity level for the former periods (range from 3.3 microvolts to 3.68 microvolts) exceeded the EMG activity level (0.5 to 3.0) that has been used by researchers (Budzynski and Stoyva, 1969) and clinicians (M. Edwards, personal communication, August 6, 1993) as an indicator of being relaxed.

It is possible but unclear whether these targeted EMG levels would have been attained if the treatment group subjects had received more relaxation training sessions or had more time to perform the exercises. This uncertainty is due in part to the controversy surrounding the validity of using EMG activity as a dependent measure of general states of relaxation (Surwit and Keefe, 1978). There is also uncertainty as to whether more of the same type of relaxation training exercises would have produced clinically meaningful treatment effects, since this strategy has not necessarily been successful in the past (Cluss, 1986). Instead of more of the same relaxation training, a different type of relaxation training may be needed as
an alternative such as EMG-induced facial relaxation which purportedly produces a limited form of relaxation that has been associated with increases in measures of airflow (Kotses, Hindi-Alexander, and Creer, 1989).

Suggestions for Future Research

There are eight suggestions for future research which arise from the findings of the current experiment. First, because the small sample size in the current study makes it premature to say that relaxation exercises have no meaningful treatment effect the most obvious suggestion for future research is to replicate the study using more subjects. The next obvious question is, "How many subjects would be needed in another group study?" Howell (1992) suggests that a minimum of 50 total subjects (25 per group) would be needed to detect a large effect, 126 subjects total subjects would be needed to detect a medium effect, and 784 subjects total subjects would be needed to detect a small effect. These are very large numbers of subjects for any individual researcher to recruit--especially if one is attempting to recruit persons with specific characteristics and/or subtypes of asthma. These numbers suggest that a collaborative research project would be necessary, one that would require a great deal of inter-researcher coordination of time, materials, and financial resources.

Second, future researchers may have trouble recruiting sufficient numbers of subjects due to parents' fears of the intervention used in
relaxation-based studies. For example, the majority of the parents who declined to have their son or daughter participate in the current study did not object to the methacholine challenge procedure as one may have anticipated. Instead, they thought the use of a "self-help" tape recording promoted a secular attitude that one could deal with personal problems by oneself—in the absence of a belief in God.

Third, the use of single case experimental designs is one answer to the problem of small sample sizes. Two types of single case designs include the withdrawal design and the multiple baseline design. The multiple baseline design is considerably weaker than the withdrawal design as the controlling effects of the treatment on each of the target behavior is not directly demonstrated as in the A-B-A withdrawal design. However, the use of sequential withdrawal or reversal designs is inappropriate when treatment variables cannot be withdrawn or reversed due to the problem of carryover effects that is often the case when therapeutic instructions are given. Thus, the multiple baseline design may be the only appropriate design to use when evaluating the effects of relaxation exercises. The effects of relaxation would be inferred from the untreated behaviors of the other subjects as in a multiple baseline design across subjects.

The issue of sample size would still be relevant because a minimum number of baselines is needed to establish confidence in the controlling effects of an intervention. A set of replications across three to four
baselines is recommended to derive useful information. The discussion of future research has so far been about the use of different designs. The remaining part of this discussion regarding suggestions for future research considers different variables that would be instructive to investigate.

Fourth, future researchers who make distinctions between asthma subtype (Lehrer et al., 1986) should also think about distinguishing between levels of relaxation. The latter distinction would be based on the difference between "staying calm" and deep relaxation that produces the relaxation response (Weiner, 1987). Lehrer et al (1986) concluded that relaxation decreases large-airway but not small-airway asthma; but, they did not differentiate between relaxation levels. More research is needed to tell if different levels of relaxation would differentially affect persons with asthma of different severities. This type of research would require an objective measure to clearly distinguish between levels of relaxation.

Fifth, before investigating the efficacy of different levels of relaxation, basic information would be needed about relaxation levels (e.g., EMG-activity levels) in children and adolescents who do and do not have asthma. Normative EMG-activity data for children and adolescents (with and without asthma) is either not available, or at least has not been widely published or used in the relaxation-asthma literature. Because this normative data is lacking, it is not known whether the target EMG level (mentioned above) of 3 microvolts is relevant for all children. This information is essential if deep-
shallow relaxation distinctions are to be based on EMG-activity level. This line of research would help answer questions about whether young persons with different types of asthma have different and perhaps diagnostically-related overall levels of arousal.

Sixth, little is known, however, about arousal levels (measured via EMG) prior to, during, or after an asthma episode. Basic research is needed to determine whether severity of asthma symptoms correlate with levels of arousal during periods prior to an asthma episode. The EMG activity of different muscle groups could be routinely assessed during the day, and during the first signs of an asthma episode, using a self-contained muscle scanner (Cram, 1986). Although this type of descriptive study could not determine whether arousal level is the cause or effect of an asthma episode, the results could be used to make predictions about whether reducing a person's arousal level would reduce the effects of an asthma episode.

Seven, the observed decrease in tolerance to methacholine in the current study may have been due to an increased amount of airborne viruses/allergens as a result of seasonal changes. A year-round assessment of the effects of relaxation would be necessary in order to avoid methodological problems associated with seasonality.

Lastly, parent's anecdotal statements during the current study suggested that if parents can remain calm during their child's asthma episode, then children can handle the episode better, i.e., the duration and
the perceived severity is lessened. Involving parents in the monitoring or guiding of the relaxation exercises would not only help ensure that their children are performing the relaxation exercises, but would have the added benefit of giving parents something constructive to do during the asthma episode (thus keeping them calm). Future research is needed to determine how reports of family disruption and/or family member’s stress levels change as a result of parent guiding and/or monitoring relaxation exercises for their children.

