

TITLE: A Behavioural Approach to Antihypertensive Therapy

A Behavioural Approach to Antihypertensive Therapy
Relaxation vs Feedback Training in a Controlled Study

by

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SCOPE AND CONTENTS: A combination of deep muscle relaxation with voluntary control procedures has earlier been shown to benefit labile hypertensives. This study reports on 16 male labile hypertensives, divided into four equal and matched groups, and treated weekly for nine weeks. To assess the relative importance of the procedures, one group received the combined treatment, one the relaxation alone, one the voluntary control procedure alone, and one group simply had repeated blood pressure measurements throughout each session. All subjects had a test session during the tenth week.

Results demonstrated clearly a beneficial effect for deep muscle relaxation. Although there was some suggestive evidence for the superiority of the combined approach, the voluntary control technique showed no significant relationship to improvement. Repeated measures were associated with only transient improvement which disappeared well before the tenth week.

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CHAPTER 1

INTRODUCTION

Hypertension of unknown cause, with its associated conditions, remains a leading cause of morbidity and mortality in our society

(1). Hypertension is the most significant known risk factor in the development of strokes, congestive heart failure and renal insufficiency (2)(3). It is also one of the most significant predisposing factors in coronary heart disease and myocardial infarction (4). Pharmacological methods are useful, but compliance to life-long drug therapy is often poor because of associated side-effects, inconvenience and expense. It would certainly be clinically desirable to be able to attain control of blood pressure without the need for medication.

There has been a growing interest in the application of behavioural techniques to the treatment of hypertension (5)(6)(7)(8)(9). Using variations of either relaxation or feedback techniques, these studies generally indicate their usefulness for some hypertensive patients. Preliminary work in our laboratory over the past two years has also shown that, for a significant minority of labile hypertensives, important clinical benefits can be obtained from a behavioural approach which combines deep muscle relaxation and feedback voluntary control training (10). However, several issues arise from these studies which warrant further exploration.

First, evaluation of an experimental treatment must include a comparison with a placebo-control condition to permit any definitive

conclusions. Most studies, with the exception of the studies by Elder, et al (8)(9), have failed to include a separate control group. Further controlled outcome studies are needed before any conclusive statements can be made on the effectiveness of behavioural techniques for the treatment of hypertension.

Second, as a potential clinical treatment, careful consideration must be given to the limiting factors such as expense and convenience that are imposed by the application of a technique on a widespread basis. The feedback and relaxation procedure differ considerably in expense and convenience of implementation. There have been no studies which directly compare the effects of the feedback and relaxation techniques. Further information is needed on the relative effectiveness of these procedures before an adequate assessment can be made on their widespread clinical application.

A third important issue concerns the generalization of the laboratory procedures. None of the studies have adequate follow-up data after the treatments completion, nor do they assess the patient's progress outside the laboratory. However, many hypertensive patient's respond with large fluctuations in blood pressure under a variety of situations. Follow-up studies are needed to determine the extent that the training given in the laboratory does in fact generalize to these situations.

The present study specifically attempts to take into account these three issues. It is a controlled outcome study designed to assess the relative therapeutic effects of three variables, namely, relaxation, feedback-voluntary control training, and repeated blood

pressure measurements. The study includes extensive follow-up on all patients who showed clinical improvements. Finally, the study has employed relatively inexpensive and easily applied procedures, in an attempt to assess the potential of behavioural techniques for the widespread treatment of the hypertensive population.

CHAPTER 2

A BEHAVIORAL APPROACH TO ANTIHYPERTENSIVE THERAPY:

II. Relaxation vs Feedback Training in a Controlled Study

Subjects

Sixteen male patients, ranging in age from 21 to 51 (median 41.5), referred by their family physicians as "labile hypertensives", were divided into four groups of four subjects each. Assignment to a group was done on a random basis at first and was completed in a manner to permit the groups to be matched as well as possible for age, medication and starting baseline blood pressure. In each group, three of the subjects were not on medication. Mean age in each group was: I: 40.5, II: 38.5, III: 40.5, IV: 38. Because of difficulty obtaining a sufficient number of referrals not on medication, it was not possible to achieve a perfect match regarding baseline blood pressures; group means for Blood Pressures were: I: 150.9/95, II: 156.5/95, III: 143.8/102.3, IV: 146/89.8.

