Applied Psychophysiology and Biofeedback, Vol. 26, No. 4, 2001

The Raynaud's Treatment Study: Biofeedback Protocols and Acquisition of Temperature Biofeedback Skills

Susan J. Middaugh,[1,9] **Jennifer A. Haythornthwaite,**[2] **Bruce Thompson,**[3] **Robin Hill,**[4,5] **Kathleen M. Brown,**[3] **Robert R. Freedman,**[6] **Virginia Attanasio,**[7] **Rolf G. Jacob,**[8] **Michael Scheier,**[8] **and Edwin A. Smith**[1]

*The Raynaud's Treatment Study (RTS) compared temperature biofeedback training and a behavioral control procedure (frontalis EMG biofeedback) with nifedipine-XL and a medication placebo for treatment of primary Raynaud's phenomenon (RP) in a large (*N = *313) multicenter trial. The present study describes the RTS biofeedback protocols and presents data on the acquisition of digital skin temperature and frontalis EMG responses in the RTS. The findings point to substantial problems with acquisition of physiological self-regulation skills in the RTS. Only 34.6% of the Temperature Biofeedback group (*N = *81) and 55.4% of the EMG Biofeedback group (*N = *74) successfully learned the desired physiological response. In contrast, 67.4% of a Normal Temperature Biofeedback group (*N = *46) learned hand warming. Multivariate analysis found that coping strategies, anxiety, gender, and clinic site predicted acquisition of hand-warming skills whereas variables related to RP disease severity did not. Physiological data showed vasoconstriction in response to the onset of biofeedback and also found that performance in the initial sessions was critical for successful acquisition. These findings indicate that attention to the emotional and cognitive aspects of biofeedback training, and a degree of success in the initial biofeedback sessions, are important for acquisition.*

KEY WORDS: Raynaud's phenomenon; temperature biofeedback; EMG biofeedback; biofeedback therapy; normal subjects.

[1]Medical University of South Carolina, Charleston, South Carolina.
[2]Johns Hopkins University, Baltimore, Maryland.
[3]Clinical Trials & Surveys Corporation, Baltimore, Maryland.
[4]National Heart, Lung, and Blood Institute, Bethesda, Maryland.
[5]Deceased.
[6]Wayne State University, Detroit, Michigan.
[7]UMDNJ New Jersey Medical School, Newark, New Jersey.
[8]University of Pittsburgh, Pittsburgh, Pennsylvania.
[9]Address all correspondence to Susan J. Middaugh, Department of Anesthesiology and Perioperative Surgery, Medical University of South Carolina, 165 Ashley Avenue, Suite 525, P.O. Box 250912, Charleston, South Carolina 29425; e-mail: middaugs@musc.edu.

1090-0586/01/1200-0251$19.50/0

The Raynaud's Treatment Study (RTS) was a multicenter, randomized clinical trial, funded by the National Heart, Lung, and Blood Institute, NIH, that was designed to compare the effectiveness of behavioral treatment (temperature biofeedback) and pharmacological treatment (sustained-release nifedipine) for primary Raynaud's phenomenon (RP). The design, methods of statistical analysis, and outcome are presented in detail elsewhere (Raynaud's Treatment Study (RTS) Investigators, 2000; Thompson et al., 1999). This paper presents the protocols for the behavioral treatment (temperature biofeedback) and the behavioral control (frontalis EMG biofeedback) arms of the study. It also presents the RTS psychophysiological and psychosocial data related to successful learning of digital skin temperature and frontalis EMG responses. It then discusses the protocols and the learning data in relationship to the RTS study outcome.

RP is the clinical manifestation of digital artery vasospasm typically provoked by cold exposure (Wrigley & Flavahan, 1996). There is also evidence that psychological stress and anticipation of cold exposure can trigger some RP attacks (Freedman, Lynn, & Ianni, 1982; Freedman & Ianni, 1985; Graham, Stern, & Winour, 1958; Melin & Sandqvist, 1994; Mittleman & Wolff, 1939; Sedlacek, 1979; Surwit, 1982; Surwit, Williams, & Shapiro, 1982). Although RP can be an early symptom of an underlying disease such as systemic lupus erythematosus or scleroderma (secondary RP), it occurs more commonly in individuals who are otherwise healthy (idiopathic or primary RP, LeRoy & Medsger, 1992). For those who seek treatment, the therapeutic options include two very different approaches, pharmacological and behavioral.

Behavioral treatments, including biofeedback, relaxation training, and classical conditioning procedures, have been used to treat RP since the 1970s (Blanchard & Haynes, 1975; Jacobson, Hackett, Surman, & Silverberg, 1973; Jacobsen, Menschreck, & Silverberg, 1979; Jobe, Sampson, Roberts, & Beetham, 1982; Jobe, Sampson, Roberts, & Kelly, 1986; Keefe, Surwit, & Pilon, 1979; Melin & Fagerstrom, 1981, 1996; Shapiro & Schwartz, 1972; Surwit, 1973). Temperature biofeedback is the most studied of the behavioral treatments for RP (Freedman, 1991; King & Montgomery, 1980; Rose & Carlson, 1987). Well-controlled studies have demonstrated that normal individuals provided with temperature feedback can voluntarily increase digital blood flow to produce reliable increases in skin temperature. Once learned, this hand-warming response can be produced without feedback, generalized to locations outside the laboratory, and retained over time (Freedman & Ianni, 1983; Grabert, Bregman, & McAllister, 1980; Keefe, 1978; Keefe & Gardner, 1979; Stoffer, Jensen, & Nesset, 1979). Individuals with primary RP can learn this skill and reduce the frequency of their RP attacks, especially when temperature biofeedback is combined with cold exposure during training (Freedman, 1991; Freedman, Ianni, & Weing, 1983, 1985; Jobe et al., 1986; King & Montgomery, 1980; Sedlacek & Taub, 1996; Stambrook, Hamel, & Carter, 1988). In a well-controlled experimental study by Freedman and colleagues, individuals with primary RP who received temperature biofeedback training reported a 66.8% reduction in RP attacks at 1-year follow-up. Those who received cold exposure during temperature biofeedback training reported a 92.5% reduction at 1 year. Reductions in RP attacks were maintained for 3 years (Freedman et al., 1985). These studies provide considerable evidence that temperature biofeedback is effective in treatment of primary RP. However, they were single-center trials and limited to small samples.

The RTS was designed to compare temperature biofeedback and extended-release nifedipine in a large ($N = 313$) prospective, multicenter trial. In this multicenter study nifedipine XL significantly ($p < .001$) reduced vasospastic attacks in the hands compared

with a medication control group (pill placebo). In contrast, temperature biofeedback did not reduce attacks compared with a behavioral control group (frontalis EMG biofeedback, RTS Investigators, 2000). These findings are at odds with previous experimental studies (Freedman et al., 1983, 1985) and also run counter to the experience of clinicians who have utilized temperature biofeedback training with RP patients since the 1970s with reported success rates of 70–80% (Freedman, 1991; Sedlacek & Taub, 1996).

This paper examines acquisition of temperature and EMG skills with biofeedback training in the RTS. It describes the temperature and EMG biofeedback protocols and presents data on acquisition rates and on the medical, physiological, and psychosocial variables related to successful learning. It also compares learned temperature increases in RP participants with a group of normal participants trained with the same temperature biofeedback protocol. The findings are discussed in relationship to the RTS outcome.

RECRUITMENT AND PARTICIPANT CHARACTERISTICS

RP Participants

Individuals with primary RP ($N = 313$) were recruited from the community, 58–72 at each of five participating university clinical sites. Media advertisements were used to locate individuals whose hands were unusually sensitive to the cold. Local physicians were also asked to refer RP patients. Primary RP was diagnosed in a clinic visit using a structured interview assisted by hand color charts (Maricq, Carpentier, Weinrich, et al., 1997; Maricq & Weinrich, 1988), medical history, physical examination, blood tests, and capillary microscopy of the nailfold area (Maricq, 1992). Participants completed a comprehensive psychosocial questionnaire and kept a daily record of RP attacks for 1 month. Those who met the inclusion criteria were randomly assigned to one of four treatment groups. Detailed information on the inclusion criteria and the numbers of participants screened, randomized, receiving treatment, and providing 1-year follow-up data for each of the four groups are presented elsewhere (RTS Investigators, 2000). Although the primary focus of the present paper is on the 155 participants randomized to the biofeedback arm of the RTS, it does include analysis of selected data from all 313 participants. Therefore, basic demographic and baseline data in Tables I and II are presented for all 313 participants. These data did not differ for any of the four study groups.

Table I presents demographic and Raynaud's phenomenon characteristics of RTS participants at baseline ($N = 313$). The population was predominantly female and White with few minority participants. There was good representation of participants who rated their RP as mild, moderate, and severe and there was good agreement between the participant self-ratings and physician ratings based on history and examination.

Table II presents reported RP attack rates during the 1 month baseline period ($N = 313$). Participants were instructed in the use of a 3×5 in. card with six miniaturized hand photographs depicting hands with blanching or cyanosis characteristic of RP attacks as well as hands of normal participants. At the time of each attack, participants inspected their hands, compared them with the photographs, and recorded in a booklet the date, time, and code of the photograph that most closely resembled the appearance of their hands. A Verified Attack was defined as one that (a) matched a picture of an RP attack and (b) occurred more than 30 min after the onset of the previous verified attack. The 30-min

Table I. Characteristics of RTS Participants at Baseline ($N = 313$)

Demographic and RP characteristics	Mean ($\pm SD$) or % of participants
Age (years)	44.5 ± 12
Gender (female)	73%
Race	
White	95%
Black	4%
Hispanic	1%
Duration of RP (years)	13 ± 11
Family member with RP	32%
Color changes of RP	
White RP only	62%
Blue RP only	5%
White and blue RP	33%
Severity of RP (self-rated)	
Mild	22%
Moderate	50%
Severe or very severe	29%
Severity of RP (MD-rated)	
Mild	25%
Moderate	60%
Severe or very severe	15%

interval was selected because the average attack duration is 15 min (Freedman et al., 1982) and it is often difficult to identify the end of an attack. This method was based on procedures previously used in epidemiological studies of Raynaud's phenomenon (Maricq et al., 1997; Maricq & Weinrich, 1988). In computing All Attacks, each attack that was recorded in the booklet was counted, whether or not it met the verification criteria. All Attacks is similar to attack-log measures reported in other RP studies (Freedman et al., 1982). As seen in Table II, 60% of All Attacks met the criteria for Verified Attacks. For both measures, the majority of participants recorded less than one attack per day during the baseline period, which occurred in the November–January time period.

Normal Participants

Normal volunteers ($N = 46$) were recruited, 8–10 at each of the five clinic sites, through media advertisements requesting normal volunteers for a study of vascular circulation in the hands. All Normal participants received temperature biofeedback training to

Table II. Baseline RP Attack Rates ($N = 313$)

	Verified attacks	All attacks
Mean attacks $\pm$ *SD*	0.6 ± 0.7	1.0 ± 0.9
Average daily attack frequency (% of RTS patients reporting)		
<1	80.5	62.6
1–2	14.7	24.6
>2–3	3.8	7.7
>3–4	0.6	4.2
>4–5	0.3	1.0
>5	0.0	0.0

check the quality of the protocol used with RP participants. Normals were younger than RP participants (37.6 ± 11 years, $p < .001$) but did not differ by gender, 78% female.