Contributions of the Current Experiment

The findings of the current experiment have contributed the following to the asthma-and-relaxation literature. First, the methodological improvements made in the current study included: (a) the use of an appropriate control group (i.e., the use of a regular-care no-treatment asthma control group; (b) attention to age when assigning subjects to groups (i.e., not including both young persons and adults in a sample); and (c) attention to severity of asthma when assigning subjects to groups (i.e., using objective criteria based on airway sensitivity for matching the treatment and control groups).

Second, while the current study was not the first to use multiple measures of pulmonary mechanics (i.e., direct, indirect, or functional correlates), it is apparently the first to do so with a pediatric population at
or under the age of 14. Regardless of age, this study is apparently the first to use and report descriptive information on the daily variability of peak expiratory flow (PEF) rate to assess the effectiveness of relaxation exercises on a long-term basis. Prior to this study, PEF rate had been used either as (a) an outcome measure of momentary improvement in pulmonary functioning as a result of different behavioral interventions, or (b) a diagnostic tool to differentiate between children who don’t have asthma and children with asymptomatic (mild) asthma (Albertini, Politano, Bernard, Boutte, and Mariani, 1989). The use of daily variability of PEF rate represents an important addition to the asthma-and-relaxation literature because traditionally used self-report measures, such as incidence of asthma symptoms and medication use, are general indicators of asthma after or during the fact. This outcome measure provides information about imminent asthma episodes and should help researchers know when to start assessment or intervention techniques.

Lastly, this study provided additional information about the question, "Are the effects of relaxation beneficial during an asthma episode?" While not statistically significant, two important trends were observed in the data. The first trend was that subjects in the treatment group had lower daily PEF rate variability and fewer days where PEF rate worsened. The second trend was a reduction in specific asthma medications including inhaled corticosteroids (ICS), Cromolyn (CRO), and inhaled beta2-agonists (IBA).
The reduction in the use of IBA's is an important trend because several investigators have postulated that overuse of IBA may be partly responsible for the increase in asthma mortality (Kaliner, Martin, O’Byrne, and Wiedemann, 1992). The conclusions of the current study must be considered tentative until replicated. Additional research is needed to substantiate (as the just-described trends suggest) whether relaxation exercises help to reduce the incidence of severe asthma episodes as well as reliance on some asthma medications.

Conclusion

The purpose of the current experiment was to assess the abortive and prophylactic effects of relaxation in young persons with moderate asthma. The observed differences between the relaxation and control group failed to achieve statistical significance with respect to methacholine sensitivity, daily airflow variability, asthma symptom ratings, and asthma medication use. There were two trends in the data that suggest that relaxation exercises may reduce the incidence of severe asthma symptoms and may reduce the use of asthma medications especially inhaled beta2-agonists which has been implicated in the increase in asthma mortality.

Based on a strict statistical analysis it would appear that relaxation exercise training and practice are of questionable clinical utility either abortively or prophylactically. However, the observation of several
important trends suggest that further research is needed to determine how relaxation may best be used as an adjunct to standard asthma therapy.

These conclusions must be considered tentative until this study is replicated using a larger subject sample and/or using a multiple baseline across subjects single subject experimental design. The small sample size likely prevented treatment effects from being detected even if such effects actually existed. The "relaxation effect" if it exists is probably not large. Lehrer et al, (1986) suggested a number of reasons for why previously published asthma-relaxation studies reported inconsistent results including not considering the distinction asthma subtypes. Another reason for these inconsistent results, proposed here for the first time, is the fact that the distinction between level or depth of relaxation was not considered.

Future research is needed to better understand the specific conditions under which different levels of relaxation may be countertherapeutic for persons with different subtypes of asthma. Basic descriptive research studies are also needed to provide objective information about the arousal level (EMG-activity) of young persons with and without asthma that would be useful in making inter- and intra-individual comparisons and predictions about whether reducing a person's arousal level (using relaxation) would prevent asthma from getting worse over time or reduce the effects of an asthma episode.
Appendix A

Informed Consent
INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY (page 1 of 7)

"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Introduction

We are asking you and your child to participate in a research study. We want you to read this form carefully. Then consider giving your consent to be a volunteer, and to volunteer your child to participate in the study. Please ask as many questions as you like. We want to be sure that you understand the study and wish to participate. Robert Obrecht is the clinical psychology doctoral student in charge of the study.

The purpose of this research study is to figure out the effects of relaxation on asthma symptoms. This study involves two groups of children. Your child might be part of one group that will be taught a relaxation technique at the beginning of the study. Or, your child might be part of a second group that will be taught a relaxation technique after the study. No matter what group your child is in, we ask you to help your child fill-out daily asthma record forms. These forms will help measure the frequency, duration, severity, location of, and peak flow meter scores for any asthma attacks. We will ask that you and your child keep these record forms from May to August of 1992.

Background

Learning to relax is a useful technique for children with asthma. Stressful situations may start an asthma attack or may one worse once it begins. This doesn't mean that stress causes asthma or that it is an emotional problem. It only means that strong emotions can lead to hyperventilation, which can lead to asthma. It is important for children with asthma to know how to remain calm when breathing problems begin. When a child becomes panicky, breathing patterns often change. When people become nervous or excited, they begin to breathe quickly and shallowly. The chest muscles get tight, and breathing muscles don't work correctly. As a result, asthma often gets worse. Also, when a child is nervous and upset, s/he can't make good decisions. Probably most importantly, when children feel nervous, adults often feel nervous--especially when children are having trouble breathing.

It is also important that children learn to deal with pressure. When pressured to do something, children often have no ability to resist. They also can become upset when given them a rough time. For example, a child might be pressured to do some physical activity that he or she shouldn't because of asthma.

