

EFFICACY OF SELF-REGULATORY STRATEGIES IN TREATING ANXIETY

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## ABSTRACT

This research project attempts to assess the clinical efficacy of self-regulatory strategies in treating anxiety. Subjects will be drawn from the medical clinic division of the psychiatry outpatient clinic at the V.A. Hospital. These subjects, on anti-anxiety medication, will be randomly assigned to one of four self-regulatory treatment groups: transcendental meditation; Zen meditation, biofeedback, progressive relaxation and a no-contact control group. The treatment groups will be led by nationally recognized experts in each of the respective self-regulatory technique. Dependent variables will include subjective pre-post tests (Speigelberg trait state inventory; Taylor Manifest Anxiety Scale Fear Survey Schedule; Rotter Internal External locus of control scale); physiological measures (Gsr repeated measures, heartrate); and patient voluntary reduction in anti-anxiety drugs. Treatment will last three months. There will be a three month and six month follow-up. The results of this study will help determine 1) the treatment of choice between different self-regulatory strategies; 2) the advisability and feasibility of non-pharmacological alternatives for relieving anxiety, and stress and tension.

# EFFICACY OF SELF-REGULATORY STRATEGIES IN TREATING ANXIETY

## INTRODUCTION

### OBJECTIVES

In the past ten years, there has been a great deal of theoretical interest in a variety of self-regulation strategies. There have been claims that these strategies, which include biofeedback, meditation, progressive relaxation, have great psychotherapeutic potential in several different areas: e.g., dealing with health problems such as drug and alcohol abuse; hypertension; stress and tension management.

Many of these techniques are now being widely used in clinical practice. However, the clinician, faced with the vast array of different self-regulation strategies, has no clear research literature to help him or her in determining the treatment of choice for various clinical problems. This research program is designed to assess the relative efficacy of different self-regulatory strategies in treating anxiety. The major strategies currently being used -- biofeedback, meditation, progressive relaxation, will be investigated. The results of the study will help determine the treatment of choice between different self-regulatory strategies. As such, this study may help give the clinician and researcher the first clear guidelines for determining which self-regulatory strategy is most effective for which particular clinical problem. In addition, the research will help determine the advisability and feasibility of non-pharmacological alternatives for relieving anxiety and stress and tension.

### BACKGROUND: REVIEW OF THE LITERATURE

#### Meditation

Meditation is a technique which involves having an individual focus in a non-cognitive, non-analytical way. Sometimes this focus is on a specific

object, sound, or image, such as Zen meditation's focus on breathing; Transcendental meditation's focus on the mantra. Othertimes the focus is on no particular object, but on all stimuli in the internal and external environment (e.g., Zen meditation Shikan-taza).

There have been four major reviews of the meditation literature (Woolfolk, 1974; Davidson, in press; Smith, 1975; Shapiro and Giber, 1976). Two of these reviews have dealt with the physiological changes during meditation which seem to help produce a state of relaxation: e.g., reduced oxygen consumption, reduced heart rate, lowered blood pressure, increased EEG alpha (Woolfolk, 1974; Davidson, in press). The other two reviews have dealt with the relationship between meditation and psychotherapy (Shapiro and Giber, 1976; Smith, 1975).

In the most recent review, Shapiro and Giber summarize the nine studies in the literature on meditation and anxiety (see Table one).

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Insert Table one about here

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This table describes the independent variables (description of technique; therapist contact; length of training); the method of subject selection; description of the dependent variable (the clinical problem); method of data collection and nature of data collected (physiological, behavioral, subjective; overt concurrent); the type of follow-up, and the quality of the control procedures. After reviewing this literature, Shapiro and Giber substantially agree with the conclusions reached in Smith's 1975 review. Smith noted that meditators showed a significant decrease in anxiety within four to six weeks when compared to a non-meditating control group.

#### Biofeedback

Biofeedback is a technique which provides the patient with relatively immediate information, or feedback, of some bioelectric response; e.g., skin

temperature, EEG, EMG. The most comprehensive review of the biofeedback literature was done in 1974 by Blanchard and Young. They reviewed five studies assessing the effects of EMG biofeedback on relaxation. These studies dealt with chronic anxiety (Raskin et al 1973); insomnia (Peper, 1973); test anxiety (Garrett and Silver, 1972, Wickramasekera, 1972) and neck muscle spasm (Jacobs and Felton, 1969). The results of the studies are described in table two

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Insert Table two about here

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The authors note that it is "fairly well established that people can learn to profoundly relax muscles when given feedback of the level of EMG activity, (Blanchard and Young, 1974, p. 97 ; cf. Green, 1969).

