A CONTROLLED COMPARATIVE INVESTIGATION

OF LARGE GROUP THERAPY FOR

GENERALISED ANXIETY DISORDER - "STRESS CONTROL"

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CHAPTER 11

THE EFFECTS OF DIFFERENT TREATMENTS : MAIN MEASURES

THE EFFECTS OF DIFFERENT TREATMENTS : MAIN MEASURES (pre- to post-therapy)

1. The Hypotheses

1) Each of the three active treatments, and to a lesser extent, the Placebo condition, will be superior to the Waiting list condition during the course of therapy.

2) Each of the three active treatments will be superior to the Placebo condition.

3) The Cognitive and Cognitive-Behavioural conditions will be superior to the Behavioural condition.

4) In particular, the Cognitive and Cognitive-behavioural conditions will be superior to the Behavioural and Placebo conditions in terms of the degree of dysfunctional attitude change.

2. Descriptive Analysis

a) Mean values

In order to provide a preliminary examination of the data, a descriptive analysis was conducted. Table 8 presents mean values and percentage changes in these values for all main measures at pre-therapy, mid-therapy and post-therapy across conditions.

TABLE 8/

TABLE 8. Comparison across experimental conditions of mean scores at pre-therapy, mid-therapy and post-therapy along with percentage change score (pre-post) for each of the main variables (+ = increase in score, - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List
STAI:A-State					
Pre	55.5	56.4	50.2	59.7	45.6
Mid	48.6	48.1	46.7	49.4	41.5
Post	40.7	40.6	42.0	46.4	48.7
% change (pre-post)	-26.7	-28.0	-16.3	-22.3	+6.8
STAI:A-Trait					
Pre	58.1	59.5	54.8	59.3	54.7
Mid	57.7	56.4	54.0	54.9	54.4
Post	50.2	51.7	48.6	51.4	56.3
% change (pre-post)	-13.6	-13.1	-11.3	-13.3	+2.9
DAS					
Pre	99.2	99.3	95.7	99.1	101.8
Mid	98.0	99.3	92.0	94.7	106.2
Post	112.3	108.8	103.3	111.1	101.2
% change (pre-post)	+13.2	+9.6	+7.9	+12.1	-0.6
FSS					
Pre	104.4	106.5	105.6	116.6	106.6
Mid	100.2	95.3	101.4	102.6	97.6
Post	79.0	75.0	83.5	95.2	102.0
% change (pre-post)	-24.3	-29.6	-20.9	-18.3	-4.3
BDI					
Pre	18.5	20.0	17.0	20.8	16.1
Mid	16.8	16.7	16.8	18.7	16.0
Post	10.6	11.4	11.5	15.1	17.4
% change (pre-post)	-42.7	-43.0	-32.4	-27.4	+8.1
MSPQ					
Pre	34.3	34.4	27.4	29.2	25.5
Mid	31.6	31.9	23.3	24.9	23.9
Post	23.1	23.7	22.3	20.6	27.4
% change (pre-post)	-32.7	-31.1	-18.6	-29.5	+7.5

Inspection of Table 8 shows that few pre-treatment differences between conditions exist on any variable (see next section for statistical evidence) and that all treatment conditions show considerable improvement in comparison with the waiting list condition which, perhaps suprisingly, shows exacerbation of distress on both STAI measures, BDI and MSPQ.

A trend across most measures suggests that the Cognitive and Behavioural conditions show most improvement. Interestingly, the Behavioural condition achieves the greatest reduction in behavioural anxiety as measured by the FSS while the Cognitive condition achieves the greatest decrease in dysfunctional attitudes (an increase in DAS scores represents decrease in dysfunction). Both groups show considerable improvement in depression with the degree of change being around 43%.

Of particular interest is the degree of improvement demonstrated by the Placebo condition which, overall, performs at least as well as the Cognitive-behavioural condition. Improvement in STAI:A-Trait and DAS scores are notable.

Figures 1 - 6 illustrate changes in the main variables across the treatment period and permit visual comparison of the mean rate of change across conditions.

i. STAI:A-State.

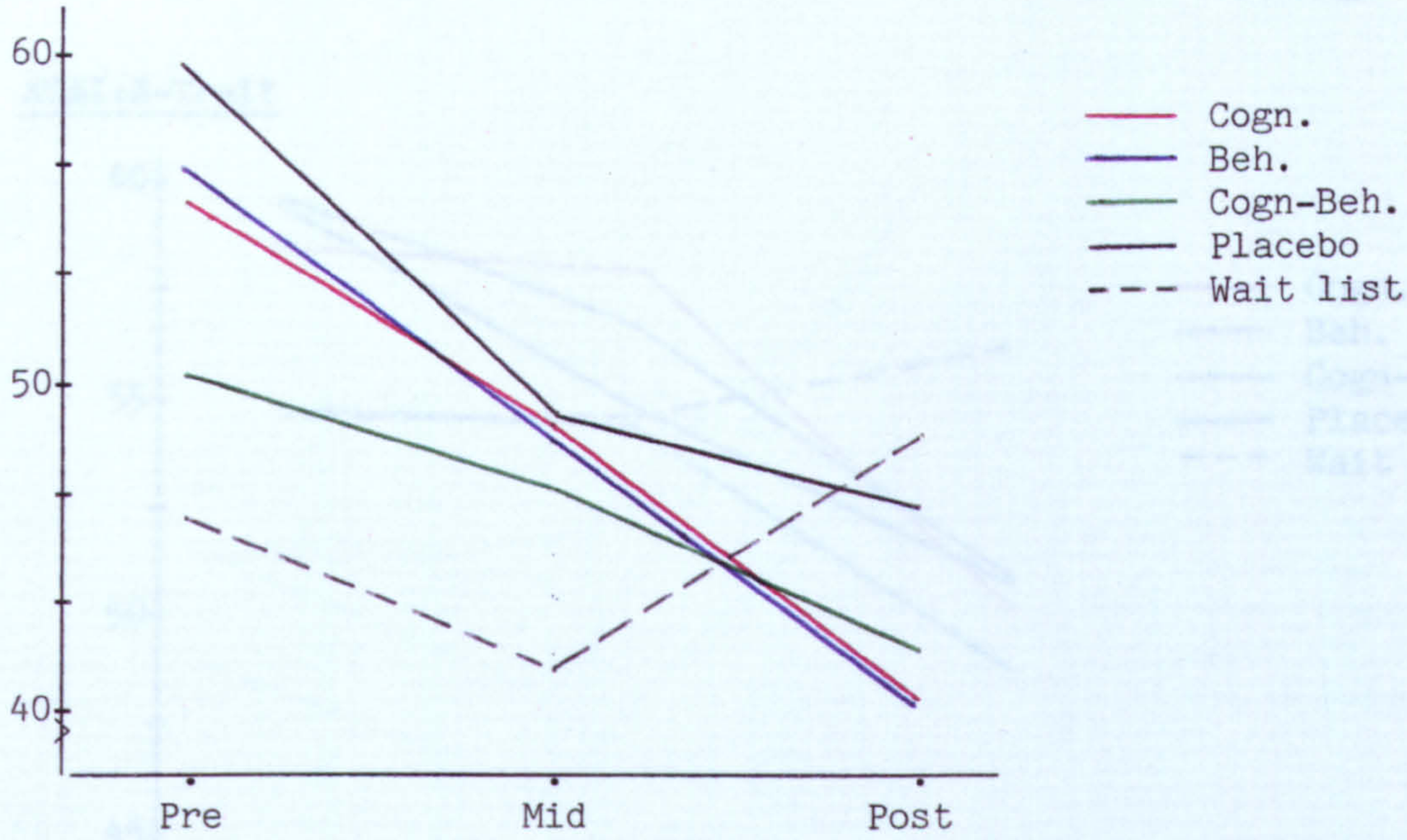

Figure 1. Comparison across experimental conditions of mean scores at pre-, mid-, and post-therapy for STAI:A-State.

Notable is the almost identical rate of change for the Cognitive and Behavioural conditons, both showing fairly even progress from pre- to mid-therapy and from mid- to post-therapy. A similar pattern, although not of the same magnitude can be identified for the Cognitive-behavioural condition. Of interest is the change in the Placebo condition. Although improving to almost the same degree as the Cognitive and Behavioural conditions, the Placebo condition shows a different pattern of change. In the first half of treatment, this group shows the greatest degree of change of all the conditions but the rate slows in the second half of treatment. It will be interesting to note what happens in the follow-up

period with this group. The Waiting list condition, after some initial change worsens in the second half of its six week monitoring.

ii. STAI:A-Trait

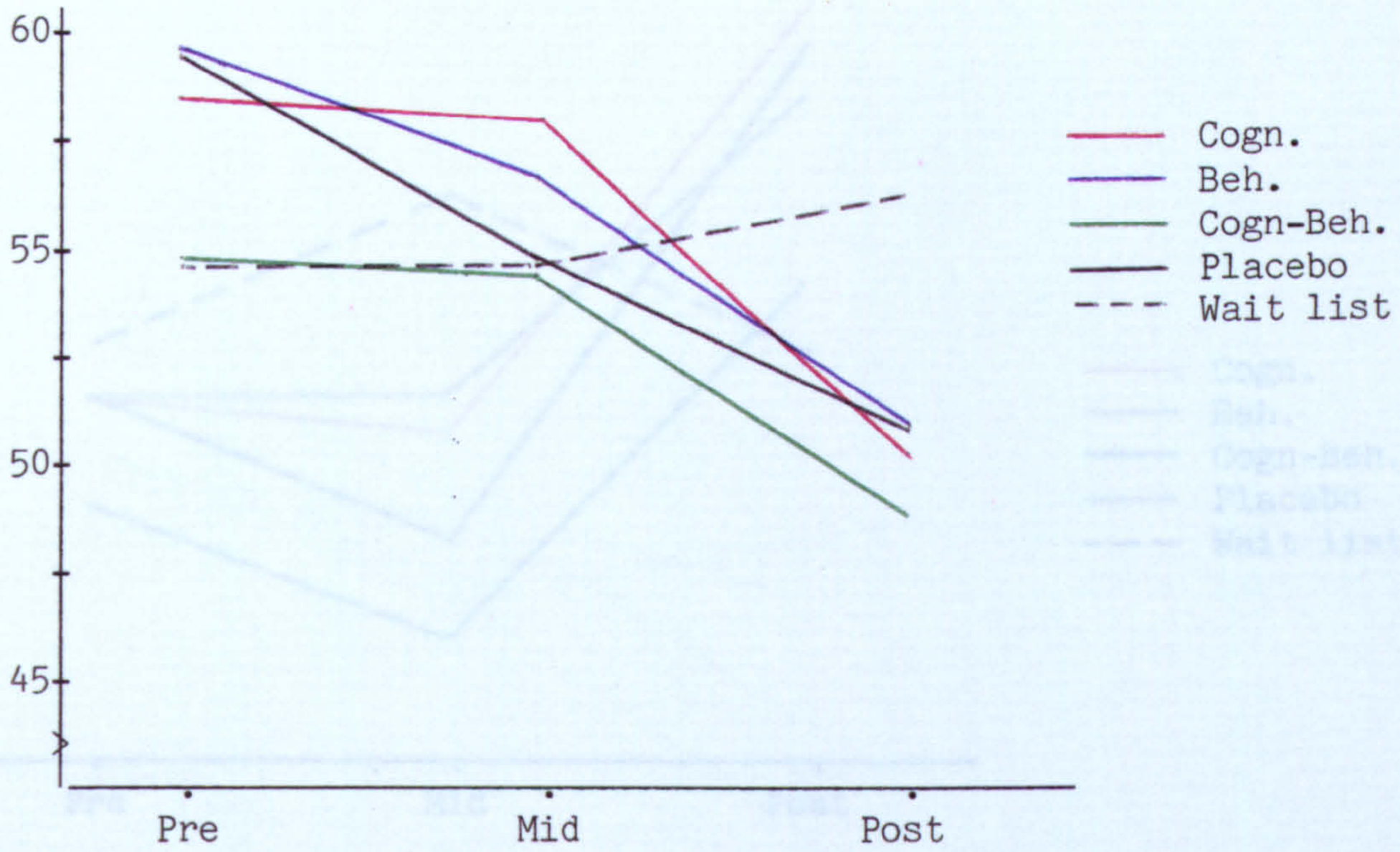

Figure 2. Comparison across experimental conditions of mean scores at pre-, mid-, and post-therapy for STAI:A-Trait.

Although overall the four treatment conditions improve to roughly the same degree, the pattern of change differs. The Behavioural and Placebo condition show uniform change from pre- to mid-therapy and from mid- to post-therapy while the Cognitive and Cognitive-behavioural condition show little change in the first half of treatment but accelerate progress during the second. The Waiting list shows little improvement.

iii. DAS.

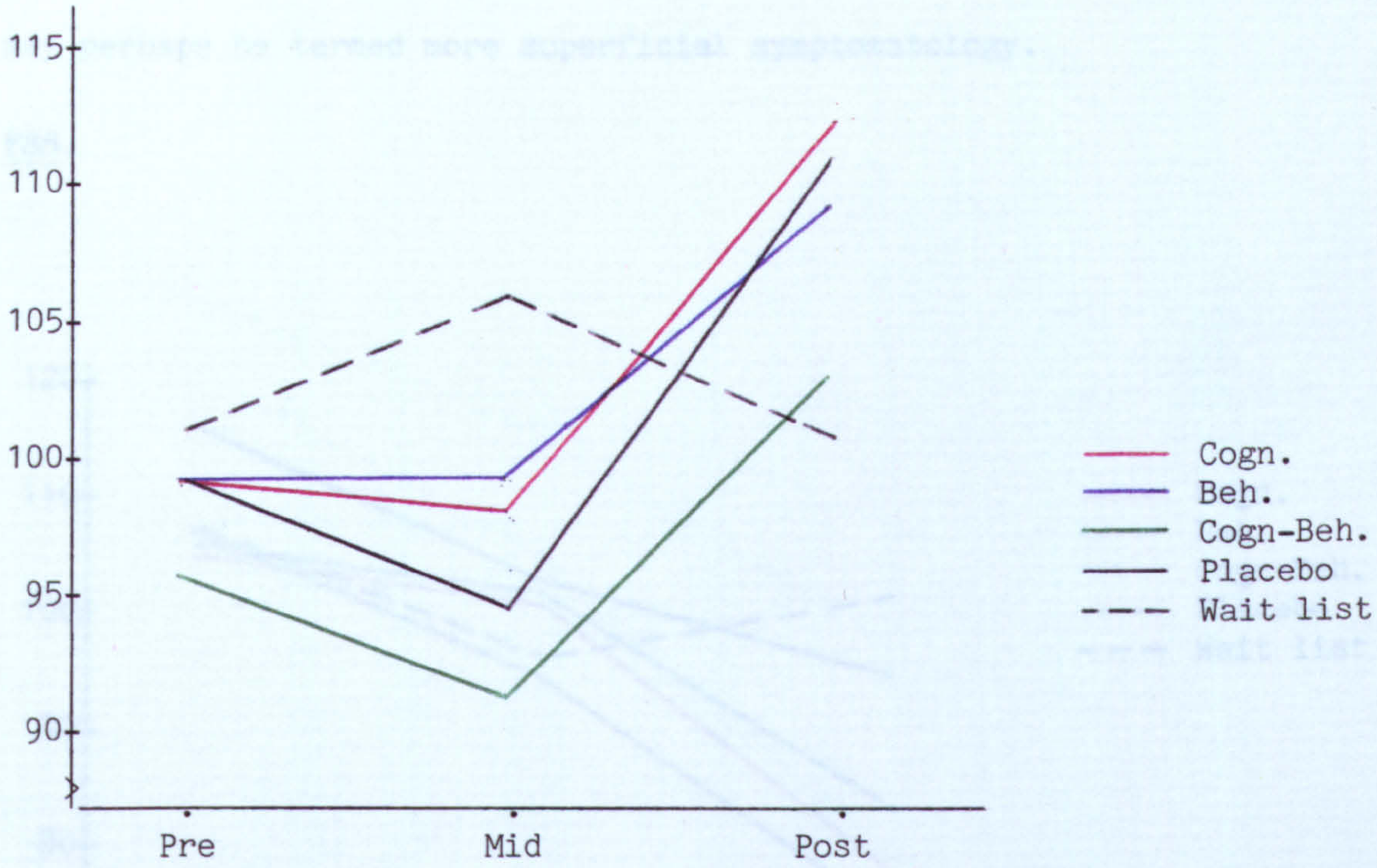

FIGURE 3. Comparison across experimental conditions of mean scores at pre-, mid-, and post-therapy for DAS

The trend towards improvement in the second half of therapy noted in the Cognitive and Cognitive-Behavioural conditions for the STAI:A-Trait can now be seen in all the treatment conditions. Of interest is the fact that, with the exception of the Behavioural condition which remains the same, the treatment conditions show a worsening in scores during pre- to mid- therapy. This deterioration is particularly marked for the Cognitive-Behavioural condition. As compared to the slight improvement in the Waiting list condition, this deterioration over the first few weeks suggests that therapy itself causes an exacerbation of symptoms.

It seems clear that, as with STAI:A-Trait scores, the DAS represents stable factors which may not be altered until changes are achieved in what may perhaps be termed more superficial symptomatology.

iv. FSS.

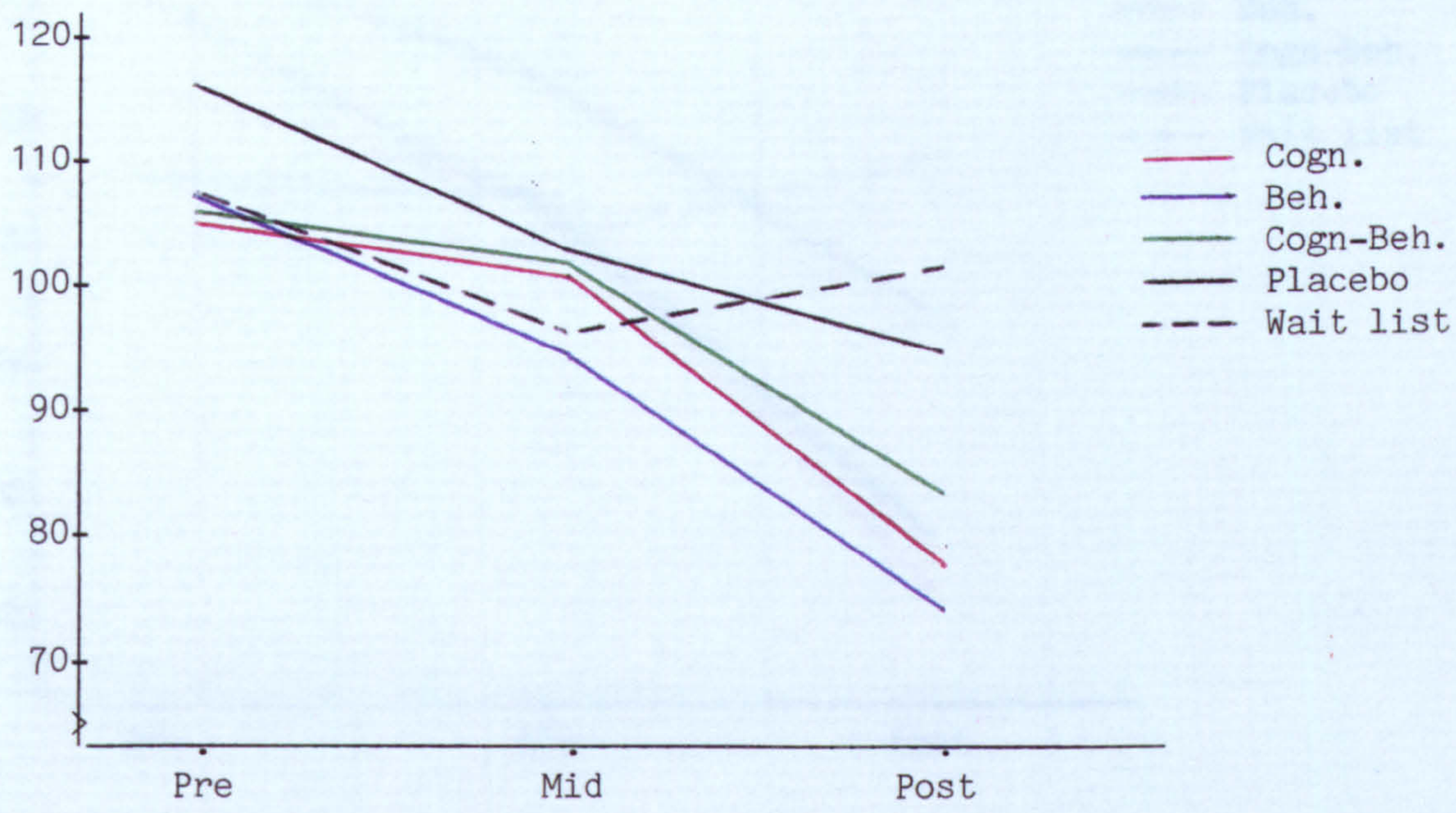

FIGURE 4. Comparison across experimental conditions of mean scores at pre-, mid-, and post-therapy for FSS.

Of interest is the trend towards greatest reduction in phobic scores in the Behavioural condition. However, considerable improvements achieved by the other treatment conditions , suggest that statistically significant differences between treatment conditions are unlikely to be found on this variable.

v. BDI.

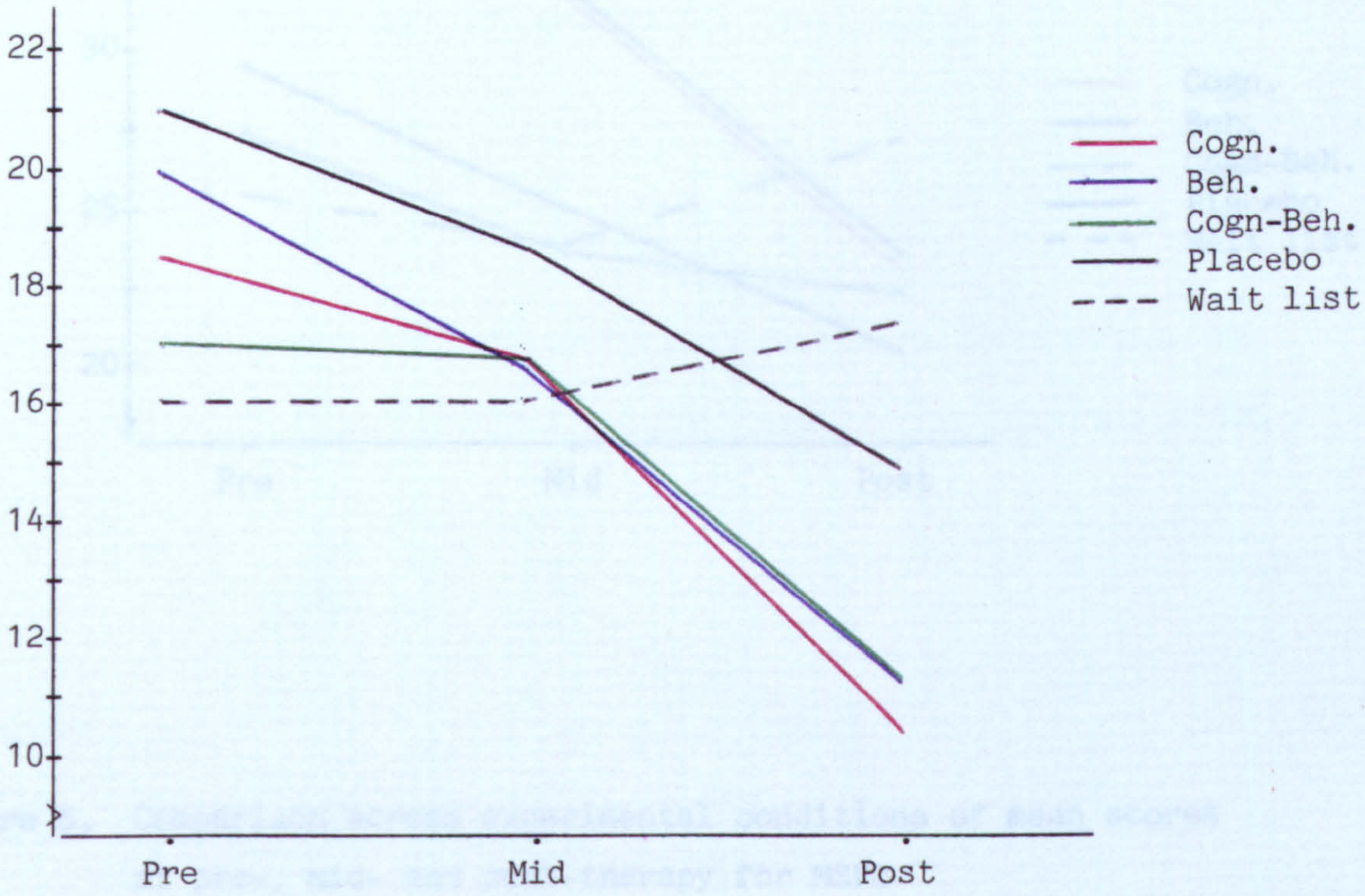

FIGURE 5. Comparison across experimental conditions of mean scores at pre-, mid-, and post-therapy for BDI.