If the child is unable to deal with the emotional pressure, he or she might go ahead and participate in a stressful activity. It is important that children with asthma learn to stay calm, especially when they have to visit a doctor for medical treatment. This includes, also, getting allergy shots. The more frightened children become, the more negative they feel about themselves and their medical care. Children with asthma--like everybody else--need to be in tune with their body's reactions to avoid going beyond limits.
Background (Cont.)

Learning about "body signals" of stress will help a child know when to stop doing an activity that may be too stressful. We will teach your child a specific relaxation technique. This relaxation technique can be done at school and at home. We are hoping that your child can use this technique to relax when they have problems breathing. This study would help decide if there are any positive effects of relaxation on symptoms of asthma.

Qualifications

1. Your child will be under the medical supervision of the pediatric pulmonology investigator (DNH).
3. Be between the ages of 8 and 14.
4. Be of any race, or either sex.
5. Be willing to sign a behavioral contract stating she or he (the child) will be willing to practice relaxation twice daily, and record information related to asthma daily, weekly, and monthly.
6. Be within 10% of age-predicted FEV₁ spirometric readings.
7. If a child, he or she can understand and sign the assent form.
8. Both parents or legal guardians can understand and sign the consent form—only after their child understands and signs the assent form.
9. No use of oral corticosteroids one month before the start of this study.
10. No history of viral or other infectious process before the start of this study.
11. No physical condition that makes repeated tensing of muscle groups painful.

Screening of the Volunteers

All parents and children will attend an informed consent session. Children will have a physical examination. An asthma history will be obtained. Volunteers will take a breathing test. Dr. Homnick will decide if your child meets the above criteria for entry into the study.
INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY (page 3 of 7)

"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Study Plans

20 children with moderate asthma, and their parents, shall participate in the study from about May to August. The relaxation technique will be taught to 10 children at the beginning of the study. The relaxation technique will be taught to 10 other children after the study. Relaxation is a skill that requires practice before mastery. So, your child will be asked to sign a behavioral contract. The contract states that your child agrees to practice the relaxation technique everyday during the study.

Parents will help their child record asthma symptoms everyday. This involves taking 7 a.m. and 7 p.m. peak flow meter readings. A peak flow meter is a small, plastic device. It measures how well the lungs are working. Your child will be taught how to correctly blow into the peak flow meter. Parent(s)/legal guardian(s) will help fill-out questionnaires daily, weekly, and monthly. Both you and your child will be taught the correct method of recording asthma symptoms such as wheezing, coughing, daily activity level, how well she or he did overnight, and medication use. You and your child will answer questions about behaviors, feelings, and thoughts that may be related to your child’s asthma.

Your child will breathe in methacholine that will cause a mild asthma attack. Your child will go through 2 of these tests at different times during the study. Dr. Homnick will medically supervise this procedure. He is a physician who specializes in the field of children’s lung disorders. He will be helped by Teri L. Dennany who is a registered respiratory therapist.

We are using the drug methacholine to help figure out the effects of relaxation when an asthma attack is happening. Professionals who study the children’s lungs say that the drug methacholine is safe when physicians follow standard procedures. Dr. Homnick and Ms. Dennany will follow the standard procedures at Bronson Methodist Hospital.

First, a muscle tension test will be used to measure your child’s level of relaxation. Then, Dr. Homnick will have your child breathe in the methacholine. Your child will inhale carefully prepared doses of methacholine. These doses will be stopped when a twenty percent (20%) drop in lung functioning is reached. Most children do not experience wheezing or coughing until a forty percent (40%) drop in lung functioning is reached.

Dr. Homnick will look for four things to help prevent your child from having severe breathing problems. One, he will ensure that lung functioning does not drop below thirty-five percent. Two, he will listen to whether your child complains of breathing problems. Three, he will watch to see whether your child’s lung functioning has returned to pre-drug levels within 1 hour. Four, he will reverse the drug effects for any reason he thinks is necessary. Dr. Homnick will reverse the effects of methacholine by administering an airway dilator. The airway dilator will provide immediate relief of asthma symptoms.
Risks and Benefits

All subjects will receive standard care for their asthma under the medical care of Douglas Homnick, M.D. Dr. Homnick is a Pediatric Pulmonologist at MSU/KCMS. All participants will be cautioned to keep using prescribed medicines during the study. Progressive muscle relaxation should not, and will not be used, when medically contraindicated. There are usually no risks involved with the use of progressive muscle relaxation in normal healthy individuals. Progressive muscle relaxation may not be recommended for people who, for example, have spinal injuries or wear contact lenses. Persons with spinal injuries may find it difficult to tense and relax certain muscles. Contact lenses should be taken out because progressive muscle relaxation requires persons to close their eyes for about 30-minutes.

Researchers have found that the methacholine is safe when used under standardized and medically supervised conditions. Research has shown that a 20 percent drop in lung function, would appear to be rarely associated with significant symptoms. In rare instances, your child might experience any of the following symptoms: decreased blood pressure, variation from the normal rhythm of the heart beat, excess salivation, sweating, temporary redness of the face and neck, gastric-intestinal cramps, nausea, vomiting, urgent need to urinate, and feeling faint or fainting. Your child also may begin to feel panicky. If your child is experiencing significant symptoms of breathing difficulty then Dr. Homnick will give your child a drug (Atropine) to block these severe bodily symptoms.

Researchers have found that no one has ever had a severe drug reaction that required hospitalization. Most persons return to normal lung functioning within 5 minutes of using an airway dilator, and they return to normal lung functioning within 45 minutes even without using an dilator. There have been no reported delayed reactions to methacholine.