#### Progressive Relaxation

The technique of progressive relaxation, first developed by Jacobsen, 1938, involves having subjects learn to systematically tense and relax different muscle groups. Based on the careful documentation and research of Jacobsen, progressive relaxation is now a standard treatment in behavioral approaches dealing with anxiety, (cf. Bernstein and Barkevec, 1973; Hagan, 1958; Jacobson, 1962, 1964, 1971; Mahoney and Thoresen, 1974) and with fears and phobias (Wolpe, 1958, 1969).

#### Comparative Studies

To date, there have been few empirical studies comparing these different self-regulation strategies. For example, with regard to meditation, although it is true that different types of meditation can produce different physiological and behavioral indexes during meditation (Anand, Chhina & Singh, 1961; Kasamatsu & Hirari, 1966), it is not yet clear whether there are in fact any differences after the occurrence of different types of meditation. Although each school of focus seems to make claims and develops rationales for the use of its own

particular technique, whether it be Zen's focus on breath (cf. Akishige, 1974; Hirari, 1974) or transcendental meditation's focus on an internal mantra (Bloomfield, Cain, & Jaffe, 1975; Kanellakos & Lukas, 1974), there has been almost no research comparing the clinical effectiveness of different types of cognitive focusing (cf. Yamaoka, 1974).

Woolfolk compared meditation and progressive relaxation and found both strategies more effective in treating insomnia than a control group, but neither significant from each other (Woolfolk, 1976). Haynes (AABT Chicago, ~~in~~ press) compared EMG biofeedback and autogenic training and found them both more effective in treating insomnia than a control group. A one-year follow-up indicated that the biofeedback group did not maintain their improvement as well as the relaxation group, but did continue to demonstrate significant improvements over baseline.

Haynes (Psychophysiology, in press) has also compared EMG feedback, progressive relaxation training, and autogenic training in the reduction of frontalis muscle tension. EMG was found the most effective, then autogenic training, then progressive relaxation.

### Rationale

The treatment of anxiety has been considered an important issue in psychotherapy since the early works of Freud and Breuer on hysteria. Certainly, there are many medical and health problems which may result from anxiety, including hypertension, ulcers, contributions to heart disease. Most therapeutic systems have devised means for dealing with and treating anxiety. Further, there has been a recent increase in pharmacological means of treating stress and anxiety. In 1975, for example, the FDA noted that 43,571,000 prescriptions for benzodiazepines were prescribed for anxiety and tension, (valium accounted for 31.7 million; and librium for 7 million). However, there may be some possible misuse of the drugs. For example, a recent NIDA report which collected statistics

furnished by more than 1200 hospital emergency rooms, crises centers, and medical examiners in 23 metropolitan areas from April 1974 to April 1975, noted that the tranquilizer valium is associated with drug abuse crises more often than heroin or any other drug; i.e., about 10% of the drug abuse cases.

Therefore, it may be important to determine whether non-chemical alternatives for stress and tension management and anxiety reduction may be effective and if so, to determine which techniques are most effective.

Finally, there is a considerable financial rationale to determining the treatment of choice for chronically anxious patients. By teaching these patients means of anxiety-management which they themselves can administer in their natural environment, we may be able to remove them from their chronic outpatient medical clinic status. This would provide a considerable financial saving to the respective hospital organizations.

#### SPECIFIC AIMS

This study attempts to address the following four major questions:

(1) replicate past studies on the effectiveness of specific self-regulation strategies (2) extend past studies by providing a comprehensive follow-up on each technique's success (3) determine whether and to what extent non-pharmacological alternatives are feasible in the treatment of anxiety (4) compare self-regulation strategies and determine which techniques are most effective in the treatment of anxiety.

Other aims which are subsets of the four major questions include the following: a) how long does it take to learn these self-regulation skills? b) how well do they generalize to other times in the day? c) how effective, in a long-term sense, is a three-month training session? d) how willing are patients to learn these skills; what will the attrition rate be? (e.g., Glueck & Strobel, 1976; Shafii, 1976) e) what can we learn about the nature of anxiety; e.g.,

cognitive, somatic, physiological components, and the differential effects of specific self-regulation strategies on different aspects of anxiety (Davidson & Schwartz, 1976).