The four groups were treated as follows with each subject receiving a minimum of ten weekly sessions (nine treatments plus one test session) lasting approximately 75 minutes each:

- i. Group I had three sessions of relaxation training, followed by six sessions of feedback-voluntary control training;
- ii. Group II had three sessions consisting of repeated blood pressure measurements, followed by six sessions of feedback-

voluntary control training;

- iii. Group III had three sessions of relaxation training, followed by six sessions of repeated blood pressure measurements; and
- iv. Group IV had all nine sessions with just repeated blood pressure measurements.

All subjects had a final test session in the tenth week.

Blood Pressure Measurements

The equipment and method are described in detail in our previous report (10). Because our system, using a Grass 7P8 preamplifier and Model 1010 pulse transducer, does not give accurate diastolic blood pressure readings, our work consisted of manipulating systolic pressure only.

Baseline Readings

Baseline readings were taken at the beginning and end of each session. In the first session, each patient received a set of instructions and an interview. Then, with the patient resting quietly on a cot, twenty readings were taken at one minute intervals and averaged to determine baseline levels of Systolic blood pressure. For the remainder of the program, five resting baseline readings were taken at the start and end of each session.

Relaxation Technique

This is described in our previous report (10) and consists of a slightly modified version of the Schultz Autogenic Regulatory Training (11).

Feedback-Voluntary Control Training

A very simple procedure was used for the voluntary control training. Five baseline readings were taken in silence at the start of each session. Patients were told their actual blood pressure at the last baseline reading. The patient was then asked for each of the subsequent thirty trials to move the blood pressure up or down. There were fifteen trials in each direction, with requests for increases or decreases interspersed in a fixed irregular order. After each trial and before the subsequent trial, the blood pressure was permitted to return to a "resting level" and a "resting reading" was taken during which the subject was instructed to lie quietly and to disregard his blood pressure. Where, during a trial, changes occurred (2 mmHg or more) in the desired direction, the experimenter rewarded the patient with immediate feedback and praise, i.e., "Very good". When the pressure failed to move in the desired direction or moved in the opposite one, the experimenter calmly indicated that to the subject.

These hypertensive patients were requested to raise as well as to lower their blood pressure even though it is the lower state that is ultimately desired. This "two-direction" strategy was employed for three reasons. First, it provided what has been called a "bi-directional control" (12). This ensures that changes in blood pressure can be attributed to the contingencies between response and feedback rather than to classical conditioning or the like. Second, we hoped that the procedure would assist the patient to achieve a more thorough control of his pressure. Third, if there are feelings which normally accompany a rise or a drop in blood pressure, we hoped that the procedure would

help make the patient more aware of these feelings and also their relationship to changes in blood pressure.

Patients were given clear instructions on the nature of the task. They were advised to use any strategy that they wished including techniques learned in the pretraining period.

Sessions with Repeated Measurements Only

In these sessions, forty baseline readings were taken with the patient lying on a cot in silence.

Test Session

The test session was the same for each group. After five baseline readings, two fifteen-trial feedback sessions were given, during which increases and decreases were requested in a fixed irregular order.

Follow-Up

At the end of the program a number of patients, some of whom had not improved, were given either the relaxation or the feedback training that they had missed in the experiment. Follow-up studies, including home charts kept by the patients, return visits to the family physicians and return visits to us, were made on all patients who showed improvements.

CHAPTER 3

RESULTS

Baseline Blood Pressure

Baseline readings were taken (as described above) at the start and at the end of each session. The mean changes over days for starting baselines were virtually identical to those for ending baselines. We are presenting data for ending baselines, which were slightly less variable (Figure 1).

A three-way analysis of variance was performed (Table 1), with the two between factors having two levels each, i.e. 1) feedback training or not and 2) relaxation or not, and the one within factor (sessions) having ten levels. This analysis revealed one significant main effect of sessions and one significant interaction, the treatment by sessions interaction ($p < .05$). The interaction seems to have occurred because the relaxation conditions showed a more marked decrease in baseline pressures over trials than the other conditions. This effect can be seen graphically in Figure 2, where the data for relaxation and non-relaxation are collapsed over the feedback factor, i.e. both relaxation groups (I and III) are combined and are compared with the non-relaxation groups (II and IV combined). There was no feedback by day interaction, and the group which received the combined procedure of feedback plus relaxation was not statistically different from the relaxation group alone.