With greatest change again occurring in the second half of therapy, the Cognitive and Behavioural conditions show the largest magnitude of change and identical rate and pattern of change.

vi. MSPQ

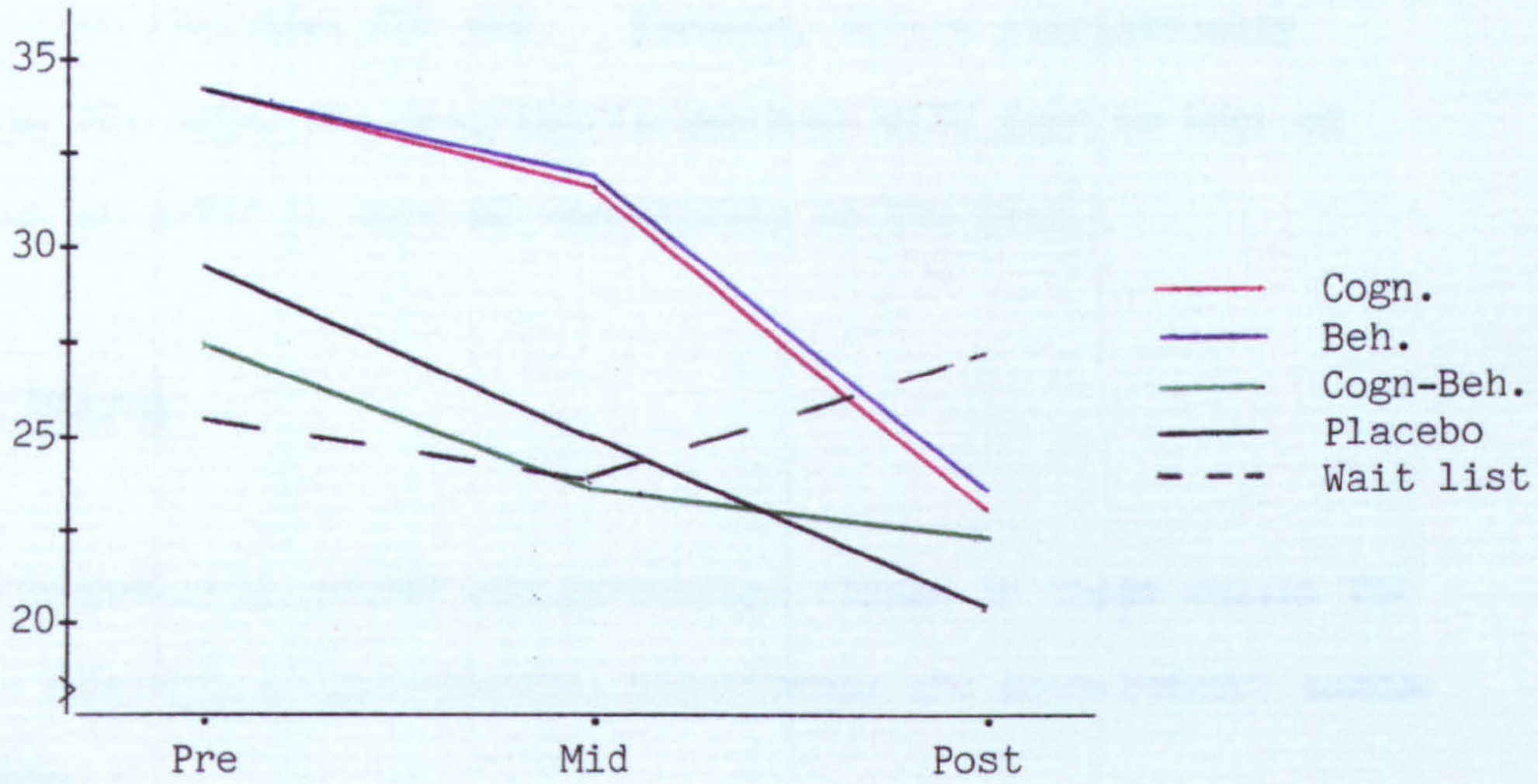

Figure 6. Comparison across experimental conditions of mean scores at pre-, mid- and post-therapy for MSPQ.

This final main measure confirms the view that the Cognitive and Behavioural condition have produced virtually identical and impressive results both in the pattern and rate of change. Improvement on this somatic anxiety measure is particularly impressive for the Cognitive condition which involved no somatically orientated technique (c.f. progressive muscular relaxtion in both the Behavioural and Cognitive-behavioural condition). The MSPQ also highlights the impressive performance of the Placebo condition which, on this and several other variables, performs at least as well as the Cognitive behavioural condition.

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The changes in mean values presented above seem to indicate that, in general, Stress Control therapy in its four variants seems to be an effective treatment for GAD. However, before statistically analysing the data, the descriptive analysis will turn to look at SD scores in order to look at variability in the data.

b). <u>SD values</u>

Table 9 presents SD values and percentage change in these values for all main measures at pre-therapy, mid-therapy and post-therapy across conditions.

TABLE 9/

TABLE 9. Comparison across experimental conditions of SD scores at pre-therapy, mid-therapy and post-therapy along with percentage change scores (pre-post) for each of the main variables (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List
STAI:A-State					
Pre	11.6	12.7	12.8	17.5	10.2
Mid	12.2	16.4	11.9	19.4	9.9
Post	11.8	13.1	12.2	18.1	9.3
% change (pre-post)	+1.7	+4.8	-4.7	+3.4	-8.8
STAI:A-Trait					
Pre	9.0	10.8	11.0	11.4	5.9
Mid	9.0	10.9	8.9	15.2	7.5
Post	10.9	12.8	12.2	13.8	6.3
% change (pre-post)	+21.1	+18.5	+10.9	+21.0	+6.7
DAS					
Pre	21.2	23.2	21.0	13.6	25.1
Mid	22.8	21.2	21.1	22.8	27.8
Post	24.7	23.3	22.8	15.0	24.2
% change (pre-post)	+16.5	+0.4	+8.6	+10.3	-3.6
FSS					
Pre	46.2	41.6	47.6	42.4	40.6
Mid	46.7	46.5	53.3	53.9	44.2
Post	50.5	41.0	48.3	65.3	40.2
% change (pre-post)	+9.3	-1.4	+1.5	+54.0	-1.0
BDI					
Pre	8.4	9.4	10.3	11.4	6.5
Mid	7.3	9.3	8.9	12.4	7.8
Post	6.1	7.2	9.9	12.1	6.6
% change (pre-post)	-27.4	-23.4	-3.9	+6.2	+1.5
MSPQ					
Pre	13.8	13.6	13.0	13.3	7.9
Mid	14.2	15.4	15.3	11.2	10.1
Post	11.3	14.0	15.4	10.8	8.9
% change (pre-post)	-18.1	+2.9	+18.5	-18.8	+5.1

In comparison with the mean score changes presented earlier, Table 9 shows a quite different picture. While little change in variability of scores is evidenced by the Waiting list condition, treatment produces an erratic effect on the distribution of scores for the other four conditions. Although only STAI:A-Trait produces a uniform increase in SD scores (pre-post), the other variables seem to contrast with the impressive reduction in mean scores presented in Table 8.

These interesting results suggest that hidden under the mean score changes, lies a more complex and potentially more interesting picture of the effect of the therapies on patients anxiety. This will be looked at in greater detail in Chapters 14-19.

3. Statistical Analysis

a) Main Effects

Table 10 presents the results of MANOVAs for the main measures. Despite some large differences in means, no variable achieves significance for group and time main effects and group x time interaction. Significant interaction effects are found for STAI:A-State, FSS, BDI and MSPQ. In addition, a near significant interaction effect is found for STAI:A-Trait. Further treatment within time analyses are, therefore, presented in order to establish where the critical between group differences exist and at which point(s) during therapy these differences emerge. As every variable demonstrates significant time main effects, we will thereafter consider the simple effects of time within treatment group on all variables.

TABLE 10/

TABLE 10. Repeated measures analysis of pre-post variables across the experimental period using MANOVA (* p < .05, ** < .01, *** < .001)

Source of variation	Pillai	Hyd. d.f.	Error d.f.	F ratio	F probab.	Signif. level
STAI: A-State						
Group		4		.21	.933	NS
Time	.342	2	103	26.80	.000	***
Group x time	.247	8	208	3.66	.001	***
STAI: A-Trait						
Group		4		.45	.776	NS
Time	.209	2	103	13.60	.000	***
Group x time	.127	8	208	1.76	.087	NS
DAS						
Group		4		.48	.749	NS
Time	.207	2	102	13.45	.000	***
Group x time	.120	8	208	1.66	.110	NS
BDI						
Group		4		.67	.614	NS
Time	.308	2	102	22.93	.000	***
Group x time	.191	8	208	2.75	.007	**
FSS						
Group		4		.50	.734	NS
Time	.418	2	102	37.01	.000	***
Group x time	.159	8	208	2.25	.025	*
MSPQ						
Group		4		.83	.507	NS
Time	.174	2	102	10.92	.000	***
Group x time	.190	8	208	2.74	.007	**

b) Treatment within time sub-effects

In order to investigate the treatment within time sub-effects, ONEWAY ANOVA's across the five experimental conditions were conducted

at mid- and post-therapy data points. The Student- NEWMAN-KEULS test was applied to identify the loci of significant differences. The results of these analyses are presented in Table 11. As no between group differences are found at the mid-point, only post-therapy is considered.

TABLE 11. ANOVAs conducted upon each main variable at post-therapy across the five experimental conditions (Cognitive = 1, Behavioural = 2, Cognitive-behavioural = 3, Placebo = 4, Waiting list = 5) using NEWMAN-KEULS (alpha level = .05).

Variable	d.f.	F ratio	F probability	Pair
STAI: A-State	4,104	7.08	.000	1 v 5
				2 v 5
				3 v 5
				4 v 5
STAI: A-Trait	4,104	2.25	.068	1 v 5
				2 v 5
				3 v 5
DAS	4,104	2.18	.076	1 v 5
FSS	4,104	3.89	.005	1 v 5
				2 v 5
				3 v 5
BDI	4,104	4.06	.004	1 v 5
				2 v 5
				3 v 5
				4 v 5
MSPQ	4,104	3.95	.005	1 v 5
				2 v 5
				3 v 5
				4 v 5

As viewed against the mean changes outlined in the descriptive analysis, it is perhaps surprising that on no variable is there a significant difference between conditions at mid-therapy. At post-therapy, while no active therapy achieves a significant difference to the Placebo condition on any variable, all active therapies achieve significant differences to the Waiting list on all variables with the exception of DAS. The Placebo condition achieves a significant difference to the Waiting list on three variables (STAI: A-State, BDI and MSPQ).

Of interest is the DAS result which discriminates between only the Cognitive and Waiting list conditions. However, as there is no strong indication, on the other variables, that the Cognitive condition produces higher levels of improvement, it is not, at this stage, clear how much significance should be attached to this finding.

c) Time within Treatment Group Sub-effects

Time within treatment effects are essentially a series of within subjects repeated measures ANOVAs and these are generated via the CONSPLUS subcommand of the MANOVA programme. These effects which provide information, within each condition, on significant variation from base-line values across the experimental period can be viewed as providing complimentary information to the treatment within time sub-effects. Table 12 provides information, separately, for each of the experimental conditions and illustrates the magnitude of effect of treatment upon each of the main measures.

TABLE 12. Time within Treatment Group simple effects and sub-effects at mid- and post-therapy presented separately for each experimental condition (* p < .05, ** p < .01, *** p < .001, NS = non-significant).

TREATMENT VARIABLE	PILLAI	F PROBAB.	MID-THERAPY	POST-THERAPY.
COGNITIVE CONDITION				
STAI: A-State	.334	25.821	**	***
STAI: A-Trait	.209	13.598	NS	***
DAS	.228	15.251	NS	***
BDI	.220	14.597	NS	***
FSS	.321	24.355	NS	***
MSPQ	.198	12.772	NS	***
BEHAVIOURAL CONDITION				
STAI: A-State	.324	24.690	***	***
STAI: A-Trait	.120	7.035	NS	***
DAS	.125	7.376	NS	***
BDI	.254	17.584	NS	***
FSS	.354	28.184	*	***
MSPQ	.205	13.313	NS	***
COGNITIVE-BEHAVIOURAL CONDITION				
STAI: A-State	.130	7.690	NS	***
STAI: A-Trait	.122	7.135	NS	**
DAS	.087	4.911	NS	**
BDI	.222	14.713	NS	***
FSS	.226	15.063	NS	***
MSPQ	.026	1.364	NS	NS

	PILLAI	F PROBAB.	MID-THERAPY	POST-THERAPY.
PLACEBO CONDITION				
STAI: A-State	.107	6.184	NS	***
STAI: A-Trait	.057	3.143	NS	*
DAS	.053	2.896	NS	*
BDI	.083	4.666	NS	**
FSS	.094	5.366	NS	***
MSPQ	.075	4.207	NS	*
WAITING LIST CONDITION				
STAI:A-State	.040	2.140	NS	NS
STAI: A-Trait	.004	0.225	NS	NS
DAS	.011	0.600	NS	NS
BDI	.009	0.471	NS	NS
FSS	.000	0.005	NS	NS
MSPQ	.025	1.324	NS	NS

The immediate visual impact of Table 12 shows the significant change over baseline associated with all 4 treatment groups compared with the Waiting list condition. Indeed the Waiting list condition shows no significant change on any variable at either mid- or post-therapy.

Looking in greater detail at the four treatment conditions, while there was some evidence of significant change at the mid-point, substantial change appears strongly at post-therapy on all variables (with the exception of the MSPQ where the Cognitive-behavioural condition show no significant change). The Cognitive and Behavioural

conditions produce consistent significant difference (< .001) on all variables at this stage. The Cognitive-behavioural condition produces less significant results while the Placebo condition results are somewhat weaker.

4. ADDRESSING THE HYPOTHESES

Having completed all the necessary analyses, it is now possible to address the hypotheses outlined earlier. It may be useful to reproduce these hypotheses at this stage.

Hypothesis 1.

Each of the 3 active treatments, and, to a lesser extent, the Placebo condition, will be superior to the Waiting list control group during the course of therapy.

This hypothesis receives considerable support. Table 11 demonstrates the superiority of Cognitive Therapy over the Waiting list on all variables, Behaviour and Cognitive-behavioural therapies on 5 of the 6 variables and Placebo Therapy on 3 of the 6 variables. Table 12 confirms the impression of Figures 1 - 6 that all variables responded differentially to treatments over time with the Waiting list condition showing no evidence of significant change.

Hypothesis 2.

Each of the 3 active treatment conditions will be superior to the Placebo condition.

This hypothesis receives weak support. While descriptive analyses suggest that, on most variables, there is a trend favouring the Cognitive and Behavioural conditions and, to a lesser extent, the Cognitive-Behavioural condition, differences from the Placebo condition at no point achieve statistical significance (see Table 11). Table 12 points to the more substantial change over time achieved by the active therapy

condition (particularly Cognitive and Behavioural conditions) than that achieved by the Placebo condition. Even so, the significant change over time associated with the Placebo condition points to the unexpected and surprising improvements accrued by patients in this condition. This finding is of significance and it will be of great interest to examine the Placebo condition functioning both on process measures and during the follow-up period.

Hypothesis 3.

The Cognitive and Cognitive-behavioural conditions will be superior to the Behavioural condition.

This hypothesis is not confirmed. There is little difference between the Cognitive and Behavioural condition on most variables. Further, both these conditions out-perform the Cognitive-behavioural condition on most variables. While the progressive relaxation component in the Behavioural condition may be of value in the treatment of GAD, in the absence of any cognitive approaches, it is difficult to see why this condition should perform as well as the Cognitive condition which the literature suggests, on empirical and theoretical grounds, as the treatment of choice for this population (see Chapter 2), or why the Behavioural condition should out-perform the Cognitive-behavioural condition.

One possibility is, as Durham and Turvey (1987) found, while cognitive and behavioural therapy produced similar significant results at post-therapy, the behaviour therapy group reverted to pre-treatment level

during the follow-up period. Another possibility relates to the effect of non-specific factors. However, little can be deduced at this stage and, hopefully, the reasons will become clearer by the follow-up.

Hypothesis 4.

The Cognitive and, to a lesser extent, Cognitive-behavioural therapy condition will be superior to the Behavioural condition in terms of the degree of dysfunctional attitude change.

This hypothesis is partially confirmed. Although all treatment conditions produced significant change over baseline on the DAS, only the Cognitive condition produces a significant difference over the Waiting list condition at post-therapy. No superior functioning is found for the Cognitive-behavioural condition. It will be interesting once all process and follow-up data have been assessed to see whether superior functioning as measured by the DAS is of clinical importance in terms of general functioning.

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Chapter 13 will assess functioning on these variables at the 6 month follow-up. At this juncture, however, we will turn to the, arguably more important, data contained in the process measures.

CHAPTER 12

THE EFFECTS OF DIFFERENT TREATMENTS : PROCESS MEASURES

THE EFFECTS OF DIFFERENT TREATMENTS: PROCESS MEASURES (pre- to post-therapy)

1). THE HYPOTHESES

i) Each of the three active treatments and, to a lesser extent, the Placebo condition, will be superior to the Waiting list condition during the course of therapy.

ii) Each of the three active treatments will be superior to the Placebo condition.

iii) The Cognitive and Cognitive-behavioural conditions will be superior to the Behavioural condition.

iv) Apart from the rate of change differences, the nature of the process will differ across conditions.

a) Daily diary measures are expected to show the Cognitive and Cognitive behavioural conditions demonstrating a greater decrease in time spent thinking or worrying about problems than the Behavioural and Placebo conditions.

b) The nature of change as measured by the FSAQ may differ across conditions. It is tentatively suggested that changes in the component which is the focus of therapy may initiate change in the other components i.e. Cognitive therapy may produce initial changes in the cognitive component, etc. No predictions are made for the Placebo condition.

c) Change, as measured by the CRQ, may vary across conditions. Cognitive therapy will produce greatest change in the active-cogntive coping scale (CRQ-C); Behaviour Therapy in the active-behavioural and avoidance coping scales (CRQ-B and CRQ-A) while the Cognitive-behavioural condition will produce equal changes in all three scales. No predictions are made for the Placebo condition.

d) The Imaginal test will discriminate between conditions. No changes in negative and positive self-statements are expected in the Behavioural and Placebo conditions both of which will also sustain high anxiety levels across sessions. The Cognitive and, to a lesser extent, Cognitive-behavioural conditions will show:

i) an increase across sessions in the production of positive self-statements.

ii) a decrease across sessions in the production of negative self-statements.

iii) a decrease across sessions of anxiety ratings.

2). DESCRIPTIVE ANALYSIS

a. Mean values:

In order to provide a preliminary examination of the data,a descriptive analysis was conducted. Tables 13 to 16 present mean values and percentage change in these values for all process variables at pre-therapy and post-therapy across conditions.

TABLE 13/

DIARY MEASURES.

TABLE 13. Comparison across experimental conditions of mean scores during baseline (pre) and the final week of therapy (post) along with percentage change scores for each of the three diary scales (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List
i. How anxious have you been today?					
Pre	5.0	6.2	5.2	6.4	4.9
Post	3.7	4.9	3.2	5.5	5.1
% change	-26.0	-21.0	- 38.5	-14.1	+4.1
ii. How much time have you spent thinking or worrying about your problems today?					
Pre	5.4	6.0	5.1	5.0	4.3
Post	3.9	4.6	3.9	4.3	4.4
% change	-27.8	-23.3	-23.5	-.4.0	+2.3
iii. How well have you coped today?					
Pre	6.5	6.0	6.8	8.3	7.3
Post	8.3	7.8	8.2	8.3	7.4
% change	+27.7	+30.0	+20.6	0	+1.4

FOUR SYSTEM ANXIETY QUESTIONNAIRE (FSAQ)

TABLE 14. Comparison across experimental conditions of mean scores at pre-therapy and post-therapy along with percentage change scores for FSAQ sub-scales and total score. (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List
COGNITIVE COMPONENT					
Pre	60.0	62.9	60.4	56.6	52.8
Post	41.1	41.8	41.9	48.1	55.9
% change	-31.5	-33.5	-30.6	-15.0	+5.9
BEHAVIOURAL COMPONENT					
Pre	43.6	49.6	46.5	47.9	47.1
Post	30.9	33.6	32.5	40.4	45.8
% change	-29.1	-32.2	-30.1	-15.6	-2.8
SOMATIC COMPONENT					
Pre	46.6	46.2	45.7	46.2	44.1
Post	33.6	36.3	29.9	30.2	42.6
% change	-27.9	-21.4	-34.6	-34.6	-3.4
MOOD COMPONENT					
Pre	56.1	56.4	55.3	60.8	56.1
Post	41.1	41.5	41.6	45.6	55.7
% change	-26.6	-26.4	-24.8	-25.0	-0.7
TOTAL SCORE					
Pre	208.2	217.8	210.5	211.5	200.5
Post	146.6	153.3	146.0	164.2	197.7
% change	-29.6	-29.6	-30.6	-22.4	-1.4

COPING RESPONSES QUESTIONNAIRE (CRQ)

TABLE 15. Comparison across experimental condtions of mean scores at pre-therapy and post-therapy along with percentage change scores for each of the three CRQ sub-scales. (+ = increase in score; - = decrease in score.)

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List
ACTIVE-COGNITIVE COPING					
Pre	9.8	10.6	10.1	13.1	8.5
Post	11.5	11.2	11.2	12.3	8.9
% change	+17.3	+5.7	+10.9	-6.1	+4.7
ACTIVE-BEHAVIOURAL COPING					
Pre	7.9	9.2	8.5	8.4	9.1
Post	10.4	9.6	9.5	8.4	7.3
% change	+31.6	+4.3	+11.8	0	-19.8
AVOIDANCE COPING					
Pre	10.2	10.6	9.6	9	9
Post	6.9	6.7	7.1	7.6	8.8
% change	-32.4	-36.8	-26.0	-15.6	-2.2

TABLE 16. Comparison across treatment conditions of mean scores during the first and final sessions along with percentage change scores for the four Imaginal Test sub-scales (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
NEGATIVE SELF-STATEMENTS				
pre	7.2	6.0	7.2	6.9
post	5.4	5.4	5.7	6.0
% change	-25.0	-10.0	-20.8	-13.0
POSITIVE SELF-STATEMENTS.				
pre	5.7	7.2	6.3	6.7
post	7.8	8.0	7.7	7.7
% change	+36.8	+11.1	+22.2	+14.9
ANXIETY RATING				
pre	6.0	5.2	5.4	6.1
post	4.2	5.1	4.8	5.7
% change	-30.0	-1.9	-11.1	-6.6
IMAGINATION RATING				
pre	8.5	8.8	8.5	9.0
post	8.5	9.2	8.7	9.0
% change	0	+4.5	+2.4	0

****

As with the main measures, inspection of Tables 13 - 16 shows few pre-treatment differences between conditions (see next section for statistical evidence). Again all treatment conditions show improvement

across virtually all variables. However process variables appear to more acutely discriminate the active therapies from the the Placebo condition.

Tables presenting pre-, post-therapy differences are, naturally, extremely limited in terms of the information they can convey about process changes. Figures 7 to 21 will allow more detailed information to be presented.

b. Diary Measures.

i. How anxious have you been today? (ANXIETY).

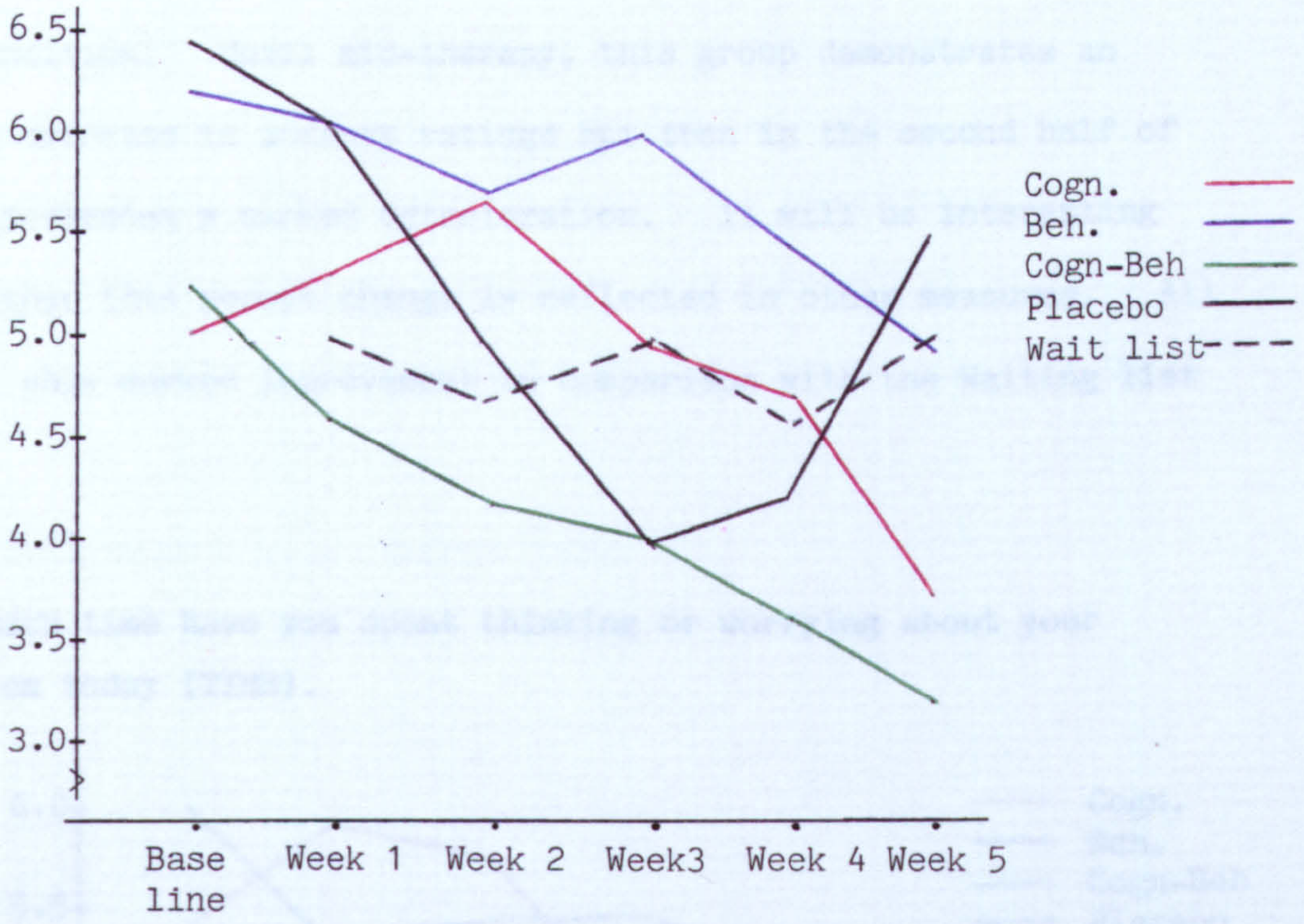

FIGURE 7. Comparison across experimental conditions of mean scores for diary ANXIETY variable during baseline and across the experimental period.

There is clear evidence of improvement in the three active therapy conditions. The Cognitive-behavioural condition shows the largest magnitude of change and improves at a consistent steady pace. The Behavioural condition, despite a slight deterioration during the week following session 3, shows a similar pattern of change as the Cognitive-behavioural condition. The process of change, however, is distinctly different for the Cognitive condition which shows an initial enhancement

of anxiety and does not show any improvement over baseline ratings until the second half of therapy. An inverted pattern is found for the Placebo condition. Until mid-therapy, this group demonstrates an impressive decrease in anxiety ratings but then in the second half of therapy experiences a marked deterioration. It will be interesting to see whether this abrupt change is reflected in other measures. All conditions show marked improvement in comparison with the Waiting list condition.

ii. How much time have you spent thinking or worrying about your problem today (TIME).

