Biofeedback and Self-Regulation, Vol. 21, No. 2, 1996

Controlled Evaluation of Thermal Biofeedback in Treatment of Elevated Blood Pressure in Unmedicated Mild Hypertension[1]

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In the first of two studies, 42 unmedicated mild hypertensives completed either 16 sessions of thermal biofeedback (TBF) training for hand (7 sessions) and foot (9 sessions) warming or 8 weeks of monitoring BPs at home. There was a trend ($p < .10$) for more of those treated (57.1%) to have DBPs lower than 90 mm Hg than for those only monitoring BPs at home (33%). Analyses of clinic BP values from random zero sphygmomanometer measurements, from 24-hour ambulatory BP monitoring, and from home BP measurements made by the patient showed no advantage for treatment versus BP monitoring. Sixteen of the 21 patients in BP monitoring were later treated. Analyses of treatment effects across all treated subjects by gender revealed a significant ($p = .02$) decrease in DBP for treated female subjects ($n = 13$) but not for males ($n = 24$). In the second study the 22 initial treatment successes, that is, those whose DBP was below 90 mm Hg at posttreatment (59.4% of those who completed treatment), were randomized to an intensive follow-up (monthly visits for 6 months, then visits every two months) emphasizing regular home practice with an electronic TBF device or regular follow-up (visits every 3 months). Twelve of the 22 were still normotensive at 12 months. There were no differences at any point during the follow-up between the two conditions in success rate or BPs despite a numerical advantage in reported frequency of home practice by those in the intensive follow-up condition.

KEY WORDS: thermal biofeedback; essential hypertension; booster treatment in follow-up.

[1]This research was supported by a grant from NHLBI, HL-31189.

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0363-3586/96/0600-0167$09.50/0

The potential role of the various nondrug procedures for treating hypertension, usually lumped under the title, "stress management," remains controversial. The Joint National Committee on Hypertension (1993) in their latest (JNC-V) statement essentially dismiss the stress management approaches: "The role of stress management techniques in treating patients with elevated blood pressure is uncertain. . .the available literature does not support the use of relaxation therapies for definitive therapy or prevention of hypertension" (p. 164). Moreover, some investigators (Jacob, Chesney, Williams, Ding, & Shapiro, 1991), who have evaluated some of these procedures in the past, have also been fairly critical in a recent review, concluding that there were little in the way of consistent, generalizable results.

Other investigators (such as Rosen, Brondolo, & Kostis, 1993) however, remain more optimistic in their overall evaluations, concluding, "The use of relaxation and stress management approaches remains highly controversial. . ." (p. 100).

In our opinion, one of the troublesome aspects of the literature on stress management approaches to the treatment of hypertension has been the variability in outcome, especially the relative lack of replicability of positive results from one evaluative study to the next, even by the same research team. Examples of this lack of replicability can be found in the use of abbreviated progressive muscle relaxation (Taylor, Farquhar, Nelson, & Agras, 1977, positive results; Brauer, Horlick, Nelson, Farquhar, & Agras, 1979, less positive results) and for direct biofeedback of blood pressure (BP) (Benson, Shapiro, Tursky, & Schwartz, 1971, positive results; Surwit, Shapiro, & Good, 1978, less positive results).

An exception to this replicability problem is the work of Engel and colleagues using a combination of relaxation and direct feedback of BP (Glasgow, Gaarder, & Engel, 1982). They were able to successfully replicate their initial positive results in a second study (Glasgow, Engel, & D'Lugoff, 1989).

A major data merging effort by the NHLBI (Hypertension Intervention Pooling Project [HIPP], Kaufmann et al., 1988), in which the results from 12 Federally funded controlled trials of various stress management approaches to hypertension were pooled and subjected to a meta-analysis, revealed "a modest benefit of behavioral interventions with respect to DBP and no benefit with respect to SBP" (p. 222). It thus seems clear that for stress management approaches to hypertension to gain widespread acceptance, it will be necessary to demonstrate the reliability or replicability of the treatment effects. Such an effort was the primary purpose of this study.

Among the stress management techniques for hypertension, one that seemed promising (McCaffrey & Blanchard, 1985) was thermal biofeedback (TBF) to teach hand warming and foot warming. Initially described in a large uncontrolled series (Fahrion, Norris, Green, Green, & Snarr, 1986), this procedure proved significantly better than relaxation training in a controlled trial with medicated hypertensives (Blanchard et al., 1986) and more effective than BP monitoring and self-relaxation for unmedicated hypertensives in a controlled, cross-cultural study (Blanchard, McCoy et al., 1988). Small uncontrolled trials of the procedure in which results were evaluated by 24-hour ambulatory BP monitoring (24-hour ABPM) were also positive (Musso, Blanchard, & McCoy, 1991; Wittrock & Blanchard, 1992). However, the "lack of replicability problem" surfaced again recently (Blanchard et al., 1993) when TBF was not found to be superior to relaxation via frontal electromyographic (EMG) biofeedback, and poorer long-term follow-up data emerged.

The present study follows from the successful cross-cultural comparison of TBF to Autogenic Training (Blanchard, McCoy et al., 1988) and had four purposes. First, we sought to see if the high level of initial positive results (95% of those treated with TBF had clinically meaningful reductions in BP [DBP below 90 mm Hg] by the end of treatment) were replicable. Second, since the initial study was limited to males only, we sought to learn whether female hypertensives would also respond positively and thus included both males and females.

Third, the previous study evaluated outcome on the basis of clinic and home BPs. Since 24-hour ABPs are emerging as a "gold standard" in evaluations of treatments for elevated BP (Pickering & James, 1989) and since Jacob et al. (1992) found a discrepancy between clinic BPs and 24-hour ABPs for patients treated with relaxation (those treated with relaxation showed effects on clinic BPs but not 24-hour ABPs), we also evaluated the results with 24-hour ABPM.