Although our work dealt with systolic blood pressure, each subject had his diastolic pressure read by an experimenter in the standard manner with sphygmomanometer and stethoscope at the end of each session. These results, unlike our systolic data, are subject to bias since they allow for interpretation by the examiner but they do give some indication that diastolic pressure decreases accompany the systolic pressure decreases. In Figure 3 it can be seen that the relaxation groups show a better performance than the non-relaxation ones. An analysis of variance of these data shows no significant effect. The sessions x treatment interaction for relaxation, however, did approach significance ($.05 < p < .10$). This suggests that the diastolic pressure tended to follow suit when systolic pressure decreased in the relaxation treatments as is illustrated in Figure 3.

These results suggest beneficial effects (beyond that seen in controls) only for the relaxation treatments. It is possible that the effect of the feedback training may have been obscured by the small sample size and the considerable variability in the data. The fact that a significant result was obtained despite this variability can be taken to emphasize the effectiveness of the relaxation training.

Voluntary Control

Data on two measures of voluntary control during the final test session (Session 10) are shown in Table 2. The average change per trial from the immediately preceding resting reading provides a measure of magnitude of control. The proportion of trials in which changes occurred in the desired direction irrespective of the size of the change provides a measure of directional consistency.

A three-way analysis of variance (Tables 3a, 3b) was performed with the two between factors having two levels each, i.e., feedback and no feedback, and relaxation and no relaxation, and the one within factor also having two levels, i.e. up and down trial scores. There was a significant main effect between up and down trials for the change scores ($p < .01$; Table 3a) and for the consistency scores ($p < .05$; Table 3b). These results indicate that the subjects were able to control blood pressure voluntarily. This effect was not large, however, and due mainly to the patients' up control. There were no significant interactions between the individual treatments and the voluntary control scores. We must conclude, therefore, that neither the relaxation nor the feedback training produced significantly more voluntary control than that achieved by the control groups. This result was supported by an analysis of variance of the data for the two feedback training groups over sessions. Neither the main effect of sessions nor the sessions by group interaction were significant. There was no improvement as a function of training. Group and within group comparisons indicate that no learning of voluntary control occurred even though considerable voluntary control was displayed. These results are consistent with those of our first experiment.

Follow-Up

A partial "cross-over" design was implemented inasmuch as subjects were offered additional treatment after the ten sessions. In the main, these consisted of relaxation training for those who had not yet received it. Results were variable but not encouraging; after ten sessions without improvement, it seemed to us that this

"failure" experience demoralized the subjects so that poor motivation and lack of adequate practice was noted. Some subjects had individualized sessions following Session 10 in order to build on progress already apparent; the results of such programs are discussed next under "Clinical Improvement".

Clinical Improvement

Five of the patients in this study showed significant decreases in blood pressure, entering a normotensive range below 140/90 (Table 4). They remained in this range for extensive follow-up studies, and in whatever return visits were made to their family physicians. Their home charts indicated that this range was maintained over a large number of situations. One of these subjects (A-1-m) showed mainly systolic improvement and still had some diastolic readings of 90 mmHg outside our lab.

Three of the five successful patients were from the group which received the combined relaxation and feedback program, one was from the feedback group and one from the relaxation group.

These improvements were unrelated to age, starting baseline levels or duration of hypertension. All were free of complicating physical factors, such as overweight or excessive smoking, and they all showed lability in the blood pressure as demonstrated by recent medical histories and home charts. Three of these patients showed an immediate "knack" for the relaxation procedure and the other two quickly learned the technique through diligent practice. Marked reductions in tension accompanying the blood pressure decreases were visible in all five patients.

Good voluntary control was not essential for the lasting improvements. In fact, three of the successful patients showed very poor voluntary control during the feedback training. Nonetheless, feedback training was thought to be helpful in improving awareness of signs of tension and in fostering the application of relaxation in tense everyday life situations.