BIOFEEDBACK PROTOCOLS

The biofeedback protocols were based on a detailed treatment manual developed by the study investigators and modeled after published methods (Freedman et al., 1983, 1985). Study personnel, primarily masters or doctoral level, were recruited at each of the study sites and trained to carry out the study protocols as the biofeedback therapist. Previous biofeedback experience varied from none to greater than 10 years. At each site, biofeedback therapists were supervised by a study investigator with extensive biofeedback experience. Biofeedback sessions were audiotape recorded and randomly checked for consistency with the study protocol.

The RP participants who were randomized to the two biofeedback groups ($N = 155$) attended 10 biofeedback training sessions plus an 11th session to test voluntary control under nonfeedback conditions. The 11 sessions were scheduled, 1 or 2 sessions per week, during the winter months, predominantly in January and February. RP participants were treated in two cohorts. For the biofeedback participants, Cohort I ($N = 57$) were treated in the initial winter of the study and Cohort II ($N = 98$) in the following winter.

Each of the 11 sessions was approximately 60 min in duration and included a 10–15-min interaction with the biofeedback therapist, a 10-min adaptation period (sensors attached), a 16-min baseline period (sitting quietly), a 16-min feedback period in which both audio and visual feedback displays were provided (or a 16-min nonfeedback period in Session 11), and a 10–15-min verbal review of the session and assignment of home practice. All sessions were carried out in a temperature controlled room ($23 \pm 1^{\circ}$C).

Digital skin temperature and frontalis EMG were recorded for all biofeedback participants. Skin temperature was recorded (J&J T-68) with a thermistor taped to the distal finger pad of both right and left index fingers. Frontalis EMG was recorded (J&J M-57, 100–200 Hz) with 0.5-cm diameter silver–silver chloride electrodes (Multi Bio Sensors) positioned over the pupil of each eye and 1 in. above the eyebrow, with the ground centered. The skin was lightly abraded to reduce resistance below 10 kΩ and cleaned with alcohol. Temperature and EMG data were quantified (J&J I-330) as consecutive 1 min means for the 32 min of baseline (minutes 1–16) and feedback or nonfeedback test in Session 11 (minutes 17–32).

Temperature Biofeedback Protocol

RP participants in the Temperature Biofeedback group ($N = 81$) were given a physiological rationale for the use of voluntary hand warming skills to reduce RP attacks, stating that both cold and emotional stress, especially anxiety about having a Raynaud's attack, can produce reflex vasoconstriction. Learning to warm the hands prior to cold exposure can increase digital blood flow and prevent both cold-related and stress-related vasoconstriction. The participants were familiarized with the feedback display of digital skin temperature (dominant hand), which consisted of a pulsed tone via speaker, 40-step LED light bar set to change in increments of 0.01–0.05°F. They were instructed to use the feedback display to guide efforts to increase hand temperature using mental strategies of their own choosing.

The rationale and training were focused on learning a relatively specific vasodilation response. Suggestions for including warmth imagery and passive volition were given, and emphasized for those who experienced temperature decreases. No adjunctive relaxation techniques were taught.

Sessions 6 and 8 included a cold challenge procedure in which the dominant hand index finger (proximal phalanx) was in contact with a temperature controlled metal plate (Physitemp NTE-2). In minutes 6–16 of the feedback period, this plate was chilled 1°C per minute from 30 to 20°C (86 to 68°F). In Session 11, no feedback was provided. Participants were asked to increase finger temperature without feedback during the 16-min test period, using the mental strategies they had developed in the previous sessions.

Frontalis EMG Biofeedback Protocol

The EMG biofeedback procedure was designed to serve as a behavioral control procedure. Based on previous research with RP participants, this protocol was designed to provide equally intensive biofeedback training without concurrent changes in finger temperature (Freedman et al., 1983; Freedman & Ianni, 1983). RP participants who were randomized to EMG biofeedback ($N = 74$) were given a physiological rationale for the use of voluntary facial muscle relaxation skills to reduce RP attacks as follows. Muscle tension produces reflex vasoconstriction in the skin, hands, and feet in order to shift blood flow to the working muscles. In addition, emotional stress, especially anxiety about having an attack, increases muscle tension. As a result, muscle tension and emotional stress can compound the vasoconstrictive effects of cold. Learning to relax the muscles prior to cold exposure can improve digital blood flow and reduce the vasoconstrictive effects of cold. The facial muscles are selected for training because they are often the first to contract, the last to relax, and are responsive to stress. The participant was familiarized with the feedback display that consisted of a pulsed tone via speaker and 40-step LED light bar (logarithmic scale, 0.3 s time constant). Participants were instructed to use the feedback display to guide efforts to relax the muscles of the face. The focus of the rationale and the training was on learning relatively specific facial muscle relaxation. No adjunctive relaxation techniques were taught.

Sessions 6 and 8 included a muscle tension challenge procedure. In minutes 6–16 of the feedback period, participants performed slow, repetitive movements of the nondominant arm (elbow flexion and extension) with a 1-lb wrist weight. In Session 11, no feedback was provided. Participants were asked to relax facial muscles without feedback during the 16-min test period, using the mental strategies they had developed in the previous sessions.

Home Practice and Applied Practice

All biofeedback participants were asked to practice at home for 10–15 min, once or twice a day, without instrumentation. Cohort I participants were regularly questioned about homework problems and compliance but did not record homework. A written homework record was implemented for Cohort II. After Session 6, for the Temperature Biofeedback group, homework included hand warming with a cold challenge, which consisted of holding a glass of cold water wrapped with one or more layers of cloth. For the EMG Biofeedback group, homework included a muscle tension challenge, which consisted of elbow flexion while holding a 1-lb can.

Participants were coached on methods for applying their hand-warming or muscle-relaxation techniques prior to cold exposures that occurred in the normal course of the day to prevent attacks. The therapist asked about specific conditions that typically precipitated RP attacks, coached the patient on preventive strategies, and asked whether these strategies had succeeded when tried. After Session 11, participants were encouraged to continue to practice and to apply these skills.

The RTS research protocol required that study personnel who were involved in treatment delivery not be involved in collection of outcome data. The primary outcome measure for the clinical trial was the participant's self-report of the number of RP attacks as recorded in daily logs. The therapists, therefore, did not employ daily attack diaries to guide treatment and did not question the participants about the specific number of RP attacks that occurred from session to session. This ensured that the therapist would not inadvertently coach the participants to report fewer attacks.

Learning Algorithm

Once Cohort I had completed biofeedback training, a quantitative algorithm was developed by the study investigators to operationally define successful acquisition of the desired temperature or EMG response. Participants were categorized as having successfully learned if they met any one of the three following criteria, in two of the last four sessions (7, 9, 10, and 11). Session 8 was excluded due to the cold stress and weight stress procedures. Based on this algorithm, nonlearners in Cohort I were identified and asked to return for four booster sessions the next fall. Those who met the learning criterion in two of four fall booster sessions were recategorized as learners. The same procedure was followed for Cohort II.

Temperature Learning Criteria

The maximum temperature in the biofeedback period (highest 1 min mean, of minutes 17–32) met any one of three criteria.

1. 1°F above the average of the last three minutes of the baseline period (minutes 14–16).
2. Between 93 and 94°F, *and* 0.5°F above the average of baseline minutes 14–16.
3. Above 94°F (no change specified).

EMG Learning Criteria

The average EMG for the biofeedback period (minutes 17–32) met any one of three criteria.

1. 1.0 μV below the average for the baseline period (minutes 1–16).
2. Between 1.0 and 2.0 μV,
   and 0.5 μV below the average EMG for the baseline period,
   and the coefficient of variation was 10% less than that of the baseline period.
3. Below 1.0 μV (no change specified).

The differences in the Temperature and EMG Learning Criteria are based on the differing characteristics of these two physiological responses. For temperature, the last three minutes (14–16) of the baseline period was selected as the reference point from which to measure change during the feedback period because temperature stabilized toward the end of the 16-min baseline period. For EMG, the mean for the entire 16-min baseline period was selected as the reference point because EMG varied considerably, from minute to minute, throughout the baseline period.

Temperature Biofeedback Protocol for Normal Participants

Normal participants ($N = 46$, 8–10 per study site) were recruited to test the quality of the biofeedback protocol. All Normal participants received 10 sessions of temperature biofeedback training, including the 2 cold challenge sessions, and an 11th session of non-feedback testing. The protocol was identical to the RP Temperature Biofeedback group and training was concurrent with Cohort II. Participants were told that this study was important for developing effective treatment protocols for RP patients. Normal participants were asked to carry out daily homework, keep a written homework record, and practice hand warming prior to cold exposure in their normal environment.

SUCCESS IN LEARNING TEMPERATURE AND EMG RESPONSES

Measures

To identify characteristics related to success in learning temperature and EMG responses, predictor variables were selected from RTS baseline data obtained by interview, laboratory measures, and pencil and paper test items completed prior to random assignment. These variables were selected to provide measures relevant to RP disease severity; measures of stress, coping and quality of life; and selected additional variables including RTS clinic site, treatment preference, baseline temperature, and baseline EMG. Table III lists these predictor variables under headings that identify the basis for selection. The outcome variables of interest were success in learning digital skin temperature increases, success in learning frontalis EMG decreases, and success in learning the respective response for the two biofeedback groups combined. Treatment preference was a predictor variable in the analyses of success in biofeedback learning and was also an outcome variable in a separate analysis to identify characteristics of participants who stated a preference for biofeedback treatment.

Pain associated with Raynaud's attacks was measured by three items from the SF-36 Health Survey (Ware, Snow, Kosinski, & Gandek, 1993) modified slightly to refer to RP pain. Anxiety was measured by four items: two items from the SF-36 Health Survey and two items from the State Anxiety Inventory (Spielberger, 1983). Chronbach's alpha for these four anxiety items in the RTS population was 0.85 (Brown, Middaugh, Haythornthwaite, & Bielory, 2001). Perceived stress was measured using the 14-item Perceived Stress Inventory (Cohen, Kamarack, & Mermelstein, 1983). Global satisfaction with life was assessed using Diener's five-item Satisfaction With Life Scale (Diener, Emmons, Larsen, & Griffin, 1985). The COPE (Carver, Scheier, & Weintraub, 1989) measured 15 strategies for coping with stress (60 items) and participants rated the extent to which they typically use

Table III. Baseline Variables Included in Multivariate Analyses

Measures of disease severity
Baseline RP attack rate (verified attacks)
Physician rating of Raynaud's severity
Patient rating of Raynaud's severity
Indicators of disease severity
Diagnosis of White Raynaud's: A white phase present in attack sequence
Diagnosis of Blue Raynaud's: A blue phase present in attack sequence
ANA titer above 1:40
Time (years) since onset of Raynaud's attacks
Pain associated with Raynaud's attacks
Modifiers of disease severity
Age
Gender
Family history of Raynaud's phenomenon (yes/no)
Smoking history (current, never, ex-smoker)
Body Mass Index
Outside temperature, mean for baseline month
Psychosocial variables related to stress, coping, and quality of life
Education
Anxiety (SF 36)
Perceived Stress Inventory
Raynaud's attacks triggered by stress (yes/no)
Satisfaction With Life Scale
Dispositional COPE: 15 coping strategies
Additional variables of interest
Digital skin temperature: Mean, baseline minutes 1–16, Sessions 1–3
Frontalis EMG: Mean, baseline minutes 1–16, Sessions 1–3
Treatment preference prior to random assignment: Prefer Biofeedback, Prefer Medication, No Preference
RTS Clinic Site: Clinic 1, Baltimore, MD; Clinic 2, Charleston, SC; Clinic 3, Newark, NJ; Clinic 4, Pittsburgh, PA; Clinic 5, Detroit, MI

each strategy in response to stress (dispositional coping). Baseline digital skin temperature and baseline frontalis EMG were measured as the mean of minutes 1–16 (the baseline period) averaged for the first three biofeedback sessions to minimize missing values due to recording problems. Treatment preference prior to random assignment was added to the pencil and paper test items for Cohort II ($N = 200$). This item was worded "At this time would you: 1) Strongly prefer biofeedback treatment; 2) Moderately prefer biofeedback treatment; 3) Have no preference for either treatment; 4) Moderately prefer drug treatment; 5) Strongly prefer drug treatment." Participants had received an explanation of the medication and biofeedback treatment protocols as part of the intake and human consent procedures. For statistical analysis, this item was condensed to three categories: (1) Prefer Biofeedback (strongly or moderately); (2) No Preference; (3) Prefer Medication (strongly or moderately). RTS Clinic Site was included to represent unknown differences in participants, such as ethnicity and culture, and unknown differences in laboratory environment, personnel and methods. Clinic Site 5, the coldest site, was the reference site for statistical analyses.