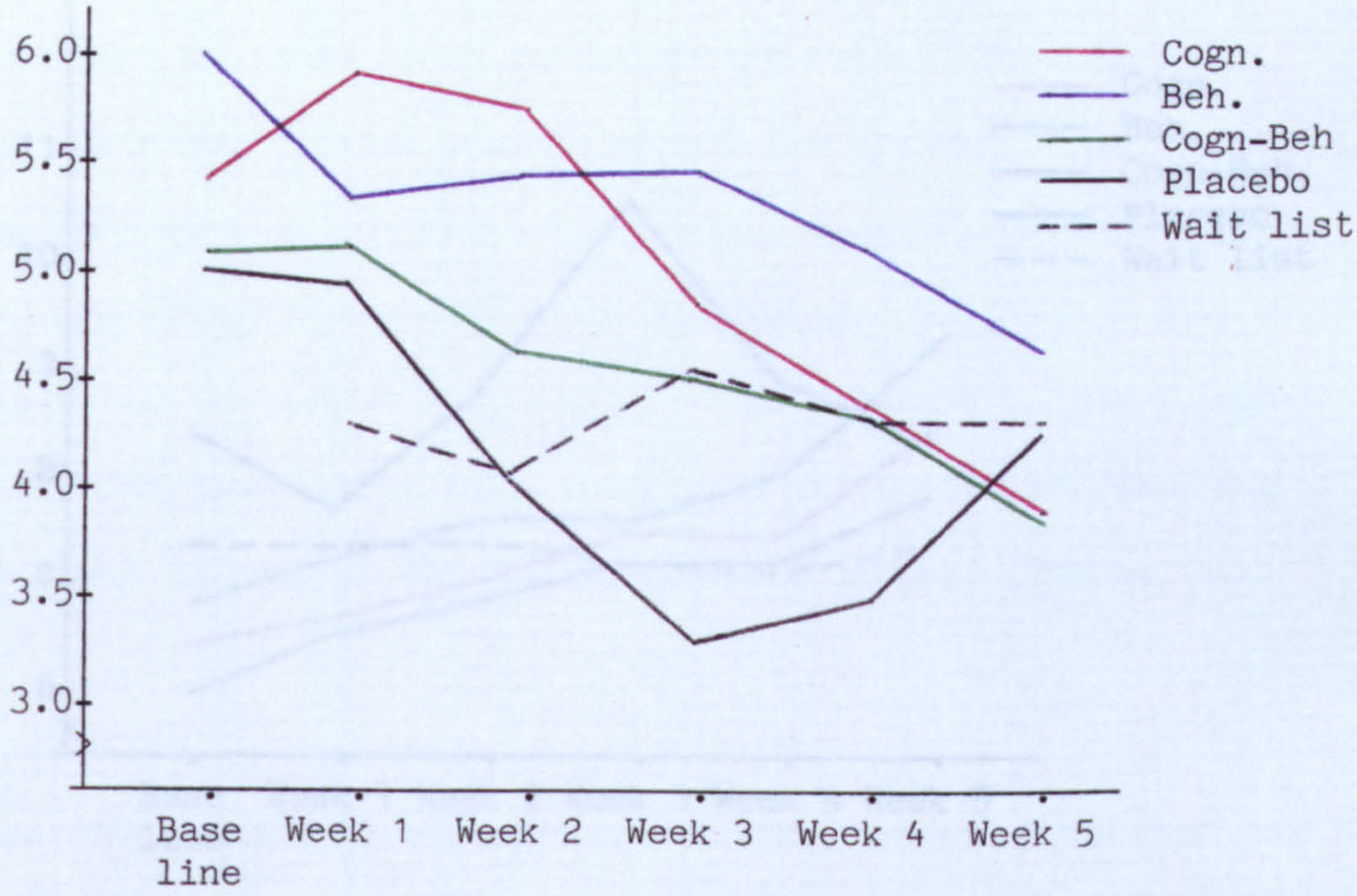

FIGURE 8. Comparison across experimental conditions of mean scores for diary TIME variable during baseline and across the experimental period.

The picture presented in Figure 8 echoes that of Figure 7. Again, after impressive change, the Placebo condition relapses in the latter stage of therapy while the Cognitive condition show an initial heightening of anxious thinking before marked improvement begins following session 3. The Cognitive-behavioural and Behavioural conditions show solid progress throughout the experimental period while the Waiting list condition show a slight worsening in time spent worrying.

iii. How well have to coped today? (COPE)

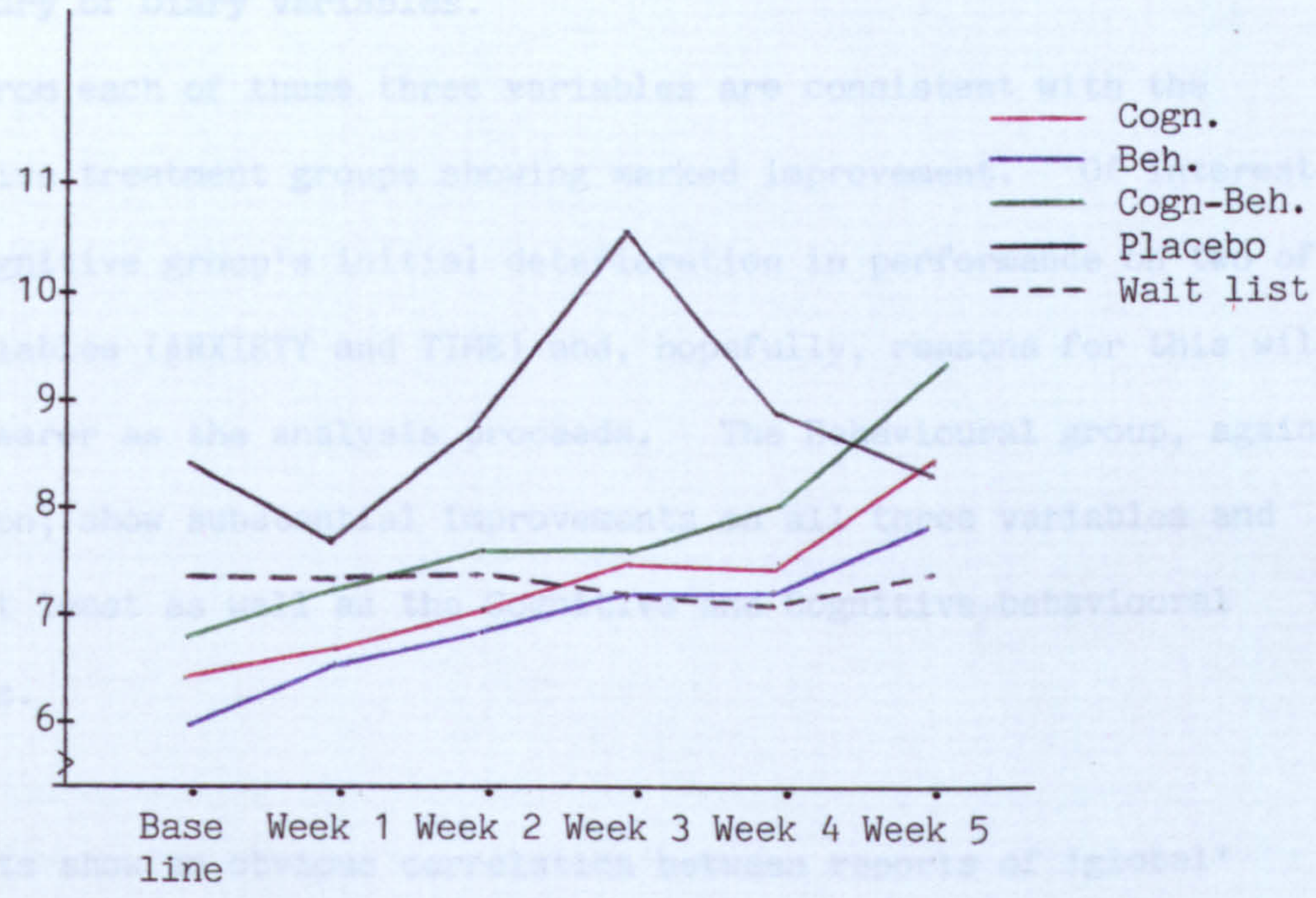

FIGURE 9. Comparison across experimental conditions of mean scores for diary COPE variable during baseline and across the experimental period.

The three active therapies are clearly shown to improve significantly as compared to the Placebo and Waiting list conditions. The improvement of the Cognitive condition is now more consistent than on the previous two diary variables. The Behavioural condition, perhaps surprisingly, shows impressive consistent improvement, again very similar to that shown by the Cognitive-behavioural condition. The nature of this change associated with the Placebo condition seems extraordinary. The magnitude of change during the first half of therapy outstrips the active treatment conditions convincingly, however the subsequent loss of these gains is equally impressive.

iv. Summary of Diary variables.

Results from each of these three variables are consistent with the three active treatment groups showing marked improvement. Of interest is the Cognitive group's initial deterioration in performance on two of these variables (ANXIETY and TIME) and, hopefully, reasons for this will become clearer as the analysis proceeds. The Behavioural group, against expectation, show substantial improvements on all three variables and perform at least as well as the Cognitive and Cognitive-behavioural conditions.

The results show an obvious correlation between reports of 'global' anxiety, anxious thoughts and reports of increased ability to cope.

While the Waiting list group generally worsen across time, the process of change associated with the Placebo condition - initial substantial improvement followed by marked deterioration (although not with the exception of COPE, to baseline) - will have to be explained following

receipt of further information. If the trend continues beyond post-therapy, we should expect this group to lose any advances made during treatment.

FOUR SYSTEMS ANXIETY QUESTIONNAIRE (FSAQ)

i. Cognitive component.

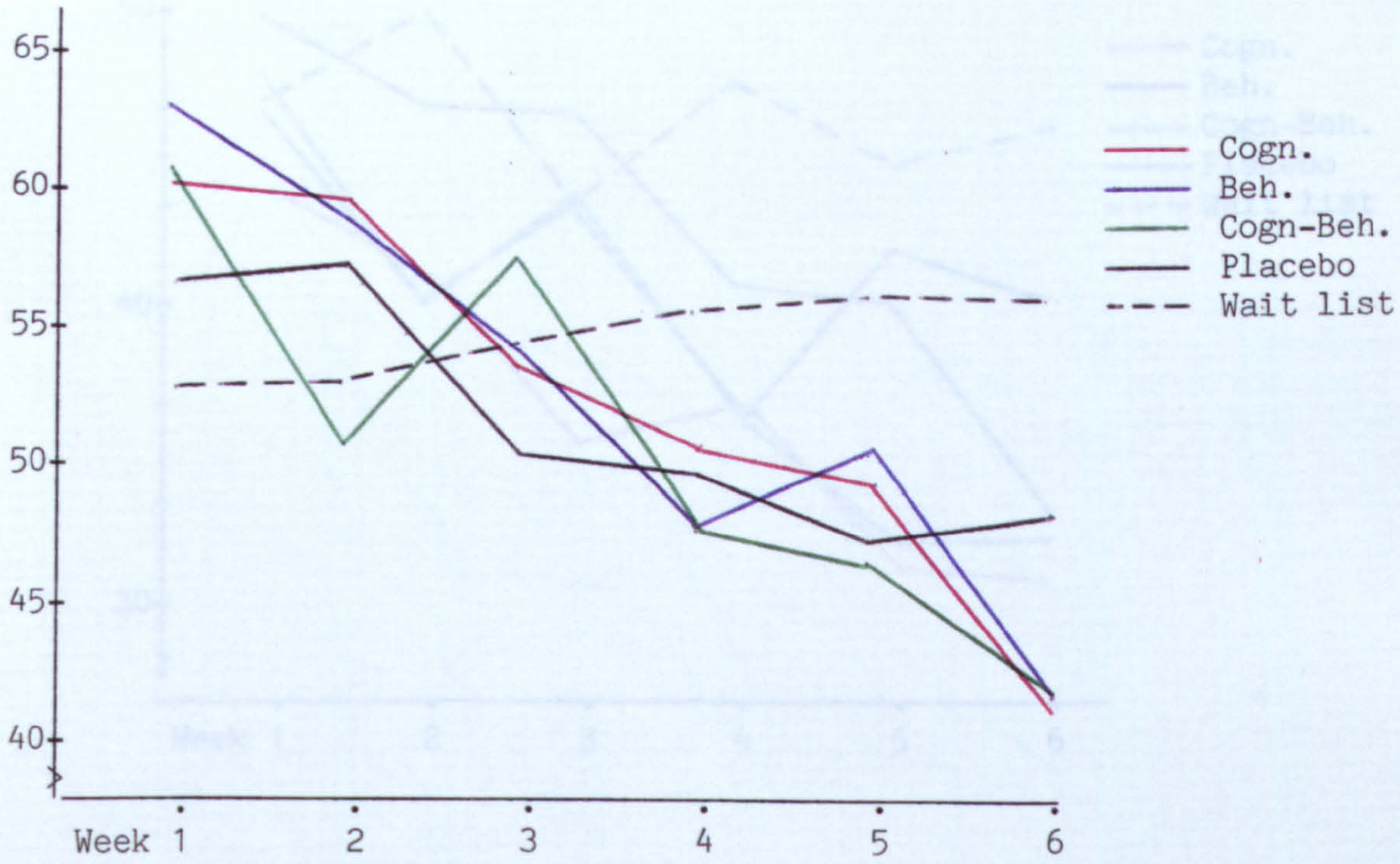

Figure 10. Comparison across experimental conditions of mean scores for the FSAQ Cognitive component across the experimental period.

Great similarities exist between the three active treatment groups, beginning and ending at virtually the same point. The process differs somewhat with the Cognitive condition showing only slight initial improvement as compared to the other two conditions, which evidence a slightly more erratic course. The Placebo condition mirrors the

Cognitive condition until the final week of treatment during which, as with the diary measures, it regresses somewhat. All therapy conditions show clear improvement in comparison to the Waiting list condition.

ii. Behavioural component.

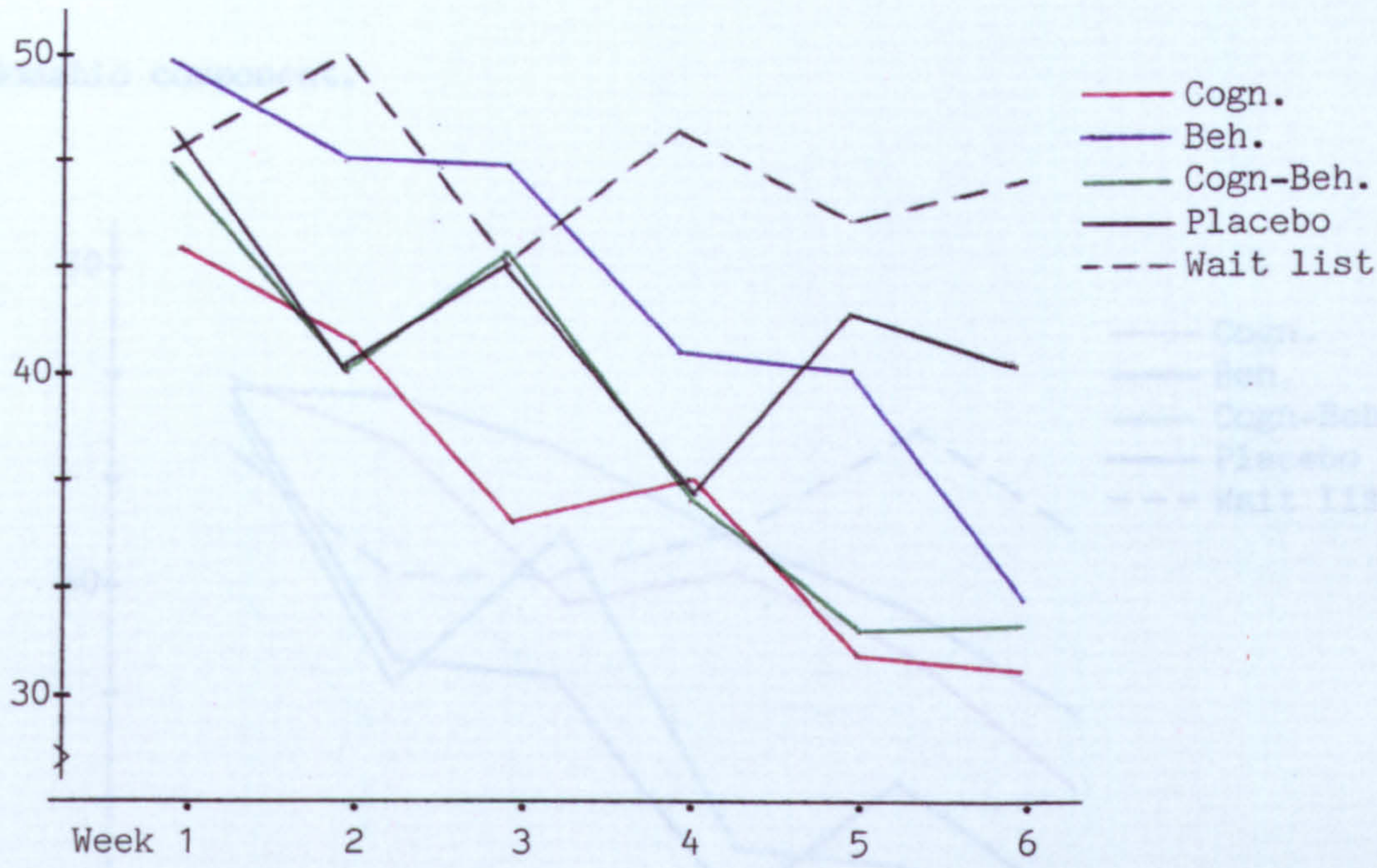

FIGURE 11. Comparison across experimental conditions of mean scores for the FSAQ Behavioural component across the experimental period.

As with the cognitive component, this variable again produces similar results for the active treatments. However, unlike the cognitive component, the Cognitive condition shows evidence of immediate improvement.

There is again evidence of slight relapse at Week 3 for the Cognitive-behavioural condition. It is interesting to note the identical process of change associated with the Placebo and Cognitive-behavioural conditions which only ends at Week 5 when the former evidences relapse. All therapy conditions again show clear improvement in comparison to the Waiting list condition.

iii. Somatic component.

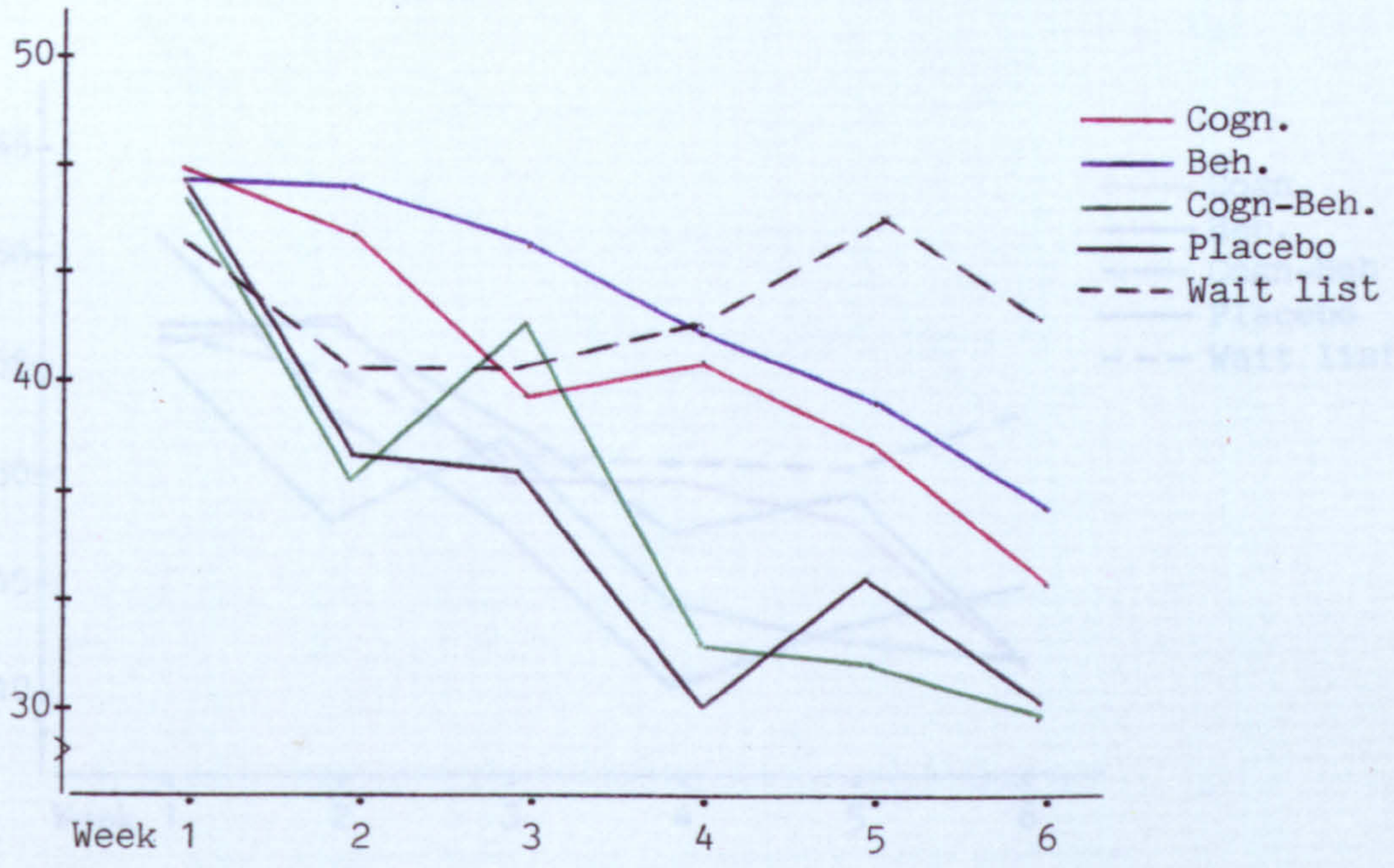

FIGURE 12. Comparison across experimental condition of mean scores for the FSAQ Somatic component across the experimental period.

The Cognitive-behavioural and Placebo condition shows the greatest magnitude of change although the former demonstrates a deterioration at Week 3, (immediately following the session devoted to cognitive

assessment and treatment). Given the inclusion of a somatically orientated technique (progressive muscular relaxation), the relatively poor performance of the Beahvioural condition is perhaps surprising. The exclusion of a somatically orientated technique (Cognitive and Placebo conditions) does not retard progress. The Waiting list condition again shows little improvement.

iv. Mood component.

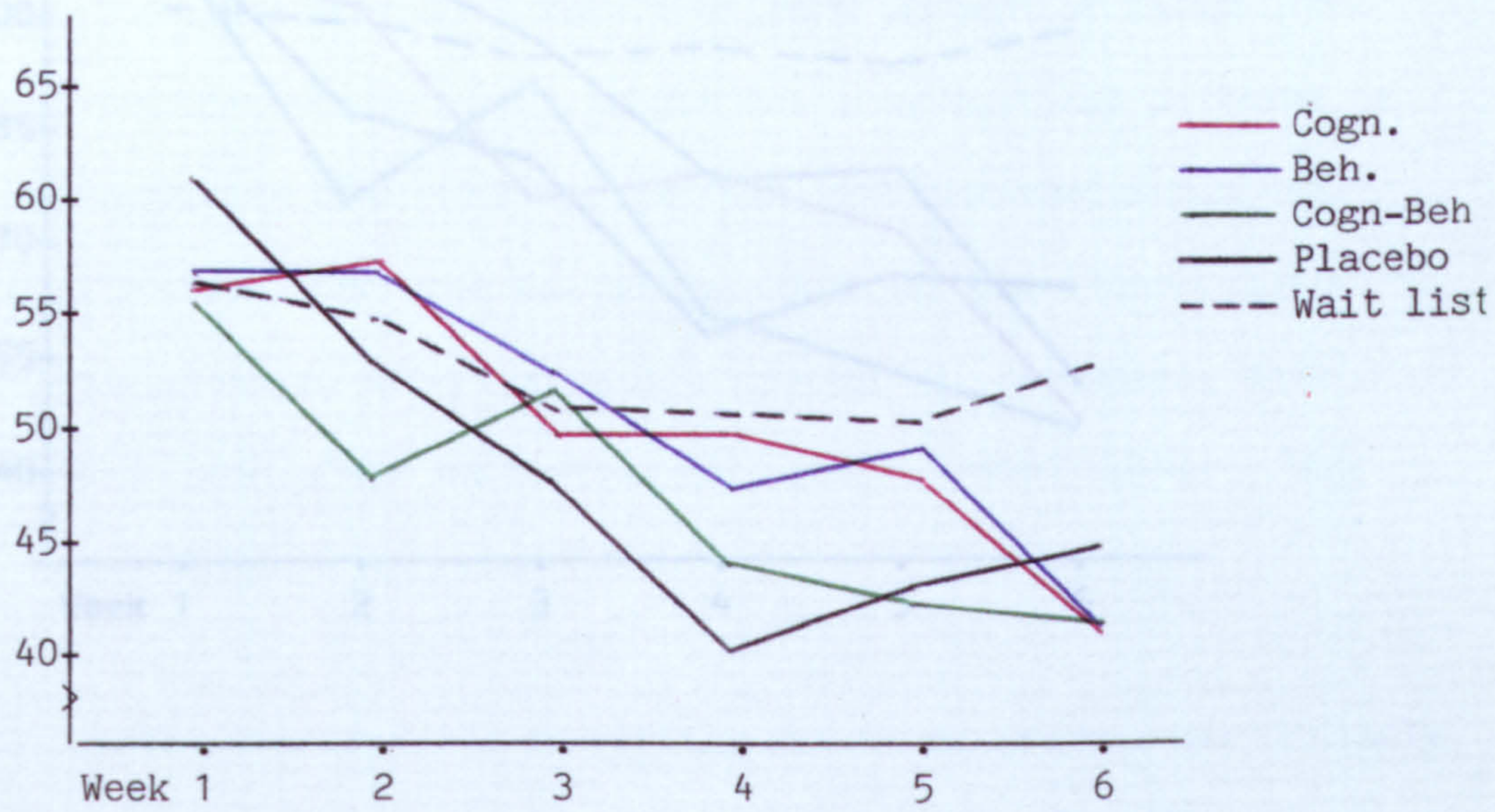

FIGURE 13. Comparison across experimental condition of mean scores for the FSAQ Mood component across the experimental period.