## METHODS OF PROCEDURE

### SUBJECTS AND SETTING

Fifty subjects will be recruited from the medical clinical division of the psychiatry outpatient at the Palo Alto VA Hospital. Patients will be on anti-anxiety medication and will be randomly assigned to one of five groups: four self-regulation groups (Zen meditation, Transcendental meditation, biofeedback, progressive relaxation, and a no-contact control.\*

Since these patients will be chronic long term users of medication who tried and were refractory to previous therapeutic intervention, it was felt there was no need for an attentional control group.

### PROCEDURES

#### Motivation Questionnaire

Subjects will be given a brief questionnaire to determine their motivation for learning to relax themselves. At the same time, an attempt will be made to assess their counter motivation -- e.g., they know medication works for them, so why would they want to change; e.g., they may be receiving money from the VA, etc., for their disability.

#### Independent Variable

The current study is investigating two different types of meditation techniques: Zen meditation and transcendental meditation. These meditation techniques represent different types of cognitive focusing strategies. TM focuses on an internal mantra; Zen on the physiological process of breathing. These techniques will be contrasted with EMG biofeedback and progressive relaxation. The



following table describes information about the length of initial training sessions; description of training procedures; length and number of follow-up sessions; and amount, if any of homework to be practiced.

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Insert Table three about here

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#### Expectation Effects

An attempt will be made to standardize expectation effects across treatment by telling subjects that all of these treatments have been proven effective, that they can expect success and relaxation and general calming, that they are easy to learn and that, with practice, they can successfully learn to relax themselves and feel a general tranquility and wellbeing.

#### Demand Characteristics

Although demand characteristics may be seen as a confounding variable, we have decided to include therapist contact as part of the independent variable. As Shapiro and Giber noted, "demand characteristics are an important part of any therapeutic treatment strategy in a clinical or educational setting, and therefore, rather than have no demand characteristics (e.g., use a tape recorder or some mechanical means of training), it might first be important in a clinically oriented project to explicitly state and then try to maximize these demand characteristics for clinical success." (Shapiro and Giber, 1976).

In order to maximize demand characteristics, in this current study, we have recruited nationally recognized leaders in each of the respective self-regulation fields to run their particular treatment. These leaders both believe in the effectiveness of their approach, as well as are respected by their colleagues for their skill in teaching it. An attempt will be made to standardize, in so far as possible, the length of therapist experience with a particular technique; also, raters will be present to monitor the amount of

verbal and non-verbal reinforcement given to subjects in order to try to operationalize this construct "demand" characteristics. An attempt will also be made to discern how the various self-regulation therapists tailor their treatment to the patients; i.e., do they focus on what anxiety means to the patient, the kinds of situations that elicit it; the consequences of it.

#### Effects of Practice

Part of the independent variable may be the homework, or practice that each subject performs. A diary will be given to each subject on which to record the frequency and type of practice.

#### Dependent Variable

Subjective measures. In past meditation studies, and in anxiety studies in general, there are certain standard tests which have been used, including the Taylor manifest anxiety scale, Spiegelberg state/trait anxiety scale. The reliability and validity of these test measures are established procedures in their respective fields. In addition, the Roter I.E. scale for internal external focus of control will be given; and a fear survey schedule.

In addition to pre and post tests (repeated measures)

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Insert Table four about here : Research Design

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subjects will be asked to keep a weekly daily diary noting what other strategies they may be using, as well as other changes related to anxiety they may be noting. As the Raskin study noted, "the best clinical results came not from direct reduction of reports of anxiety, but relief of anxiety related symptoms such as tension, headaches, insomnia." (Raskin, 1973)

#### Concurrent/overt

Subjects will be instructed to feel free to lower their medication, as they feel able to do so.

### Physiological Measures

Concurrent with the subjective reports, an attempt will be made to assess physiologically a measure of reduced autonomic arousal. The measure used will be spontaneous fluctuations in galvanic skin response, which has been used as a measure of autonomic arousal in several past studies (e.g., Orme-Johnson, 1973; Hirari, 1974; Aksishige). Also subjects will be instructed to take their heart rate each morning before they brush their teeth, and record it on daily feedback forms.