Methods of Statistical Analysis

The dependent variables were first tested for association with the independent variable by univariate analysis, predominantly t test and chi-square. Variables with $p \leq .1$ were retained for multivariate analysis using logistic regression by backward selection

Table IV. Predictors of Treatment Preference[a] ($N = 196$)

Predictor	Coefficient	OR	Chi-square	*P* value
Intercept 1	−1.94	—	8.26	.0041
Intercept 2	−0.57	—	0.76	.38
Sex (male)	−0.90	0.41	8.44	.0037
Raynaud's triggered by stress	1.36	3.88	14.19	.0002
Dispositional COPE: Focus on venting emotions	0.19	1.22	6.66	.0098

Note. Model fitting score statistic $p = .0001$.
[a] 1 = Prefer Biofeedback (reference group); 2 = No Preference; 3 = Prefer Medication.

(Proc Logistic, SAS Institute Inc., 1990). A value of $p \leq .05$ was accepted for statistical significance.

RESULTS

Treatment Preference

As reported in Table IV, three variables predicted treatment preference. Biofeedback was more often preferred by those who reported stress as a trigger for attacks, by those who focused on venting emotions as a coping strategy, and by women. Of the 200 Cohort II participants, 44% (88/200) stated a preference for biofeedback, 28% (56/200) preferred medication, and 28% (56/200) stated no preference. These preferences differed substantially by gender. More women (49.3%) than men (31%) preferred biofeedback, whereas more men (44.8%) than women (21.1%) preferred medication ($p < .002$). Equal percentages of men (24.2%) and women (29.6%) stated no preference. A minority of participants ($49/200 = 24.5\%$) reported that RP attacks were triggered, at times, by stress or emotion. For this minority, there was a strong preference for biofeedback treatment ($33/49 = 67.3\%$) and few preferred medication ($8/49 = 16.3\%$), or had no preference ($8/49 = 16.3\%$; $p < .001$).

Learning Biofeedback Skills

The 155 RP participants who were randomized to the two biofeedback groups were classified as Learners or Nonlearners based on the algorithm described in Learning Algorithm section. The percentage of Learners versus Nonlearners was calculated based on all 155 RP participants who were randomized to biofeedback groups. Those who dropped out prior to the criterion sessions used in the algorithm (Sessions 7–11) were classified as Nonlearners, as were participants who completed all sessions and failed to meet the algorithm definition of successful learning. This is a conservative approach, based on intention to treat, which assumes that difficulty with learning is likely to be a contributor to participant drop-out. Acquisition rates for RP participants were low, with 34.6% (28/81) of Temperature Biofeedback and 55.4% (41/74) of EMG Biofeedback participants classified as Learners, and a higher percentage of EMG Learners than Temperature Learners ($p < .02$). For the 46 Normal participants who entered the study, a higher percentage, 67.4% (31/46), learned hand-warming skills compared with the Temperature Biofeedback group ($p < .001$).

Table V. Predictors of Learning, Temperature Biofeedback Group[a] ($N = 80$)

Predictor	Coefficient	OR	Chi-square	P value
Intercept 1	−1.71	—	2.50	.1136
Intercept 2	0.79	—	0.55	.4566
Clinic 2	2.20	8.99	10.81	.0010
Dispositional COPE: Positive Reinterpretation and Growth	0.18	1.99	4.80	.0285
Dispositional COPE: Denial	−0.27	0.76	4.22	.0399

Note. Model fitting score statistic $p = .0003$.
[a] 1 = Learner (reference group); 2 = Nonlearner Completer; 3 = Nonlearner Noncompleter.

However, 22 (14.2%) of the 155 RP participants and 4 (8.7%) of the 46 Normal participants dropped out prior to attending a single biofeedback session or early in the course of biofeedback training (by Session 3). For these participants, the reasons for drop out are likely to include nonacceptance of assignment to biofeedback treatment and lack of interest in participating in a relatively demanding behavioral protocol, once the requirements such as daily homework became evident. Learners were recalculated as a percentage of the 129 RP and 41 Normal participants who completed a minimum of six biofeedback training sessions. This method eliminates early dropouts and includes only those with an operationally defined minimum commitment (attendance for six sessions) to participation in the biofeedback protocols. By this method, acquisition rates are still low for RP participants, with 43.1% (28/65) of Temperature Biofeedback and 64.1% (41/64) of EMG Biofeedback participants classified as Learners, and a higher percentage of EMG Learners than Temperature Learners ($p < .03$). In contrast 75.6% (31/41) of Normal participants learned hand-warming skills, a higher percentage than the RP Temperature Biofeedback group ($p < .003$).

Biofeedback learning was treated as a three category variable for multivariate analysis, with each participant categorized as a Learner, a Nonlearner Completer (attended $\geq$6 sessions), or a Nonlearner Noncompleter (attended <6 sessions). As reported in Table V, three variables predicted acquisition of skin temperature increases in the Temperature Biofeedback group. Successful learning was most strongly associated with clinic site (Odds Ratio [OR] = 8.99) and acquisition rates ranged from 12.5 to 75% of participants for the five clinic sites. Successful learning was also associated with greater use of the positive coping strategy Positive Reinterpretation and Growth (OR = 1.99) and with lesser use of the negative strategy Denial (OR = 0.76, COPE, Carver et al., 1989). Use of Denial was highest in Nonlearner Noncompleters, that is, those who dropped out early in the study ($p < .05$).

As reported in Table VI, two variables predicted acquisition of frontalis EMG decreases in the EMG Biofeedback group, Humor and Gender. Acquisition rates varied widely by

Table VI. Predictors of Learning EMG Biofeedback Group[a] ($N = 73$)

Predictor	Coefficient	OR	Chi-square	P value
Intercept 1	−1.21	—	1.88	.1698
Intercept 2	0.70	—	0.62	.4318
Sex (male)	−1.72	0.18	11.01	.0009
Dispositional COPE: Humor	0.27	1.31	5.74	.0166

Note. Model fitting score statistic $p = .0005$.
[a] 1 = Learner (reference group); 2 = Nonlearner Completer; 3 = Nonlearner Noncompleter.

clinic site, but this variable did not reach the significance level needed for inclusion in the MVA regression equation because the reference site (Clinic Site 5) fell in the middle of this distribution. A separate comparison between the clinic with the lowest (28.6 %) versus highest (78.6 %) success rates was significant ($p = .02$, OR $= 9.2$). In the multivariate analysis use of Humor as a coping strategy was associated with more successful learning (OR $= 1.31$). Male gender was strongly associated with less successful learning (OR $= 0.18$). Inspection of the gender data indicated that men dropped out of EMG Biofeedback training at a higher rate than women: 28% of men versus 6% of women were Nonlearner Noncompleters ($p < .05$). Also, men who completed EMG Biofeedback training had a lower success rate than women: 32% of men versus 67.3% of women were Learners ($p < .01$). This gender difference was not due to higher baseline EMG values in men, because baseline EMG did not differ by gender and was not a predictor of successful EMG learning (Table VI). In contrast, gender was unrelated to learning in the Temperature Biofeedback group (Table V). Men had a slightly lower drop out rate than women:14.3% of men versus 21.7% of women were Nonlearner Noncompleters (nonsignificant). Men who completed training were as likely as women to learn hand warming: 33.3% of men versus 35% of women were Learners.

In Table VII, data are combined for Temperature and EMG Biofeedback groups to examine predictors of successful biofeedback learning independent of modality, either temperature increases in the Temperature Biofeedback group or EMG decreases in the EMG Biofeedback group. Three variables predicted learning with physiological feedback. Clinic site was the strongest predictor (OR $= 0.27$) and acquisition rates varied from 20 to 66.7% of participants. Greater use of the positive coping strategy Emotional Social Support was associated with more successful learning (OR $= 1.15$). Greater anxiety was associated with less successful learning (OR $= 0.97$).

Comparison of Acquisition in RP and Normal Participants

Digital skin temperature and frontalis EMG data were examined in more detail and compared for RP and Normal groups to provide additional information on acquisition of physiological responses with biofeedback training in the RTS. Figures 1–6 present digital skin temperature and frontalis EMG for three biofeedback groups: Temperature Biofeedback, EMG Biofeedback, and Normals receiving temperature biofeedback. Data during the biofeedback period (minutes 17–32) are expressed as change from the end of the respective session baseline period (mean of minutes 14–16). The number of participants who

Table VII. Predictors of Biofeedback Learning, Biofeedback Groups Combined[a] ($N = 150$)

Predictor	Coefficient	OR	Chi-square	*P* value
Intercept 1	−0.27	—	0.13	.7207
Intercept 2	1.74	—	5.07	.0243
Clinic 3	−1.29	0.27	10.15	.0014
Anxiety (SF-36)	−0.03	0.97	6.32	.0119
Dispositional COPE: Emotional Social Support	0.14	1.15	4.65	.0311

Note. Model fitting score statistic $p = .0001$.
[a] 1 = Learner (reference group); 2 = Nonlearner Completer; 3 = Nonlearner Noncompleter.

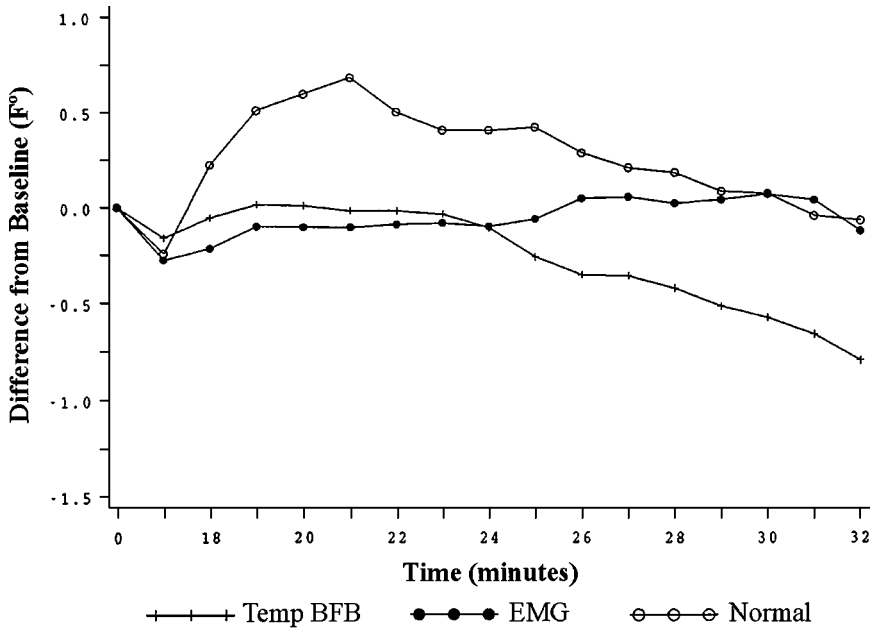

Fig. 1. Change in digital skin temperature early in biofeedback training (Session 4) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 63, 84.3 \pm 8.0^{\circ}$F); EMG Biofeedback ($N = 60, 84.3 \pm 8.5^{\circ}$F; Normals receiving temperature biofeedback ($N = 42, 87.6 \pm 5.7^{\circ}$F).