Finally, in our earlier cross-cultural trial, comparable positive results were initially found at both sites (USA and USSR) for both active treatments; however, maintenance of reduced BP was significantly superior among the Soviet patients by 3 months. At one year 75% of their treated patients were still normotensive as compared to only 24% of the American treated patients. It was speculated that faithfulness of continued home practice accounted for these results. The fourth purpose of this study was to evaluate, in a controlled fashion, an enhanced maintenance and follow-up regimen for treatment successes versus our previous less intensive follow-up to see if maintenance could be improved.

OVERVIEW

For the sake of clarity this project is described as two studies: Study 1 was concerned with the initial treatment comparison of TBF to BP monitoring and as such represents a partial systematic replication of the Blanchard, McCoy et al. (1988) study; Study 2 was concerned with a controlled evaluation of two follow-up procedures for those patients who were successfully treated in Study 1.

STUDY 1

Methods

Subjects and Patient Flow

One-hundred and eighteen individuals were initially screened for this project, while 42 eventually completed treatment and were eligible to enter Study 2. In Table I is a description of the patient flow through Study 1.

As one can see from Table I, 118 individuals initially began the project; 87 were initially screened for eligibility based on BP; and 46 were initially randomized to treatment. Three of those randomized were taken out of treatment because their BPs went too high (repeated readings of greater than 105 mm DBP or 180 mm SBP) or another medical problem developed. There was only one dropout (during baseline).

Patients were matched into pairs primarily based on screening or eligibility BPs, and secondarily on gender, age, and years known to be hypertensive. In Table II are the demographic characteristics of those individuals who completed Study 1, summarized by the two conditions to which they were initially randomized.

Thus, one can see that the sample was 67% male, of average age 50.5, who had been hypertensive for an average of 8.3 years, and was 9.5% minority. Part of the sample was directly referred by their personal physicians, while the others volunteered based on local media coverage and advertising.

The two groups were not different on any of the characteristics in Table II except previous medication status [$\chi^2(1, N = 46) = 4.85, p = .028$]; those initially randomized to treatment were more likely to have discontinued antihypertensive medication to enter the study.

Table I. Patient Flow Through Study 1: Eligibility Screening, Baseline, and Treatment

	Patient's medication status at time of initial contact	
	Medicated	Unmedicated
Screened at SUNY		57
Dropouts		3
Ineligible BP too low		12
Ineligible BP too high		5
Referred to Albany Medical Center	61	37
Take outs based on medical records	20	5
Take outs based on physical/history	7	1
Takes outs — personal physician refused	4	0
Withdrawn from medication	30	—
Screened at SUNY	30	
Dropouts	3	
Ineligible BP too low	12	
Ineligible BP too high	0	
Started baseline BP monitoring	15	31

	Medicated		Unmedicated	
Treatment conditions	TBF	Monitoring	TBF	Monitoring
Randomized to conditions	11	4	12	19
Dropouts in baseline	0	0	0	1
Dropouts in treatment	0	0	0	0
Takeouts in treatment (BP became too high [2], other medical problem)	1	0	1	1
Completed treatment	10	4	11	17

Assessment Procedures: Overview

As indicated in Table I, the sequence of assessment procedures was different depending on whether patients initially volunteered in a medicated or nonmedicated state. Informed consent for the assessment procedures was obtained at the first visit to the Center for Stress and Anxiety Disorders (CSAD). Those who were not on antihypertensive medication were initially screened for eligibility by personnel at the CSAD. If they were eligible (diastolic BP [DBP] equal to or greater than 90 mm Hg on 2 of 3 eligibility screening visits, and the average of the 3 eligibility DBPs was $\geq$ 90 mm Hg), they were then scheduled for a physical examination and review of medical records by the study physician (GE).

Table II. Characteristics of the Sample

Characteristics	Initial treatment condition: Thermal biofeedback	Initial treatment condition: BP monitoring
Gender (M/F)	15/6	13/8
Age $\bar{X}$ (*SD*)	50.0 (7.3)	51.0 (6.8)
Range	32-61	40-62
Previously medicated (Yes/No)	10/11	4/17
Minority	2	2
Years known to be hypertensive $\bar{X}$ (*SD*)	8.3 (8.1)	8.4 (5.4)
Eligibility screening PBs		
SBP (*SD*)	140.7 (8.5)	143.4 (12.2)
DBP (*SD*)	93.4 (3.0)	95.6 (4.1)

If they remained eligible after the physical exam, they were then started on recording of BPs at home for 4 weeks. During this 4-week baseline interval, two separate 24-hour ambulatory BP monitoring assessments (24-hour ABPMs) were conducted by CSAD personnel. Subjects were randomized to either initial treatment or continued home BP monitoring during this baseline phase.

For patients who were initially on antihypertensive medications, the initial formal contact with the project began with an assessment by the study physician which included a review of medical records and physical examination. About half of the medicated patients were excluded based on medical records or the examination. If found eligible, they were also started on recording home BPs and the study physician gave them a schedule for discontinuing their antihypertensive medication. At a point two weeks after they were medication-free, they were seen briefly by the research nurse (LG) at the physician's office and scheduled for eligibility screening at CSAD.

These previously medicated patients were then screened for eligibility at the CSAD. If eligible (DBP $\geq$ 90 mm Hg on 2 of 3 eligibility screening visits), their 4 weeks of home BP recording for baseline were begun, the 2 ABPMs were scheduled, and they were randomized to condition. If their DBP had not risen to the eligibility level, they were reassessed in a month. These reassessments continued until the patient was eligible or for 5 months. If DBP had not risen to the hypertensive range they were dismissed and sent back to their personal physician along with a record of their screening BPs.