Other research has shown that in studying children around 10-years-old there were no adverse effects during or after the methacholine procedure. All children tolerated the methacholine procedure well. These children returned to normal lung functioning within 30 minutes. The attending physician did not have to do anything to help the return of regular lung functioning. Research also suggests that the methacholine procedure is safer and more reliable than other forms of airway challenge procedures. These other airway challenge procedures include exercise and antigen challenge. The methacholine airway challenge procedure has fewer risks of late onset and immediate severe reactions.

A benefit of the current research is that your child's level of compliance with asthma self-management procedures is likely to improve. Unintentional noncompliance may occur because a person does not understand asthma, or does not see the need for treatment. Your child's understanding of asthma may improve as a result of orientation meetings, training sessions, and debriefing discussions.
"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Risks and Benefits (Cont.)

Your child is most likely to comply if she or he feels involved, informed, and self-reliant. Also, your child is most likely to comply if parents/guardians are supportive. The current research requires each child and parent volunteer to be highly involved, informed, self-reliant, cooperative, and supportive.

The ability to relax is a beneficial skill for your child to learn. Children who can relax can concentrate on the steps that bring attacks under control. There is a greater chance that the attacks will intensify and be more difficult to manage if you cannot relax. This is because it is harder to attend to the skills necessary to bring an attack under control.

The current research study directly involves the following four specific methods that improve the use of asthma medications: (1) increase family supervision of self-medication and beginning a positive reward system; (2) an asthma record form will be used every day to record physical symptoms, medication use, and behavior changes; (3) monitoring patients by reviewing diaries, inhaler technique, medication bottles, and peak flow data; and (4) there are no expenses because peak flow meters may be kept without charge for further use under medical supervision, and progressive muscle relaxation training will be provided by the clinical psychology doctoral student at no charge. Lastly, a reduction in the frequency of asthma attacks is the primary expected benefit for your child.

Family Acknowledgement

"I had an opportunity to ask questions regarding this study. The investigators answered these questions to my satisfaction. I can ask more questions by contacting Mr. Obrecht (616) 345-9393, or Dr. Homnick at (616) 345-9393."

"In giving my consent, I understand that I/my child’s participation in this research study is voluntary, and that I may withdraw myself/him/her whenever I want without changing, penalizing, or jeopardizing my/my child’s current/future medical care, or relationship with any of the investigators, Michigan State University/Kalamazoo Center for Medical Studies, Bronson Methodist Hospital, or Western Michigan University. I also understand that the investigator in charge of this study (Robert Obrecht, M.A.), with my/my child’s welfare as a basis, may decide that I/he/she should no longer participate in this study."

"I authorize Mr. Obrecht to release the information obtained in this study to the medical science, psychological or respiratory therapy literature. I understand that I/my child will not be identified by name. A code number will be assigned to each participant and used to identify all information used for analysis in this research. I understand that all information obtained during this study will be held in the strictest of confidence."
INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY (page 6 of 7)

"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Family Acknowledgement (Cont.)

"I understand that two sets of files will be kept. One set of files will be for research purposes, and the other set of files will be kept for possible medical purposes. Within the research files will be names and matching code numbers, informed consent information, and all subject data from the research study. These research files will be kept in a locked file cabinet in Mr. Obrecht's office at Midtown Medical Center. An identical set of the research files will be kept in a locked file cabinet in Dr. Homnick's office. The contents of these files will never become part of the participant's medical record. Identifying names and matching code numbers will be destroyed after the study ends in September of 1992."

"Within the files kept for possible medical purposes there will be copies of each signed informed consent, and the results of the methacholine inhalation challenge that might have a diagnostic/medical benefit for the child participant. These medical-research files will be kept and secured at Bronson Hospital's Respiratory Care Unit, in a locked file cabinet separate from patient records. These medical-research files will be treated with the same security as any medical file at Bronson Hospital. These medical-research files will be destroyed seven years after the completion of this research study (September of 1999)."

"Additionally, I understand that the Food and Drug Administration (FDA) may inspect Bronson's Methodist Hospital's medical-research files. I understand that the FDA may wish to interview me regarding my/my child's participation in this study."

"If physical injury or illness results because of the research procedures, Bronson Methodist Hospital, Michigan State University/Kalamazoo Center for Medical Studies, Western Michigan University, Robert Obrecht, M.A., Douglas N. Homnick, M.D., Teri L. Dennany, R.R.T., R. Wayne Fuqua, Ph.D., and/or Helen Pratt, Ph.D. will provide or arrange to provide for all necessary medical care to help me/my child recover. But, they do not commit themselves to pay for such care, or to provide any additional compensation."

"I also understand that neither Bronson Methodist Hospital, Michigan State University/Kalamazoo Center for Medical Studies, Western Michigan University, Robert E. Obrecht, M.A., Douglas N. Homnick, M.D., Teri L. Dennany, R.R.T., R. Wayne Fuqua, Ph.D., nor Helen D. Pratt, Ph.D., agree to bear the expense or medical care for any new illness or complications that may develop during my/my child's participation in this study, but are not a result of the research procedures."

"If I have further questions or concerns regarding my/my child's participation in this study, I may direct them to Robert Obrecht, M.A. at (616) 345-9393, or Douglas Homnick, M.D., at (616) 345-9393. If I have questions about research subjects' rights, I may call Gregg A. Baxter, Patient Advocate, at (616) 385-6882."
Informed Consent for Participation in a Research Study (page 7 of 7)

"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Family Acknowledgement (Cont.)

"I acknowledge that I have read and understand the above information." "I agree to allow myself/my child to participate in this study." I have received a copy of this document for my records."

"I understand that if either parent/guardian is unavailable to give their consent, I may still enroll my child in this research study by providing evidence in the form of legal custodial documents or birth records to the effect that I am the sole custodial parent or guardian. I may request assistance from the investigators to obtain copies of these documents. I understand that information about custodial arrangements or parentage will be held in the strictest confidence."