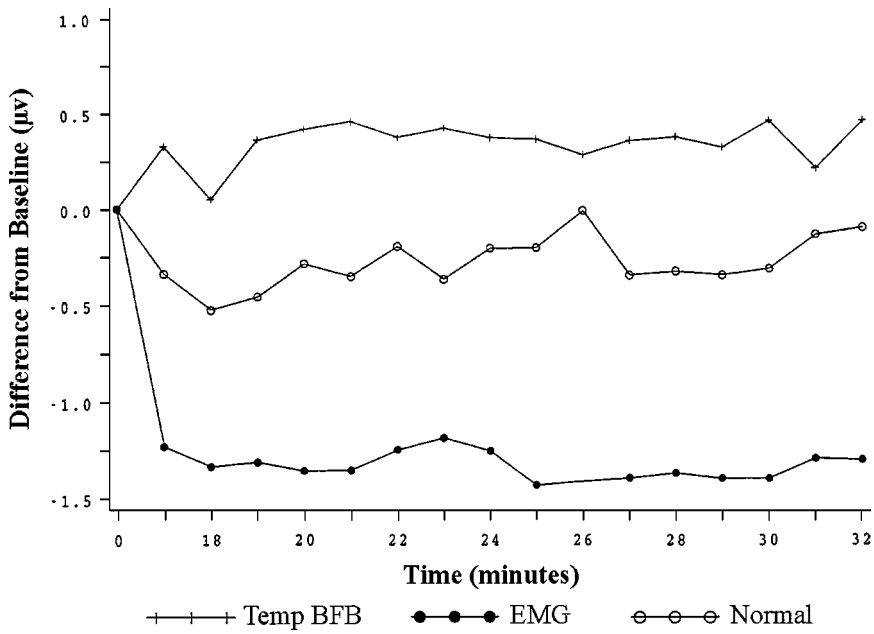

Fig. 2. Change in frontalis EMG early in biofeedback training (Session 4) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 61, 3.9 \pm 2.7\ \mu$V); EMG Biofeedback ($N = 60, 4.0 \pm 2.7\ \mu$V); Normals receiving temperature biofeedback ($N = 39, 4.0 \pm 2.5\ \mu$V).

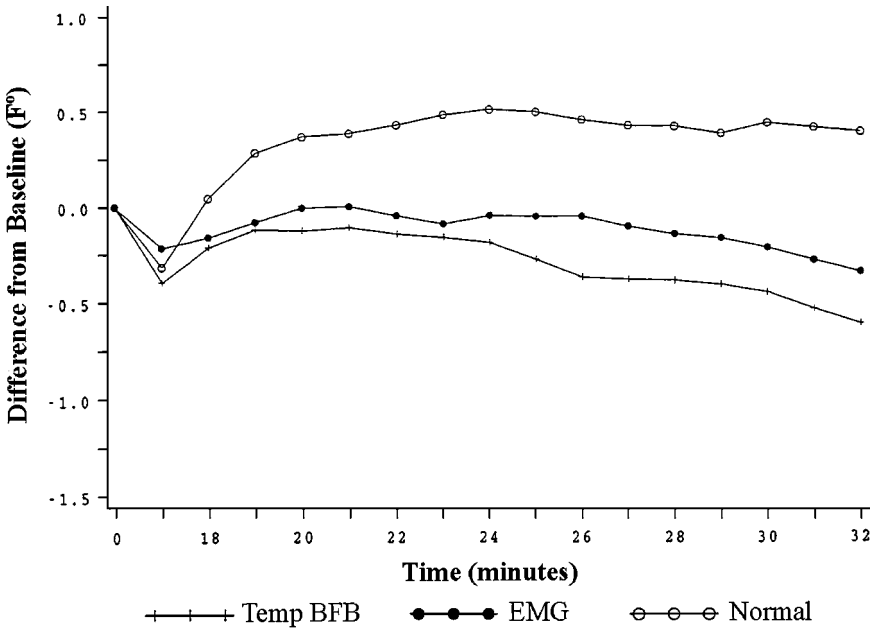

Fig. 3. Change in digital skin temperature late in biofeedback training (Sessions 7, 9, and 10) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 58, 84.4 \pm 7.8^{\circ}$F); EMG Biofeedback ($N = 61, 85.9 \pm 7.8^{\circ}$F); Normals receiving temperature biofeedback ($N = 41, 87.4 \pm 5.7^{\circ}$F).

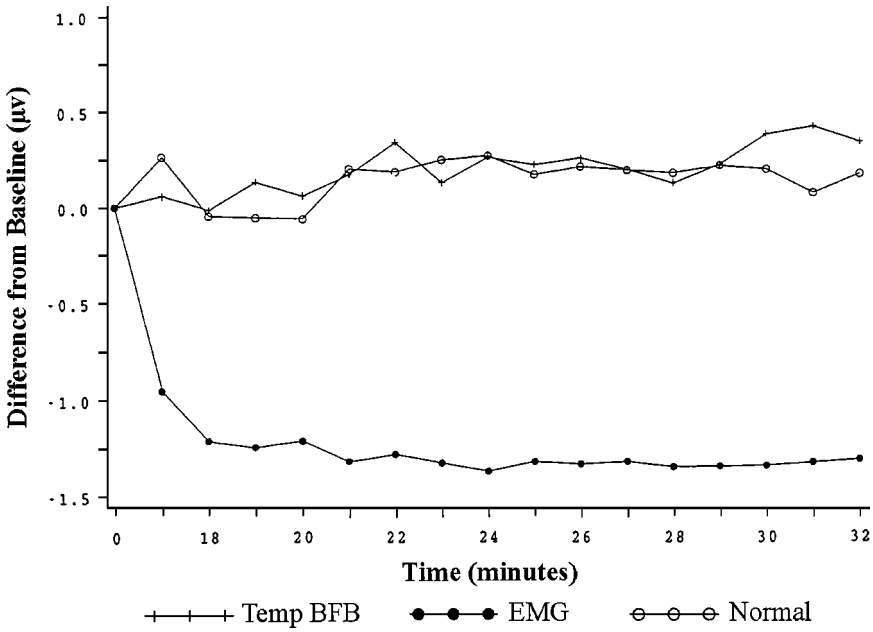

Fig. 4. Change in frontalis EMG late in biofeedback training (Sessions 7, 9, and 10) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 58, 4.2 \pm 3.5\ \mu$V); EMG Biofeedback ($N = 62, 3.5 \pm 2.3\ \mu$V); Normals receiving temperature biofeedback ($N = 41, 3.5 \pm 2.3\ \mu$V).

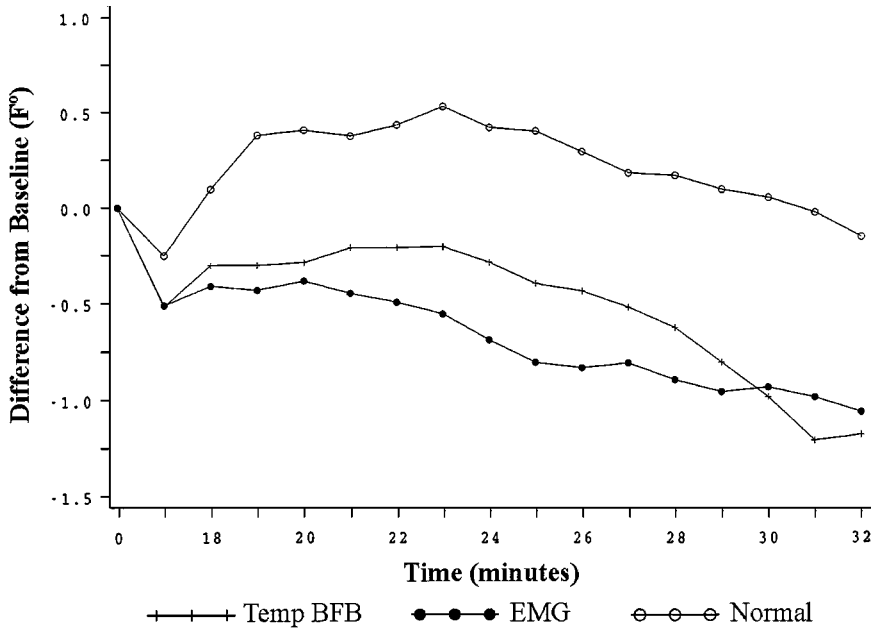

Fig. 5. Change in digital skin temperature during nonfeedback test (Session 11) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 53, 83.8 \pm 7.6°$F); EMG Biofeedback ($N = 57, 85.8 \pm 7.5°$F); Normals receiving temperature biofeedback ($N = 40, 88.3 \pm 5.0°$F).

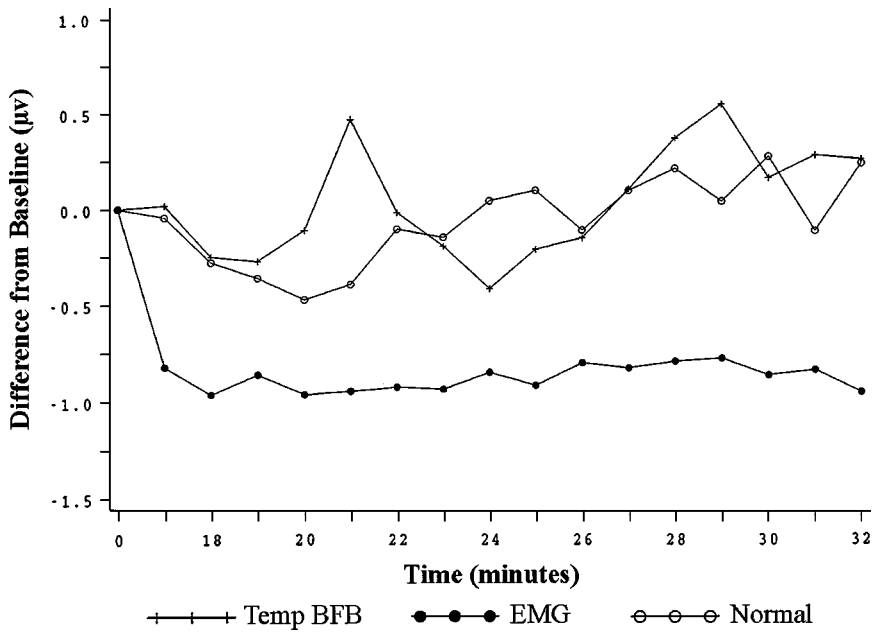

Fig. 6. Change in frontalis EMG during nonfeedback test (Session 11) for three groups ($N, \bar{x}$ baseline $\pm$ *SD*): Temperature Biofeedback ($N = 51, 4.0 \pm 3.0\,\mu$V); EMG Biofeedback ($N = 57, 3.2 \pm 1.7\,\mu$V); Normals receiving temperature biofeedback ($N = 40, 3.4 \pm 2.0\,\mu$V).

provided data varied from session to session because of physiological recording errors and study drop out. Figure captions state the number of participants who provided data and the mean ($\pm SD$) baseline value from which change was measured for the respective session. Baseline temperature was significantly higher ($p < .05$) in the Normal group compared with either biofeedback group in Fig. 1, and also higher for the Normal group compared with the Temperature Biofeedback group in Figs. 3 and 5. Baseline EMG did not differ by group.