Eligibility Screening. Determination of eligibility was always based on BPs measured by random zero sphygmomanometer. The patient sat quietly erect in a straight-back chair with feet on the floor for about 10 minutes. Then 3 BP determinations were made, approximately 3 minutes apart. These 3 values, corrected by the random offset, were averaged. If the average DBP equaled or exceeded 90 mm Hg, it was counted as positive. Repeat assessments were scheduled at least 2 days apart. If patients were below 90 mm Hg on the 2 consecutive visits, they were thanked and dismissed or rescheduled (if previously medicated). If they were below 90 on the first visit, but eligible on the next 2 visits, or eligible on the first visit, below 90 on the second visit, and then eligible on the third visit, they were declared eligible if the average DBP of the 3 visits was $\geq$ 90 mm Hg.

Treatment Clinic BPs. The same procedure, 3 BP determinations by random zero sphygmomanometer at a visit, were used for so-called Clinic BPs for purposes of evaluating the two experimental conditions. The pretreatment assessment took place in the week before treatment or BP monitoring began.

Physician Assessment. The study physician (GE) reviewed the patient's medical records, took a history, and conducted a physical examination. In the course of the latter he measured BP with a mercury sphygmomanometer. Medicated patients who, in the judgment of the physician, could not be safely withdrawn from their medication (e.g., patients with cardiac arrhythmia on propranolol) were disqualified as were those with a history of life-threatening illness (e.g., carcinoma). As shown in Table I, 33 cases were eliminated at this step.

At this visit the research nurse trained the patients to take their own BPs at home using a dual earpiece stethoscope and aneroid sphygmomanometer.

Home BPs. Patients were asked to take their BPs at home four times per day, twice in the morning shortly after arising and in the evening. BP was to be taken in a *supine position* after lying still for 2 minutes and in an upright *standing position* 30 seconds after arising. These values were recorded on postcards for a week and then mailed back to the research nurse so that she and the study physician could track BPs. When cards were late, CSAD personnel prompted the subjects. Medicated patients indicated what dose they were taking and when they had finished tapering from their medication. Regular home monitoring of BPs continued for at least 4 weeks before treatment began.

24-Hour Ambulatory BP Monitoring. As mentioned earlier, after a patient became eligible based on BPs taken at the treatment setting, patients underwent two 24-hour ABPM assessments, approximately one week apart.

The Space Labs model 90207 was used for all ABP determinations. It is relatively quiet and weighs 14 ounces. It measures BP by an oscillometric technique. The device is programmable and was set to measure BP every 15 minutes from 6:00 a.m. to 12:00 midnight and every 30 minutes from midnight to 6:00 a.m. If the device cannot obtain a measurement due to movement, external noise, etc., it records an error and tries again in two minutes.

Treatment Procedures: Thermal Biofeedback

As described above, after matching and randomization, approximately half of the sample immediately began a 16-session thermal biofeedback (TBF) treatment program where the goal was to teach the participant initially to warm his/her hands and then his/her feet. All treatment took place in small groups of 3 to 5 patients who met twice a week for 8 weeks. Missed sessions were made up at the end of treatment such that all participants had at least 15 treatment sessions.

Participants were comfortably seated in upholstered recliners in a semicircle. Each had access to an individual TBF device, a Cyborg model J42, which displayed temperature digitally to 0.1°F. The device was oriented so that it was visible only to the participant. The thermistor was initially attached to the ventral surface of the left index finger by paper tape. Care was taken *not* to encircle the finger, which could have created a tourniquet.

Subjects also had an aneroid sphygmomanometer attached to the left upper arm, which remained on the arm, deflated, throughout the session. BPs were taken before the formal TBF training at each session and at its conclusion. Subjects were seated upright with feet on the floor for these measurements. Otherwise, they were semirecumbant with feet elevated for the TBF training.

An experienced doctoral level psychologist who had conducted half of the American treatments in our earlier study (Blanchard, McCoy *et al.*, 1988) (EBB), led the group at Sessions 1, 2, and 8 where key explanations and rationale were given. Otherwise the groups were led by one of 4 advanced doctoral students in clinical psychology who had been trained and supervised by the doctoral psychologist. One graduate therapist stayed with the group for its entire history, from initial meeting through follow-up. At the first session the procedures were explained, informed consent for treatment obtained, the rationale for the treatment given, questions answered, and then initial treatment expectancies assessed. (Verbatim descriptions are available in Blanchard, Martin, & Dubbert, 1988). Then BPs were taken.

It had been emphasized that each participant should taken an exploratory attitude, as well as one of passive volition, that is, allowing the response to occur rather than trying to force it to occur, and try out different strategies that might work for them in warming the hands. It was stressed that each individual needs to discover his/her own strategy.

As assistance in discovering a personal strategy, the participants were taken through a series of autogenic phrases that focus on relaxation, warmth, and heaviness as a demonstration of one technique that might assist in relaxation and peripheral vasodilation. During this time, participants were urged to focus on the self-instructions and bodily sensations while checking the feedback meter occasionally. This feedback trial lasted about 20 minutes.

The graduate assistant recorded temperatures at the beginning of the session and about every 5 minutes throughout the session. BPs were taken at the end of the session.

There followed a discussion of the experiences and questions. Finally, participants were given an alcohol-in-glass thermometer and asked to use it for home practice. They were asked to practice for at least 20 minutes per day, either one 20-minute or two 10-minute sessions and to record duration and temperature on sheets provided.

At the second session, there was a discussion of home practice experiences, a review of the rationale and again questions were answered. The treatment session again included the autogenic phrases. After that autogenic phrases were not formally incorporated into treatment.

Sessions 3 through 7 and 9 through 16 followed the same format: After discussion of practice and other issues, the participants sat quietly for about 5 minutes and BPs were taken. Next, participants were asked to warm their hands (or feet for sessions 9-16) for 4 minutes without feedback (while the experimenter recorded hand temperatures; the device was oriented so the participant could not see it). There followed a 16-minute session during which feedback was available. BPs were taken again and any other matters discussed. In-session BP values were made available to participants at the session.