Signature of Legal Guardian/Parent __________________________ Date and Time __________________________

Signature of Legal Guardian/Parent __________________________ Date and Time __________________________

If only one parent/guardian signature is affixed above, the below signed witness verifies that proof of sole legal custody or parentage was presented by the above signed person.

Signature of Witness __________________________ Date and Time __________________________

If minor is older than 5 years, was assent obtained after parental consent was obtained? Yes____ No____

Signature of Participant (Child) __________________________ Date and Time __________________________

"The principal investigator adequately explained the information in this Participant Consent Form to the legal guardian(s)/parent(s)."

Signature of Witness __________________________ Date and Time __________________________

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Appendix B

Informed Assent
INFORMED ASSENT FOR PARTICIPATION IN A RESEARCH STUDY (page 1 of 1)

"The Effects of Progressive Muscle Relaxation on Children with Moderate Asthma"

Investigators: Robert E. Obrecht, M.A., R. Wayne Fuqua, Ph.D., Helen D. Pratt, Ph.D., Teri L. Dennany, R.R.T., and Douglas N. Homnick, M.D.

Informed Assent for Minor Participants Older than Five (5) Years of Age

"This research study will be looking at whether relaxation helps children to deal with their asthma better. I understand I must practice a relaxation exercise twice a day for about three months. I also understand that I must use a peak flow meter at 7 am and at 7 pm. The peak flow meters measure how my lungs are working."

"I understand that to be in this study I will be given a special lung test at Bronson Methodist Hospital. I must breathe in a chemical that is safe if used correctly. I understand that Dr. Homnick will be at Bronson Hospital. He will make sure that I am given the drug methacholine correctly. Dr. Homnick also will be at the hospital to help me if I have problems breathing."

"I understand that I must keep on taking my regular asthma medication." "Also, I must fill-out certain forms on a daily and weekly basis."

"I understand that if I wish to stop participating/volunteering in this study I can do so. I also understand that if I have any questions about this research study I can call Robert Obrecht at (616) 345-9393. I also can call Dr. Homnick at (616) 345-9393."

______________________________  ______________________________
Signature or Printed Name of Date and Time
Participant(Child)

"I have witnessed that the principal investigator adequately explained this Informed Assent Form to the child participant who is a minor older than five (5) years of age."

______________________________  ______________________________
Signature of Witness Date and Time
Appendix C

Compliance With Human Subjects Institutional Review Boards
Date: May 6, 1992
To: Robert E. Obrecht
From: Mary Anne Bunda, Chair
Re: HSIRB Project Number 92-03-18

This letter will serve as confirmation that your research protocol, "The acute and Chronic effects of progressive muscle relaxation on children with moderate bronchial hyper-responsiveness (ASTMHA)" has been approved after full review by the HSIRB. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the approval application.

You must seek reapproval for any change in this design. You must also seek reapproval if the project extends beyond the termination date.

The Board wishes you success in the pursuit of your research goals.

xc: Fuqua, Psychology

Approval Termination: May 6, 1993

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INTEROFFICE MEMO
The Upjohn Company

Subject: APPROVED BCIU/JASPER AND BMH PROTOCOLS

Date: April 13, 1992

From: B. L. Al-Khamis
Protocol Coordinator

To: LIST

<table>
<thead>
<tr>
<th>LIST:</th>
<th>BMH700</th>
<th>BMH722</th>
<th>BC953</th>
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<tr>
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<td>AVThompson</td>
<td>REObrecht</td>
<td>AIDietz</td>
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<tr>
<td></td>
<td>BMH722</td>
<td>DNHomnick</td>
<td>GRPeters</td>
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<tr>
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<td>BC959</td>
<td>REObrecht</td>
<td>EShay</td>
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<tr>
<td>LIST:</td>
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</tr>
<tr>
<td></td>
<td>GRPeters</td>
<td>BMH722</td>
<td>BMH722</td>
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<td></td>
<td>DHBatts</td>
<td>JSMohrland</td>
<td>MDCharlton</td>
</tr>
<tr>
<td></td>
<td>BGPeel</td>
<td>FTMurray</td>
<td>CRSpillers</td>
</tr>
<tr>
<td></td>
<td>CRKanover</td>
<td>GHDunn</td>
<td>DFBohan</td>
</tr>
</tbody>
</table>

For Info: KGNeel

Attached is the statement of approval letter signed by Robert H. Hume, M.D., Chairman of the Bronson Methodist Hospital Human Use Committee for your respective protocols.

After these final corrections have been made please send me one corrected copy of the final protocol and informed consent document. The corrected copy should have the signature of all investigators and/or monitors on the face sheet of the protocol along with the date. These corrections must be made prior to the implementation of the study.

On all protocols that involve an investigational drug under an IND, please forward me one copy of the signed 1572 form.

Should you have any questions please do not hesitate to contact me at 384-9448. Thank you.

b attachment
BMH792 The Effects of Progressive Muscle Relaxation on Children and Adolescents with Moderate Asthma (REObrecht/DNHomnick)

At the April 9, 1992 Meeting of the Bronson Methodist Hospital Human Use Committee, BMH792 and the informed consent were approved with the following changes:

1. In the consent form simplify the language to an 8th grade reading level.
2. In the consent form include the risks associated with the methacholine challenge.
3. In the consent form clarify that the progressive muscle relaxation should not be used where medically contraindicated.
4. In the consent form under Family Acknowledgement. Include the following after the last paragraph before the signature lines: "I agree that if I am the sole custodial parent or guardian I will provide evidence in the form of legal custodial documents prior to my child being enrolled in this research study."
5. The BMH Human Use Committee determined the continuing review interval for this study to be set at 12 months.
6. Before this protocol can be implemented i.e., prior to a drug being given or a procedure undertaken, all changes must be made and a corrected signed copy of the protocol and informed consent filed with the BMH Human Use Committee Chairman (or designee). The clinical investigator is required to receive approval from the BMH Human Use Committee prior to initiating any changes in approved research during the period for which BMH Human Use Committee approval has been given. Douglas N. Homnick, M.D. attended this meeting and has agreed to the above changes and procedures.