The five successful patients adopted a slower, less "driven" approach to life and they continued to practice the relaxation technique at home. In all cases this attitudinal change was greeted by positive comments from families and work associates, possibly resulting in further reinforcement.

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CHAPTER 4

DISCUSSION

There are a number of differences between this study and other studies that have applied behavioral techniques to the treatment of hypertension (13). Our study has employed a separate control group, rather than following the most common design of using patients as their own controls. This control group (the repeated measurements group) received the same amount of time and attention as the others, and were even led to believe that they were receiving a program of possible benefit. None of the four control patients showed a lasting improvement compared with starting baselines.

Furthermore, our study made a serious attempt to investigate the therapeutic effects of the procedures during the patients' regular activities and following the treatment program. While most studies have used daily sessions, we purposely used weekly sessions which take into account more of the natural variation over the course of the patient's life activities, and place more stringent criteria on the patient's final improvement. Considering the variability which is found in many hypertensive patients, it is important that any final assessment include a consideration of these fluctuations. Home charts were included for successful patients at the end of the program to assess whether the low readings found in the sessions did in fact generalize to other situations. We found that this was not always the case. In addition, these patients came in for several follow-up sessions; the follow-up

period for the five successful subjects averaged 14 months with a minimum of five months and a maximum of 18. Four of the five subjects returned to the family physician who, completely independently from us, confirmed the progress.

The main purpose of this study was to assess the relative effects of feedback and relaxation and their possible beneficial interaction. Since our feedback technique was unsophisticated, our conclusions regarding it must be limited. We can say, however, that the results demonstrate that relaxation training can effectively lower blood pressure. Furthermore, the procedure uses a minimum of equipment, and thus is both inexpensive and easily administered. Even though this technique applies to a minority of clinical hypertensives, the condition is so prevalent and so dangerous that this minority represents an important group in the population.

Since the results of this study and of our earlier work (1) both indicate that a sizeable minority of patients can benefit from our behavioral techniques, it becomes important to seek "markers" which would predict success prior to treatment. We will report shortly on a prospective study in which subject variables have been measured before the onset of treatment; it is hoped that some of these variables will correlate with eventual success or lack of it.

CHAPTER 5

CONCLUSIONS

1. A behavioral method of treatment, using relaxation and feedback training, was clinically successful in a number of labile hypertensives.

2. Relaxation training stands out as the single most important treatment variable, with some suggestion that feedback-voluntary control training can be usefully combined with relaxation for long-term benefits.

3. Subject variables, including motivation, ability to tolerate relaxation and willingness to alter life style, appear to be very important.

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TABLE 1

Analysis of Variance

<u>Source</u>	<u>ss</u>	<u>df</u>	<u>ms</u>	<u>F</u>	<u>p</u>
Feedback	1317.9131=	1=	1317.9131=	0.6006	ns
Relaxation	4289.0501=	1=	4289.0501=	1.9545	ns
Feedback x Relaxation	2588.8760=	1=	2588.8760=	1.1797	ns
Error	26333.996=	12=	2194.4997		
Sessions	1384.7305=	9=	153.8590=	2.8633	< .001
Feedback x Sessions	541.0720=	9=	60.1191=	1.1188	ns
Relaxation x Sessions	1028.7446=	9=	114.3050=	2.1272	< .05
[Feedback x Relaxation] x Sessions	220.5664=	9=	24.5074=	0.4561	ns
Error	5803.4385=	108=	53.7356		
TOTAL	43508.390=	159=	273.6377		

TABLE 2

VOLUNTARY CHANGES IN BLOOD PRESSURE (SYSTOLIC)
IN FINAL TEST SESSION

Group	Training	Up Trials					Down Trials				
		Amount of Change			Directional Consistency		Amount of Change			Directional Consistency	
		Mean change per trial			% of trials Showing Increase		Mean change per trial			% of Trials Showing Decrease	
		Maximum mmHg	mmHg	S.E.	Mean	S.E.	Maximum mmHg	mmHg	S.E.	Mean	S.E.
1	Relaxation + Feedback	+21	+4.74	1.67	76.0%	8.42	-19	-0.04	1.30	52.5%	10.46
2	Feedback	+20	+4.35	1.96	75.0%	9.8	-17	-2.68	2.42	61.8%	13.64
3	Relaxation	+25	+3.30	2.07	64.0%	8.43	-19	-2.11	1.19	64.3%	7.49
4	Measure Only	+25	+4.97	1.73	76.8%	4.33	-19	-0.51	0.86	51.0%	6.92
TOTAL ALL GROUPS		---	+4.34	0.85	72.9%	3.82	---	-1.34	0.75	57.4%	4.7