At the eighth session the senior clinician returned and introduced the topic of foot warming by demonstrating the thermistor placement, on the ventral side of the great toe of the left foot. The rationale for this part of the treatment was given; subjects were warned that temperatures would be lower and that they might well have to learn the skill again, even if they were proficient at hand warming. Home practice continued for hand warming with attention devoted to sensations in the feet.

Sessions 9 through 16 were devoted to foot warming. Care was taken to keep the room temperature between 72 and 76°F. Room temperature was recorded for each session. At Session 16, appointments were made for a repeat BP assessment by the research nurse and for another 24-hour ABPM.

BP Monitoring Control Condition. Participants in this condition were told that the treatment program was oversubscribed and that they would have to wait for 8 weeks before treatment began. They were asked to continue to monitor BPs at home twice per day. They were seen at 4 weeks to maintain contact and measure BP at the Treatment Clinic.

Posttreatment Assessment

All participants, those initially receiving TBF and those in the BP monitoring condition, underwent the same assessment posttreatment. BP was measured in the treatment clinic as before: 3 determinations of BP in the seated position by random zero sphygmomanometer. The average of these 3 measurements dictated the decision of whether the subject would enter the follow-up study (Study 2) or return to the care of his/her physician.

Based upon the treatment clinic random zero BP, a subject was called a success (DBP < 90 mm Hg) or failure. Failures were counseled to return to their physicians. Advice on diet and exercise was also given to the failure. Successes entered Study 2.

A 24-hour ABPM assessment was also made within a week of the completion of treatment

Treatment of BP Monitoring Controls

The participants in this condition were offered the TBF treatment as soon as the posttreatment assessment was complete. Five declined treatment. Treatment was identical to that described above, 16 sessions of TBF for hand warming and foot warming, delivered in small groups with regular home practice expected and aided by the alcohol-in-glass thermometer.

At the conclusion of treatment, these participants underwent the posttreatment assessment again.

Table III. Clinical End Point Results for Study 1

Condition (or characteristic)	End point: Success (DBP < 90 mm)	End point: Failure (DBP > 90 mm)
Thermal biofeedback	12	9
Male	8	7
Female	4	2
Previously medicated	7	3
Nonmedicated	5	6
BP Monitoring	7	14
Male	4	9
Female	3	5
Previously medicated	1	3
Nonmedicated	6	11
BP Monitoring who later entered treatment (n = 16) (declined treatment n = 5)	10	6
Male	5	4
Female	5	2
Previously medicated	3	0
Nonmedicated	7	6

Results

Clinical End Point Analysis

Our desired clinical end point was DBP less than 90 mm Hg as measured at the treatment clinic by random zero sphygmomanometer. The results of these evaluations are presented in Table III.[3]

Examining Table III, one can see that 57.1% of those initially treated with TBF met our clinical end point at the end of treatment, as compared to 33.3% of those who merely monitored BP. This result only approaches significance ($\chi^2[1,N = 42] = 2.41, p < .10$).

One can also see that 62.5% of those crossed over to TBF after BP monitoring met our clinical end point. This yields an overall success rate of 59.4% of those treated (or 52.4% of the total sample), and meant that 22 participants were eligible for Study 2.

[3]Interestingly, having previously been on antihypertensive medication prior to the study shows a nonsignificant trend to be associated with achieving the clinical end point after receiving TBF treatment

Treatment Clinic BPs

In Table IV are the values of random zero sphygmomanometer BPs measured in the treatment clinic.[4] Since one of the questions in this study was whether both sexes responded the same, the data were analyzed with 2 (Treatment Condition) × 2 (Sex) ANCOVA on posttreatment BPs with pretreatment BP as the covariate.

Neither ANCOVA yielded significant main effects or interactions (all p's > .25), meaning that treatment was not superior to BP monitoring. Examination of Table IV shows that the BP reductions for the TBF group were very modest.

Home BPs

The results of the analyses of home BP data also failed to reveal any significant decrease in BP or any significant effect of treatment versus BP monitoring (all p's > .20).

24-Hour Ambulatory BPs

Analysis of 24-hour ABP data are complex if one is to take full advantage of the wealth of data gathered under many conditions in the participant's naturel environment. We have followed the procedures of Jaccard and Wan (1993), as described in detail in earlier studies by Musso, Blanchard, and McCoy (1991) and Wittrock and Blanchard (1992).

The essence of the analyses is idiographic regression analyses of the results from each individual subject as to whether ABP is different at posttreatment from the pretreatment values correcting for location, postural position, and activity at the time the reading is taken. These results can be followed by nomothetic analyses in which the results of all of the idiographic analyses are combined in a procedure analogous to metaanalysis (Jaccard & Wan, 1993).

[4]A comparison of the data in Table IV for pretreatment BPs to those in Table II, eligibility screening BPs, shows substantial reduction in DBP for those subjects eventually randomized to the BP monitoring condition. DBP dropped from 95.6 mm Hg to 90.1 mm Hg, while SBP also showed a slight decrease, 143.4 mm Hg to 140.0 mm Hg. Such decreases during a home BP monitoring baseline have been noted previously (Engel, Gaarder, & Glasgow, 1981). With hindsight it might have been better to match and randomize at the pretreatment assessment point rather than at the eligibility assessment point. We could not easily disqualify subjects at the pretreatment assessment point since they had undergone extensive assessment procedures by that point. Nevertheless, this reduction in BP in the baseline phase may have accounted in part for the lack of a treatment effect.