Robert H. Hume, M.D., Chairman
Bronson Methodist Hospital
Human Use Committee
252 East Lovell Street
Kalamazoo, MI 49007
(616) 341-7988

cc: REObrecht
DNHomnick

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### Classification of Asthma by Severity of Disease

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Pretreatment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of exacerbations</td>
<td>Exacerbations of cough and wheezing no more often than 1-2 times/week.</td>
<td>Exacerbation of cough and wheezing on a more frequent basis than 1-2 times/week. Could have history of severe exacerbations, but infrequent. Urgent care treatment in hospital emergency department or doctor’s office &lt; 3 times/year.</td>
<td>Virtually daily wheezing. Exacerbations frequent, often severe. Tendency to have sudden severe exacerbations. Urgent visits to hospital emergency departments or doctor’s office &gt; 3 times/year. Hospitalization &gt; 2 times/year, perhaps with respiratory insufficiency or, rarely, respiratory failure and history of intubation. May have had cough syncope or hypoxic seizures.</td>
</tr>
<tr>
<td>Frequency of symptoms</td>
<td>Few clinical signs or symptoms of asthma between exacerbations.</td>
<td>Cough and low-grade wheezing between acute exacerbations often present.</td>
<td>Continuous albeit low-grade cough and wheezing almost always present.</td>
</tr>
<tr>
<td>Degree of exercise tolerance</td>
<td>Good exercise tolerance but may not tolerate vigorous exercise, especially prolonged running.</td>
<td>Exercise tolerance diminished.</td>
<td>Very poor exercise tolerance with marked limitation of activity.</td>
</tr>
<tr>
<td>Frequency of nocturnal asthma</td>
<td>Symptoms of nocturnal asthma occur no more often than 1-2 times/month.</td>
<td>Symptoms of nocturnal asthma present 1-3 times/week.</td>
<td>Considerable, almost nightly sleep interruption due to asthma. Chest tight in early morning.</td>
</tr>
<tr>
<td>School or work attendance</td>
<td>Good school or work attendance.</td>
<td>School or work attendance may be affected.</td>
<td>Poor school or work attendance.</td>
</tr>
<tr>
<td>Pulmonary function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Peak Expiratory Flow Rate (PEFR)</td>
<td>PEFR &gt; 80% predicted. Variability** &lt; 20%.</td>
<td>PEFR 60-80% predicted. Variability 20-30%.</td>
<td>PEFR &lt; 60% predicted. Variability &gt; 30%.</td>
</tr>
<tr>
<td>• Spirometry</td>
<td>Minimal or no evidence of airway obstruction on spirometry. Normal expiratory flow volume curve; lung volumes not increased. Usually a &gt;15% response to acute aerosol bronchodilator administration, even though baseline near normal.</td>
<td>Signs of airway obstruction on spirometry are evident. Flow volume curve shows reduced expiratory flow at low lung volumes. Lung volumes often increased. Usually a &gt;15% response to acute aerosol bronchodilator administration.</td>
<td>Substantial degree of airway obstruction on spirometry. Flow volume curve shows marked concavity. Spirometry may not be normalized even with high dose steroids. May have substantial increase in lung volumes and marked unevenness of ventilation. Incomplete reversibility to acute aerosol bronchodilator administration.</td>
</tr>
<tr>
<td>• Methacholine sensitivity</td>
<td>Methacholine PC_{20} &gt; 20 mg/mL***</td>
<td>Methacholine PC_{20} between 2 and 20 mg/mL.</td>
<td>Methacholine PC_{20} &lt; 2 mg/mL.</td>
</tr>
<tr>
<td><strong>B. After optimal treatment is established</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response to and duration of therapy</td>
<td>Exacerbations respond to bronchodilators without the use of systemic corticosteroids in 12-24 hours. Regular drug therapy not usually required except for short periods of time.</td>
<td>Periodic use of bronchodilators required during exacerbations for a week or more. Systemic steroids also usually required for exacerbations. Continuous around-the-clock drug therapy required. Regular use of anti-inflammatory agents may be required for prolonged periods of time.</td>
<td>Requires continuous, multiple around-the-clock drug therapy including daily corticosteroids, either aerosol or systemic, often in high doses.</td>
</tr>
</tbody>
</table>

*Characteristics are general, because asthma is highly variable, these characteristics may vary. Furthermore, an individual may switch into different categories over time.

**Variability means the difference either between a morning and evening measure or among morning peak flow measurements each day for a week.

***While the degree of methacholine/ballamine sensitivity generally correlates with severity of symptoms and medication requirements, there are exceptions. See Chapter 2, Objective Measures of Lung Function, Section C. Bronchoprovocation.

Appendix E

Behavioral Contract
BEHAVIORAL CONTRACT

I _________________________________________________
AGREE TO PRACTICE RELAXATION TWICE A DAY
(AROUND 7:00 A.M. AND AROUND 7:00 P.M.).