There appears to be an extraordinary correlation between the Behavioural, Cognitive-behavioural and Cognitive conditions although, again, we note

the relapse associated with the Cognitive-behavioural condition. The Cognitive component shows an interesting initial relapse (as noted on diary variables) and all therapy conditions again show clear improvement as compared to the Waiting list.

v. Total score.

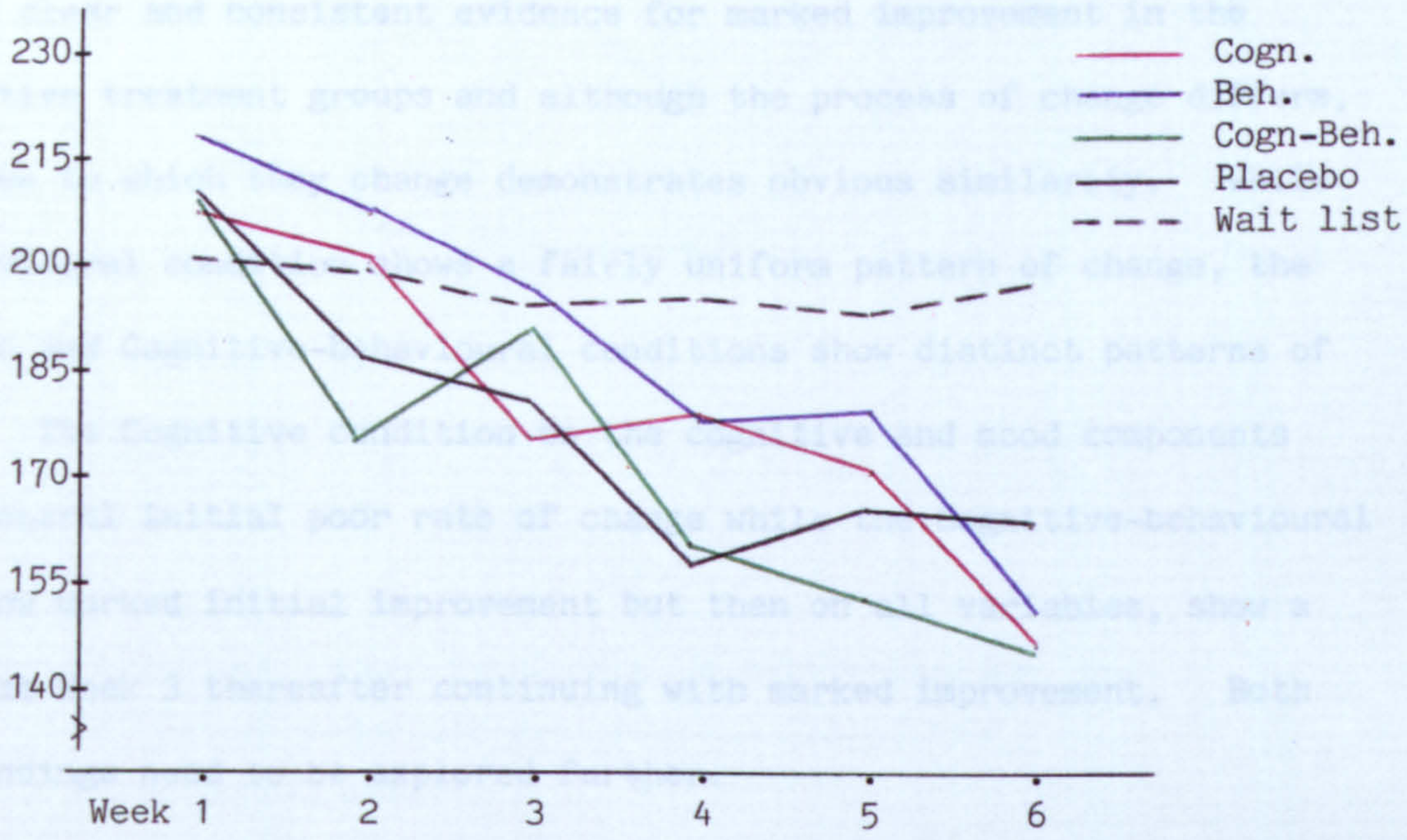

FIGURE 14. Comparison across conditions of mean scores for the FSAQ Total score across the experimental period.

As an amalgam of the four components, the total score should highlight the trends previously noted. Again the Waiting list condition shows minimal change and that this contrasts sharply to the treatment conditions all of whom show marked improvement. Although the three active treatment conditions improve to roughly the same degree, the process of

change associated with the Cognitive-behavioural condition is more erratic than that associated with the Cognitive and Behavioural conditions. The Placebo condition, until Week 4 shows the greatest magnitude of change but then levels off.

vi. Summary of FSAQ variables.

There is clear and consistent evidence for marked improvement in the three active treatment groups and although the process of change differs, the degree to which they change demonstrates obvious similarity. While the Behavioural condition shows a fairly uniform pattern of change, the Cognitive and Cognitive-behavioural conditions show distinct patterns of change. The Cognitive condition on the cognitive and mood components show a general initial poor rate of change while the Cognitive-behavioural group show marked initial improvement but then on all variables, show a relapse at Week 3 thereafter continuing with marked improvement. Both these findings need to be explored further.

The Placebo condition produces a surprising degree of change, particularly over the first half of therapy, although perhaps not to the same degree as the above treatments. However, this improvement is against expectation and has to be explained. The Waiting list condition shows little evidence of change.

On visual inspection, there appears to be a high correlation between the change associated with each variable within conditions. This, too, will be examined more closely.

COPING RESPONSES QUESTIONNAIRE (CRQ)

i. Active-Cognitive coping.

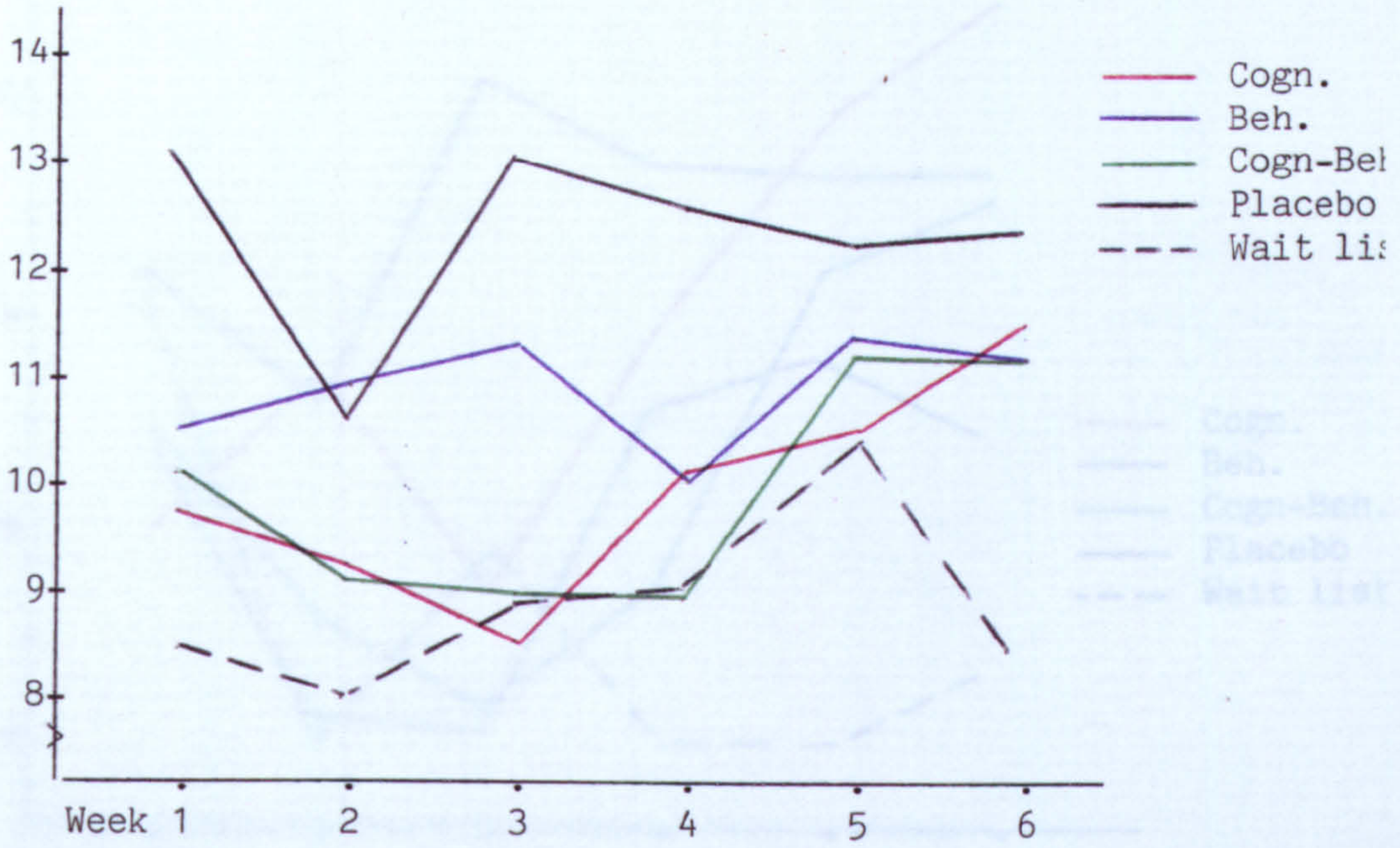

FIGURE 15. Comparison across conditions of mean scores for the CRQ Active-cognitive coping scale across the experimental period.

The similar course of change demonstrated by the Cognitive and Cognitive-behavioural conditions are of interest and, in particular, the initial deterioration in functioning reported by these groups. Relapse occurs at Week 4 in the Behavioural group and it will be interesting if further analysis can throw light on why this should occur. Also of note is the initial relatively high scores associated with the Placebo condition and the immediate relapse during Week 2. The three active treatment groups show clear improvement in comparison with the Waiting list group.

ii. Active-Behavioural coping

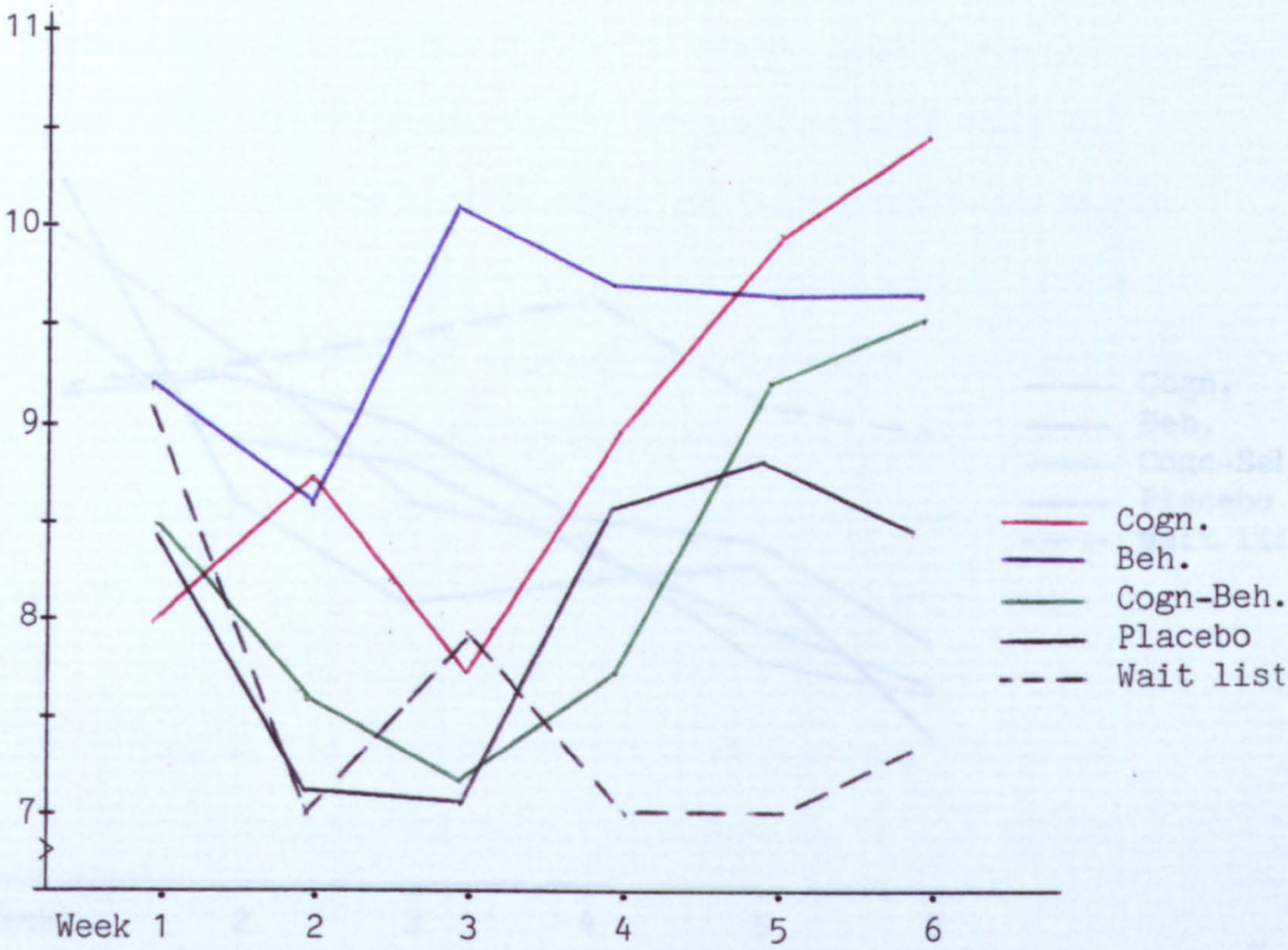

FIGURE 16. Comparison across conditions of mean scores for the CRQ Active-behavioural coping scale across the experimental period.

Clearly, the cognitive condition performs best on this variable. Unlike all of the other conditions, there is no initial deterioration although relapse does occur to an extent during Week 3. The Placebo condition shows, to a degree, a similar trend to that evidenced by the Behavioural condition although may be relapsing at the end of therapy. After marked improvement, the Behavioural condition appears to peak after Week 3 and thereafter levels out. The Cognitive-behavioural condition show immediate deterioration thereafter mirroring the progress associated with the Cognitive condition.

iii. Avoidance coping.

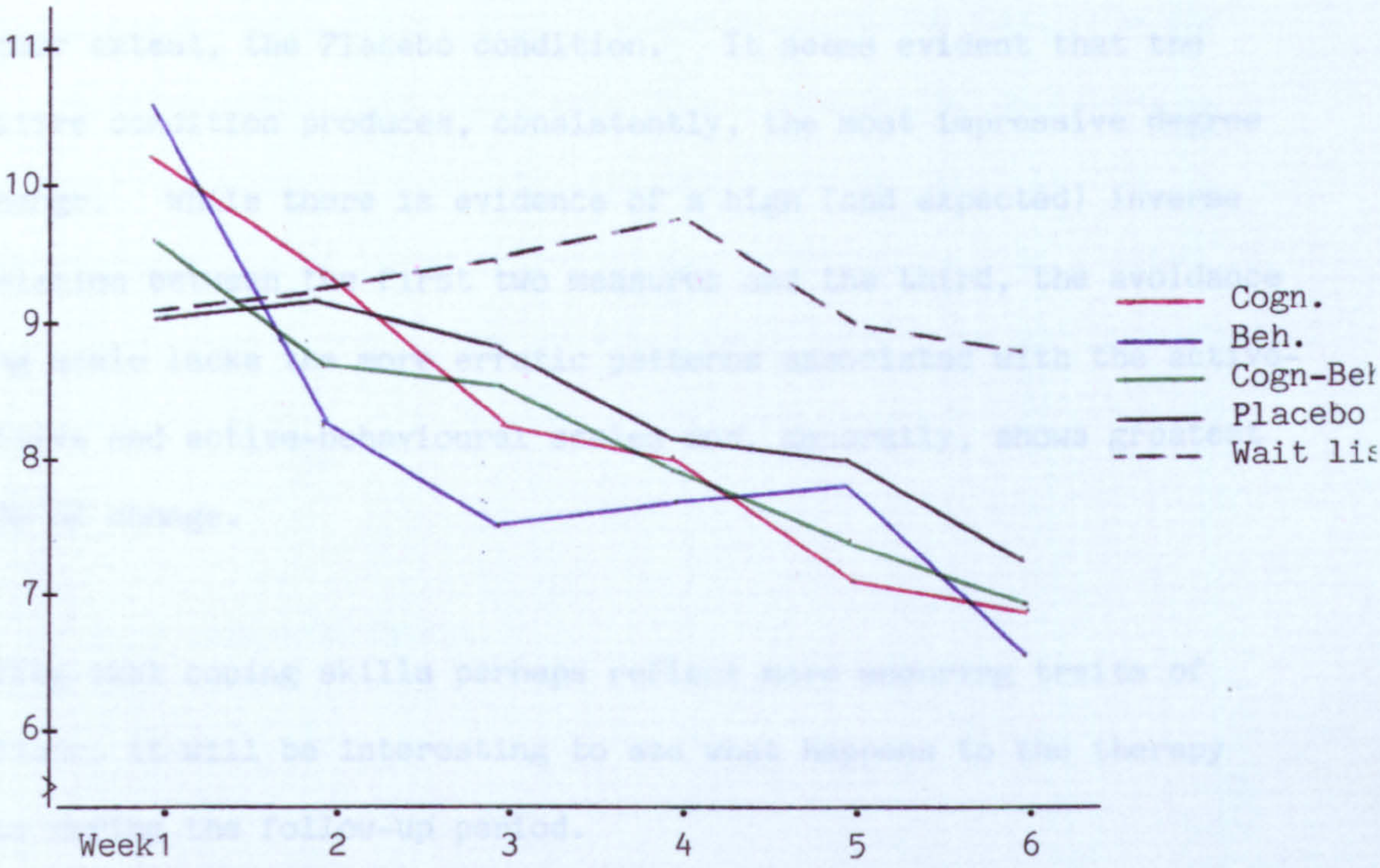

FIGURE 17. Comparison across conditions of mean scores for the CRQ- Avoidance coping scale across the experimental period.

There is again a similar pattern of change associated with the Cognitive condition and Cognitive-Behavioural condition although the former shows the greater magnitude of change. The Behavioural condition appears to level out at Week 3 but shows marked change at the end of therapy. Although not as impressive, the Placebo condition shows consistent improvement. All four treatment conditions show superior functionning compared to the Waiting list condition.

Summary of CRQ variables.

All three scales produce improvement for the active conditions and, to a lesser extent, the Placebo condition. It seems evident that the Cognitive condition produces, consistently, the most impressive degree of change. While there is evidence of a high (and expected) inverse correlation between the first two measures and the third, the avoidance coping scale lacks the more erratic patterns associated with the active-cognitive and active-behavioural scales and, generally, shows greatest degree of change.

Assuming that coping skills perhaps reflect more enduring traits of behaviour, it will be interesting to see what happens to the therapy groups during the follow-up period.

IMAGINAL TEST

i. Negative self-statements.

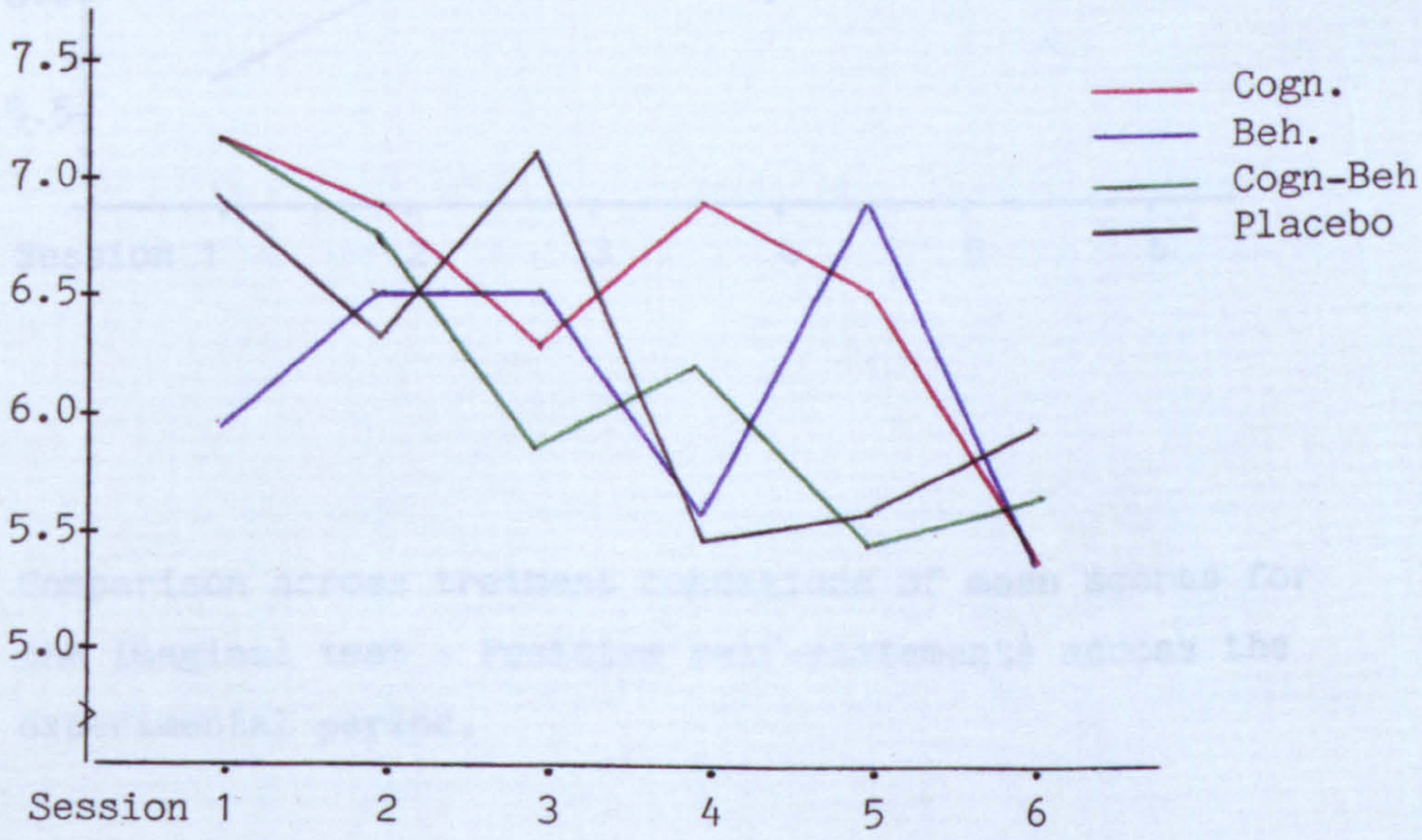

FIGURE 18. Comparison across treatment conditions of mean scores for the Imaginal test - Negative self-statements across the experimental period.

Due to the erratic nature of the patterns of change, interpretation should be cautious. While all of the therapy conditions show an overall decrease in negative self-statements, only the Cognitive and Cognitive-behavioural conditions show fairly consistent decreases in negative self-statements over the sessions. Of interest is the increased reporting of these self-statements during Session 4 noted in both of these conditions. The patterns associated with the Behavioural, and to a lesser extent, the Placebo conditions are more difficult to interpret.

ii. Positive Self-statements.

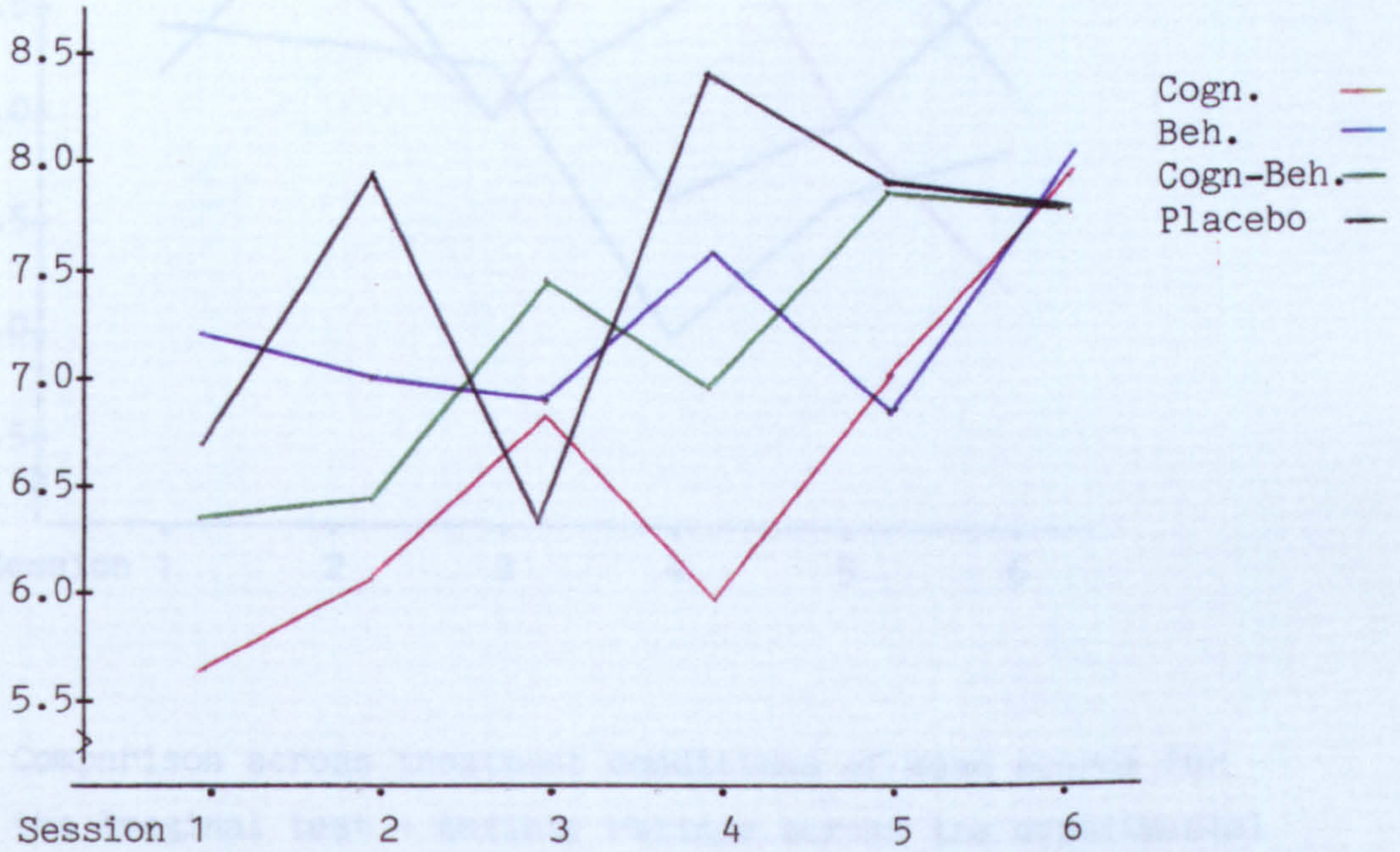

FIGURE 19. Comparison across tretment conditions of mean scores for the Imaginal test - Positive self-statements across the experimental period.