Table IV. Treatment Setting Random Zero Sphygmomanometer Blood Pressures Before and After Treatment

	Condition			
	Thermal biofeedback		BP monitoring	
Time of measurement	Male	Female	Male	Female
Pretreatment (n)	15	6	13	8
SBP $\bar{X}$	141.9	142.7	142.9	135.1
(SD)	(8.1)	(12.0)	(14.2)	(14.9)
Both sexes combined $\bar{X}$	142.1		140.0	
(SD)	(9.1)		(14.6)	
DBP $\bar{X}$	93.0	93.8	90.7	89.5
(SD)	(4.8)	(7.1)	(5.9)	(6.4)
Both sexes combined $\bar{X}$	93.2		90.1	
(SD)	(5.4)		(6.0)	
Posttreatment				
SBP $\bar{X}$	139.8	143.7	143.8	138.9
(SD)	(12.7)	(9.0)	(20.4)	(13.1)
Both sexes combined $\bar{X}$	140.9		141.9	
(SD)	(11.7)		(17.7)	
DBP $\bar{X}$	92.2	89.0	91.6	90.3
(SD)	(7.1)	(2.1)	(6.2)	(6.6)
Both sexes combined $\bar{X}$	91.3		91.1	
(SD)	(6.2)		(6.2)	

	Treatment of BP monitoring	
	Male (n = 9)	Female (n = 7)
Pretreatment		
SBP $\bar{X}$	137.3	136.72
(SD)	(11.1)	(15.3)
DBP $\bar{X}$	87.9	90.0
(SD)	(5.8)	(6.6)
Posttreatment		
SBP $\bar{X}$	137.6	136.3
(SD)	(13.4)	(15.5)
DBP $\bar{X}$	88.8	87.0
(SD)	(5.9)	(6.4)

Table V. Summary of Idiographic Analyses of 24-Hour Ambulatory BP Monitoring Data for Both Conditions

Treatment condition	Treatment effects (comparison of post-treatment to two pre-treatment values)		
	Post-treatment higher	No change	Post-treatment lower
		Systolic BP	
Thermal biofeedback	6	9	2
BP monitoring	1	9	2
		Diastolic BP	
Thermal biofeedback	9	6	2
BP monitoring	1	6	5

Idiographic Results. Despite our best efforts, analyzable data from the three 24-hour ABPMs (two pretreatment and one posttreatment) were available on only 29 of 42 subjects (17 TBF and 12 BP monitoring controls). Data were not analyzable primarily because of excessive loss of diary data or to excessive error messages from the recording device.

The idiographic analyses, based on individual regression equations that test with F for significant sources of variance, yield a result of whether an individual subject shows a significant ($p < .05$ or greater) increase or decrease in SBP or DBP for the posttreatment assessment in comparison to the two pretreatment ABPMs. These results are summarized in Table V.

Examining Table V, one can see that in only a small minority of cases (2/17) did patients initially receiving TBF have significantly lower 24-hour ABPs at posttreatment than at pretreatment, and that in many instances, the posttreatment ABPs were significantly higher for the treated subjects. Patients in the BP monitoring condition, as a group, did as well or better than the treated subjects.

Process Measures

Given these results, one might ask questions about how well were the treatments delivered. The following results address these issues.

Initial Expectancies. The initial expectancies for the treatment group were relatively high, 7.1 on a 1 to 9 scale, across all six items. This is comparable to values seen in previous studies (Wittrock, Blanchard, & McCoy, 1988). Treatment successes ($n = 22$) did not differ on initial expectations from treatment failures ($n = 15$).

Home Practice. It is an article of faith in the TBF treatment of hypertension that regular home practice is beneficial. Our successful subjects reported an average of 37 practices over the 8 weeks while the failures reported only an average of 25 practices over the duration of treatment ($F[1,34] = 4.17, p < .05$). Thus, even the failures had over 5 hand or foot warming practices per week (3 per week at home plus 2 treatment sessions per week). Practice was at a reasonable level overall and again in the range previously reported (Wittrock et al., 1988).

Temperature Change. How best to represent the within-session temperature data is a complex issues. We (Blanchard, McCoy, et al., 1988; Wittrock et al., 1988) have previously reported two parameters: (1) whether the within-session temperature change was statistically reliable as determined by comparing the average (across all treatment sessions) change from in session baseline to the highest temperature achieved during the training, and (2) the number of trainees who reached an arbitrary temperature level at some point in treatment.

The within-session data show significant ($p < .001$) average increase of about 2.8°F for hand warming and 1.6°F for foot warming. The eventual successes did not show greater hand temperature increases than the treatment failures. However, there was a trend ($p = .09$) for successes to show greater increases in foot temperature than failures.

In terms of reaching certain temperature criteria, overall 77% of the 22 treatment successes reached 95°F on hand temperature and 68% reached 90°F on foot temperature, whereas 53% of the 15 treatment failures reached 95°F on hand temperature and 53% also reached the 90°F foot temperature criterion. None of these differences are significant.

It appears that a reasonable level of temperature control mastery was achieved.

Treatment of BP Monitoring Controls

Data on the posttreatment clinic BPs for those initial controls crossed over to the TBF condition are presented in Table IV. One-way repeated measures ANOVAs on premonitoring, postmonitoring (pretreatment), and posttreatment BP values for this group revealed no significant differences across measurement occasions ($p > .20$).

Table VI. Pretreatment and Posttreatment Clinic BPs of all Treated Subjects as a Function of Sex

	Time					
	Pretreatment		Posttreatment			
Sex (*n*)	$\bar{X}$	*SD*	$\bar{X}$	*SD*	*t*	*p*
			Systolic BP			
Female (13)	139.5	13.6	139.7	12.7	-.15	*ns*
Male (24)	140.2	9.4	139.0	12.7	.48	*ns*
			Diastolic BP			
Female	91.8	6.8	87.9	4.8	2.68	.020
Male	91.1	5.7	90.9	6.7	.11	*ns*

Gender Effects

In line with one of the major purposes of the study, to examine the effects of TBF on women who were unmedicated hypertensives, we combined the data on all treated subjects ($n = 37$) and compared the results for the two sexes with ANCOVAs on posttest clinic BPs with pretest values as a covariate. Means are presented in Table VI. There were no effects on SBP but a trend ($F[1,36] = 2.80, p = .09$) for DBP. Individual correlated *t*-tests revealed that, for the 13 females, DBP decreased significantly ($t[12] = 2.68, p = .020$) while the value for males did not change. Thus, while there is no significant between-gender effect of treatment, the within-group analyses do show an effect of treatment on female hypertensives.