IF THIS TASK IS COMPLETED, THE FOLLOWING WILL HAPPEN:

_____________________________________________________

IF THIS TASK IS NOT COMPLETED THE FOLLOWING WILL HAPPEN:

_____________________________________________________

SIGNATURE OF PARTICIPANT ____________________________ DATE ___________

SIGNATURE OF PRIMARY INVESTIGATOR __________________ DATE ___________

SIGNATURE OF WITNESS/Parent __________________________ DATE ___________
Appendix F

Weekly Asthma Record Form
WEEKNLY ASTHMA RECORD FORM

THE WEEK OF: [ ]
CODE NUMBER: [ ]

NOTE: Place name, and/or Robert Ormond, in stamped addressed envelope, and begin next Weekly Asthma Record Form

<table>
<thead>
<tr>
<th>MONDAY PEAK FLOWS</th>
<th>WEDNESDAY PEAK FLOWS</th>
<th>FRIDAY PEAK FLOWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Peak Flow</td>
<td>2nd Peak Flow</td>
<td>3rd Peak Flow</td>
</tr>
<tr>
<td></td>
<td>1st Peak Flow</td>
<td>2nd Peak Flow</td>
</tr>
<tr>
<td></td>
<td>1st Peak Flow</td>
<td>2nd Peak Flow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>THURSDAY PEAK FLOWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Peak Flow</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SATURDAY PEAK FLOWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Peak Flow</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SUNDAY PEAK FLOWS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Peak Flow</td>
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</tbody>
</table>

REFLEXION DISTURBANCE

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<tr>
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<th>WEDNESDAY</th>
<th>FRIDAY</th>
</tr>
</thead>
<tbody>
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<table>
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<th>JULY</th>
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MEDICATION

<table>
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<th>DOSE</th>
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<td></td>
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WHEEZING SCALE

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<tr>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>none</td>
<td>moderate</td>
<td>a lot</td>
<td>severe</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

COUGHING SCALE

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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>a few</td>
<td>many times</td>
<td>a lot</td>
<td>can't stop</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

ACTIVITY RESTRICTIONS SCALE

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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>scales, no restrictions</td>
<td>can sustain limited activity</td>
<td>can walk only</td>
<td>missed school; reduced activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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NIGHT TIME BREATHING PROBLEMS SCALE

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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>sleep well, a bit wheezy</td>
<td>sleep 3-5 times, with wheezing</td>
<td>had short, wake most of the night</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

RELAXATION SCALE

<table>
<thead>
<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>very relaxed</td>
<td>relaxed</td>
<td>relaxed, but a bit tense</td>
<td>tense</td>
<td>very tense</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Appendix G

Determination of Methacholine Units

110
### Determination of Methacholine Units (Roche Laboratories, 1987)

<table>
<thead>
<tr>
<th>Serial Concentration</th>
<th>Number of Breaths</th>
<th>Cumulative Units per Concentration</th>
<th>Total Cumulative Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.025 mg/mL</td>
<td>5</td>
<td>0.025</td>
<td>0.025</td>
</tr>
<tr>
<td>0.25 mg/mL</td>
<td>5</td>
<td>0.25</td>
<td>0.25</td>
</tr>
<tr>
<td>2.5 mg/mL</td>
<td>5</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>10.0 mg/mL</td>
<td>5</td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>25.0 mg/mL</td>
<td>5</td>
<td>25.0</td>
<td>25.0</td>
</tr>
</tbody>
</table>
Appendix H

Relaxation Exercises for Young Persons With Moderate Asthma
Relaxation Exercises for Young Persons With Moderate Asthma

Think of a number from 0 to 10. Very relaxed is 0. Very tense is 10. Which number matches how relaxed you feel now? Print this number in the right box on the Weekly Asthma Record Form. Save room for another number later.

Sit back in a comfortable chair. You may feel more comfortable if you don’t cross your arms or legs. If you feel comfortable doing so close your eyes and let them relax. Listen to my voice and ignore other noises you hear.

Put your hand above your belly button so you can feel yourself breathing. Think of your belly as a container for air. Your hand will feel the container move up and down as you breathe. Inhale through your nose, and slowly fill the bottom of the container first. Keep filling the container until your belly feels puffed out like a balloon. Exhale through your mouth slowly. Empty the container and make your belly flat before inhaling again. Keep belly-breathing as you listen to my voice. As you inhale, think "I am." As you exhale, think "relaxed." Inhale and think "I am." Exhale and think "relaxed." Think "I am," when you inhale. Think "relaxed" when you exhale.

Now, scrunch up your face. Squeeze your eyes shut, grit your teeth, and wrinkle your nose. Keep scrunching. Feel how tight your face muscles are. Now let your face muscles relax all at once. Think "I am" when you inhale. Think "relaxed" when you exhale. Let your face muscles relax more fully each time you exhale.

Now shrug your shoulders as high as you can. Keep shrugging and feel how tense your muscles are. Now, let your shoulder muscles relax all at once. Think "I am" when you inhale. Think "relaxed" when you exhale. Let your shoulders relax more fully each time you exhale.

Now hold your arms out straight, and make your elbows and your fists as stiff as you can. Keep holding them out and feel how tense your muscles are. Now let your arm and hand muscles relax all at once. Think "I am" when you inhale. Think "relaxed" when you exhale. Let your arms and hands relax more fully each time you exhale.

Now hold your legs and feet up and make them tense all the way down to your toes. Keep holding them tight and feel how tense your muscles are. Now let your leg and feet muscles relax all at once. Think "I am" when you inhale. Think "relaxed" when you exhale. Let your legs and feet relax more fully each time you exhale.
Relaxation Exercises for Young Persons With Moderate Asthma

Now, let your body be like a floppy rag doll. Each time you exhale let your muscles get more loose and floppy. Think about your muscles to make sure each is relaxed. Imagine someone lifting up your legs and feet, and then letting them down gently until they flop on the floor. Imagine someone lifting up your arms and hands and then letting them down gently until they flop to your sides. Imagine your neck and shoulders rolling gently around. Imagine your head becoming as light as a feather.

Begin to think about the most relaxing place you’ve ever been. Think about how you felt when you were there. Listen to the noises, smell the air, feel the temperature. Belly breathe soft and easy. Let yourself relax more and more. Enjoy your relaxing place as more tension leaves your body each time you exhale.