The pattern of change associated with this variable is almost a complete inverse of that associated with negative self-statement change. Again, the Cognitive and Cognitive-behavioural conditions produce the greatest, and most consistent change. Although the other two conditions improve, they do so in a more erratic and less impressive manner.

iii. Anxiety ratings.

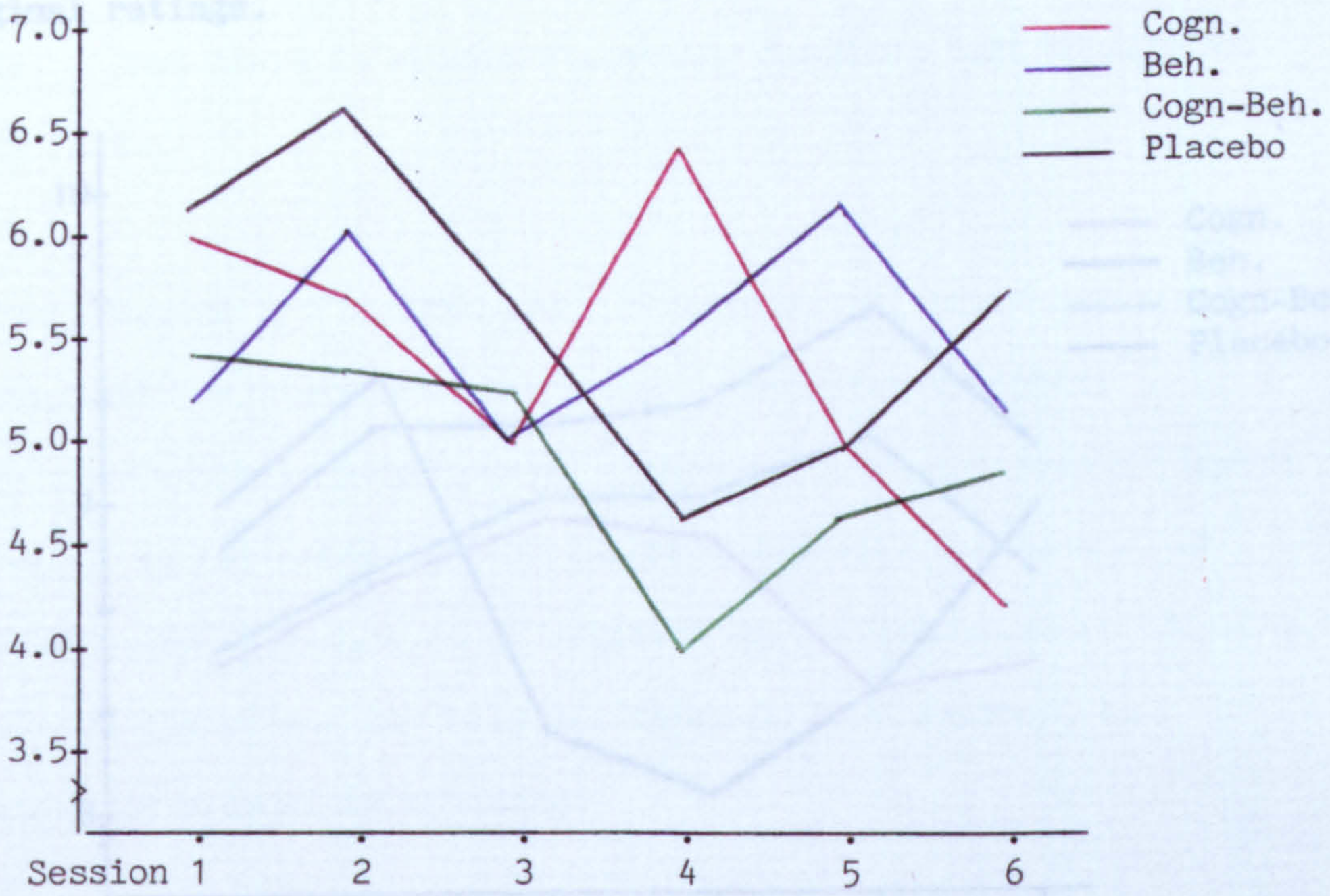

FIGURE 20. Comparison across treatment conditions of mean scores for the Imaginal test - Anxiety ratings across the experimental period.

There appears to be a correlation between level of negative self-statements and anxiety in the Cognitive and Behavioural, and, to a lesser extent, the Cognitive-behavioural conditions. The relationship in the Placebo condition appears to be more erratic.

With respect to positive self-statements, both the Cognitive and Behavioural conditions appear to demonstrate an inverse relationship between production of positive self-statements and anxiety ratings. An inverse relationship appears to exist only in the first half of therapy for the Cognitive-behavioural condition and , in the second half of therapy, for the Placebo condition.

iv. Imaginal ratings.

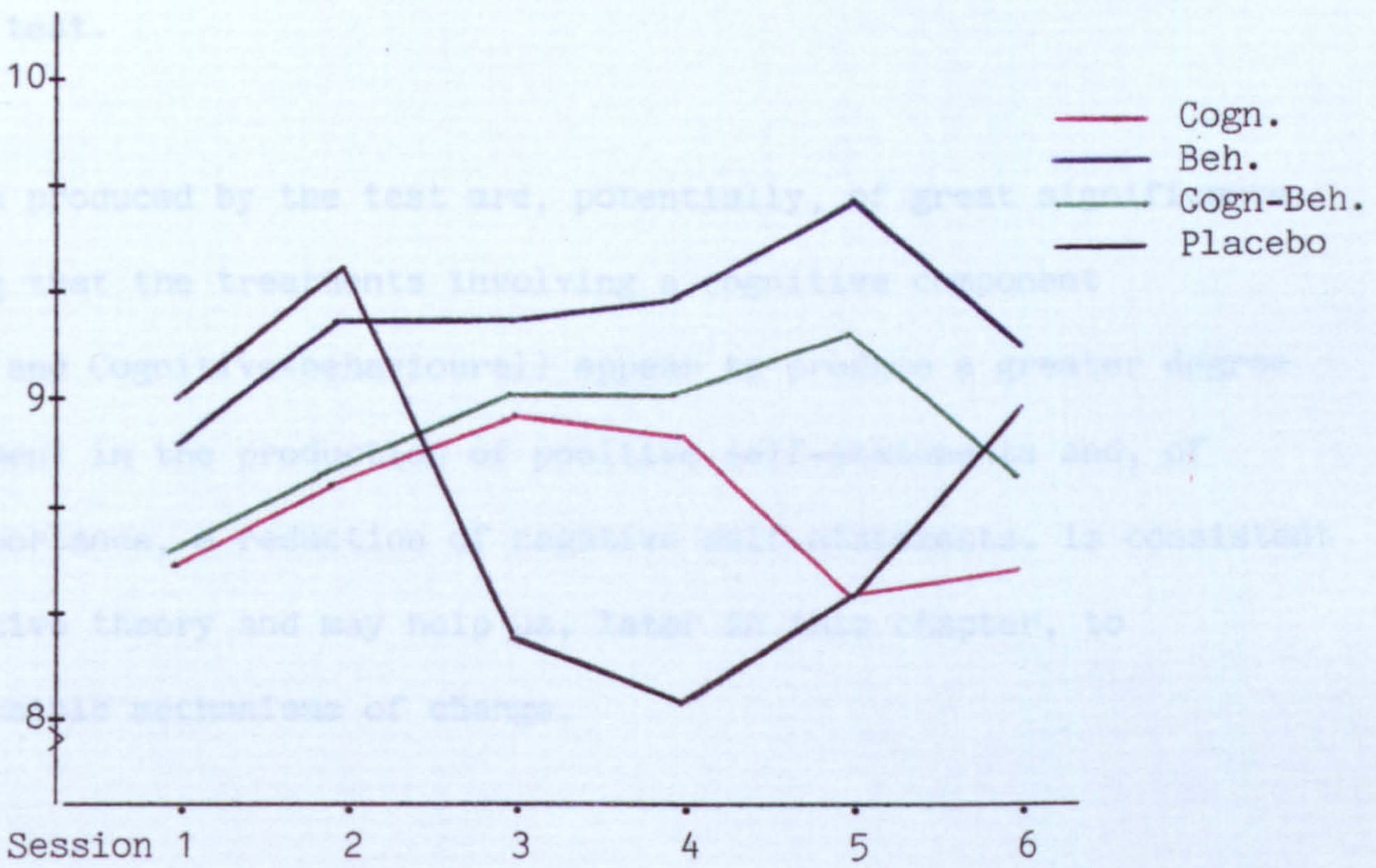

FIGURE 21. Comparison across treatment conditions of mean scores for the Imaginal test - Imaginal ratings across the experimental period.

The three active treatment groups show a uniform pattern while the Placebo condition shows a more erratic pattern. In general, however,

it is clear that patients report the ability to imagine the situations without apparent difficulty and showed a consistent ability to do so throughout the six presentations of the Imaginal test.

Summary of Imaginal Test ratings.

Patients were able to clearly imagine the scenes throughout therapy, induce anxiety while imagining the scenes and to rate the positive and negative self-statements associated with this anxiety without apparent difficulty. Thus there is evidence that the Imaginal test appears to be a valid test.

The results produced by the test are, potentially, of great significance. The finding that the treatments involving a cognitive component (Cognitive and Cognitive-behavioural) appear to produce a greater degree of improvement in the production of positive self-statements and, of greater importance, a reduction of negative self-statements, is consistent with cognitive theory and may help us, later in this chapter, to suggest possible mechanisms of change.

b. SD values

Before statistically analysing the data, the descriptive analysis will assess SD scores in order to look at variability in the data during the course of therapy.

Tables 17 to 20 presents SD values and percentage changes in these values for all process variables at pre-therapy and post-therapy across conditions.

DIARY MEASURES/

TABLE 17. Comparison across experimental conditions of SD scores during baseline and the final week of therapy (post) along with percentage change scores for each of the three diary scales.

	Cognitive	Behavioural	Cogn-Beh.	Placebo	Waiting List.
i. How anxious have you been today?					
baseline	1.6	1.9	1.3	2.0	1.2
post	1.3	1.5	1.5	1.6	1.4
% change	-18.8	-21.1	+15.4	-20.0	+16.7
ii. How much time have you spent thinking or worrying about your problems today?					
baseline	2.0	2.1	1.9	1.7	0.7
post	1.4	1.3	2.4	1.2	0.9
% change	-30.0	-38.1	+26.3	-29.4	+28.6
iii. How well have you coped today?					
baseline	1.7	1.7	1.5	1.8	0.8
post	1.6	1.6	1.9	1.7	0.9
% change	-5.9	-5.9	+26.7	-5.6	+12.5

FOUR SYSTEMS ANXIETY QUESTIONNAIRE (FSAQ)

TABLE 18. Comparison across experimental conditions of standard deviation scores at pre-therapy and post-therapy along with percentage change scores for the FSAQ measures.

	Cognitive	Behavioural	Cogn-Beh	Placebo	Waiting List
COGNITIVE COMPONENT					
pre	20.5	18.5	20.7	20.8	15.6
post	24.2	27.5	27.8	24.6	21.8
% change	+18.1	+48.6	+34.3	+18.3	+39.7
BEHAVIOURAL COMPONENT					
pre	22.1	23.2	19.6	24.0	16.3
post	21.0	23.3	18.1	23.5	14.9
% change	-5.0	+0.4	-7.7	-2.1	-8.6
SOMATIC COMPONENT					
pre	14.7	16.8	17.0	14.6	14.3
post	14.9	18.2	16.3	18.8	19.6
% change	+1.4	+8.3	-4.1	+28.8	+37.1
MOOD COMPONENT					
pre	20.8	19.0	20.7	24.5	15.7
post	22.0	23.9	23.3	29.4	21.6
% change	+5.8	+25.8	+12.6	+20.0	37.6
TOTAL SCORE					
pre	64.4	68.2	67.1	60.0	38.4
post	68.2	80.0	71.6	89.6	52.3
% change	+5.9	+17.3	+6.7	+49.3	+36.2

COPING RESPONSES QUESTIONNAIRE (CRQ)

TABLE 19. Comparison across experimental conditions of SD scores at pre-therapy and post-therapy along with percentage change scores for the CRQ measures.

	Cognitive	Behavioural	Cogn-Beh	Placebo	Waiting List
COGNITIVE COPING					
pre	4.3	5.3	5.2	3.7	4.9
post	4.1	5.4	4.9	4.9	4.5
% change	-4.6	+1.9	-5.8	+32.4	-8.2
BEHAVIOUR COPING					
pre	4.7	2.9	5.1	2.9	4.7
post	5.5	4.2	4.9	3.8	5.2
% change	+17.0	+44.8	-3.9	+31.0	+10.6
AVOIDANCE					
pre	5.2	3.2	5.0	7.7	6.7
post	3.9	5.0	4.2	7.7	5.6
% change	-25.0	+56.3	-16.0	0	-16.4
IMAGINAL TEST/					

IMAGINAL TEST

TABLE 20. Comparison across experimental conditions of SD scores at Session 1 and Session 6 along with percentage change scores for the Imaginal test measures.

	Cognitive	Behavioural	Cogn-Beh	Placebo	Waiting List
NEGATIVE SELF-STATEMENTS					
pre	1.8	2.2	1.9	1.4	
post	1.9	2.3	2.4	1.3	
% change	+5.6	+4.5	+26.3	-7.1	
POSITIVE SELF-STATEMENTS					
pre	2.3	1.7	1.8	1.7	
post	2.2	2.0	2.2	1.8	
% change	-4.3	+17.6	+22.2	+5.9	
ANXIETY RATINGS					
pre	3.0	2.9	2.6	2.6	
post	2.4	3.0	2.8	2.1	
% change	-20.0	+3.4	+7.7	-19.2	
IMAGINAL RATINGS					
pre	2.6	2.1	2.2	2.9	
post	2.1	1.8	1.8	1.2	
% change	-19.2	-14.3	-18.2	-58.6	

****

The marked variability in SD scores pre and post stands in contrast to mean scores at the same points. Thus there may be a potentially interesting explanation to be found in further analyses and this will be undertaken and reported in Chapters 14-19.

3). STATISTICAL ANALYSIS

Diary Measures

a). Main effects

Table 21 presents the results of MANOVAs for the three diary process measures over the experimental period. Ratings of daily anxiety (ANXIETY) produces significant effects for the group and time main effects and the group x time interaction. Ratings of time spent worrying (TIME) and ratings of how well the subjects has coped (COPE) produce significant effects for time and group x time interaction.

TABLE 21. Repeated measures analysis of diary variables across the experimental period using MANOVA (* p < .05; ** p < .01; *** p < .001)

Source of Variation	Pillai	Hyp. d.f.	Error d.f.	F ratio	F probab.	Signif. level
ANXIETY:						
Group		4		2.758	.032	*
Time	.284	5	100	7.933	.000	***
Group x time	.674	20	412	4.174	.000	***
TIME:						
Group		4		1.432	.229	NS
Time	.191	5	100	4.736	.001	***
Group x time	.540	20	412	3.215	.000	***
COPE:						
Group		4		2.027	.096	NS
Time	.247	5	100	6.562	.000	***
Group x time	.484	20	412	2.839	.000	***

b). Treatment within Time sub-effects.

In order to investigate the treatment within time sub-effects, ONEWAY ANOVAs across the five experimental conditions were conducted at each of the 5 data points (Week 1 = baseline - Week 1 of therapy with Week 1 representing days between Sessions 1 and 2). The STUDENT NEWMAN KEULS was applied to identify the loci of significant differences.

The results of the analyses are presented in Table 22.

TABLE 22. ANOVAs conducted upon diary measures during the experimental period across the five experimental conditions (Cognitive = 1 Behavioural = 2, Cognitive-behavioural = 3, Placebo = 4, Waiting list = 5) using NEWMAN-KEULS (alpha level = .05).

	d.f.	F ratio	F probab.	Pair
ANXIETY				
Week 1	4,104	2.760	.032	3 v 1
Week 2	4,104	6.553	.000	2 v 1
				3 v 1
				4 v 1
				5 v 1
Week 3	4,104	5.553	.000	3 v 1
				3 v 2
				4 v 1
				4 v 2
				4 v 5
Week 4	4,104	4.541	.002	3 v 1
				3 v 2
				4 v 1
Week 5	4,104	3.655	.008	3 v 5
				3 v 4

TABLE 22. (contd.)

	d.f.	F ratio	F probab.	Pair
TIME				
Week 1	4,104	3.649	.008	2 v 1
Week 2	4,104	3.040	.020	2 v 1
				3 v 1
Week 5	4,104	2.219	.031	3 v 5
				2 v 5
				1 v 5
COPE				
Week 6	4,104	6.149	.000	1 v 4
				1 v 5
				2 v 4
				2 v 5
				3 v 4
				3 v 5

As viewed against Figures 7 - 9, the initial deterioration associated with the Cognitive condition on ANXIETY reaches statistical significance when contrasted at Week 1 with the Cognitive-behavioural condition and, at Week 2, with all of the other conditions. Both the Cognitive-behavioural and Placebo conditions retain this statistically significant difference with the Cognitive condition until the final week of therapy when only the Cognitive-behavioural condition demonstrates statistically significant differences to the Placebo and Waiting list conditions.

TIME, again, demonstrates the statistically significant deterioration of the Cognitive condition compared to the other two active conditions

early in therapy. COPE, however, demonstrates the superior functioning of the active therapies over the Waiting list condition during the final week of therapy. It is perhaps surprising that the Placebo condition does not attain a significant difference from the Waiting list condition particularly at Week 3 when the former, as seen in Figure 9, shows marked improvement.

c). Time within Treatment Group Sub-effects

Time within treatment effects are essentially a series of within subjects repeated measures ANOVAs and these are generated via the CONSPLUS subcommand of the MANOVA programme. These effects which provide information within each condition on significant variation from baseline values across the experimental period can be viewed as provding complimentary information to the treatment within time sub-effects. Table 23 provides information separately for each of the experimental conditions and illustrates the magnitude of effect of treatment upon each of the diary process measures.

TABLE 23. Time within Treatment group simple effects and sub-effects at each data-point (baseline - week n) presented for each experimental condition for the diary measures.
(* p < .05, ** p < .01, *** p 1 .001)

TREATMENT VARIABLE	-Pillai	F probab.	WEEK OF THERAPY 1	2	3	4	5
COGNITIVE CONDITION							
Anxiety	.459	.000	*	***			***
Time	.318	.000	**	*			***
Cope	.280	.000		*	***	*	***
BEHAVIOUR CONDITION							
Anxiety	.194	.000				*	***
Time	.130	.014					***
Cope	.269	.000	**	***	***	***	***
COGN-BEH. CONDITION							
Anxiety	.313	.000		**	***	***	***
Time	.245	.000			*	*	***
Cope	.112	.034		**	**	**	***
PLACEBO CONDITION							
Anxiety	.232	.000		*	***	**	
Time	.164	.003			**	*	
Cope	.254	.000			***		
WAIT-LIST CONDITION							
Anxiety	.034	.618					
Time	.072	.177					
Cope	.051	.377					

The immediate visual impact of Table 23 shows the significant change over baseline associated with the three active therapy conditions on all three diary measures with particularly strong evidence of marked change by the final week of therapy. It is interesting to see that the initial deterioration recorded by the Cognitive condition on ANXIETY

and TIME reaches statistical significance before improvement results in statistical significance in the other direction. Although the results for all these conditions are impressive, the Cognitive-behavioural group slightly surpass the others.

While the Waiting list condition at no point changes significantly over baseline, the Placebo condition shows, statistically, the improvements achieved in early and middle therapy being whittled away by the end of the therapy.

2). FOUR SYSTEMS ANXIETY QUESTIONNAIRE (FSAQ)

a) Main effects

Table 24 presents the results of MANOVAs for the four sub-scales and the Total score FSAQ measures. Ratings of the Cognitive and Somatic sub-scales and the Total score produce significant effects for the group and time main effects and the group x time interaction. The Behaviour and Mood sub-scales produce significant time and group x time interaction.

TABLE 24. Repeated measures analysis of FSAQ variables across the experimental period using MANOVA(*p < .05,** p < .01, *** p < .001).

Source of Variation	Pillai	Hyp. d.f.	Error d.f.	F ratio	F probab.	Signif. level.
COGNITIVE COMPONENT						
Group	.824	4		2.628	.039	*
Time	.191	5	100	4.723	.001	***
Group x time	.328	20	412	1.841	.015	*
BEHAVIOUR COMPONENT						
Group	.979	4		1.674	.162	NS
Time	.245	5	100	6.489	.000	***
Group x time	.288	20	412	1.601	.049	*
SOMATIC COMPONENT						
Group		4		4.744	.001	***
Time	.334	5	100	10.020	.000	***
Group x time	.374	20	412	2.127	.003	**
MOOD COMPONENT						
Group		4		0.852	.496	NS
Time	.107	5	100	2.396	.043	*
Group x time	.290	20	412	1.568	.037	*
TOTAL SCORE						
Group	.759	4		5.076	.001	***
Time	.355	5	100	11.019	.000	***
Group x time	.423	20	412	2.437	.001	***

b). Treatment within Time sub-effects.

ONEWAY ANOVAs across the five experimental conditions were conducted at each of the 5 data points in order to investigate the treatment within time sub-effects. The STUDENT NEWMAN KEULS was applied to identify the loci of significant differences. The results of the analyses are presented in Table 25.

TABLE 25. ANOVAs conducted upon FSAQ variables during the experimental period across the five experimental conditions (Cognitive = 1, Behavioural = 2, Cognitive-behavioural = 3, Placebo = 4, Waiting List = 5) using NEWMAN-KEULS (alpha level = .05).

	d.f.	F ratio	F probab.	Pair
COGNITIVE COMPONENT				
Week 4	4,104	3.899	.005	1 v 5 2 v 5 3 v 5 4 v 5
Week 5	4,104	2.135	.082	2 v 5 3 v 5
Week 6	4,104	6.299	.000	1 v 5 2 v 5 3 v 5 4 v 5
BEHAVIOUR COMPONENT				
Week 4	4,104	2.920	.025	1 v 5 2 v 5 3 v 5 4 v 5
Week 5	4,104	2.932	.024	1 v 5 2 v 5 3 v 5
Week 6	4,104	2.480	.048	1 v 5 2 v 5 3 v 5

Contd./

TABLE 25. (contd.)

	d.f.	F ratio	F. probab.	Pair
SOMATIC COMPONENT				
Week 2	4,104	3.306	.014	3 v 2
Week 4	4,104	4.411	.002	3 v 1 3 v 2 3 v 5 4 v 5
Week 5	4,104	4.889	.001	1 v 5 2 v 5 3 v 5 4 v 5
Week 6	4,104	4.731	.001	1 v 5 2 v 5 3 v 5 4 v 5
MOOD COMPONENT				
No differences exist at any point.				
TOTAL SCORE				
Week 2	4,104	2.382	.056	3 v 1
Week 4	4,104	7.249	.000	1 v 5 2 v 5 3 v 5 4 v 5
Week 5	4,104	3.894	.005	1 v 5 2 v 5 3 v 5 4 v 5
Week 6	4,104	5.829	.000	1 v 5 2 v 5 3 v 5 4 v 5

Viewed alongside Figures 10 - 14, there is again statistical confirmation of the marked improvement the 4 therapy conditions achieve in comparison to the Waiting list condition - the statistically significant differences generally arising in the latter part of therapy. The Total score variable emphasises this point although we see evidence of the statistically significant differences achieved only after the initial deterioration or, at least, slower degree of improvement found in the Cognitive condition.

Three of the four components evidence much the same picture. The 3 active components, to a degree, outperform the Placebo condition and although the Cognitive-behavioural group achieve significant differences over mainly the Waiting list condition at an earlier stage, there appears to be little between the active groups by the end of therapy. It will be interesting to see if the Time within Treatment sub-effects provide additional evidence to support this. The partial exception to this appear in the Somatic component where the Cognitive-behavioural condition are statistically superior to the other two active conditions during mid-therapy. The particularly interesting finding concerns the absence of significant differences at any point on the Mood component - in sharp contrast to the others. Hopefully further information will help explain this.

c). <u>Time within Treatment sub-effects</u>.

Table 26 provides information separately for each of the experimental conditions and illustrates the magnitude of effect of treatment upon ech of the FSAQ measures.

TABLE 26. Time within Treatment group simple effects and sub-effects at each data point (baseline - week n) presented for each experimental condition for the FSAQ measures (* p < .05, ** p < .01, *** p < .001).

TREATMENT VARIABLE	Pillai	F probab.	Week of Therapy 1	2	3	4	5
COGNITIVE CONDITION							
Cognitive	.217	.000			**	**	***
Behavioural	.201	.000		*		***	***
Somatic	.190	.001		*		**	***
Mood	.132	.013					
Total	.295	.000		**	***	**	***
BEHAVIOURAL CONDITION							
Cognitive	.254	.000			***	*	***
Behavioural	.204	.000			**	**	***
Somatic	.182	.001				**	***
Mood	.141	.009					
Total	.295	.000			***	**	***
COGN-BEH. CONDITION							
Cognitive	.229	.000			***	**	***
Behavioural	.261	.000			**	***	***
Somatic	.347	.000	**		***	***	***
Mood	.114	.030					
Total	.332	.000	**		***	***	***
PLACEBO CONDITION							
Cognitive	.029	.697					
Behavioural	.046	.446					*
Somatic	.149	.006	*		***	**	***
Mood	.077	.148					
Total	.135	.001		*	***	**	**
WAIT-LIST CONDITION							
Cognitive	.039	.544					
Behavioural	.044	.464					
Somatic	.037	.567					
Mood	.015	.909					
Total	.051	.373			*		

As with the diary measures, there is clear evidence of the superiority of the active treatments over the Waiting list and, to a lesser extent, Placebo conditions. There appears to be no evidence of a 'homeopathic' effect, i.e. cognitive therapy does not boost cognitive component scores earlier or to a greater magnitude than scores in the behavioural or somatic components. There is a marked similarity between the three active therapy conditions and of particular interest is the lack of significant change over baseline, across conditions, associated with the mood component. This echoes the lack of significance, in the Treatment with Time section. This seems particularly curious and will have to be explained.