Discussion

In many ways these results are disappointing because they fail to replicate our (Blanchard, McCoy et al., 1988) very positive results with TBF with unmedicated male hypertensives. Previously, 90% of those treated with TBF met our clinical end-point criteria for success as opposed to 59.4% in the present study (or 52.4% of all treated subjects). Moreover, TBF previously led to a significant initial reduction of DBP of approximately 8 mm Hg, whereas in the present study the decrease in DBP was only 2 mm Hg and was not significant. Moreover, the BP monitoring controls showed better results than previously (33% success [DBP less than 90 mm Hg], but an overall *increase* of 1 mm Hg in DBP). As a result, the treated subjects as a group were not superior to the BP monitoring controls. These clinic BPs (by random zero sphygmomanometer) are more or less confirmed by the 24-hour ABPM results, which show essentially no positive effects on ABPs of thermal biofeedback.

The one interesting new finding in these initial results is that for females, 69% of those eventually treated with TBF were initially successful and that the DBPs of the treated females did show a significant ($p = 0.02$) decrease of almost 4 mm Hg.

As noted earlier, a primary question for this project was whether reductions of BP could be maintained over a 12-month follow-up through an enhanced follow-up schedule with great emphasis on regular home practice, our Study 2 described below.

STUDY 2

One of the major difficulties with our (Blanchard, McCoy et al., 1988) earlier trial with TBF as a treatment for mild hypertension in unmedicated patients was the relatively poor maintenance of reduced BPs among the American sample. Whereas 90% were initially successful in reducing DBP to a meaningful degree, only 20% of those treated with TBF remained successful at a one-year follow-up, as compared to 70% of the treated Soviet sample. We speculated that a higher level of compliance with regular practice among the latter sample led to this overwhelming advantage.

Thus, in this second study we planned to compare experimentally two different follow-up conditions: In the first, we attempted to enhance regular practice during the follow-up by repeatedly emphasizing its importance. In the second, regular contact was maintained and the importance of regular practice mentioned.

Methods

Subjects

The participants in this part of the research were the 22 hypertensives who had been successful at lowering DBP in the treatment clinic below 90 mm Hg. These individuals were matched into pairs based on posttreatment DBPs, and secondarily on gender, and then randomly assigned to one of the two follow-up conditions. Characteristics of the two subsamples are presented in Table VII.

Comparisons of the two subsamples revealed no significant differences between the two on any of these characteristics.

Table VII. Characteristics of Sample for Study 2 by Follow-up Condition

Characteristic	Condition	
	Intensive follow-up	Regular follow-up
Gender (M/F)	7/5	6/4
Previous medication (Y/N)	7/5	3/7
Age $\bar{X}$	52.0	49.1
(*SD*)	(8.6)	(7.4)
Range	39-64	33-58
Years known to be hypertensive $\bar{X}$	10.2	6.6
(*SD*)	(9.4)	(5.6)
Range	1-35	1-19
Eligibility BPs		
SBP $\bar{X}$	140.5	139.4
(*SD*)	(8.7)	(8.6)
DBP $\bar{X}$	92.9	94.3
(*SD*)	(2.8)	(3.6)
Start of treatment BPs		
SBP $\bar{X}$	138.7	137.9
(*SD*)	(10.0)	(4.3)
DBP $\bar{X}$	89.9	90.1
(*SD*)	(5.7)	(7.4)
Start of follow-up BPs		
SBP $\bar{X}$	134.6	133.1
(*SD*)	(9.8)	(14.3)
DBP $\bar{X}$	86.4	85.9
(*SD*)	(1.5)	(4.8)

Procedures

BP Measurement. All BPs at the treatment clinic were determined by random zero sphygmomanometer in the manner described in Study 1. Patients continued to take home BPs for one week prior to each return visit. At the end of one year, patients were scheduled for a repeat 24-hour ABPM assessment and a visit to the study physician.

Experimental Condition. In this condition, the subject, at entry into the follow-up, met with the project director, who stressed the importance of regular home practice for maintaining reduced BP. Moreover, patients were lent battery-operated electronic home TBF trainers (Bio Medical Instruments, model PST-100), which provided a digital display of temperature.

Patients were told these were being provided because of the importance of home practice. This message was reinforced by the patient's therapist (the doctoral student who had conducted most of their group training sessions and the person who would follow them individually).

Patients in this condition were seen once per month at the treatment clinic for an individual booster TBF session for 6 months and then every two months. At these visits logs of home BPs and home practice were reviewed. The whole thrust of contact with patients in this condition was to maintain regular home practice.

Control Condition. In this condition the subject also met individually with the project director, who congratulated them on their initial success and described the follow-up. Regular home practice was mentioned as important but not stressed as heavily.

These individuals continued to practice with the alcohol-in-glass thermometer. They also were followed individually by the doctoral student therapist who had run their group.

These individuals were seen every three months throughout follow-up and instructed to keep track of their home practice but to keep home BP records for only a week before these visits.

Subjects in both conditions answered a locally constructed questionnaire on expectancies of continued success and on perceptions of the importance of continued practice at the conclusion of the initial visit.

Results

Clinical End Point

In Table VIII are data on the frequencies with which patients in both conditions continued to be successful (DBPs at the Treatment Clinic less than 90 mm Hg) throughout the year.

There were no significant differences in BPs of the successes at any point during the follow-up. The 12 patients who continued to have reduced DBPs at one year represent 54.5% of those who entered follow-up (but only 32.4% of those who completed treatment). There were clearly no differences between the two conditions in terms of survival curves.

The 32.4% long-term success of treatment completers compares favorably to the 20% of TBF completers who were still normotensive at one year in the American sample of Blanchard, McCoy et al., (1988) but is much below the 70% for the Soviet sample in that study.