### Miscellaneous information

We will also send out forms at four different intervals to significant others in the patient's life, including family and job, to determine whether external life events change during or after the course of treatment.

### Data Analysis

Anecdotal Data: There will be several different types of data analysis. First, data will be collected from the subjective report of changes on weekly diary forms, as well as information from significant others. This information will be collected and codified.

#### 1. Subjective paper and pencil tests

The different repeated measures tests will be analyzed separately using standard ANOVA procedures. This includes the Roter I.E. test; the Taylor Anxiety test; the Spiegelberg, Trait-State Inventory; the fear survey schedule.

#### 2. Drug reduction

The change in drug usage across groups will be monitored and an ANOVA performed.

#### 3. Physiological measures

GSR. ANOVA across groups on repeated measures. Heartrate: ANOVA across group on change in mean heartrate from baseline (two weeks prior to

intervention) to intervention phase. Two one-week follow-ups at three months and six months will also be included.

#### Significance

This study is significant for several reasons. First, there is the obvious clinical significance. Both clinicians and researchers will have gained knowledge about the treatment of choice for chronic anxiety. This will be one of the best controlled studies assessing the different self-regulation treatment strategies, and the only study to do a comparison between these different self-regulation techniques. From the patient standpoint, we have pointed out the various health and medical problems often associated with anxiety. To reduce anxiety therefore, will significantly help the patient's health, especially by giving the patient strategies by which he can learn to reduce his own anxiety. Third, we have pointed out some of the potential problems with pharmacological approaches to anxiety management. This study will help determine the feasibility of non-pharmacological alternatives for reducing stress and tension. Fourth, from a financial standpoint, if, in a limited time, patients can be taught self-regulation skills, then this will take a burden off the VA's medical clinical which dispenses medication to patients twice weekly for an indeterminate period. Finally, the study will help provide additional evidence involving philosophical issues about anxiety as a trait or as a learned behavior (i.e., a state-cognitive phenomena (Mischel, 1968, 1973).

#### Facilities Available ?

Collaborative Arrangements: Not applicable

#### Principal Investigator Assurance:

"The undersigned agrees to accept responsibility for the scientific and technical conduct of the research project and for provision of required progress reports if a grant is awarded as the result of this application."

Follow-up Study

Important follow-up studies would involve the following:

1. Taking a similar population to the current study and randomly assign them to two groups. Give the experimental group the treatment of choice. Give no treatment to the control group. Randomly give half the control group and half the experimental group a chemical placebo. Use "double-blind" professional raters to assess effectiveness. This 4-cell study would appear as follows:

	Experimental	Control
Chemical Placebo	Treatment ----- Tr. + Placebo	
Anti-anxiety Medication	Treatment ----- Tr. + Placebo	

2. Try to tease out variance of treatment success involved in the treatment of choice. For example, if the most successful treatment is meditation, to compare just sitting versus expectation of relief versus demand characteristics versus mantra (internal verbal focus) to ferret out active versus inert variables.

THE EFFECTS OF SELF-REGULATION STRATEGIES IN THE TREATMENT OF ANXIETY

TABLE ONE:<sup>3</sup> INDEPENDENT VARIABLES

<i>Name of Technique</i>	<i>Length/description of Initial Training Sessions</i>	<i>Follow-up (checking) to ensure proper practice</i>	<i>Amount and Description of homework practice (if any)</i>
<p>Transcendental Meditation</p>	<p>Focus on internally generated sound.                      1 hr. introduction; 1 hr. preparation; 1½ hrs. personal instruction; 4½ hrs. verification of experience (1½ hrs per day for three days.</p> <p>Total Contact over Twelve weeks:                      8½ hours</p>	<p>½ hr. fifteen days after initial training session.                      cf. also checking during three days after training</p>	<p>Practice of the technique two times a day for twenty minutes each time=40 minutes per day.</p>
<p>Biofeedback (accompanied by autogenic training)</p>	<p>EMG and temperature training plus training in autogenic training as described by Schultz and Luthe</p> <p>One hour per week training for ten to twelve weeks</p> <p>Total Contact over Twelve Weeks:                      10-12 hours</p>	<p>Each week would involve a review of the previous material covered plus teach new material</p>	<p>Practice the training of the lesson three times a day for five minutes= fifteen minutes per day</p>
<p>Relaxation training</p>	<p>Progressive relaxation as described by Jacobson; addition of generalization training</p> <p>One hour per week for three months. Training plus checking</p> <p>Total Contact over Twelve Weeks:                      10-12 Hours</p>	<p>Each week would involve a review of the previous material covered plus teach new material.</p>	<p>In the beginning practice would be 45 minutes five days per week; however, the generalization effects should make practice 16 hrs. per day seven days per week.</p>