TABLE 3

Analysis of Variance - Voluntary ControlTable 3a. "Size of Change" Scores

<u>Source</u>	<u>ss.</u>	<u>df</u>	<u>ms</u>	<u>F</u>	<u>P</u>
Feedback	0.2503=	1=	0.2503=	0.0190	ns
Relaxation	0.0294=	1=	0.0294=	0.0022	ns
Feedback x Relaxation	19.8923=	1=	19.8923=	1.5102	ns
Error	158.0678=	12=	13.1723		
Direction of Trials ("Ups & Downs")	257.1345=	1=	257.1345=	24.2260	<.001
Feedback x Direction	0.4301=	1=	0.4301=	0.0405	ns
Relaxation x Direction	2.6970=	1=	2.6970=	0.2541	ns
[Feedback x Relaxation] x Direction	2.3599=	1=	2.3599=	0.2223	ns
Error	127.3677=	12=	10.6140		
TOTAL	568.2291=	31=	18.3300		

Table 3b. "Consistency of Change" Scores

<u>Source</u>	<u>ss</u>	<u>df</u>	<u>ms</u>	<u>F</u>	<u>P</u>
Feedback	0.0043=	1=	0.0043=	0.1315	ns
Relaxation	0.0030=	1=	0.0030=	0.0923	ns
Feedback x Relaxation	0.0038=	1=	0.0038=	0.1177	ns
Error	0.3904=	12=	0.0325		
Direction of Trials ("Ups & Downs")	0.1938=	1=	0.1938=	5.8424	<.05
Feedback x Direction	0.0063=	1=	0.0063=	0.1908	ns
Relaxation x Direction	0.0124=	1=	0.0124=	0.3740	ns
[Feedback x Relaxation] x Direction	0.0657=	1=	0.0657=	1.9812	ns
Error	0.3980=	12=	0.0332		
TOTAL	1.0776=	31=	0.0348		