Figure 1 presents changes in digital skin temperature early in the course of biofeedback training, in Session 4, for each of the three groups. The Normal group showed evidence of learning hand warming as early as the 4th temperature biofeedback training session whereas the Temperature Biofeedback group (RP) did not. Note that hand temperatures dropped in the first minute of feedback (minute 17). This indicated a vasoconstrictive reaction to the audiovisual display and the demand characteristics of the feedback period or both. This decrease was present in most sessions and had to be reversed before increases above baseline could be achieved. The Normal group was able to accomplish this by Session 4 whereas the Temperature Biofeedback (RP) group could not. Figure 2 presents changes in frontalis EMG in Session 4 for the same three groups. The EMG Biofeedback group demonstrated substantial EMG decreases in the first minute of feedback (minute 17). The Normal group (receiving temperature feedback) showed small EMG decreases whereas the Temperature Biofeedback group showed slight increases in EMG.

Figure 3 presents changes in digital skin temperature late in the course of biofeedback training for each of the three groups. The data were averaged for the last three biofeedback sessions without cold/tension challenge, Sessions 7, 9, and 10, the sessions that were used (with test Session 11) in the learning classification algorithm. All three groups still showed a vasoconstrictive reaction to the onset of the biofeedback period (minute 17). The Normal group continues to show digital skin temperature increases. Neither the Temperature Biofeedback nor EMG Biofeedback groups increased hand temperature above baseline (mean of minutes 14–16). Figure 4 presents changes in frontalis EMG late in the course of biofeedback training for each of the three groups (Sessions 7, 9, and 10 combined). The EMG Biofeedback group showed substantial EMG decreases. The Temperature Biofeedback group and the Normal group (receiving temperature biofeedback) showed little EMG change from baseline.

Figures 5 and 6 illustrate changes in digital skin temperature and frontalis EMG that occurred in Session 11, the nonfeedback test session, for each of the three groups. In Fig. 5, vasoconstriction is still evident in minute 17 for all three groups, without the audio or visual feedback display. The Normal group shows retention of temperature increases, above baseline, under nonfeedback conditions whereas the other two groups do not. In Fig. 6, the EMG Biofeedback group shows retention of frontalis EMG decreases under nonfeedback conditions. There are no systematic EMG changes for the two temperature feedback groups.

Figures 7 and 8 present additional information on the time course of acquisition across the 10 biofeedback training sessions, the extent of within-session change, and the extent of retention in Session 11. Each group was divided into two subgroups, Learners and Nonlearners. Only participants who completed six or more biofeedback training sessions were included (Nonlearner Completers) so that performance could be examined across sessions in participants who received a substantive amount of training. The number of participants who provided data varied from session to session due to physiological recording

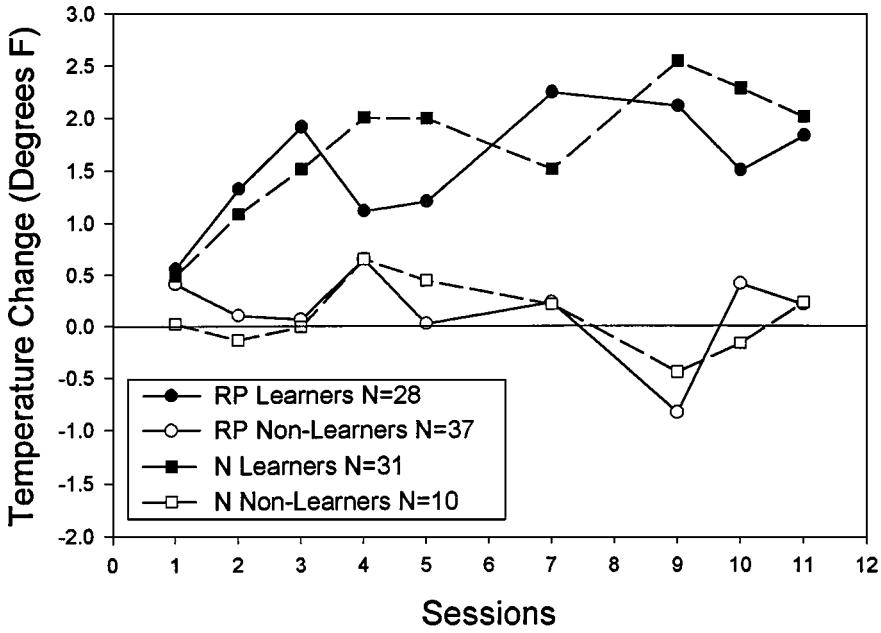

Fig. 7. Mean within-session change in digital skin temperature, shown session-by-session, comparing Learners versus Nonlearners in Normal and Temperature Biofeedback groups. The value of the zero baseline, and *N* per group, varies from session to session.

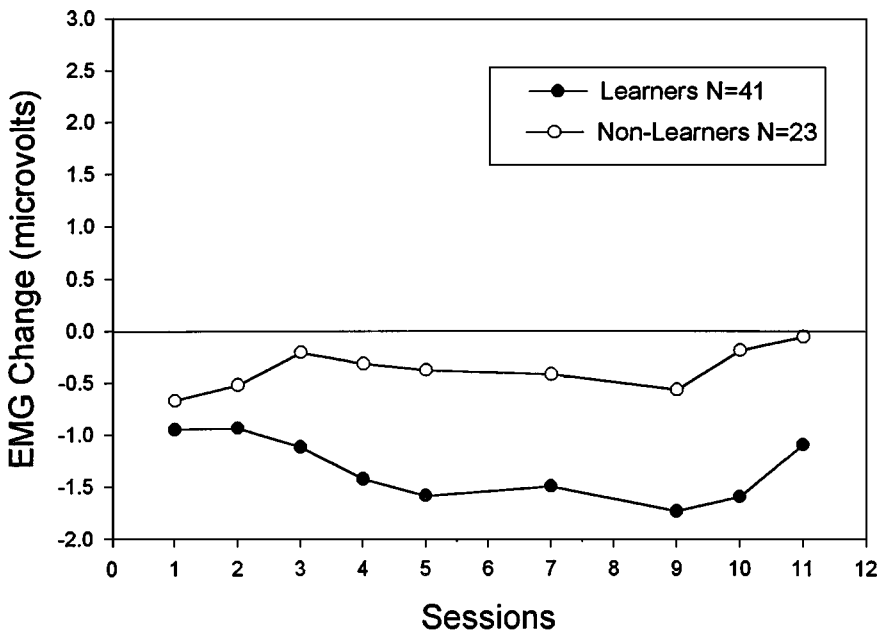

Fig. 8. Mean within-session change in frontalis EMG, shown session-by-session, comparing Learners versus Nonlearners in the EMG Biofeedback group. The value of the zero baseline, and *N* per group, varies from session to session.

errors and study drop out after Session 6. Figure captions do not provide the baseline value from which change was measured because this value varied for each of the 11 sessions. Relevant baseline issues are addressed ahead.

Figure 7 presents the mean within-session change in digital skin temperature, session-by-session, for each of the 11 sessions (excluding the cold challenge Sessions 6 and 8) for Learners versus Nonlearners in the Temperature Biofeedback and Normal groups. For each participant, temperature change within each session was calculated (as in the learning algorithm) as the change from the end of baseline (mean of minutes 14–16) to the peak 1 min mean in the feedback or test period (minutes 17–32). As shown in Fig. 7, the mean temperature change in Session 1 is similar for the four subgroups (0–0.6°F). Beginning in Session 2 Learners—both Temperature Biofeedback and Normal—began to improve whereas Nonlearners did not, and in Session 3 this difference reached significance ($p < .04$). For Learners, temperature increases were substantial ($\bar{x} = 1.5$–2.3°F) in the later training sessions (Sessions 7, 9, and 10) and retained under nonfeedback test conditions (Session 11 $\bar{x} = 1.8$–2°F). The data were averaged for the four later sessions (7, 9, 10, and 11) that were used in the learning classification algorithm. Learners had significantly larger within-session temperature increases than Nonlearners, both for the Temperature Biofeedback group ($\bar{x} = 1.9 \pm 3.7$°F vs. 0.0 ± 2.3°F respectively, $p < .02$) and for the Normal group ($\bar{x} = 2.1 \pm 2.4$°F vs. 0.0 ± 1.1°F respectively, $p < .02$). Although the mean within-session change scores in Fig. 7 varied considerably from session to session, these change scores were very similar for Learners in the Temperature Biofeedback group and the Normal group with respect to the time course of acquisition across the 11 sessions and the extent of within-session change that was achieved.

Figure 8 presents the average within-session change in frontalis EMG for each of the 11 sessions (excluding the muscle tension challenge Sessions 6 and 8) for Learners versus Nonlearners in the EMG Biofeedback group. For each participant, EMG change within each session was calculated (as in the learning algorithm) as the change from mean baseline (mean of minutes 1–16) to the mean for the feedback or test period (mean of minutes 17–32). As shown in Fig. 8 the average EMG change in Session 1 is similar for Learners ($\bar{x} = 0.9 \pm 1\,\mu$V) and Nonlearners ($\bar{x} = 0.7 \pm 1.1\,\mu$V). By Session 3, EMG was significantly lower for Learners ($\bar{x} = 1.1 \pm 1.3\,\mu$V) than Nonlearners ($\bar{x} = 0.2 \pm 1.2\,\mu$V, $p < .01$). For Learners, EMG decreases averaged 1.4–1.8 μV in the late training sessions (Sessions 7, 9, and 10) and were partially ($1.0 \pm 1.2\,\mu$V) retained under nonfeedback test conditions (Session 11). The data were averaged for the four later Sessions (7, 9, 10, and 11) that were used in the learning classification algorithm. Learners ($\bar{x} = 1.5 \pm 1.3\,\mu$V) had significantly larger within-session EMG decreases than Nonlearners ($\bar{x} = 0.3 \pm 0.8\,\mu$V $p < .001$).

Baseline Digital Skin Temperature and EMG

The change scores in Figs. 7 and 8 serve to illustrate, in a concise and comparable manner, the extent of temperature increases and EMG decreases that were achieved, session-by-session, throughout the 11-session protocol. However, the baseline values from which the change scores were calculated are also relevant, because systematic increases in baseline values across sessions could potentially reduce the extent of within-session change. In addition, if Learners differed from Nonlearners with respect to initial baseline values, this

could also effect the extent of within-session change. To examine these two issues, baseline digital skin temperature (mean of minutes 14–16) and baseline EMG (mean of minutes 1–16) were averaged for Sessions 1–3 as an index of baseline values early in the 11-session protocol. A three session average was selected because the size of the subgroups of interest were relatively small, the baseline values could differ by large amounts between individuals and, as a result, one or two missing values could have a substantial impact on the group mean for a single session. The average for Sessions 7, 9, 10 and 11—the four sessions included in the learning algorithm—was selected as an index of baseline values late in the protocol.