Table VIII. Clinical End Point Data (Frequency [and Percent] with DBP < 90 mm Hg) for One Year Follow-up — Both Conditions

	Condition			
Time	Intensive follow-up		Regular follow-up	
Start of follow-up	12	(100%)	10	(100%)
3 Months	10	(83%)	8	(80%)
6 Months	8	(67%)	7	(70%)
12 Months	6	(50%)	6	(60%)

Those patients who failed in follow-up showed no decrease in BP with treatment, whereas those who were long-term successes showed a significant effect of treatment on both SBP and DBP.

It should be noted that 6 patients (4 Experimental, 2 Control) were removed from the study by their personal physicians, who found BPs elevated at routine visits. Four other patients (2 experimental, 2 control) took themselves out of the follow-up study for various reasons.

Clinic BPs

Once subjects left the follow-up study, most were placed on antihypertensive medications by their personal physician. Thus, their BPs are contaminated by this situation. In Table IX are the mean clinic random zero sphygmomanometer BPs combined for the participants from the two follow-up conditions at start of treatment, start of follow-up, and at 3-, 6-, and 12-month follow-ups. At each follow-up point, the BPs are significantly lower than at pretreatment ($ps < .05$ or better by correlated t-test), but these data are biased because only survivors who continue off of medications and with DBPs below 90 mm Hg are included. Start of treatment and end of treatment BPs for eventual failures are also presented.

Process Variables

Home practice records during follow-up for the subjects were analyzed so as to compare the average number of reported practices per month for participants in each follow-up condition. Over the first 7 months of follow-up, the intensive follow-up group averaged 20 practices per month as compared to 13 for the regular follow-up group. For the last 5 months

Table IX. Treatment Clinic Random Zero Sphygmomanometer Blood Pressures for Follow-up Sample Successes at Pre- and Posttreatment and Three-, Six-, and Twelve-Month Follow-ups and for Failures in Follow-up at Pre- and Posttreatment

Time of measurement	SBP		DBP	
		Successes		
Start of treatment (n = 12)	140.6	(11.8)	92.3	(6.6)
Post-treatment (start of follow-up)	133.0	(13.2)	85.1	(3.0)
3 Months	129.5	(9.7)	85.2	(3.6)
6 Months	127.3	(10.4)	84.3	(3.7)
12 Months	129.4	(7.4)	85.1	(3.5)
		Failures		
Start of treatment (n = 10)	135.6	(10.7)	87.3	(5.2)
Posttreatment (start of follow-up)	135.0	(10.4)	87.5	(3.3)

both groups averaged 10 practices per month. Only in month 6 of follow-up was the difference in reported rate of practice different (p = .03). Thus, although there was a clear numerical advantage in frequency of reported relaxation practice by the intensive follow-up condition (almost 50% greater rate per month for the first 7 months), this difference was not usually significant, owing to high variability. Moreover, it did not make any difference in maintenance of reduced BP over those first 7 months.

Discussion of Study 2

It is clear that our intensive follow-up condition conveyed no advantage to patients assigned to it over that found with routine (visits for BP checks once per 3 months) follow-up. Those in the intensive follow-up reported more regular home practice (about 50% more over the first 7 months) but, contrary to our expectations, this did not prove to be an important variable.

Depending upon how one views the follow-up results from Study 2, one could be encouraged or discouraged. Of the 22 patients who were initially successful in lowering DBP below 90 mm Hg, 12 (54.5%) were still normotensive 12 months later. This is better than our previous American results (Blanchard, McCoy, et al., 1988) but still not as good as the Russians were able to achieve (70%) in that cross-cultural study.

Viewed from the perspective of all patients who completed treatment (n = 37), our long-term success rate is only 32.4%, a value not noticeably better than we found initially. Moreover, long-term maintenance was not related to initial medication status or gender.

OVERALL DISCUSSION

From a practical perspective, the results of these two studies are disappointing. We were not able to replicate our previously (Blanchard, McCoy, et al., 1988) strong initial treatment results using TBF with unmedicated patients with mild hypertension. Across all treated subjects we did not obtain a significant decrease in DBP; moreover, only 22 of 37 treated patients (59.4%) were initially successful, as compared to 90% in the earlier study.

The results of our intensive follow-up condition were also disappointing; it was no better than routine follow-up. The overall results for all follow-up patients were somewhat better than found earlier: 54.5% of those who entered follow-up were still normotensive; this represents 32.4% of those treated. There is also the intriguing result that women showed a significant lowering of DBP while the males did not.

Given these results, one could legitimately ask, Why has the "lack of replicability problem" struck once again? The males in the present study, as a group, are comparable to our initial (1988) sample in age, BPs, and years known to be hypertensive. The female subjects were new to the study but their presence does not account for the failure; if anything they would bias the data positively since they responded significantly on DBP whereas the males did not. The treatment setting, procedures, and key treatment personnel were the same, thus there were no changes in these variables that could account for the poorer results. Moreover, the treatments were delivered by a proponent of the procedure and patient expectations of benefit were very positive. Finally, the initial sample sizes for the treatment and BP monitoring conditions in this study (n = 21) were twice as large as those that previously yielded a significant difference (n = 10); thus based on earlier results adequate statistical power was available in this study.

We are left with no ready explanation for this failure to replicate. It could be that the present results, obtained on a sample almost 4 times as large as the original (1988) sample who received TBF, are a more stable representation of treatment effects and come closer to representing the true state of nature. This implies that the initial results were perhaps a fortuitous function of a small sample. Moreover, the present BP monitoring group improved noticeably more than in the previous sample.

There may also be individual difference variables of which we are not aware which could account for the results. Only a large study in which many patients are assessed on many relevant dimensions before all received the same treatment could answer this question.