P R O G R E S S

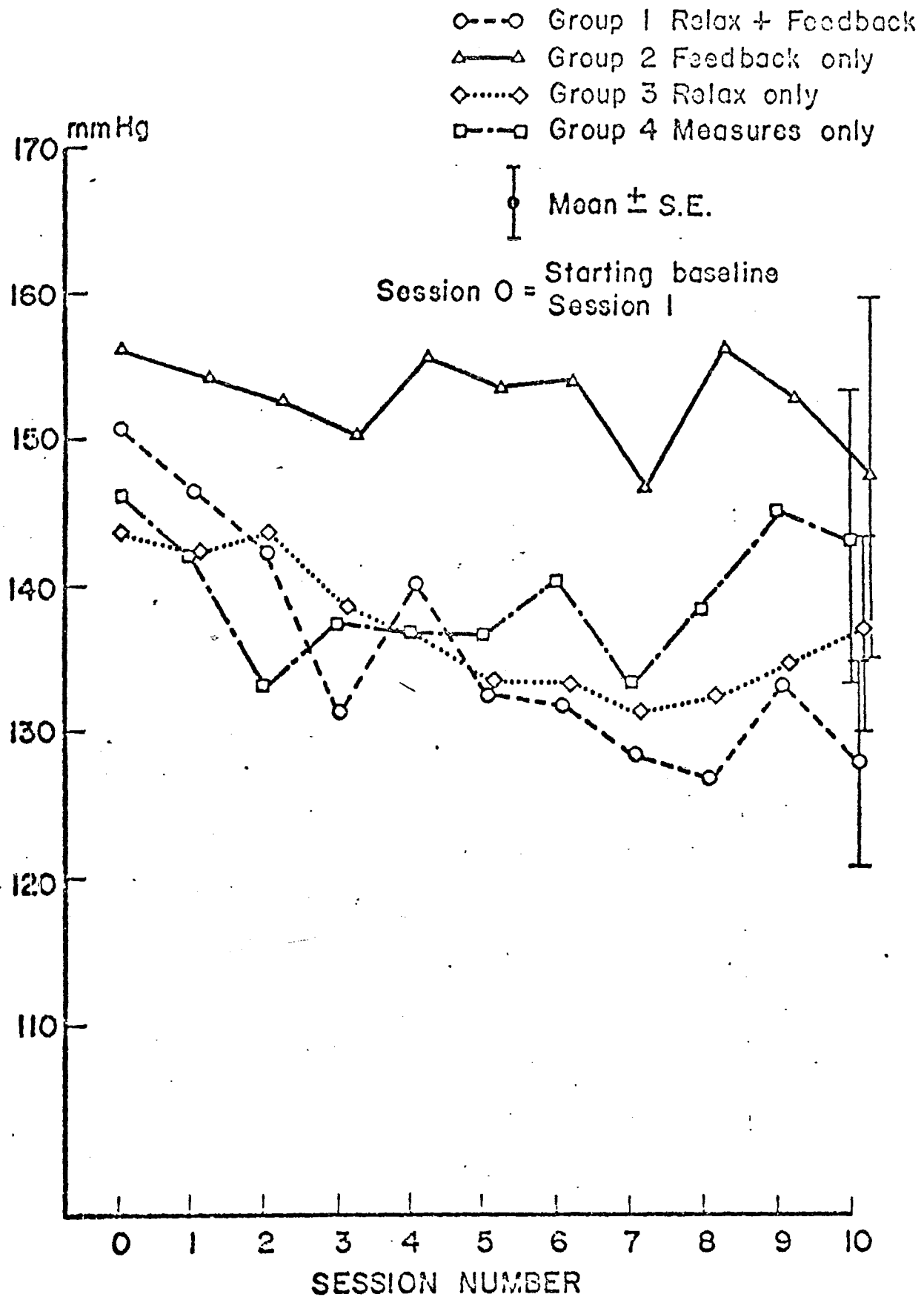
TABLE 4 - CLINICAL IMPROVEMENTS

Subject	Starting Baseline	Avg./end 10 wks	Avg./end of further trng.	Family Doctor's Report	Follow-Ups	Home Chart	Comments
Subject A-1 Age 38 yrs.	170/102	138/88	--	Before program: 142/102 After program: 138/88	1. 135/88 2. 135/88 3. 127/82 4. 137/88 (18 mo.)	All normotensive range: 124/80 to 138/88	Still intimidated by strangers and authority figures
Subject A-3 Age 36 yrs.	138/98	124/87	112/84 [4 additional sessions with training in control during conversation]	Before program: 140-150/90-100 After program: 1. 112/78* 2. 125/80 *by Public Health Nurse	1. 113/84 2. 115/88 3. 122/88*(9 mo) * Despite heavy work load	All normotensive range: 110/76 to 126/90	Still a bit tense in conver- sation
Subject B-3 Age 25 yrs.	130/92	116/80	114/78 [5 sessions relaxation after Session 10]	Before program: 152/92 No visit after.	1. 114/60 2. 123/66 3. 117/80 4. 130/78 (5 mo.)	Almost all in normotensive range: 113/78 to 135/90* * occurred only once	Moved out of town.

TABLE 4 - CLINICAL IMPROVEMENTS

P R O G R E S S

Subject	Starting Baseline	Avg./end 10 wks	Avg./end of further trng.	Family Doctor's Report	Follow-Ups	Home Chart	Comments
Subject C-3 Age 48 yrs.	133/100	122/80	123/81 [16 sessions feedback and desensitization to conversation after Session 10]	Before program: variable; patient on 25 mgm Valium daily After program: 110/68	1. 112/70 2. 116/80 3. 124/72 4. 123/76 5. 118/84 6. 130/80 7. 106/70 8. 114/74 (13 mo)	Almost all nor- motive range: 110/70 to 148/84* * occurred only once; tension at work	Valium reduced to 5 mgm per <u>week</u>
Subject A-1M Age 41 yrs.	140/90	121/85	--	Before program: 1. 146/102 2. 134/90 Late in program: 134/102 After program: 126/90	1. 110/82 2. 122/85 3. 128/88* (17 mo) * Subject had reduced his meds that day	Mostly normo- tensive range: 122/86 to 130/95	Still on same meds, diastolic still a bit too high