First, early baseline values (Sessions 1–3) were compared for Learners versus Nonlearners who completed six sessions (Fig. 7). For the Temperature Biofeedback group, Learners ($\bar{x} = 85.3 \pm 7.6^{\circ}$F) did not differ from Nonlearners ($\bar{x} = 82.9 \pm 8.4^{\circ}$F, $p > .05$). However, for the Normal group Learners ($\bar{x} = 89.2 \pm 4.7^{\circ}$F) had a higher mean baseline temperature than Nonlearners ($\bar{x} = 83.2 \pm 7.6^{\circ}$F, $p < .01$). For the EMG group (Fig. 8) early baseline values for Learners ($\bar{x} = 3.5 \pm 1.9\,\mu$V) did not differ from Nonlearners ($\bar{x} = 3.1 \pm 1.6\,\mu$V, $p > .05$).

Next, late baseline values (Sessions 7, 9, 10, and 11) were compared with the early baseline values (Sessions 1–3) to determine whether baseline values changed with biofeedback training. For all comparisons, late baseline values did not differ from the early baseline values ($p > .05$). For Temperature Biofeedback Learners: late baseline $\bar{x} = 85.5 \pm 7.6^{\circ}$F (early baseline $\bar{x} = 85.3 \pm 7.6^{\circ}$F). For Temperature Biofeedback Nonlearners: late baseline $\bar{x} = 83.0 \pm 7.9^{\circ}$F (early baseline $\bar{x} = 82.9 \pm 8.4^{\circ}$F). For Normal Learners: late baseline $\bar{x} = 88.8 \pm 4.4^{\circ}$F (early baseline $\bar{x} = 89.2 \pm 4.7^{\circ}$F). For Normal Nonlearners: late baseline $\bar{x} = 83.8 \pm 7.1^{\circ}$F (early baseline $\bar{x} = 83.2 \pm 7.6^{\circ}$F). For EMG Learners: late baseline $\bar{x} = 3.6 \pm 1.9\,\mu$V (early baseline $\bar{x} = 3.5 \pm 1.9\,\mu$V). For EMG Nonlearners: late baseline $\bar{x} = 2.8 \pm 1.7\,\mu$V (early baseline $\bar{x} = 3.1 \pm 1.6\,\mu$V).

Early baseline values (Sessions 1–3) were also examined for participants who dropped out prior to Session 6 (Nonlearner Noncompleters, not included in Figs. 7 and 8) to determine whether exceptionally low baseline skin temperature or high baseline EMG were related to early dropout for the RP participants. For the Temperature Biofeedback group, 11 early dropouts provided baseline data for at least one session ($\bar{x} = 82.1 \pm 8.6^{\circ}$F) and did not differ from the Temperature Biofeedback Nonlearners who completed six sessions in Fig. 7 ($\bar{x} = 82.9 \pm 8.4^{\circ}$F). For the EMG Biofeedback group, 7 early dropouts provided baseline data for at least one session ($\bar{x} = 3.0 \pm 1.8\,\mu$V) and did not differ from the EMG Nonlearners who completed six sessions in Fig. 8 ($\bar{x} = 3.1 \pm 1.6\,\mu$V). For the Normal group, 5 early dropouts provided early baseline data ($\bar{x} = 87.2 \pm 4.2^{\circ}$F) and were intermediate between, and not statistically different from, the Normal Learners ($\bar{x} = 89.2 \pm 4.7^{\circ}$F) and the Normal Nonlearners who completed six sessions in Fig. 7 ($\bar{x} = 83.2 \pm 7.6^{\circ}$F).

Early baseline values (Sessions 1–3) were also compared for RP versus Normal participants regardless of learning status, with data combined for all participants who provided baseline data for at least one session. Digital skin temperature was significantly lower for the Temperature Biofeedback group ($\bar{x} = 83.7 \pm 8.1^{\circ}$F) than the Normal group ($\bar{x} = 87.7 \pm 5.3^{\circ}$F, $p < .003$). Frontalis EMG averaged $3.3 \pm 1.8\,\mu$V for the EMG Biofeedback group. Finally, throughout the study two different methods for quantifying baseline temperature and EMG were used as deemed appropriate for the data analyses, the learning algothrithms, and the figures, that is the mean of baseline minutes 1–16 and the mean of baseline minutes 14–16. Baseline values proved to be very similar for these two quantification

methods. Baseline digital skin temperature (Sessions 1–3) for the Temperature Biofeedback group averaged $83.6 \pm 6.9^{\circ}$F for minutes 1–16 and $83.7 \pm 8.1^{\circ}$F for minutes 14–16. The Temperature Biofeedback learning subgroups were equally close for the two baseline quantification methods. Baseline frontalis EMG (Sessions 1–3) for the EMG Biofeedback group averaged $3.2 \pm 1.6\,\mu$V for minutes 1–16 and $3.3 \pm 1.8\,\mu$V for minutes 14–16. This indicates that no systematic bias was introduced by use of one or the other method of baseline quantification.

Reduction of RP Attacks at 1 Year

At 1-year follow-up, daily attack cards and daily diaries were completed by 85% of those randomized to biofeedback and 83% of those randomized to medication. The median time of follow-up, which was carried out in the winter months, was 13.5 months after initiation of treatment. The 1-year attack data were corrected for missing values to guard against selective dropout of treatment failures and differential dropout between treatment groups. The RTS outcome data and the methods for statistical analysis are presented in considerable detail elsewhere (RTS Investigators, 2000); however, the following information is relevant to the present paper.

Because behavioral and medication treatments are intrinsically very different in the amount and nature of patient–therapist interactions, there was no direct statistical comparison between behavioral versus medication groups. Rather, each treatment was compared with its planned control group. As reported previously, the Nifedipine group showed a significantly lower attack rate at 1-year follow-up compared with the Pill Placebo group ($p < .001$) whereas the Temperature Biofeedback group did not differ from the EMG Biofeedback group ($p > .05$). However, this statistical approach raises a legitimate concern. In the RTS, the EMG Biofeedback procedure was designed to serve as a behavioral placebo. If EMG biofeedback were an equally effective behavioral treatment, this could yield a statistical finding of "no difference" between Temperature Biofeedback and EMG Biofeedback groups. To address this concern, Table VIII provides mean attack rates per day at 1-year follow-up for the four study groups, both for Verified Attacks and for All Attacks. These means are adjusted for differences (nonsignificant) in baseline attack rate for the four treatment groups . On both outcome measures, the EMG Biofeedback group was very similar to the Pill Placebo group at 1-year follow-up. The Temperature Biofeedback group averaged 30.4% fewer Verified Attacks ($p = .37$) and 7.1% fewer All Attacks than the EMG Biofeedback control group. The Nifedipine group averaged 66.7% fewer Verified Attacks and 56% fewer All Attacks than Pill Placebo. The Nifedipine group averaged 56.3% fewer attacks than the Temperature Biofeedback group. Because the 1-year follow-up attack

Table VIII. Daily Attack Frequency at 1-Year Follow-Up ($N = 313$)

	Verified attacks[a]	All attacks[a]
Temperature biofeedback	0.16	0.39
EMG biofeedback	0.23	0.42
Nifedipine	0.07	0.20
Pill placebo	0.21	0.46

[a] Geometric means, adjusted for baseline attack rate.

rates are statistically adjusted they cannot be compared with the baseline attack rates. Also, the 1-year follow-up data were collected during the winter months whereas the baseline procedures were initiated in the warmer Fall months. The means in Table VIII are geometric means which are reconstituted from the log values that were used for statistical analyses in the RTS to reduce variability due to outliers and are, accordingly, lower than unadjusted raw attack rates (arithmetic means) as in Table II and in many published RP studies.

DISCUSSION

These findings indicate that there were substantial problems with acquisition of physiological self-regulation skills in the RTS. Only 34.6% of RP participants who were randomized to temperature biofeedback intervention met the study criteria for successful learning. This can not easily be attributed to deficiencies in instrumentation, feedback display parameters, or the algorithm that operationally defined successful learning, because 67.4% of Normal participants met the acquisition criteria. For the Normal group, hand-warming skills were evident as early as Session 4 (Fig. 1) and retained under nonfeedback conditions (Fig. 5). RP participants randomized to EMG biofeedback training fared better, and 55.4% met the EMG learning criteria. Frontalis relaxation skills were evident early in the course of training (Fig. 2) and retained under nonfeedback conditions (Fig. 6). Although the 55.4% acquisition rate seems low for a response that is considered relatively easy to learn, no comparative EMG data were obtained for normal participants.

The characteristics of successful RP learners (Tables V–VII) provide relevant information on acquisition in the RTS. Of particular interest is the finding that variables related to RP disease severity in Table III did not predict acquisition of physiological responses. Temperature Biofeedback participants with higher baseline attack rates, physician ratings of more severe RP symptoms, presence of pain with attacks, or colder baseline skin temperatures were neither more nor less likely to learn hand warming to the specified criterion level. This indicates that the ability to learn the vasodilation task was not limited to the mildest cases. In contrast, several psychosocial and demographic variables did predict acquisition of physiological responses, and these findings suggest that the individual participant comes to the biofeedback training situation with personal characteristics that are relevant to successful learning. Specifically gender, coping skills, and anxiety were significant predictors.

Male gender was strongly associated with poorer acquisition (OR = 0.18) and early dropout for the EMG Biofeedback group, but not the Temperature Biofeedback group. The treatment preference data (Table IV) provide a possible explanation. Biofeedback was more often preferred by those who acknowledged stress-related RP attacks, by those who reported use of venting emotions as a common coping strategy for managing stressful events, and by women. This suggests that prior to treatment onset biofeedback was viewed as a psychological therapy related to stress management rather than a physiological intervention designed to reduce peripheral vasoconstriction. Once biofeedback training began, the clear connection between temperature biofeedback, increased digital blood flow, and reduced vasospasm in RP is likely to have increased acceptance of temperature biofeedback. EMG biofeedback, which focused on facial muscle relaxation, may have continued to be viewed as psychological—and less acceptable to men.

Coping strategies for managing stressful events as measured by the COPE (Carver et al., 1989) proved to be relevant predictors of acquisition. The positive strategy, Positive Growth and Reinterpretation, predicted greater success in learning temperature increases (e.g., I try to learn something from the experience). A negative strategy, Denial, predicted less successful learning and early drop out with temperature biofeedback (e.g., I act as though it hasn't even happened). This suggests that learning may be enhanced by instruction on coping skills to foster positive engagement and counteract denial-associated withdrawal. The positive strategy, Humor, predicted frontalis EMG decreases (e.g., I laugh about the situation). A plausible explanation comes from research on muscles of facial expression. The Corrugator muscle, which contributes to forehead EMG as recorded in this study, is often associated with negative affect (frowning) whereas the Zygomatic muscle is associated with positive affect (smiling), and these two muscles have been reported to have a reciprocal relationship. Lang, Greenwald, Bradley, and Hamm (1993) found that Corrugator EMG increased in proportion to unpleasant content in viewed pictures and decreased below baseline levels when viewing very pleasant content, and Zygomatic EMG was high. McCanne and Anderson (1987) reported similar EMG findings when imagining positive scenes (low Corrugator, high Zygomatic EMG) versus negative scenes (high Corrugator, low Zygomatic EMG). These studies provide a rationale for frequent use of Humor being helpful for learning forehead muscle relaxation. These studies also suggest the value of maintaining positive affect and avoiding negative affect if difficulties are encountered during frontalis biofeedback training and further suggest that pleasurable imagery may be helpful.