It may also be that psychosocial treatments of hypertension are subject to very subtle experimenter effects such that initial trials work and replications do not. As noted in the introduction, such a pattern of results has been reported several times before. The nature of such effects is not apparent.

One thing does seem clear to us: Treatments with ephemeral results, which work sometimes and not at other times, present a difficult basis on which to build a science and on which to claim a strong role for stress management approaches to the treatment of hypertension. More stability of results with replications across samples and across clinics needs to be demonstrated.

REFERENCES

Benson, H., Shapiro, D., Tursky, B., & Schwartz, G. E. (1971). Decreased systolic blood pressure through operant conditioning techniques in patients with essential hypertension. *Science, 173,* 740-742.

Blanchard, E. B., Eisele, G., Gordon, M. A., Cornish, P. J., Wittrock, D. A., Gilmore, L., Vollmer, A., & Wan, C. (1993). Thermal biofeedback as an effective substitute for sympatholytic medication in moderate hypertension: A failure to replicate. *Biofeedback and Self-Regulation, 18,* 237-253.

Blanchard, E. B., Martin, J. E., & Dubbert, P. M. (1988). *Non-Drug Treatments for Essential Hypertension.* Elmsford, NY: Pergamon Press.

Blanchard, E. B., McCoy, G. C., McCaffrey, R. J., Musso, A., Wittrock, D. A., Berger, M., Gerardi, M. A., Pangburn, L., Khramelashvili, V. V., Aivasyan, T. A., & Salenko, B. B. (1988). The USSR-USA collaborative cross-cultural comparison of autogenic training and thermal biofeedback in the treatment of mild hypertension. *Health Psychology, 7,* 19-33.

Blanchard, E. B., McCoy, G. C., Musso, A., Gerardi, M. A., Pallmeyer, T. P., Gerardi, R. J., Cotch, P. A., Siracusa, K., & Andrasik, F. (1986). A controlled comparison of thermal biofeedback and relaxation training in the treatment of essential hypertension: I. Short-term and long-term outcome. *Behavior Therapy, 17,* 563-579.

Brauer, A. B., Horlick, L., Nelson, E., Farquhar, J. W., & Agras, W. S. (1979). Relaxation therapy for essential hypertension: A Veterans Administration out-patient study. *Journal of Behavioral Medicine, 2,* 21-29.

Engel, B. T., Gaarder, K. R., & Glasgow, M. S. (1981). Behavioral treatment of high blood pressure. I. Analyses of intra- and inter-daily variations of blood pressure during a one-month baseline. *Psychosomatic Medicine, 43,* 255-270.

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,* 257-278.

Glasgow, M. S., Engel, B. T., & D'Lugoff, B. C. (1989). Control study of a standardized behavioral stepped treatment for hypertension. *Psychosomatic Medicine, 51,* 10-26.

Glasgow, M. S., Gaarder, K. R., & Engel, B. T. (1982). Behavioral treatment of high blood pressure II. Acute and sustained effects of relaxation and systolic blood pressure biofeedback. *Psychosomatic Medicine, 44,* 155-170.

Jaccard, J., & Wan, C. K. (1993). Statistical analysis of temporal data with many observations: Issues for behavioral medicine data. *Annals of Behavioral Medicine, 15,* 41-50.

Jacob, R. G., Chesney, M. A., Williams, D. M., Ding, Y., & Shapiro, A. P. (1991). Relaxation therapy for hypertension: Design effects and treatment effects. *The Annals of Behavioral Medicine, 13,* 5-17.

Jacob, R. G., Shapiro, A. P., O'Hara, P., Portser, S., Kruger, A., Gatsonis, C., & Ding, Y. (1992). Relaxation therapy for hypertension: Setting-specific effects. *Psychosomatic Medicine, 54,* 87-101.

Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. (1993). The fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC-V). *Archives of Internal Medicine, 153,* 154-183.

Kaufman, P. G., Jacob, R. G., Ewart, C. K., Chesney, M. A., Muenz, L. R., Doub, N., & Mercer, W. (1988). Hypertension intervention pooling project. *Health Psychology, 7,* 209-223.

McCaffrey, R. J., & Blanchard, E. B. (1985). Stress management approaches to the treatment of essential hypertension. *Annals of Behavioral Medicine, 7,* 5-12.

Musso, A., Blanchard, E. B., & McCoy, G. C. (1991). Evaluation of thermal biofeedback treatment of hypertension using 24-hour ambulatory blood pressure monitoring. *Behaviour Research and Therapy, 29,* 469-478.

Pickering, T. G., & James, G. D. (1989). Some implications of the differences between home, clinic, and ambulatory blood pressure in normotensive hypertensive patients. *Journal of Hypertension, 7* (Supplement 3), S65-S72.

Rosen, R. C., Brondolo, E., & Kostis, J. B. (1993). Nonpharmacological treatment of essential hypertension: Research and clinical applications. In R. J. Gatchel and E. B. Blanchard (Eds.), *Psychophysiological disorders: Research and clinical application* (pp. 63-110). Washington, DC: American Psychological Association.

Surwit, R. S., Shapiro, D., & Good, I. M. (1978). Comparison of cardiovascular biofeedback, neuromuscular biofeedback, and meditation in the treatment of borderline essential hypertension. *Journal of Consulting and Clinical Psychology, 46,* 252-263.

Taylor, C. B., Farquhar, J. W., Nelson, E., & Agras, W. S. (1977). Relaxation therapy and high blood pressure. *Archives of General Psychiatry, 34,* 339-343.

Wittrock, D. A., & Blanchard, E. B. (1992). Thermal feedback treatment of mild hypertension: A comparison of effects of conventional and ambulatory blood pressure measures. *Behavior Modification, 16,* 283-304.

Wittrock, D. A., Blanchard, E. B., & McCoy, G. C. (1988). Three studies on the relation of process to outcome in the treatment of essential hypertension with relaxation and thermal biofeedback. *Behaviour Research and Therapy, 26,* 53-66.