Now, think about when breathing gets difficult for you. Say to yourself, "I can handle my asthma because I can relax." Relaxing helps me breathe easier, and helps my medicine work better. When breathing becomes difficult for you, say to yourself, "I can handle this because I can relax." Then belly breathe at least 5 times. Think "I am" when you inhale. Think "relaxed" when you exhale. Tighten and relax your muscles. Remember when you can’t hold them tight any longer, let them relax all at once. And imagine your body as loose and relaxed as a floppy rag doll. Remember to say to yourself, "I can handle my asthma, because I can relax."

Think about how relaxed you feel now. Think of a number between 0 and 10. Very relaxed is zero. Very tense is ten. Which number from 0 to 10 matches how relaxed you feel now? Don’t write anything down now, just remember your number. I am going to count from 1 to 5. When I get to 5, this relaxation exercise will be done.

1: You’ll relax deeper and faster each time you practice.
2: Now become aware of everything around you.
3: Move around and stretch, and get ready to open your eyes.
4: Inhale deeply, and as you exhale, let your eyelids open.
5: You’re wide awake. Now, write down your relaxation number on the Weekly Asthma Record Form below the number you wrote earlier. Now rewind your tape and you will be ready for your next relaxation exercise.
Appendix I

Bronson Methodist Hospital’s Methacholine Inhalation Challenge Protocol
Bronson Methodist Hospital's Methacholine Inhalation Challenge Protocol

1. Three baseline spirograms for FEV₁ will be done initially. The two best FEV₁'s are averaged.

2. Five inhalations of buffered diluent are administered and FEV₁ measured 10 minutes later.

3. If post diluent FEV₁ has not decreased by more than 10%, then the subject can proceed to further inhalation challenges. The post diluent FEV₁ is recorded.

4. If greater than 10% fall occurs with diluent, then repeat FEV₁. If the greater than 10% drop is sustained, then give two puffs of Isuprel and repeat FEV₁ in 3 minutes. If FEV₁ has not returned to within 10% of the baseline, then notify physician monitoring the test.

5. If the 10% drop in FEV₁ is not sustained, then the highest FEV₁ is recorded and testing proceeds.

6. Five inhalations from FRC of each serial dilution of Methacholine is administered. B.P. and pulse are recorded. Three minutes after each inhalation an FEV₁ is recorded. If FEV₁ does not decline by more than 15% from the baseline, the next dilution is administered.

7. If the FEV₁ decline is borderline (i.e. 15-20%) from baseline, then three inhalations of the next dilution is given.

8. When the FEV₁ declines by 20% from baseline, the FEV₁ should be repeated to confirm the drop.

9. Testing procedure is terminated when FEV₁ declines 20% from baseline.

10. Testing is also terminated if:
   A. Pulse becomes irregular
   B. Bradycardia (i.e. less than 60) develops
   C. B.P. falls by 15 mm/Hg or more
   D. Obvious significant wheezing occurs

11. After the last dilution is given, the patient takes two puffs from an Isuprel inhaler and an FEV₁ is repeated in 3 minutes.
Bronson Methodist Hospital's Methacholine Inhalation Challenge Protocol

12. The physician monitoring the study should be notified at end of testing.

13. It is possible, although unlikely, that the patient may experience systemic side effects. Side effects that may result in terminating the testing are:

   A. Decreased B.P.
   B. Arrhythmias
   C. Excess salivation
   D. Sweating
   E. Flushing
   F. G.I. cramps, nausea, vomiting
   G. Urinary urgency
   H. Syncope

Systemic effects are blocked by Atropine 1.0 mg. I.M. or I.V. but should be used only to reverse severe symptoms.

CONTRAINDICATIONS

1. Currently having asthmatic symptoms.
2. Hyperthyroidism.
3. Hypertension, i.e., B.P. 140/90 mm/Hg.
4. Taking antihypertensive medications other than diuretics.
5. Cardiac arrhythmias or taking antiarrhythmic drugs.
6. Peptic ulcer disease (recent symptoms).
7. Cerebrovascular disease, i.e. TIA's, CVA.
8. Diabetes.
9. Pregnancy or lactation.
10. FEV₁ less than 75% predicted or FEV₁ less than 1.5 liters.

POSTPONE STUDIES

1. Current acute URI or within the preceding 3 weeks.
2. Currently taking anticholinergics, B antagonists, Theophyllines, Cromolyn or antihistamines. Studies may be done after holding medications for 24 hours if the FEV₁ is still adequate.
## Bronson Methodist Hospital's Methacholine Inhalation Challenge Protocol

### Data Recording Sheet

<table>
<thead>
<tr>
<th>CL Concentration</th>
<th>B.P.</th>
<th>Pulse</th>
<th>FEV-1 % Baseline</th>
<th>FVC % baseline</th>
<th>Cumul. Dosage</th>
<th>Total Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diluent</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>0.025 mg/mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.125</td>
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</tr>
<tr>
<td>0.25 mg/mL</td>
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<td></td>
<td></td>
<td></td>
<td>1.25</td>
<td>1.375</td>
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<tr>
<td>2.5 mg/mL</td>
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<td>12.5</td>
<td>13.88</td>
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<tr>
<td>10.0 mg/mL</td>
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<td></td>
<td></td>
<td></td>
<td>50.0</td>
<td>63.88</td>
</tr>
<tr>
<td>25.0 mg/mL</td>
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<td></td>
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<td>125.0</td>
<td>188.88</td>
</tr>
</tbody>
</table>

**NOTES:**

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Rackemann, F. (1918). A clinical study of one hundred and fifty cases of bronchial asthma. Archives of Internal Medicine, 22, 522.