The Temperature Biofeedback and EMG Biofeedback groups were combined (Table VII) to highlight variables that may be predictive of successful physiological learning in the RTS regardless of modality, such as an initial preference for biofeedback treatment over medication. Use of the positive coping strategy, Emotional Social Support, predicted better learning (e.g., I talk to someone about how I feel). Greater anxiety, as measured in the RTS, was also associated with less successful learning. These findings provide further evidence that the emotional aspects of participation in biofeedback interventions are relevant to learning.

Clinic site, however, was the strongest predictor of successful learning in the RTS. Acquisition rates varied widely, both for Temperature Biofeedback (12.5–75%) and for EMG Biofeedback (28.6–78.6%) in spite of considerable efforts to standardize the biofeedback procedures to insure consistency. The instrumentation and the biofeedback training protocols were the same at all study sites, and biofeedback therapists attended a protocol training workshop. This variation in acquisition rate for the Temperature Biofeedback group can not be accounted for by climate. Although the highest learning rate was found at Clinic 2, which had the warmest outdoor temperature, the lowest learning rate was found at Clinic 3, which was the second warmest site. In addition, mean outdoor temperature was not a predictor of successful hand warming, which took place indoors in a temperature controlled environment. This variation in acquisition is also difficult to attribute to unmeasured disease-related differences between Raynaud's populations at the clinic sites. The two clinic sites with the lowest acquisition rate for hand warming also had the lowest success rate for frontalis relaxation that is unrelated to the RP disease process. These findings suggest that unmeasured cultural differences could have played a role. These findings also point to the laboratory environment as a likely factor, including the interactions between the biofeedback therapist

and the participant. There is previous evidence of a strong "person factor" in temperature biofeedback training. Taub (1977) reported acquisition rates of 9.1% versus 90.5% for two groups of normal subjects who were trained by two different technicians in his laboratory, both using the same standard temperature biofeedback protocol. He identified differences in the quality of the interpersonal interactions between the trainers and their subjects. In a subsequent prospective study, Taub and School (1978) found large differences in digital skin temperature increases when a single experimenter adopted an operationally defined "friendly" versus "impersonal" approach, 4.2°F versus 1.3°F, respectively (mean within-session change for Sessions 8, 9, and 10). The temperature biofeedback training procedures used by Taub were similar to those in the RTS in that mental strategies, including use of thermal imagery, were encouraged but adjunctive techniques, such as progressive muscle relaxation and autogenic training, were not included.

The physiological data (Figs. 1–8) provide further information relevant to acquisition in the RTS. There was a substantial and persistent vasoconstrictive reaction to the onset of the biofeedback period (minute 17, Figs. 1, 3, and 5) . This indicates a counterproductive reaction to the demand characteristics of the biofeedback protocol that may have been a problem. The time course of acquisition over the 11 sessions, for Learners versus Nonlearners (Figs. 7 and 8) suggests that the initial biofeedback training sessions were critical for successful learning, both for Normal and for RP participants learning hand warming and also for RP participants learning frontalis relaxation. As a subgroup, those who were identified as Learners (based on their performance near the end of the protocol) showed progress in the first three sessions. In comparison Nonlearners, as a subgroup, had difficulty producing the desired response in the initial three sessions and showed little evidence of progress over the remaining training sessions. These findings suggest that acquisition may be improved by methods that minimize reactions to the audiovisual feedback display and methods that foster a degree of success in early sessions. These findings also suggest that early intervention is needed for participants who experience difficulties. In the RTS, however, the standardized protocol did not allow for additional sessions, or the addition of adjunctive strategies, early in the course of the study to address problems with basic hand-warming skills. Instead, all Temperature Biofeedback participants progressed to cold challenge in Session 6, and also began applied practice in the environment at that time, independent of a demonstrated ability to produce digital skin temperature increases in the previous sessions. Nonlearners were not formally identified until the end of the 11-session protocol, and the intervention—four additional sessions—were offered the following fall. For Nonlearners, this was likely too late.

Clinicians have long recognized that hand-warming skills can be difficult for patients to learn. Accordingly, experienced biofeedback clinicians use multiple peripheral warming strategies depending on the individual client's needs (Tibbetts, Charbonneau, & Peper, 1987). More easily learned techniques such as progressive muscle relaxation, autogenic training, and frontalis EMG biofeedback are introduced first and then temperature biofeedback is phased in. Inexpensive feedback devices are used to provide supplemental temperature biofeedback practice at home. Patients are trained to a criterion level of mastery rather than a set number of sessions (Fahrion, Norris, Green, Green, & Snarr, 1986; Libo & Arnold, 1983; Sedlacek, 1989). Using these clinical strategies, Sedlacek has reported that 80% of patients with primary RP in his case series ($N = 62$) were able to learn hand-warming skills (goal = increase of 3–9°F) and substantially reduce RP symptoms. On average, 20–30 sessions were needed for this clinical population (Sedlacek, 1989; Sedlacek & Taub, 1996).

The Temperature Biofeedback group in the RTS not only had problems with learning basic hand-warming skills, but also had problems applying hand-warming skills to reduce RP attacks. The RTS Investigators (2000) reported a subgroup analysis that found no difference in RP attack rate at 1-year follow-up for Temperature Biofeedback Learners compared with Nonlearners. This finding simply may be due to the small number of Learners in the RTS. That is, with the best of protocols, not all who learn basic hand-warming skills (Learners) will also learn to apply these skills effectively to reduce RP attacks. When the number of Learners is small, it becomes correspondingly difficult to demonstrate a clinical impact. In addition, RP participants who did not meet the learning criteria during Sessions 1–11 were nevertheless classified as Learners if they could meet the digital skin temperature criteria in two of the four booster sessions the following fall. This was the case for 32% (9/28) of the Temperature Biofeedback Learners. For these Learners the application training, which occurred in Sessions 6–11, may simply not have been effective because it occurred *before* basic hand-warming skills had developed. Another consideration is the standardized RTS protocol that restricted the interactions between the biofeedback therapist and the participants. Most notably, the therapist could not review the daily attack records or query the participants about the number of attacks, because there was a legitimate concern that the participants would be coached inadvertently to report fewer attacks or alter their self-report. In contrast, biofeedback therapists in clinical practice rely on daily diaries, and also inexpensive skin temperature monitoring devices, to identify problems with generalization of skills to the natural environment (Sedlacek, 1989; Sedlacek & Taub, 1996; Tibbetts et al., 1987). The experimental studies by Freedman et al. (1983, 1985) also included regular review of daily attack records with the participants to identify progress, and this provided reinforcement to maintain motivation. Furthermore, in the RTS the baseline attack frequency was relatively low, 1/day for All Attacks, compared with 2/day using a similar daily log in Freedman's studies. A low event rate adds to the difficulty of identifying progress without attack records and also provides fewer opportunities for reinforcement of success.

The RTS recruitment method may also have been a factor, both for acquisition of hand-warming skills and for application of hand-warming skills to reduce RP attacks. The RP participants in this study were not specifically recruited to participate in a behavioral study and were not necessarily good candidates for behavioral treatment. This is in contrast to previous studies (Freedman et al., 1983, 1985) and is certainly different from clinical practice in which both the patient and the therapist seek a good match between treatment candidates and treatment techniques. Clinicians can, and do, work effectively with patients who are referred for biofeedback therapy with little knowledge of what is involved and with questionable interest in behavioral treatment. This, however, places a premium on the clinician's ability to educate the patient, enhance motivation and compliance, and individualize protocols to fit the orientation of the patient. The RTS, however, combined nonspecific recruitment with a standardized protocol that limited the biofeedback therapist's flexibility, and this combination may have been a substantial problem.

Fewer Temperature Biofeedback (34.6%) than Normal (67.4%) participants successfully learned hand warming. The RTS Investigators (2000) raised the relevant question of whether this difference was due to the nature of primary RP, as diagnosed in the RTS. The physiological data in this study (Fig. 7) indicates that Temperature Biofeedback Learners were very similar to Normal Learners with respect to the time course of acquisition across

sessions and the size of within-session temperature changes. RP Learners, on average, did not progress more slowly and did not produce smaller within-session changes. The difference was in the percentage who learned rather than the learning process. These physiological data are in agreement with the multivariate analyses (Table V), which found that within the Temperature Biofeedback group, those with more severe RP symptoms did not have greater difficulties learning. If the RP disease process were the primary factor in failure to learn hand warming, then the severity of RP should be relevant. At the same time, RP participants on average did have significantly lower baseline digital skin temperatures than the Normal group. Furthermore, within the Normal group, Nonlearners had significantly lower baseline temperatures than Learners. That is, Normal Nonlearners were more like the RP Temperature Biofeedback group with respect to baseline skin temperatures. Although lower baseline skin temperatures were not associated with poorer learning within the Temperature Biofeedback group, this may be due to the low baseline temperatures for this group as a whole. This raises the possibility that hand warming is simply more difficult for individuals with cooler hands—whether the individual is normal or diagnosed with primary RP. If this is indeed the case, then hypothetically a RP group and a normal comparison group that is selected to match RP baseline skin temperatures should have equal difficulty learning hand warming. Alternatively, the low baseline skin temperatures in primary RP may be an index of disease characteristics that uniquely increase the difficulty of learning hand warming. If this is the case, then a RP group hypothetically should have greater difficulty learning hand warming than a normal control group that is selected for equally cool hands. These interesting alternatives can be tested.

Normal and RP participants also differed with respect to age and method of recruitment, and these may have been factors in learning. Normal participants ($\bar{x} = 37.6 \pm 11$ years) were significantly younger than the RP participants ($\bar{x} = 44.5 \pm 12$ years), but neither group had many geriatric participants. Also Middaugh, Woods, Kee, Harden, and Peters (1991) found that digital skin temperature increases, within session, were identical for younger ($\bar{x} = 38.5$ years) and older ($\bar{x} = 62.4$ years) groups of pain patients during biofeedback-assisted relaxation training. With regard to recruitment, as described in the Recruitment and Participant Characteristics section, care was taken to recruit both RP and Normal participants without initial reference to the treatment procedures being offered. However, the RP participants ultimately had to agree to random assignment to two very different conditions: medication, to be taken over 15 months; and biofeedback, to include 11 training sessions plus daily homework. In contrast, Normal participants had to agree to the temperature biofeedback procedures. These are very different requirements that may have led to substantial differences between groups with consequences for learning. In this respect, the recruitment process for Normals was similar to the recruitment process for the RP participants in previous studies (Freedman et al., 1983, 1985). There are also inescapable differences due to the RP participant's goal of personal benefit versus the orientation of the normal volunteer in a short term study with no health consequences. This is an interesting area for further investigation.

As noted in the Learning Algorithm section, Learner and Nonlearner subgroups were operationally defined, and other investigators may choose different criteria. The defining algorithms in the RTS were based on within-session changes reported in previous studies (Freedman et al., 1983, 1985), on blind examination of minute-by-minute session graphs for a sample of participants in Cohort I, and on statistical considerations. These methods were

approved by the RTS oversight board and the NIH staff. The goal was to provide a quantitative and objective basis for computer classification of all RP participants. This classification was used to offer remedial sessions to the poorer learners and to provide a dichotomous variable for statistical analysis. It is more accurate to think of the resulting Learners and Nonlearners as those with greater versus lesser evidence of having learned the desired physiological responses. The data in Figs. 7 and 8 indicate that the algorithms achieved a meaningful and statically significant separation between Learners and Nonlearners for each of the three biofeedback groups (Figs. 7 and 8). This degree of separation was not inherent in the algorithms and provides good support for the validity of the selected criteria.