ENDING BASELINE BLOOD PRESSURE (SYSTOLIC)

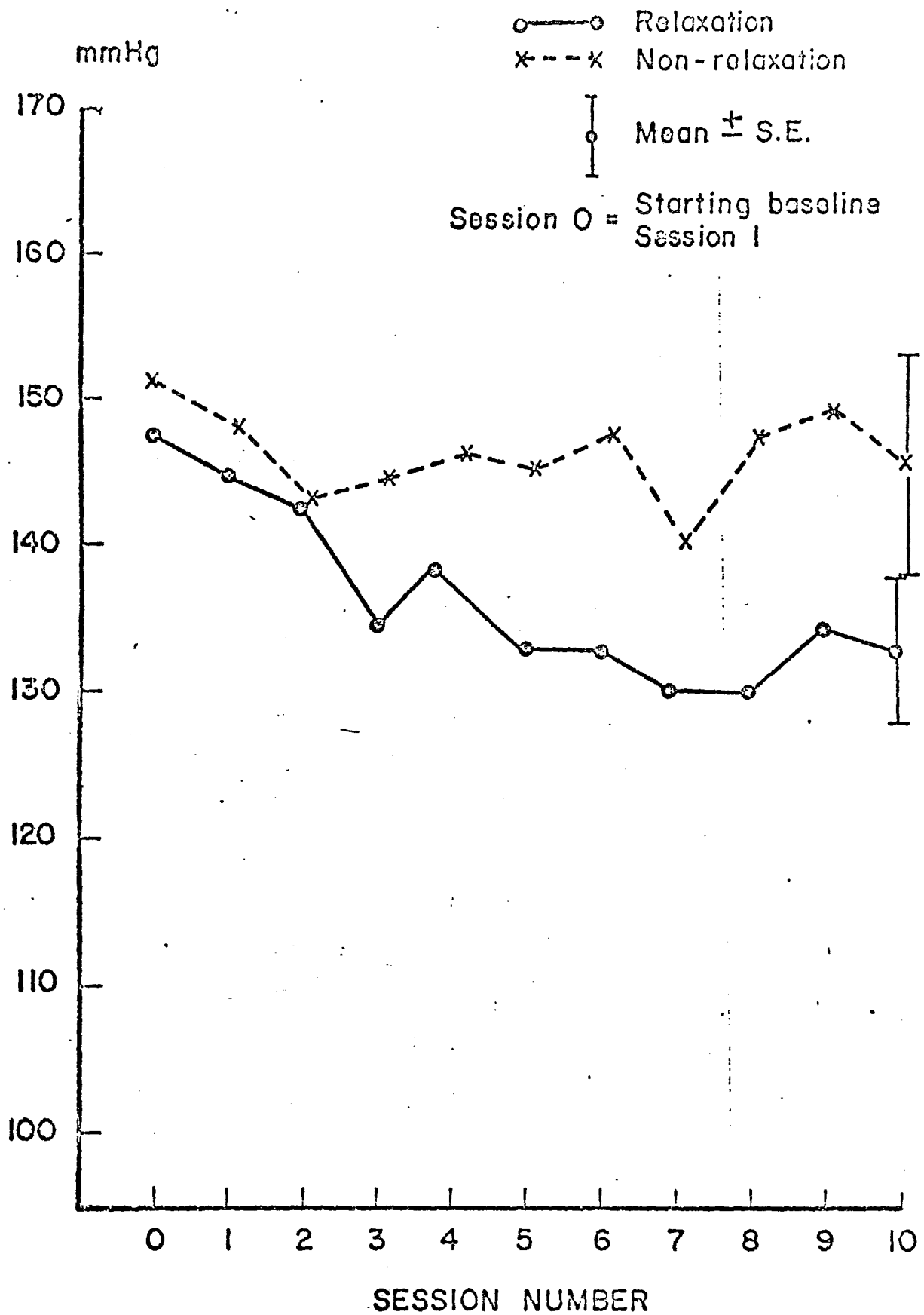
ENDING BASELINE BLOOD PRESSURE (SYSTOLIC)

FIG. 3

25.