3). COPING RESPONSES QUESTIONNAIRE (CRQ)

a). Main Effects

Table 27 presents the results of MANOVAs for the three CRQ measures. The Active-behavioural coping scale (CRQB) and the Avoidance coping scale (CRQA) produce significant effects for the group and time main effects and the group x time interaction. The Active-cognitive coping scale (CRQC) produced significant time main effects and group x time interaction effects.

TABLE 27. Repeated measures analysis for CRQ variables across the experimental period using MANOVA (* p < .05, ** p < .01, *** p < .001).

Source of variation	Pillai	Hyp d.f.	Error d.f.	F ratio	F probab	Signif. level
COGNITIVE COPING(CRQC)						
Group		4		.669	.615	NS
Time	.109	5	100	2.453	.038	*
Group x time	.324	20	412	1.821	.017	*
BEHAVIOUR COPING(CRQB)						
Group		4		2.615	.039	*
Time	.158	5	100	3.752	.004	**
Group x time	.396	20	412	2.264	.002	**
AVOIDANCE (CRQA)						
Group		4		8.282	.000	***
Time	.220	5	100	5.653	.000	***
Group x time	.422	20	412	2.429	.000	***

b). Treatment within Time sub-effects.

Table 28 presents the Treatment within time sub-effects.

TABLE 28. ANOVAs conducted upon CRQ process variables during the experimental period across the five experimental conditions (Cognitive = 1, Behavioural = 2, Cognitive-behavioural = 3, Placebo = 4, Waiting list = 5) using NEWMAN-KEULS (alpha level = .05).

	d.f.	F ratio	F probab.	Pair
ACTIVE-COGNITIVE COPING (CRQC)				
	No differences exist at any point.			
ACTIVE-BEHAVIOUR COPING (CRQB)				
Week 6	4,104	5.782	.000	1 v 2 1 v 5 2 v 5 3 v 5
AVOIDANCE COPING (CRQA)				
Week 2	4,104	3.906	.005	1 v 5 2 v 5 3 v 5
Week 3	4,104	6.437	.000	1 v 5 1 v 4 2 v 5 3 v 4 3 v 5
Week 4	4,104	5.754	.000	1 v 5 2 v 5 3 v 5 4 v 5
Week 5	4,104	8.361	.000	1 v 2 1 v 5 2 v 5 3 v 5 4 v 5
Week 6	4,104	11.093	.000	1 v 5 2 v 5 3 v 5 4 v 5

There is remarkable disparity between the three variables. While the Active-Cognitive coping scale cannot differentiate between conditions at any stage (although statistical significance is almost found at Week 6 (Cognitive v Waiting list)), and differences between the active therapy condition and the Waiting list condition only are found at Week 6 on the Active-Behavioural scale, the Avoidance scale shows acute sensitivity from Week 2 onwards separating the Therapy conditions from the Waiting list condition. The results do match the descriptive analysis (see Figures 15 - 17) although why change is very much more evident on the Avoidance scale is unclear.

c). **Time within Treatment Group sub-effects.**

Table 29 provides information separately for each of the five experimental conditions and illustrates the magnitude of effects of treatment upon each of the CRQ process measures.

TABLE 29./

TABLE 29. Time within Treatment group simple effects and sub-effects at each data point presented for each experimental condition for the CRQ variables (* p < .05, ** p < .01, *** p < .001)

TREATMENT VARIABLE	Pillai	F probab.	Week of Therapy 2	3	4	5	6
COGNITIVE CONDITION							
Active-Cognitive coping	.135	.001			*	*	**
Active-Behaviour coping	.294	.000	*		**	***	***
Avoidance coping	.269	.000	***	*	***	***	
BEHAVIOURAL CONDITION							
Active-Cognitive coping	.034	.626					
Active-Behaviour coping	.042	.495					
Avoidance coping	.098	.062	*				***
COGNITIVE-BEHAVIOURAL CONDITION							
Active-Cognitive coping	.132	.013					
Active-Behaviour coping	.187	.001					*
Avoidance coping	.123	.021				**	***
PLACEBO CONDITION							
Active-Cognitive coping	.019	.856					
Active-Behaviour coping	.034	.615					
Avoidance coping	.066	.219					
WAITING LIST CONDITION							
Active-Cognitive coping	.064	.299					
Active-Behaviour coping	.059	.274					
Avoidance coping	.036	.643					

The above Table provides complimentary evidence to that produced in Table 26. The lack of significant change over time (with the exception of the Cognitive condition) associated with the Active-Cognitive coping scale is evident. On the Active-Behavioural coping scale, on the evidence of Table 27, it is surprising that no between group difference existed before Week 6.

The cognitive condition clearly demonstrate the greatest magnitude of change on all three variables. While we may provide plausible explanations for cognitive therapy resulting in active-cognitive coping change, it is not evident why this condition should show such marked improvement on active-behavioural and, more particularly, marked improvement in the use of avoidance as a coping technique. It may be that coping skills may develop over a longer period than the relatively short duration of the therapy. It will be of interest to look at CRQ change during the follow-up period.

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4). IMAGINAL TEST.

a. Main measures.

Table 30 presents the results of MANOVAs for the four Imaginal test measures. Ratings of NEGATIVE (self-statements) produces significant effects for the group and time main effects and the group x time interaction. Ratings of POSITIVE (self-statements) produces significant effects for time and group x time interaction. IMAGINE and ANXIETY produce no significant effects.

TABLE 30. Repeated measures analysis of Imaginal test process variables across the experimental period using MANOVA (* p < .05, ** p < .01, *** p < .001)

Source of Variation	Pillai	Hyp. d.f.	Error d.f.	F ratio	F probab	Signif. level
NEGATIVE						
Group		3		4.291	.007	**
Time	.194	5	90	4.327	.001	***
Group x time	.410	15	276	2.915	.000	***
POSITIVE						
Group		3		1.442	.235	NS
Time	.171	5	90	3.718	.004	**
Group x time	.336	15	276	2.321	.004	**
IMAGINE						
Group		3		.037	.990	NS
Time	.066	5	90	1.277	.281	NS
Group x time	.125	15	276	.804	.673	NS
ANXIETY						
Group		3		1.181	.321	NS
Time	.086	5	90	1.702	.142	NS
Group x time	.209	15	276	1.380	.156	NS

b). Treatment within Time sub-effects.

In order to investigate the treatment within time sub-effects, ONEWAY ANOVAs across the four treatment conditions were conducted at each of the five data points. The STUDENT NEWMAN-KEULS was applied to identify the loci of significant differences. The results of the analyses are presented in Table 31.

TABLE 31. ANOVAs conducted upon Imaginal test variables during the experimental period across the four treatment conditions. (Cognitive = 1, Behavioural = 2, Cognitive-Behavioural = 3, Placebo = 4) using Newman-Keuls (alpha level = .05).

	d.f.	F ratio	F probab.	Pair
NEGATIVE				
Week 3	3,94	6.111	.000	1 v 2 3 v 2
Week 5	3,94	6.647	.000	1 v 2 3 v 2 4 v 2
POSITIVE				
	No groups are significantly different at any point			
IMAGINE				
Week 5	3,94	2.752	.047	1 v 2 3 v 2
ANXIETY				
	No groups are significantly different at any point.			

With only one exception, there are no differences between groups with regard to how well patients were able to imagine the anxiety-provoking scene (IMAGINE) and the absence of differences on ANXIETY (how anxious were you while listening?) provides evidence that all groups responded to the same degree. These results strengthen the case that results from NEGATIVE and POSITIVE are valid representations of the patients' internal dialogue. While no differences are found on POSITIVE, the results from NEGATIVE are provoking. The Behavioural condition show significantly more negative self-statements at points 3 and 5 than the two cognitively orientated therapies and, curiously, the Placebo condition at point 5.

Time within Treatment Group sub-effects.

Table 32 provides information separately for each of the four therapy conditions and illustrates the magnitude of effect of treatment upon each of the Imaginal test measures.

TABLE 32. Time within Treatment group simple effects and sub-effects at each data point presented for each treatment condition for the Imaginal test variables (* p < .05, ** p < .01, *** p < .001).

TREATMENT VARIABLE	Pillai	F probab.	Weeks of therapy. 2	3	4	5	6
COGNITIVE CONDITION							
Negative	.194	.001					***
Positive	.270	.000	**	**		***	***
Imagine	.049	.466					
Anxiety	.109	.061			*		
BEHAVIOURAL CONDITION							
Negative	.261	.000		**		**	
Positive	.100	.084					
Imagine	.059	.346					
Anxiety	.122	.037	**			**	
COGNITIVE-BEHAVIOURAL CONDITION							
Negative	.150	.011		**		**	**
Positive	.092	.115		*		**	*
Imagine	.048	.474				*	
Anxiety	.064	.299					
PLACEBO CONDITION							
Negative	.077	.196					
Positive	.109	.061			*		
Imagine	.054	.395					
Anxiety	.036	.643					

The above Table strongly suggests the superiority of the Cognitive and Cognitive-Behavioural condition over the Behavioural and Placebo

condition. Indeed, the significant results produced by the Behavioural condition represent an increase in negative self-statements in marked contrast to the decrease in these statements recorded by the Cognitive conditions. It does appear that the 'purer' the cognitive content of the course, the more marked the improvement. An important question will clearly concern whether these results are of importance in affecting treatment outcome and maintenance of improvement as measured by the other variables.

Summary of Process variables

Looking at the descriptive and statistical data presented on the four process measures (diary, FSAQ, CRQ, Imaginal test), the first noticeable outcome is that, on the whole, these measures seem to be a good deal more sensitive to change and allow greater discrimination between conditions. The consistent finding is of greatest improvement being recorded by the active therapy groups with perhaps the Cognitive condition performing at the highest level. Again, we see impressive improvement recorded by the Placebo condition - a result which will have to be explained on receipt of further information. In general, all therapy conditions show marked improvement in comparison to the Waiting list control.

While there is ample evidence of significant improvement on these measures pre- to post-therapy, the more important questions relate to the process of change and here we find some interesting patterns.

While the Placebo condition, overall, shows significant improvement, several of the measures suggest that improvement in this condition 'peaks' in mid-therapy (often after spectacular gains) and thereafter starts to go downhill (although not to baseline). If this process is to continue, we should expect to see signs of continued deterioration in this group during the follow-up period.

The Behavioural conditions shows erratic patterns across variables.

Sometimes smooth consistent progress is achieved (diary measures, FSAQ), sometimes inconsistent progress (CRQ measures) and sometimes an erratic performance which results in little improvement (Imaginal test). The importance of these findings is unclear.

An interesting pattern emerges in the Cognitive and Cognitive-behavioural conditions. The Cognitive condition experiences an initial deterioration in scores in the earliest stages of therapy and this trend is particularly evident on the diary variables. Although a deterioration affects the Cognitive-behavioural condition, it is not until after the third session of therapy and this trend is noticable on all variables with, surprisingly, the exception of the diary measures. As an explanation of this curious finding, we might profitably search for clues in the content of the therapy sessions on Week 1 for the Cognitive condition and Week 3 for the Cognitive-behavioural.

What we find is tht both of these sessions are dominated by cognitive explanations of anxiety and a delineation of cognitive techniques. Why should this be associated with marked deterioration during the following week (as patients complete process measures) or even later in the session when patients carry out the Imaginal test? This interesting question will be studied in detail at a later stage.

4. ADDRESSING THE HYPOTHESES

Having completed all the necessary analyses, it may be useful to reproduce the hypotheses at this stage.

Hypothesis 1.

Each of the three active treatments and, to a lesser extent, the Placebo condition, will be superior to the Waiting list condition during the course of therapy.

This hypothesis receives substantial support. On all variables there is unambiguous evidence of significant improvement for all four treatment groups and significant difference with the Waiting list condition on almost all variables. This is particularly evident with the three active conditions.

Hypothesis 2.

Each of the three active treatments will be superior to the Placebo condition.

This hypothesis receives support. Most variables demonstrate a greater magnitude of change associated with the three active treatments (exceptions are FSAQ, Somatic and Mood scales). Although this difference rarely reaches statistical significance, the time within treatment scores consistently show superior functioning associated with the active therapy conditions. As with the main measures, however, the Placebo condition improvement is above expectation.

Hypothesis 3.

The Cognitive and Cognitive-behavioural conditions will be superior to the Behavioural condition.

With the important exception of the Imaginal test variables, there is no support for this hypothesis. Indeed, not only does the Behavioural condition perform almost as well as the Cognitive condition, it generally outperforms the Cognitive-Behavioural condition. It clearly does lag behind the other two conditions on the Imaginal test. It is not immediately clear how important this is.

Hypothesis 4.

Apart from the rate of change differences, the nature of the process will differ across conditions:

a). Diary measures are expected to show the Cognitive and Cognitive-behavioural conditions demonstrating a greater decrease in time spent thinking or worrying about problems (TIME) than the Behavioural and Placebo conditions.

The hypothesis is supported in relation to the Placebo condition and rejected in relation to the Behavioural condition.

b). The nature of change as measured by the FSAQ may differ across conditions. It is tentatively suggested that changes in the component which is the focus of therapy may initiate change in the other components, i.e. cognitive therapy may produce initial changes in the cognitive component, etc. No predictions are made for the Placebo condition.

This hypothesis is not supported. Within each group, one component seems highly correlated with the others and that across conditions, this pattern is replicated.

c) **Changes as measured by the CRQ may differ across conditions. Cognitive therapy will produce greatest change in the Active-cognitive coping scale (CRQC), Behaviour therapy in the Active-behavioural coping and avoidance coping scales (CRQB, CRQA), while the Cognitive-behavioural condition will produce equal changes on all three scales. No predictions are made for the placebo condition.**

This hypothesis is not supported. Although the Cognitive condition is associated with greatest change in the Active-cognitive coping scale, it also achieves greatest change in the Active-behavioural coping and Avoidance coping scales thus pointing to the generally superior functioning by the Cognitive condition on these variables.

d). The Imaginal test will discriminate between conditions. No changes in negative or positive self-statements are expected in the Behavioural and Placebo conditions who will also sustain high anxiety levels across sessions. Cognitive and, to a lesser extent, Cognitive-behavioural therapies will show:

1) an increase across sessions in the production of positive self-statements

2) a decrease across sessions in the production of negative self-statements.

3) a decrease across sessions of anxiety ratings.

These hypotheses are strongly supported. While the ability to imagine each situation remains stable, the Cognitive therapy condition shows significant reduction in negative self-statements and anxiety ratings. The Cognitive-behavioural condition mirrors these results although not to the same degree. The Behavioural and Placebo conditions although showing change in the same direction in terms of negative and positive self-statements, do so at a much reduced level and show little change in anxiety ratings.

****

Before turning to the follow-up results, we can look for additional evidence supporting 'Stress Control' therapy by addressing the global ratings of anxiety (patient and spouse) and the generalisation of improvement into the areas of everyday coping.

5. OTHER MEASURES - pre-post variables

a) Global anxiety

Having considered in some detail, main and process measures of change, we can now look at global ratings of anxiety(on a 12 point scale) made before the course and again at the end of the course both by the patient and by the patient's spouse (or other close relative).

In order to analyse pre-post differences, PAIRED T-TESTS were applied on mean scores within each treatment condition.

Table 33 presents mean values and standard deviations pre- and post-therapy, percentage change in these values and probability of t-value.

TABLE 33./

TABLE 33. Comparison across treatment groups of mean and SD scores pre- and post-therapy, percentage change scores and significance levels of PAIRED T-TESTS applied on mean scores within each treatment condition. (* p < .05, ** p < .01, *** p < .001) for patient and spouse global ratings of anxiety.

	Cognitive	Behavioural	Cogn-Beh.	Placebo
Patient rating				
pre	7.87(2.2)	7.58(1.9)	7.19(2.1)	8.40(2.3)
post	4.83(1.6)	5.13(1.8)	4.73(1.8)	6.00(2.5)
% change	-38.63(-27.3)	-32.32(-5.3)	-34.21(-14.3)	-28.57(+8.6)
probability level	***	***	***	*
Spouse rating				
pre	7.31(3.0)	8.52(2.2)	9.07(1.7)	9.58(2.9)
post	5.42(1.7)	5.67(1.5)	4.70(1.5)	6.89(2.3)
% change	-25.85(-43.3)	-33.45(-31.8)	-48.18(-11.8)	-28.08(-20.7)
probability level	***	***	***	***

In order to test for differences on mean scores between conditions, ONEWAY ANOVAs were applied. No differences emerged on patients' ratings, however a significant difference was found between the Cognitive-behavioural and Cognitive conditions on spouse ratings ($F(3,94) = 3.118$, $P = .030$).

These findings mirror the previous results. It is interesting to see the contrast between patients and spouse at pre-therapy where, with the exception of the Cognitive condition, spouses tend to rate anxiety levels higher. Patients' ratings show higher percentage changes in the active treatment conditions as compared to the Placebo

condition and this trend is also highlighted, with the exception of the Cognitive condition, in spouses' ratings. It is interesting to note the discrepancies at post-therapy. Cognitive-behavioural condition patients rate themselves as less improved than their spouses rate them although this may reflect that initial lower ratings. SD values, with the exception of patients' ratings in the Placebo condition, show fairly consistent decreases from pre- to post-therapy. Generally, however, Table 31 provides further evidence of significant improvement occurring across conditions

b). Coping questionnaire.

In order to look at generalisation of improvement, this questionnaire looked for evidence of improvement in the areas of job, handling financial affairs, social life, marriage/relationship, family and finally general coping with life. As inspection of the raw data pertaining to these six questions revealed marked improvements, it was decided to collapse the data and present evidence for global ratings of 'coping'.

Table 34 presents mean values and standard deviations pre- and post-therapy, % change in these values and probability levels obtained from PAIRED T-TESTS carried out on mean scores. (increased scores represents increased coping).

TABLE 34/

TABLE 34. Comparison across treatment groups of mean scores, standard deviations, pre- and post-therapy, percentage change scores and significance levels of PAIRED T-TESTS applied on mean scores within each treatment condition for patients' global ratings of 'coping' (based on collapsed data). (* p < .05, ** p < .01, *** p < .001).

	Cognitive	Behavioural	Cogn-Beh.	Placebo.
Global 'coping'				
pre	5.17(1.4)	4.80(1.2)	4.75(1.3)	5.29(1.2)
post	7.21(1.4)	7.04(1.4)	7.12(0.9)	6.83(1.4)
% change	+39.46(0)	+46.66(+16.7)	+49.90(-31.0)	+29.11(+16.7)
probability level	***	***	***	*

Changes in 'coping' reflect the changes in global anxiety. Marked improvement is associated with the three active therapy groups with, surprisingly, the Behavioural condition achieving the second highest changes. Although clearly lagging behind these groups, the significant change associated with the Placebo group adds additional evidence to the unexpected degree of improvement attained by this group on most main and process variables. SD changes again do not demonstrate the same uniform decreases as evidenced by the mean values.

****

At this stage there is reasonable support for the beneficial nature of the 'Stress Control' therapy. However, only if long term benefits accrue can it be said to be of value. As Zielinski (1978) notes, failure to achieve maintenance of gain becomes 'an exercise in futility' (p 353). Prior to further investigations into the variability in the

data, as evidenced by the SDs, it is, therefore, to the questions relating to maintenance of improvement that we now turn our attention.

CHAPTER 13

THE EFFECTS OF DIFFERENT TREATMENTS : SIX MONTHS FOLLOW-UP

THE EFFECTS OF DIFFERENT TREATMENTS : SIX MONTH FOLLOW-UP.

This chapter divides into four sections:

1). Follow-up : Main measures.

2). Follow-up: Process measures.

3). Generalisation effects and global ratings.

4). Component analysis.

Patients in the four treatment groups were sent, by post, all main and some process measures (CRQ, FSAQ) six months after completion of therapy. Return rates were satisfactory and as follows:

Cognitive Condition	84%
Behavioural Condition	84%
Cogn-Beh. Condition	81%
Placebo Condition	90%

1). FOLLOW-UP : MAIN MEASURES

a. Mean Values.

Evidence has been produced that all three active conditions, and to a lesser extent, the Placebo condition have shown significant improvements over the course of therapy on the main measures. Although it was hypothesised that the Cognitive and Cognitive-behavioural conditions would perform well, the magnitude of change evidenced by the Behavioural and, in particular, the Placebo conditions was against expectations. As a result, no hypotheses are forwarded at this stage.

Table 35 presents mean values at pre-therapy, post-therapy, six month follow-up, percentage change in post-therapy to follow-up values and in pre-therapy to follow-up values across treatment conditions.

TABLE 35/

TABLE 35. Comparison across treatment conditions of mean scores pre- and post-treatment and follow-up, and percentage change in post-therapy to follow-up values and in pre-therapy to follow-up values (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
STAI:A-State				
pre	55.5	56.4	50.2	59.7
post	40.7	40.6	42.0	46.4
follow-up	35.5	34.8	36.2	46.9
% change (post-f.u.)	-12.8	-14.3	-13.8	+1.1
% change (pre-f.u.)	-36.0	-38.3	-27.9	-21.4
STAI:A-Trait				
pre	58.1	59.5	54.8	59.3
post	50.2	51.7	48.6	51.4
follow-up	45.4	45.4	45.0	50.4
%change (post-f.u.)	-9.6	-12.2	-7.4	-1.9
% change (pre-f.u.)	21.9	-23.7	-17.9	-15.0
DAS				
pre	99.2	99.3	95.7	99.1
post	112.3	108.8	103.3	111.1
follow-up	118.7	114.8	107.4	112.4
% change (post-f.u.)	+5.7	+5.5	+4.0	+1.2
% change (pre-f.u.)	+19.6	+15.6	+12.2	+13.4
FSS				
pre	104.4	106.5	105.6	116.6
post	79.0	75.0	83.5	95.2
follow-up	71.8	69.6	80.0	96.2
% change (post-f.u.)	-9.1	-7.2	-4.2	+1.0
% change (pre-f.u.)	-31.2	-34.6	-24.2	-17.5
BDI				
pre	18.5	20.0	17.0	20.8
post	10.6	11.4	11.5	15.1
follow-up	7.8	8.6	10.0	12.7
% change (post-f.u.)	-26.4	-24.6	-13.0	-15.9
% change (pre-f.u.)	-57.8	-57.0	-41.2	-38.9
MSPQ				
pre	34.3	34.4	27.4	29.2
post	23.1	23.7	22.3	20.6
follow-up	19.1	15.4	12.7	26.0
% change (post-f.u.)	-17.3	-35.0	-43.0	+26.2
% change (pre-f.u.)	-44.3	-55.2	-53.6	-11.0

Figures 22 to 27 offer further descriptive information.

STAI:A-State

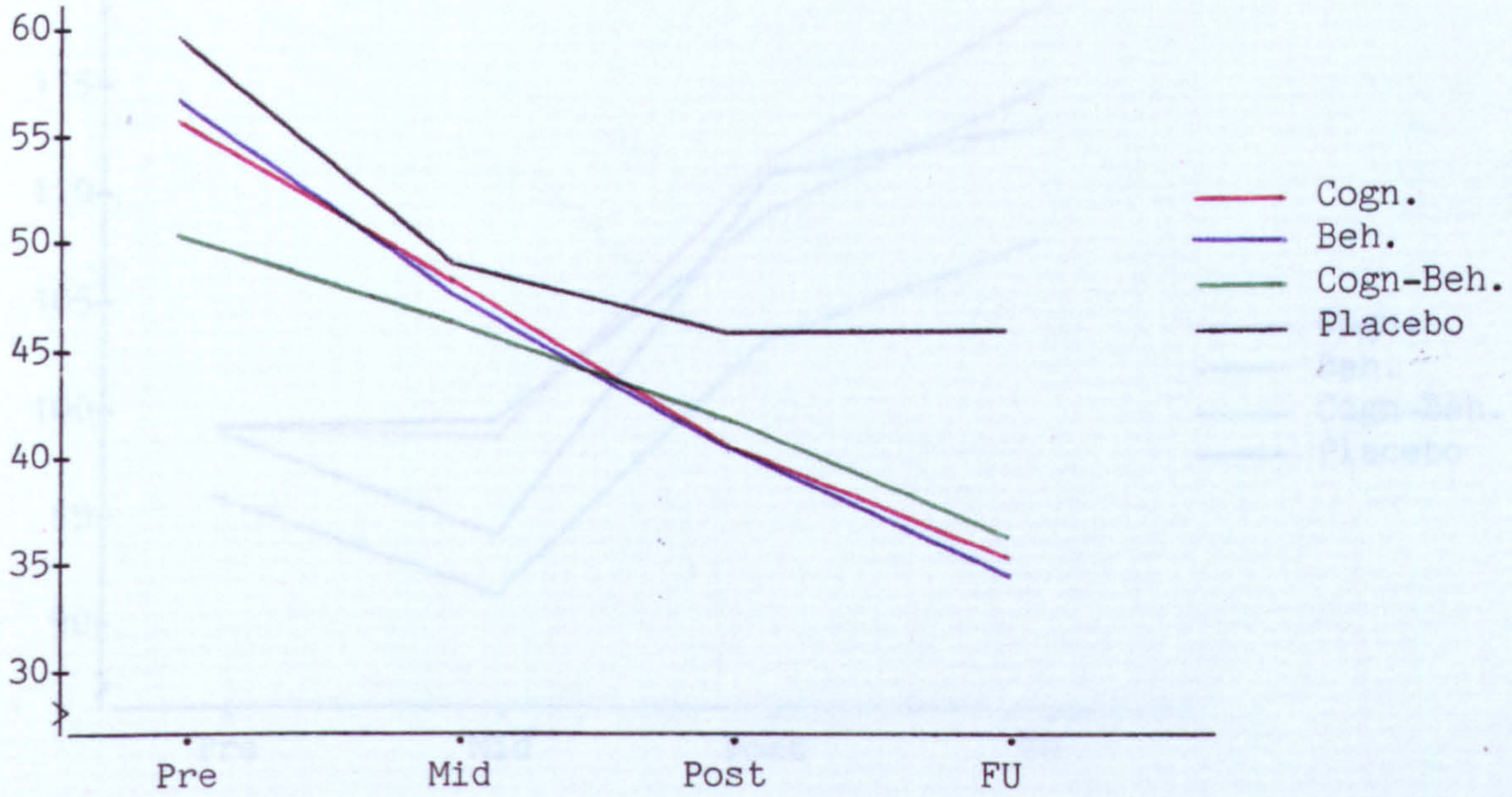

Figure 22. Comparison across treatment conditions of mean scores at pre-, mid-, and post-therapy and six month follow-up for STAI:A-State.