INDEPENDENT VARIABLES (CON'T)

Name of Technique	Length/description of Initial Training sessions	Follow-up (checking) to ensure proper practice	Amount and Description of Homework practice, if any
<p>Meditation (Zen) Plus behavioral self-control strategies</p>	<p>Zen breath meditation <del>combined with behavioral self-control strategies (self-observation, covert self-modeling, self-instructions)</del></p> <p>Five 1½ hr training sessions</p> <p>Total Contact over Twelve Weeks: 10½ hours</p>	<p>Three one-hour review sessions</p>	<p>Practice of meditation two times a day for twenty minutes; <del>plus instructions to note anxiety producing cues in the environment and use them as S<sup>d</sup> for engaging in self-control strategies.</del></p>
<p>NOTE: The above four seemed the most clinical interesting techniques to use as independent variables. However, given time, interest, and funding, other techniques such as the following may be considered:</p> <ul style="list-style-type: none"> <li>Behavioral Self-Control (alone)</li> <li>Zen meditation (alone)</li> <li>Self-hypnosis</li> <li>Cognitive focusing strategies involving external object of attention</li> </ul>			

RESEARCH DESIGN: TABLE FOUR

SEPTEMBER, 1977	OCTOBER---DECEMBER, 1977	December, 1977	March, 1978	June, 1978
<p>Obtain Subjects            --sign consent form            --read standard expectations</p> <p>Give Ss psychological tests to measure anxiety            --State-Trait Anxiety Inventory            --Taylor Manifest Anxiety Inventory</p> <p>Give Ss additional anxiety-related tests            --fear survey schedule            --Rotter I.E. Scale</p> <p>Give Ss physiological test            --GSR            --Begin two week heart rate baseline</p> <p>Give questionnaire to Ss significant others</p> <p>Train raters for observing teachers' verbal and non-verbal cues</p> <p>Randomize assignment of Ss to treatment groups</p>	<p style="text-align: center;"><u>INTERVENTION</u></p> <p>Group one:            Transcendental            Meditation</p> <p>Group two:            EMG biofeedback</p> <p>Group three:            Zen meditation</p> <p>Group four:            progressive relaxation</p> <p>Group five:            control (to be given            treatment of choice            at completion of study</p> <p style="text-align: center;">-----</p> <p>Diary Forms Kept:            --reporting practice            --reporting anxiety related            changes            --daily heart rate monitoring</p>	<u>Repeat Tests</u>	<u>Repeat tests</u>	<u>Repeat Tests</u>



D - This is a nice, tight study. Also raises some imp. questions - esp. the comparative ones or what is anxiety about going! of

1978!

ABSTRACT

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*Expect a lot of drop out*

*think you would need greater n.*

*must be selected to have been stable on meds for specified period. before study*

*with drop out you will be shafted.*



verbal and non-verbal reinforcement given to subjects in order to try to operationalize this construct "demand" characteristics. An attempt will also be made to discern how the various self-regulation therapists tailor their treatment to the patients; i.e., do they focus on what anxiety means to the patient, the kinds of situations that elicit it; the consequences of it.

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Subjects will be instructed to feel free to lower their medication, as they feel able to do so.

*Better way - at end, Ask how many would wish to lower meds + follow them 2 on practice and lower med. Enforced everythg if lower med. practically during study.*

*why not  
reduce med  
immediately.  
want them  
need you go.*

Physiological Measures

Concurrent with the subjective reports, an attempt will be made to assess physiologically a measure of reduced autonomic arousal. The measure used will be spontaneous fluctuations in galvanic skin response, which has been used as a measure of autonomic arousal in several past studies (e.g., Orme-Johnson, 1973; Hirari, 1974; Aksishige). Also subjects will be instructed to take their heart rate each morning before they brush their teeth, and record it on daily feedback forms.

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