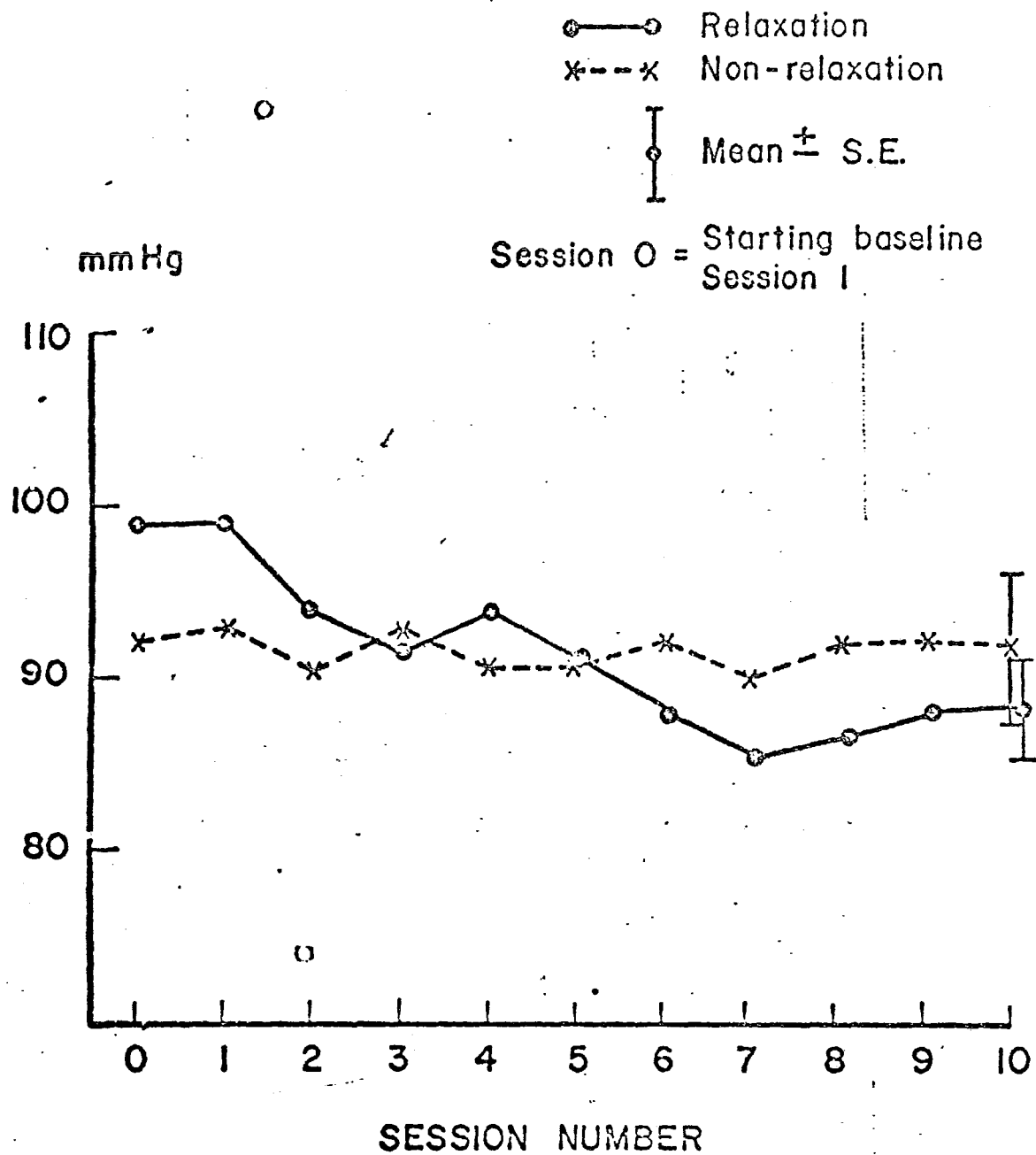
ENDING BASELINE BLOOD PRESSURE (DIASTOLIC)

FIG. 4CONSISTENCY SCORES OVER TRAINING : ALL FEEDBACK SUBJECTS