STAI:A-Trait

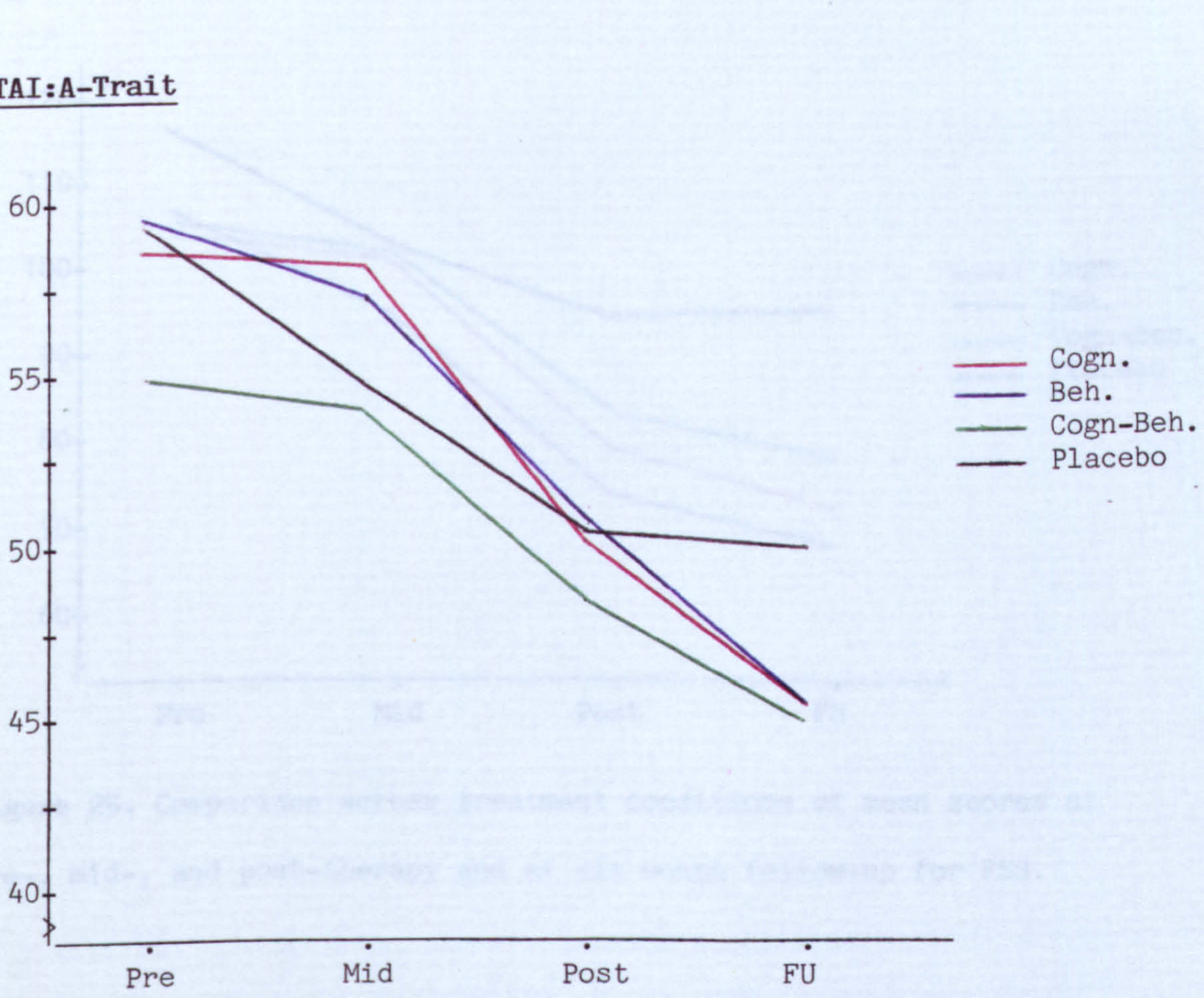

Figure 23. Comparison across treatment conditions of mean scores at pre-, mid-, and post-therapy and six month follow-up for STAI:A-Trait.

DAS

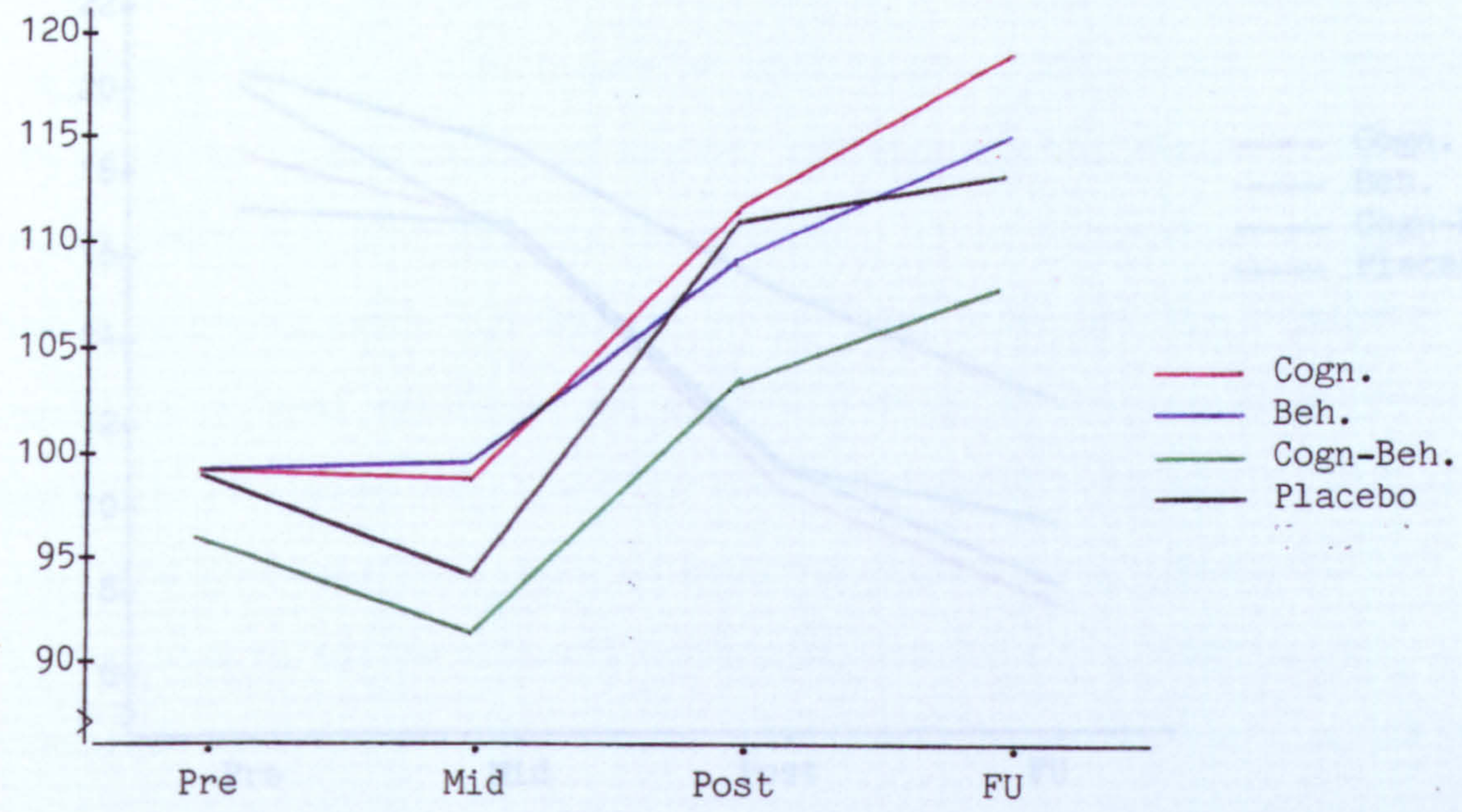

Figure 24. Comparison across treatment conditions of mean scores at pre-, mid-, and post-therapy and six month follow-up for DAS.

FSS

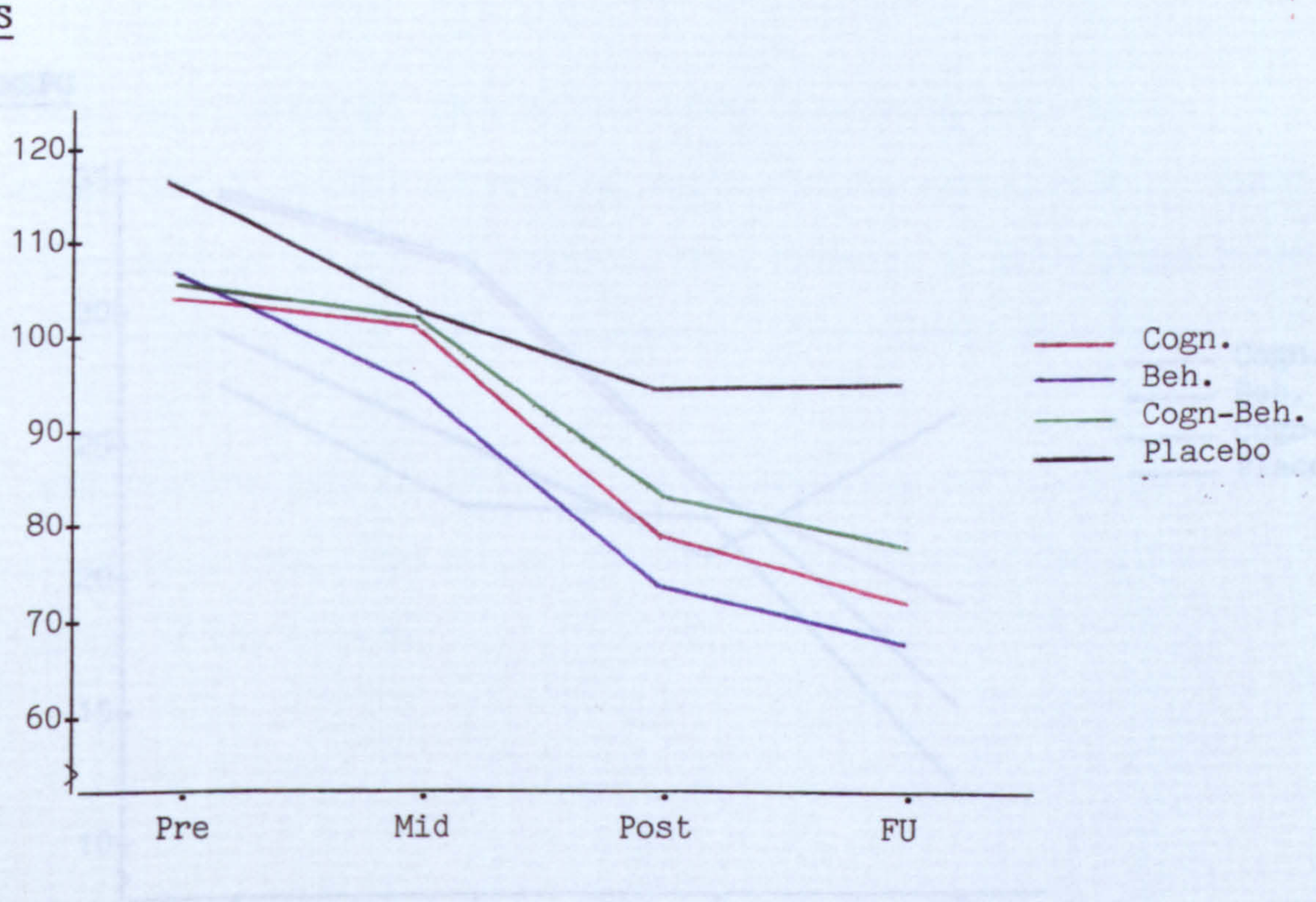

Figure 25. Comparison across treatment conditions of mean scores at pre-, mid-, and post-therapy and at six month follow-up for FSS.

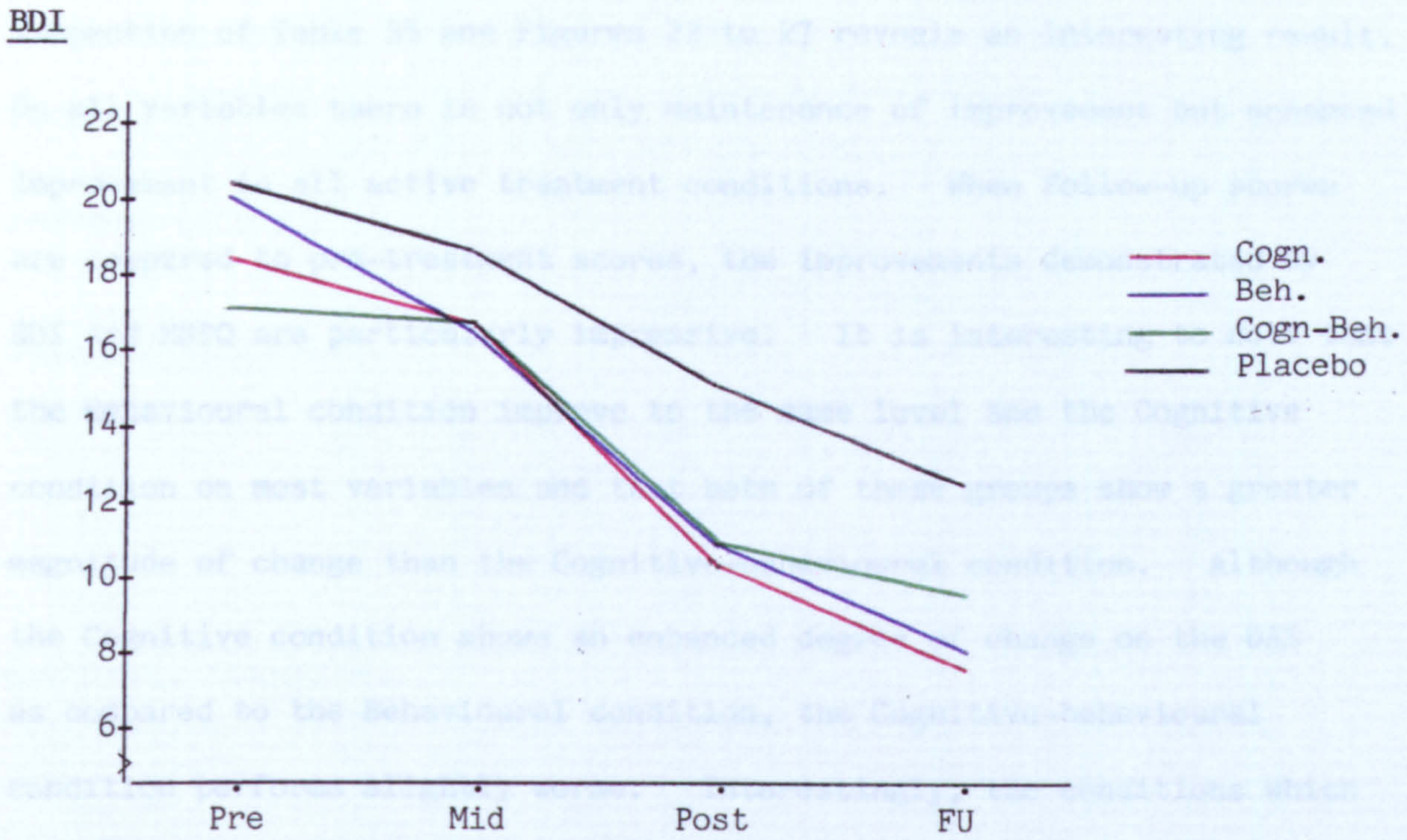

Figure 26. Comparison across treatment conditions of mean scores at pre-, mid- and post-therapy and at six month follow-up for BDI.

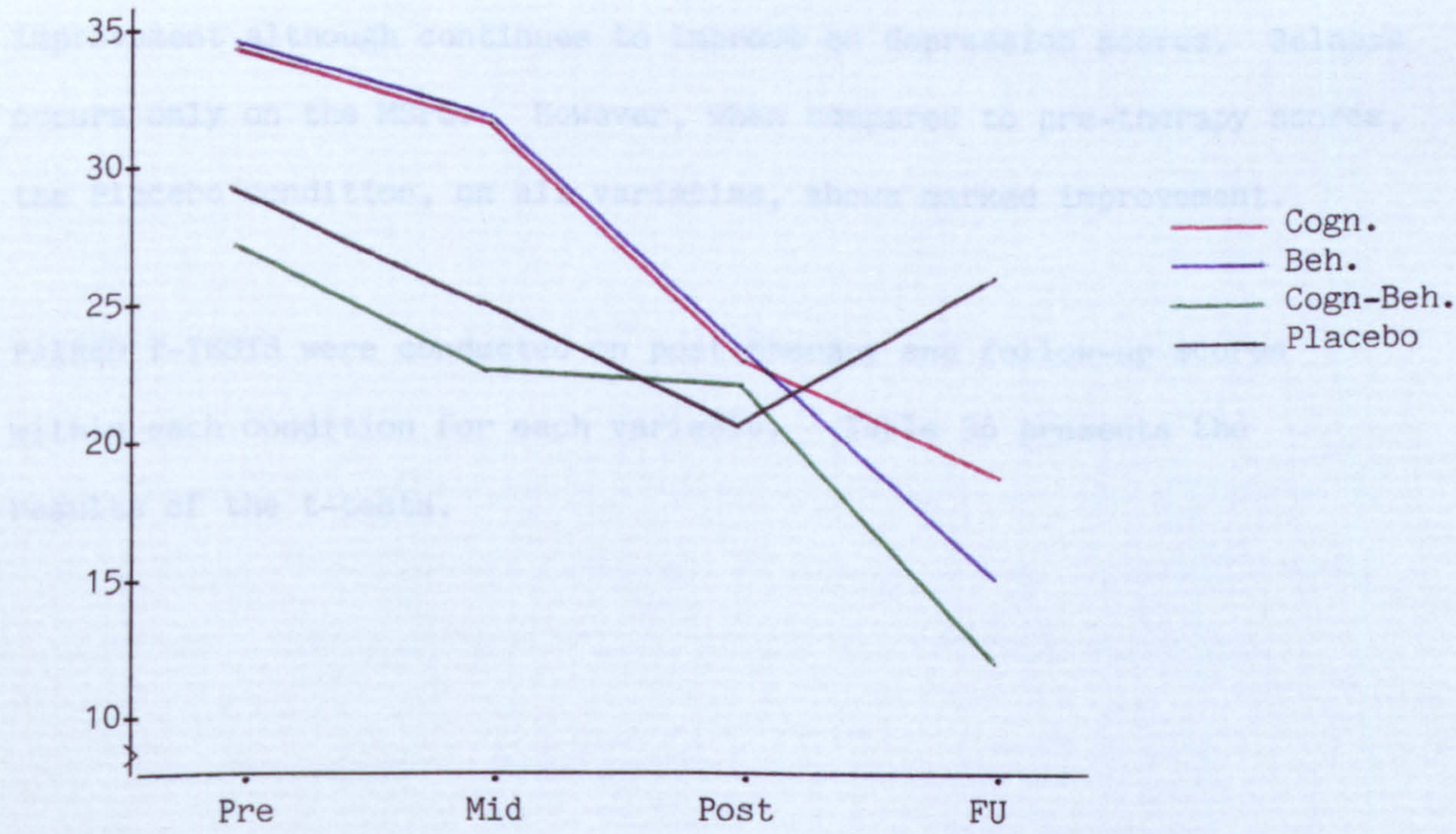

Figure 27. Comparison across treatment conditions of mean scores at pre-, mid- and post-therapy at six month follow-up for MSPQ.

Inspection of Table 35 and Figures 22 to 27 reveals an interesting result. On all variables there is not only maintenance of improvement but enhanced improvement in all active treatment conditions. When follow-up scores are compared to pre-treatment scores, the improvements demonstrated by BDI and MSPQ are particularly impressive. It is interesting to note that the Behavioural condition improve to the same level and the Cognitive condition on most variables and that both of these groups show a greater magnitude of change than the Cognitive-behavioural condition. Although the Cognitive condition shows an enhanced degree of change on the DAS as compared to the Behavioural condition, the Cognitive-behavioural condition performs slightly worse. Interestingly, the conditions which contained progressive relaxation techniques (Behavioural and Cognitive-behavioural) produce the greatest reductions in somatic symptoms as measured by the MSPQ.

The Placebo condition, on most variables, maintains post-therapy improvement although continues to improve on depression scores. Relapse occurs only on the MSPQ. However, when compared to pre-therapy scores, the Placebo condition, on all variables, shows marked improvement.

PAIRED T-TESTS were conducted on post-therapy and follow-up scores within each condition for each variable. Table 36 presents the results of the t-tests.

Table 36. T-Test comparisons (post-therapy - follow-up) of the main measures for each of the treatment conditions.
(* p < .05, ** p < .01, *** p < .001).

TREATMENT VARIABLE	T	d.f.	Probab.	Signif. level.
COGNITIVE CONDITION				
STAI:A-State	2.35	30	.026	*
STAI:A-Trait	2.51	30	.018	**
DAS	-2.58	30	.015	*
FSS	0.67	30	.508	NS
BDI	3.49	30	.002	**
MSPQ	1.61	30	.118	NS
BEHAVIOURAL CONDITION				
STAI:A-State	2.78	30	.009	**
STAI:A-Trati	3.28	30	.003	**
DAS	-2.09	30	.045	*
FSS	0.85	30	.401	NS
BDI	2.94	30	.006	**
MSPQ	4.07	30	.000	**
COGNITIVE-BEHAVIOURAL CONDITION				
STAI:A-State	2.67	25	.013	**
STAI:A-Trait	1.96	25	.061	NS
DAS	-1.93	25	.066	NS
FSS	0.30	25	.769	NS
BDI	1.14	25	.263	NS
MSPQ	4.39	25	.000	***
PLACEBO CONDITION				
STAI:A-State	-0.09	9	.930	NS
STAI:A-Trait	0.24	9	.816	NS
DAS	-0.61	9	.555	NS
FSS	-0.12	9	.907	NS
BDI	0.78	9	.455	NS
MSPQ	-1.23	9	.248	NS

Having examined the within subject effects, between subject effects were analysed using ONEWAY ANOVAs conducted on change scores from post-therapy to follow-up. The only significant effect was for MSPQ where the

Cognitive-behavioural condition was superior to Placebo [F (4,104) = 3.59, F probability .009] although STAI:A-State almost achieved significance [F (4,104) = 2.10, F probability .086] between the Cognitive, Behavioural and Placebo conditions.

Summary of mean values descriptive analysis.

There is overwhelming evidence of maintenance, and indeed, enhancement, of post-therapy gains in all three active therapy conditions. The Cognitive and, surprisingly, the Behavioural conditions appear to perform at a slightly higher level than the Cognitive-behavioural condition. The Placebo condition, on the whole, maintains treatment gains although it is more clearly distinguished from the active therapies at this stage.

b) SD Values

In order to assess variability during the follow-up period, Table 37 presents SD values.

TABLE 37/

TABLE 37. Comparison across treatment conditions of SD scores pre- and post-treatment and follow-up, and percentage change in post-therapy to follow-up values and in pre-therapy to follow-up values for main measures (+ = increase in score, - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
STAI-A-State				
pre	11.6	12.7	12.8	17.5
post	11.8	13.1	12.2	18.1
follow-up	10.3	7.5	9.5	20.9
% change (post-f.u.)	-12.7	-42.7	-22.1	+15.5
% change (pre-f.u.)	-11.2	-40.9	-25.8	+19.4
STAI:A-Trait				
pre	9.0	10.8	11.0	11.4
post	10.9	12.8	12.2	13.8
follow-up	9.9	8.7	9.1	11.8
% change (post-f.u.)	- 9.2	-32.0	-25.4	-14.5
% change (pre-f.u.)	+10.0	-19.4	-17.3	+3.5
DAS				
pre	21.2	23.2	21.0	13.6
post	24.7	23.3	22.8	15.0
follow-up	22.3	18.1	21.7	18.6
% change (post-f.u.)	-9.7	-22.3	-4.8	+24.0
% change (pre-f.u.)	+4.7	-22.0	+3.3	+36.8
FSS				
pre	46.2	41.6	47.6	42.4
post	50.5	41.0	48.3	65.3
follow-up	36.6	35.0	32.6	52.9
% change (post-f.u.)	-27.5	-14.6	-32.5	-19.0
% change (pre-f.u.)	-20.8	-15.9	-31.5	+24.8
BDI				
pre	8.4	9.4	10.3	11.4
post	6.1	7.2	9.9	12.1
follow-up	6.5	5.0	8.2	10.1
% change (post-f.u.)	+6.6	-30.6	-17.2	-16.5
% change (pre-f.u.)	-22.6	-46.8	-20.4	-11.4
MSPQ				
pre	13.8	13.6	13.0	13.3
post	11.3	14.0	15.4	10.8
follow-up	11.8	7.8	7.3	21.4
% change (post-f.u.)	+4.4	-44.3	-52.6	+98.1
% change (pre-f.u.)	+14.5	-42.6	-43.8	+60.9

Table 37 demonstrates clear differences between conditions. The Behavioural and the Cognitive-behavioural conditions show consistent decreases in variability as evidenced by SD values which are generally of the magnitude of mean value change. The Cognitive condition shows more variable change while the Placebo condition evidences a highly erratic picture. Although SD changes will not be statistically analysed at this point, the results presented here will be analysed in depth in the following chapter.

2). FOLLOW-UP : PROCESS MEASURES

a) Mean values.

As with the main measures at follow-up no hypotheses are forwarded.

Table 38 presents mean values at pre-therapy, post-therapy, six month follow-up, percentage change in post-therapy to follow-up values and in pre-therapy to follow-up values across treatment conditions for process measures.