In conclusion, hand-warming skills were difficult to learn and difficult to apply for symptom management in primary RP, under the conditions of the RTS. RP participants were recruited from the community and randomly assigned to biofeedback versus medication treatments. Temperature biofeedback was administered as a single modality treatment, without adjunctive techniques, using a standardized 11 session training sequence to maximize experimental control and insure consistency at five clinic sites. Under these conditions, only 34.6% of the RP participants assigned to the Temperature Biofeedback group successfully learned digital skin temperature increases to an objective criterion level. This is well below the 80% acquisition rate in previous experimental studies (Freedman et al., 1983, 1985) and clinical reports (Sedlacek & Taub, 1996).

Coping strategies, anxiety, gender, and especially clinic site predicted acquisition of hand-warming skills in RP participants. There was evidence of vasoconstriction in response to the onset of biofeedback. There was also evidence that a degree of success in producing the desired physiological response in the first three biofeedback sessions was relevant to acquisition. These findings suggest that attention to psychosocial aspects of training and flexibility in the initial biofeedback sessions is important for successful biofeedback learning. The "person factor" in single modality temperature biofeedback studies may operate through attention to this aspect of training. The clinician's use of adjunctive techniques may serve the same function.

ACKNOWLEDGMENTS

This research was supported by Contract N01-HC-35127 from the National Heart, Lung, and Blood Institute.

REFERENCES

Blanchard, E. B., & Haynes, M. (1975). Biofeedback treatment of a case of Raynaud's disease. *Journal of Behavior Therapy and Experimental Psychiatry, 6,* 230–234.

Brown, K. M., Middaugh, S. J., Haythornthwaite, J., & Bielory, L. (2001). The effects of stress, anxiety and outdoor temperature on the frequency and severity of Raynaud's attacks: The Raynaud's treatment study. *Journal of Behavioral Medicine, 24,* 137–153.

Carver, C. S., Scheier, M. F., & Weintraub, J. K. (1989). Assessing coping strategies: A theoretically based approach. *Journal of Personality and Social Psychology, 56,* 267–283.

Cohen, S., Kamarack, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24,* 385–396.

Diener, E., Emmons, R. A., Larsen, R. J., & Griffin, S. (1985). The Satisfaction With Life Scale. *Journal of Personality Assessment, 49,* 71–75.

Fahrion, S., Norris, P., Green, A., Green, E., & Snarr, C. (1986). Biobehavioral treatment of essential hypertension: A group outcome study. *Biofeedback and Self-Regulation, 11,* 257–277.
Freedman, R. R. (1991). Physiological mechanisms of temperature biofeedback. *Biofeedback and Self-Regulation, 16,* 95–115.
Freedman, R. R., & Ianni, P. (1983). Self-control of digital temperature: Physiological factors and transfer effects. *Psychophysiology, 20,* 682–689.
Freedman, R. R., & Ianni, P. (1985). Effects of general and thematically relevant stressors in Raynaud's disease. *Journal of Psychosomatic Research, 29,* 275–280.
Freedman, R. R., Ianni, P., & Wenig, P. (1983). Behavioral treatment of Raynaud's disease. *Journal of Consulting and Clinical Psychology, 51,* 539–549.
Freedman, R. R., Ianni, P., & Wenig, P. (1985). Behavioral treatment of Raynaud's disease: Long term follow-up. *Journal of Consulting and Clinical Psychology, 53,* 136.
Freedman, R. R., Lynn, S. J., & Ianni, P. (1982). Behavioral assessment of Raynaud's disease. In F. J. Keefe & J. A. Blumenthal (Eds.), *Assessment strategies in behavioral medicine* (pp. 99–129). New York: Grue and Station.
Grabert, J. C., Bregman, N. J., & McAllister, H. A. (1980). Skin temperature regulation: The effects of suggestion and feedback. *International Journal of Neuroscience, 10,* 217–221.
Graham, D. T., Stern, J. A., & Winour, G. (1958). Experimental investigation of the specificity of attitude hypothesis in psychosomatic disease. *Psychosomatic Medicine, 20,* 446–457.
Jacobsen, A. M., Hackett, T. P., Surman, O. S., & Silverberg, E. L. (1973). Raynaud's phenomenon. Treatment with hypnotic and operant technique. *Journal of the American Medical Association, 225,* 739–740.
Jacobsen, A., Menschreck, T., & Silverberg, E. (1979). Behavioral treatment for Raynaud's disease: A comparative study with long-term follow-up. *American Journal of Psychiatry, 136,* 844–846.
Jobe, J. B., Sampson, J. B., Roberts, D. E., & Beetham, W. P., Jr (1982). Induced vasodilation as treatment for Raynaud's disease. *Annals of Internal Medicine, 97,* 706–709.
Jobe, J. B., Sampson, J. B., Roberts, D. E., & Kelly, J. A. (1986). Comparisons of behavioral treatments for Raynaud's disease. *Journal of Behavioral Medicine, 9,* 89–96.
Keefe, F. J. (1978). Biofeedback vs instructional control of skin temperature. *Journal of Behavioral Medicine, 1,* 383–390.
Keefe, F., & Gardner, E. (1979). Learned control of skin temperature: Effects of short and long-term biofeedback training. *Behavior Therapy, 10,* 202–210.
Keefe, F., Surwit, R., & Pilon, R. (1979). A 1-year follow-up of Raynaud's patients treated with behavioral therapy techniques. *Journal of Behavioral Medicine, 2,* 385–391.
King, N. J., & Montgomery, R. B. (1980). Biofeedback-induced control of human peripheral temperature: A critical review of the literature. *Psychological Bulletin, 88,* 738–752.
Lang, P. J., Greenwald, M. K., Bradley, M. M., & Hamm, A. O. (1993). Looking at pictures: Affective, facial, visceral and behavioral reactions. *Psychophysiology, 30,* 261–273.
LeRoy, T. A., & Medsger, T. A., Jr (1992). Raynaud's phenomenon: A proposal for classification. *Clinical Experimental Rheumatology, 10,* 485–488.
Libo, L. M., & Arnold, G. E. (1983). Does training to criterion fluence improvement? A follow-up study of EMG and thermal biofeedback. *Journal of Behavioral Medicine, 6,* 397–404.
Maricq, H. R. (1992). Capillaroscopy in Raynaud's syndrome. *Vascular Medicine Review, 3,* 3–20.
Maricq, H. R., Carpentier, P. H., Weinrich, M. C., Keil, P. E., Palesch, Y., Biro, C., Vionnet-Fuasset, M., Jiguet, M., & Valter, I. (1997). Geographic variation in the prevalence of Raynaud's phenomenon: A 5 region comparison. *Journal of Rheumatology, 24,* 879–889.
Maricq, H. R., & Weinrich, M. C. (1988). Diagnosis of Raynaud's phenomenon assisted by color charts. *Journal of Rheumatology, 15,* 454–459.
McCanne, T. R., & Anderson, J. A. (1897). Emotional responding following experimental manipulation of facial electromyographic activity. *Journal of Personality and Social Psychology, 52,* 759–768.
Melin, B., & Fagerstrom, K. O. (1981). Treatment of peripheral vasospasm. *Scandanavian Journal of Behavioral Therapy, 10,* 97–110.
Melin, B., & Fagerstrom, K. O. (1996). A one year follow-up of a placebo-controlled behavioral treatment of peripheral vasospasm. *Scandinavian Journal of Behavioral Therapy, 25,* 27–35.
Melin, B., & Sandqvist, D. (1994). Effects of thematically relevant visual stimuli in Raynaud's disease. *Scandinavian Journal of Behavioral Therapy, 23,* 53–60.
Middaugh, S., Woods, E. S., Kee, W. G., Harden, R. N., & Peters, J. R. (1991). Biofeedback-assisted relaxation training for the aging chronic pain patient. *Biofeedback and Self-Regulation, 16,* 361–377.
Mittleman, B., & Wolff, H. (1939). Affective states and skin temperature: Experimental study of subjects with "cold hands" and Raynaud's syndrome. *Psychosomatic Medicine, 1,* 271–292.
Raynaud's Treatment Study (RTS) Investigators. (2000). Comparison of sustained-release nifedipine and temperature biofeedback for primary Raynaud's phenomenon: Results from a randomized clinical trial with one-year follow-up. *Archives of Internal Medicine, 160,* 1101–1108.

Rose, G. D., & Carlson, J. G. (1987). The behavioral treatment of Raynaud's disease: A review. *Biofeedback and Self-Regulation*, *12*, 257–272.
SAS Institute Inc. (1990). *SAS/STAT users guide* (Version 6, 4th ed., Vol. 2). Cary, NC: The SAS Institute.
Sedlacek, K. (1979). Biofeedback for Raynaud's disease. *Psychosomatics*, *20*, 535–541.
Sedlacek, K. (1989). Biofeedback treatment of primary Raynaud's disease. In J. V. Basmajian (Ed.), *Biofeedback: Principles and practice for clinicians* (3rd ed., pp. 317–321). Baltimore: Williams & Wilkins.
Sedlacek, K., & Taub, E. (1996). Biofeedback treatment of Raynaud's disease. *Professional Psychology: Research and Practice*, *27*, 548–553.
Shapiro, D., & Schwartz, G. E. (1972). Biofeedback and visceral learning: Clinical applications. *Seminars Psychiatry*, *4*, 171–184.
Spielberger, C. D. (1983). *Manual for the State-Trait Anxiety Inventory (Form Y)*. Palo Alto, CA: Consulting Psychologist Press.
Stambrook, M., Hamel, E. R., & Carter, S. A. (1988). Training to vasodilate in a cooling environment: A valid treatment for Raynaud's phenomenon? *Biofeedback and Self-Regulation*, *13*, 9–23.
Stoffer, G. R., Jensesn, J. A. S., & Nesset, B. L. (1979). Effects of contingent versus yoked temperature feedback on voluntary temperature control and cold stress tolerance. *Biofeedback and Self-Regulation*, *4*, 51–61.
Surwit, R. (1973). Biofeedback: A possible treatment for Raynaud's disease. *Seminars in Psychiatry*, *5*, 483–489.
Surwit, R. S. (1982). Behavioral treatment of Raynaud's syndrome in peripheral vascular disease. *Journal of Consulting and Clinical Psychology*, *50*, 922–933.
Surwit, R. S., Williams, R. B., Jr, & Shapiro, D. (1982). *Behavioral approaches to cardiovascular disease.* New York: Academic Press.
Taub, E. (1977). Self-regulation of human tissue temperature. In G. Schwartz & J. Beatty (Eds.), *Biofeedback: Theory and practice* (pp. 265–300). New York: Academic Press.
Taub, E., & School, P. J. (1978). Some methodological considerations in thermal biofeedback training. *Behavior Research Methods and Instrumentation*, *10*, 617–622.
Thompson, B., Geller, N. L., Hunsberger, S., Frederick, M., Hill, R., Jacob, R. G., et al. (1999). Designing clinical trails with behavioral and pharmacologic interventions: The Raynaud's treatment study. *Controlled Clinical Trials*, *20*, 52–63.
Tibbetts, V., Charbonneau, J., & Peper, E. (1987). Adjunctive strategies to enhance peripheral warming: Clinical techniques. *Biofeedback and Self-Regulation*, *12*, 313–320.
Ware, J. E., Snow, K. K., Kosinski, M., & Gandek, B. (1993). *SF-36 health survey manual and interpretation guide.* Boston, MA: The Health Institute.
Wrigley, F. M., & Flavahan, N.A. (1996). Raynaud's phenomenon. *Rheumatic Disease Clinics of North America*, *22*, 765–781.