TABLE 38/

TABLE 38. Comparison across treatment conditions of mean scores pre- and post-treatment, at follow-up and percentage change scores for each of the FSAQ and CRQ measures (post-fu; pre-fu)
+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn.-Beh.	Placebo
FSAQ				
Cognitive component				
pre	60.0	62.9	60.4	56.6
post	41.1	41.8	41.9	48.1
follow-up	31.1	32.9	32.2	45.1
% change (post-fu)	-24.3	-21.3	-23.1	-6.2
% change (pre-fu)	-48.2	-47.7	-46.7	-20.3
Behaviour component				
pre	43.6	49.6	46.5	47.9
post	30.9	33.6	32.5	40.4
follow-up	26.8	28.6	30.9	41.3
% change (post-fu)	-13.3	-14.9	-4.9	+2.2
% change (pre-fu)	-38.5	-42.3	-33.5	-13.8
Somatic Component				
pre	46.6	46.2	45.7	46.2
post	33.6	36.3	29.9	30.2
follow-up	30.0	28.3	25.5	39.7
% change (post-fu)	-10.7	-22.0	-14.7	+31.5
% change (pre-fu)	35.6	-38.7	-44.2	-14.1
Mood Component.				
pre	56.0	56.4	55.3	60.8
post	41.1	41.5	41.6	45.6
follow-up	30.3	28.5	33.6	45.8
% change (post-fu)	-26.3	-31.3	-19.2	+0.4
% change (pre-fu)	-45.9	-49.5	-39.2	-24.7
Total Score				
pre	208.2	217.8	210.5	211.5
post	146.6	153.3	146.0	164.2
follow-up	118.5	118.4	122.2	171.3
% change (post fu)	-9.2	-22.8	-16.3	+4.3
% change(pre-fu)	-43.1	-45.6	-41.9	-19.0

CRQ/

CRQ

	Cognitive	Behavioural	Cogn-Beh.	Placebo
Active-Cognitive coping				
pre	9.8	10.6	10.1	13.1
post	11.5	11.2	11.2	12.3
follow-up	13.4	13.6	12.6	13.6
% change (post-fu)	+16.5	+21.4	+12.5	+3.8
% change (pre-fu)	+36.7	+28.3	+24.8	+3.8
Active-Behavioural coping				
pre	7.9	9.2	8.5	8.4
post	10.4	9.6	9.5	8.4
follow-up	10.6	10.5	10.6	9.4
% change (post-fu)	+1.9	+9.4	+11.6	+11.9
% change (pre-fu)	+34.2	+14.1	+24.7	+11.9
Avoidance coping scale				
pre	10.2	8.5	9.6	9.0
post	6.9	6.7	7.1	7.6
follow-up	6.7	5.6	6.4	8.8
% change (post-fu)	-2.9	-16.4	-9.9	-15.8
% change (pre-fu)	-34.3	-34.1	-33.3	-2.2

Figures 28 to 35 offer further descriptive information

FOUR SYSTEMS ANXIETY QUESTIONNAIRE (FSAQ)

i Cognitive component

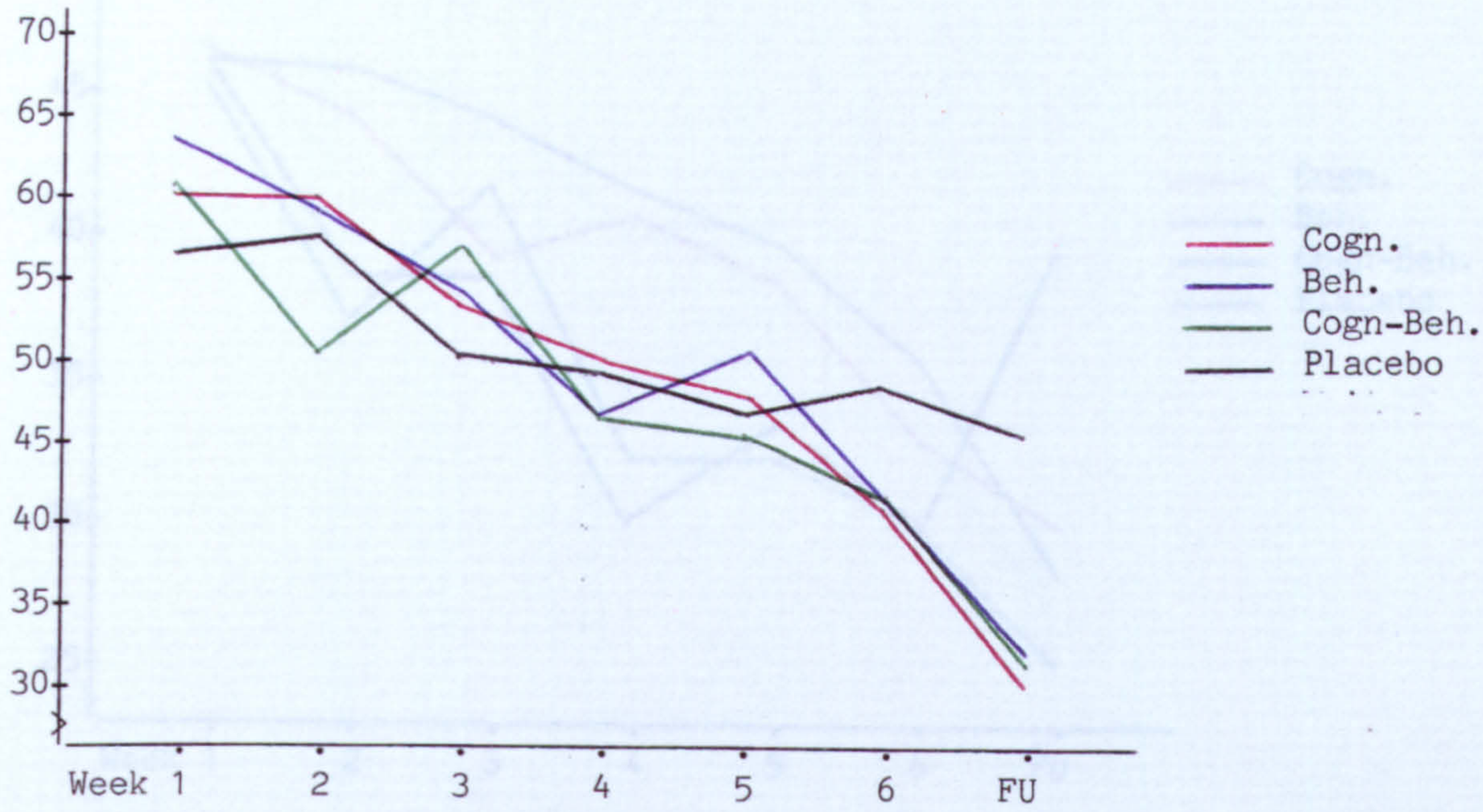

Figure 28. Comparison across treatment conditions of mean scores across the experimental period and six month follow-up for FSAQ:Cognitive component.

ii. Behavioural component

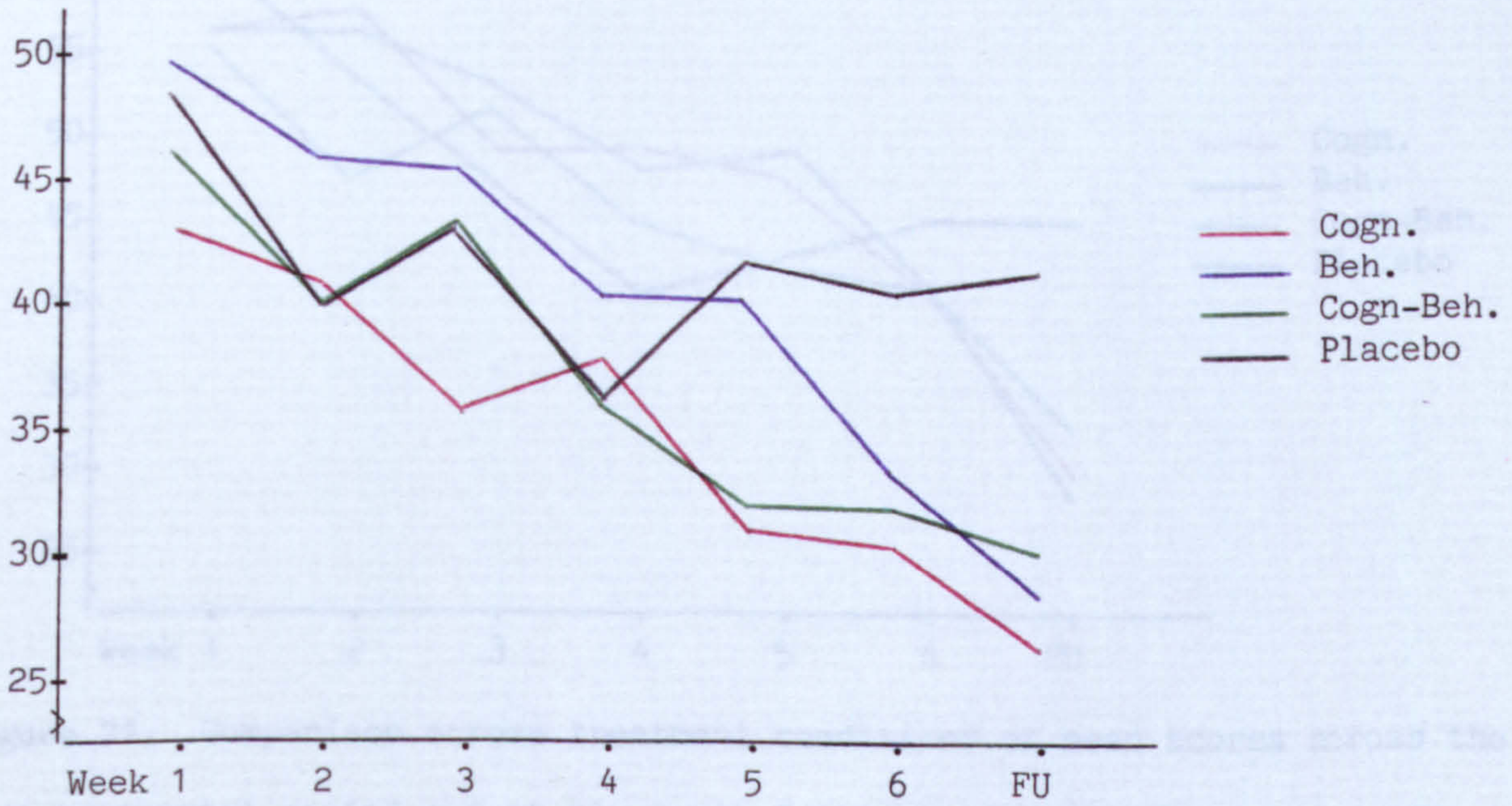

Figure 29. Comparison across treatment conditions of mean scores across the experimental period and six month follow-up for FSAQ:Behavioural component.

iii. Somatic component

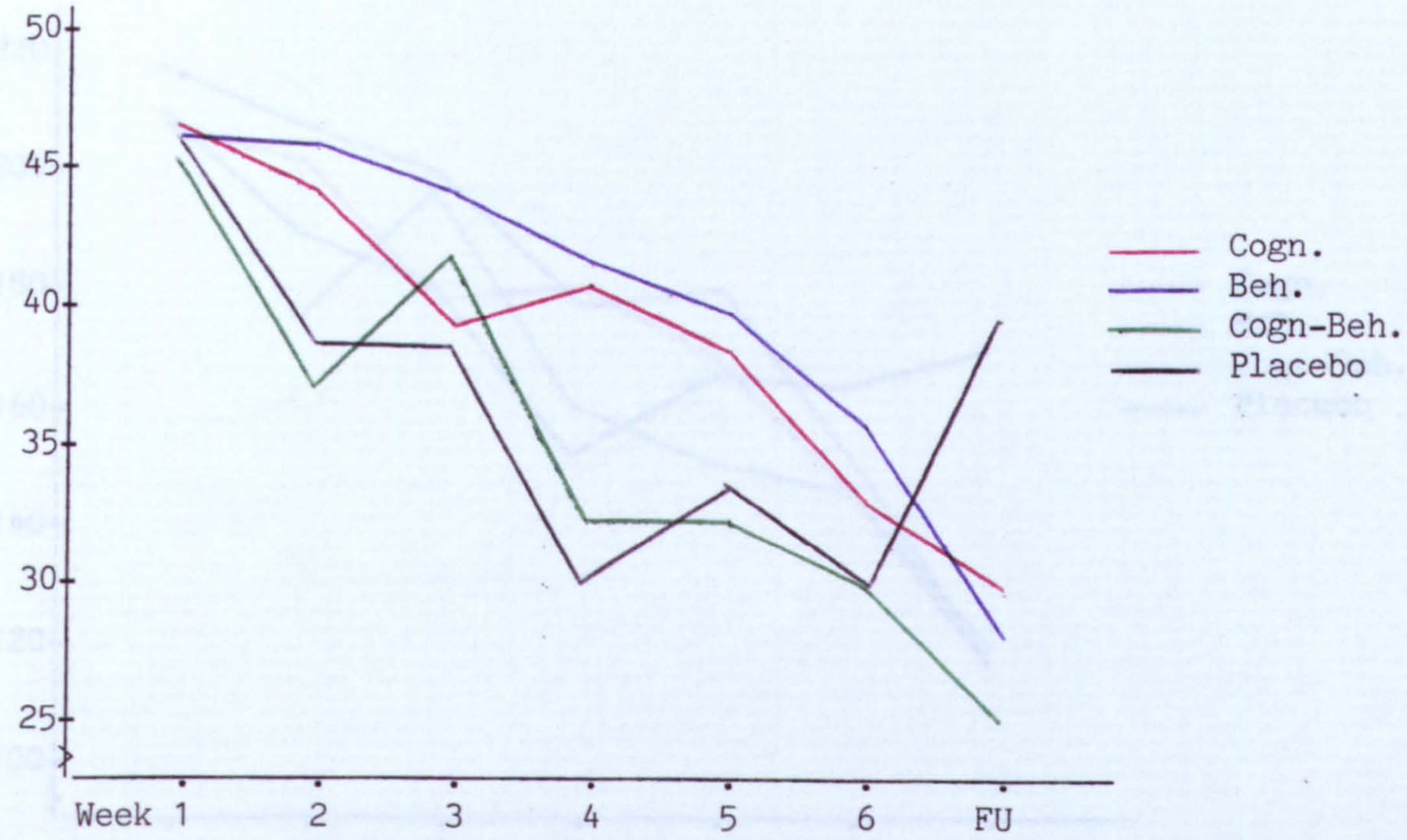

Figure 30. Comparison across treatment conditions of mean scores across the experimental period and at six month follow-up for FSAQ:Somatic component.

iv. Mood component

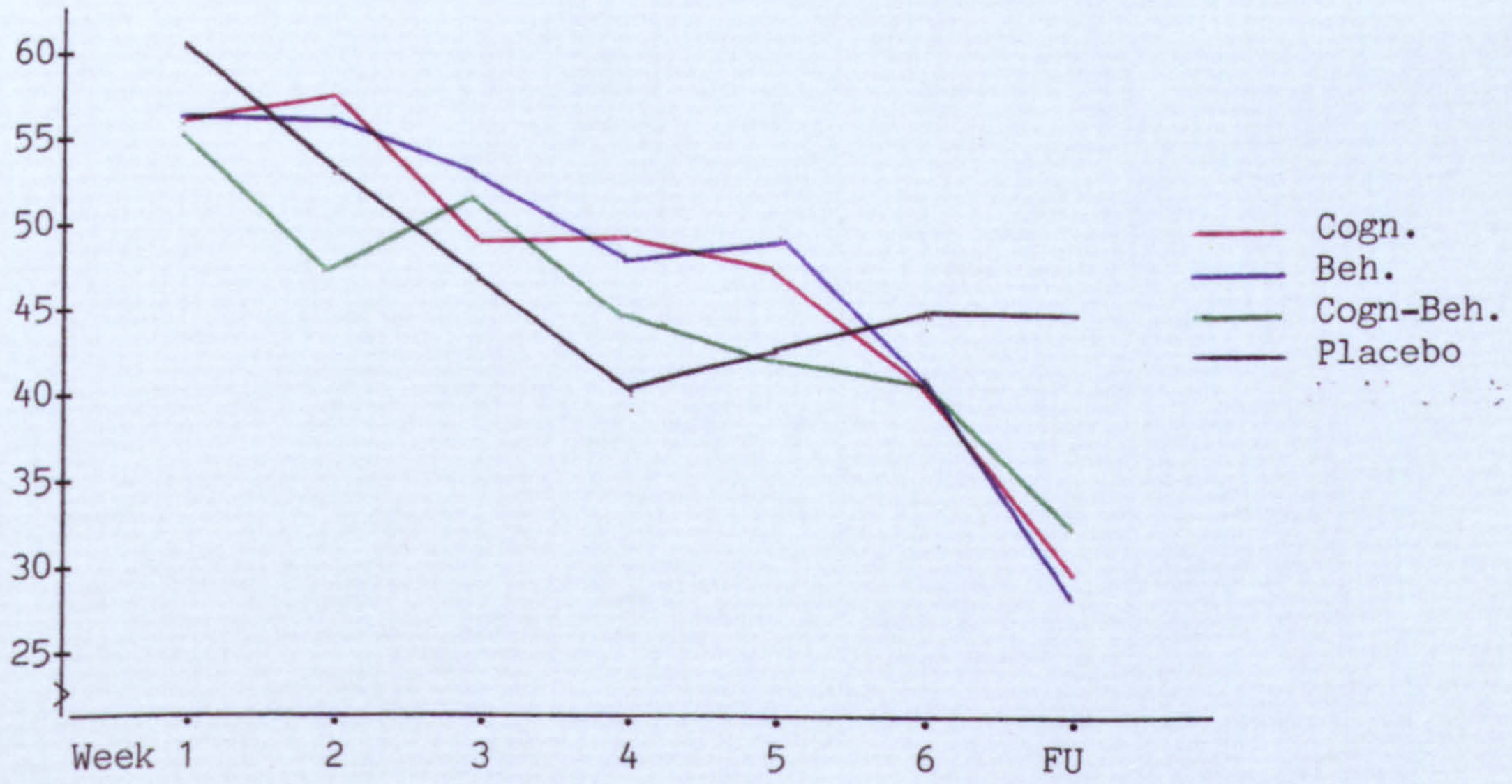

Figure 31. Comparison across treatment conditions of mean scores across the experimental period and at six month follow-up for FSAQ:Mood component.

v. Total score

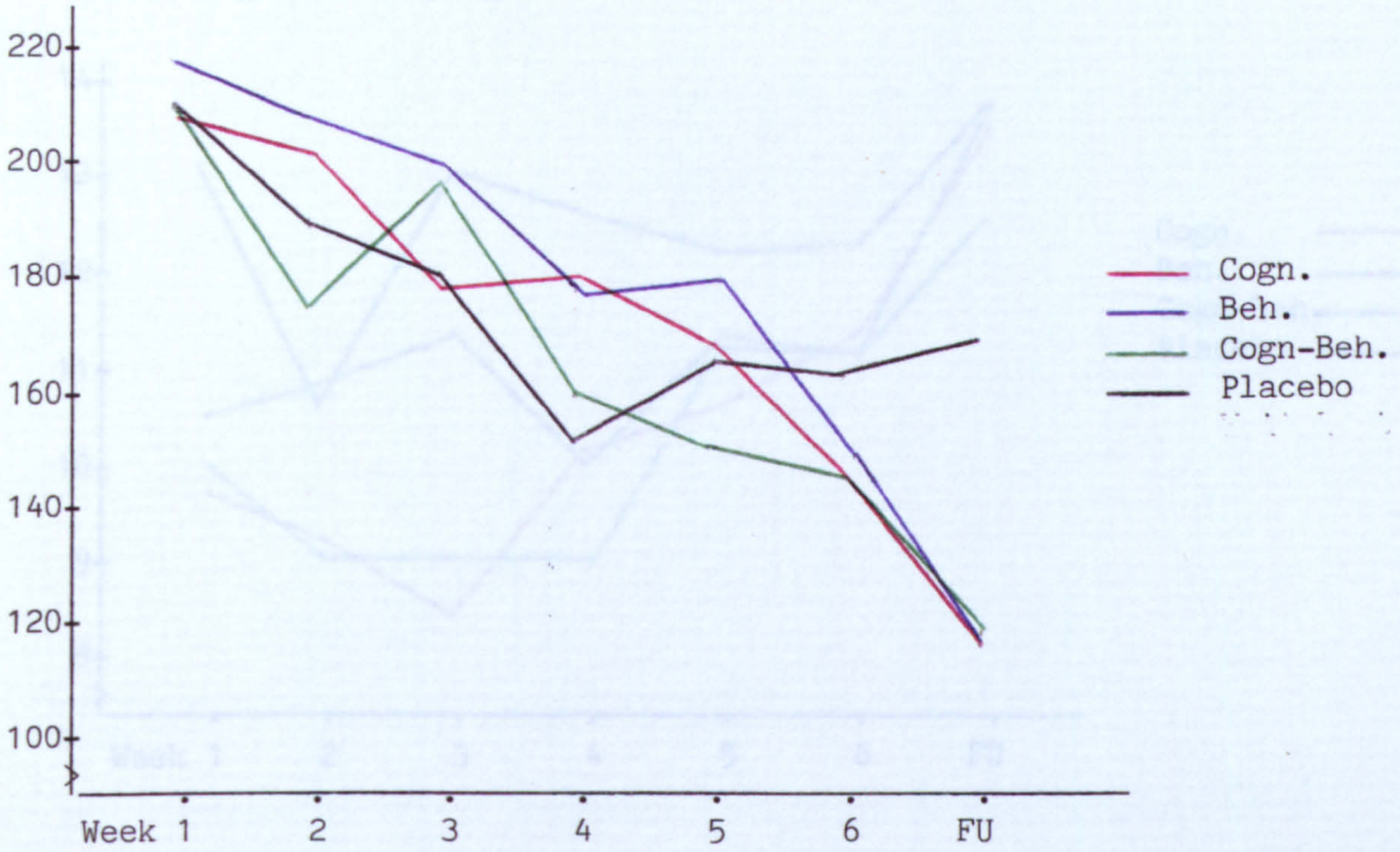

Figure 32. Comparison across treatment conditions of mean scores across the experimental period and at six month follow-up for FSAQ: Total score.

COPING RESPONSES QUESTIONNAIRE (CRQ)

i. Active-Cognitive coping.

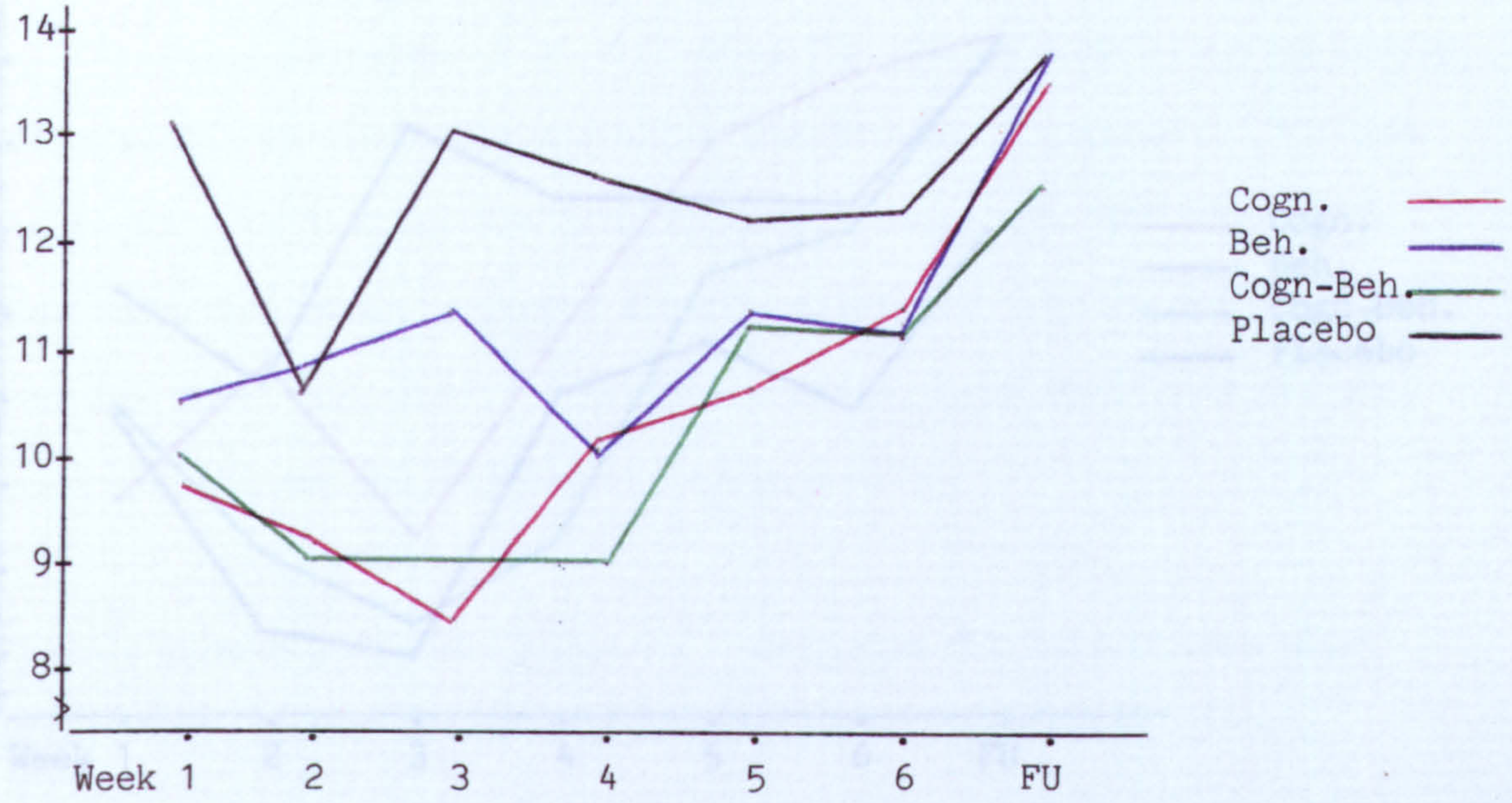

Figure 33. Comparison across treatment conditions of mean scores across the experimental period and six months follow-up for CRQ - Active-Cognitive coping scale.

ii. **Active Behavioural Coping**

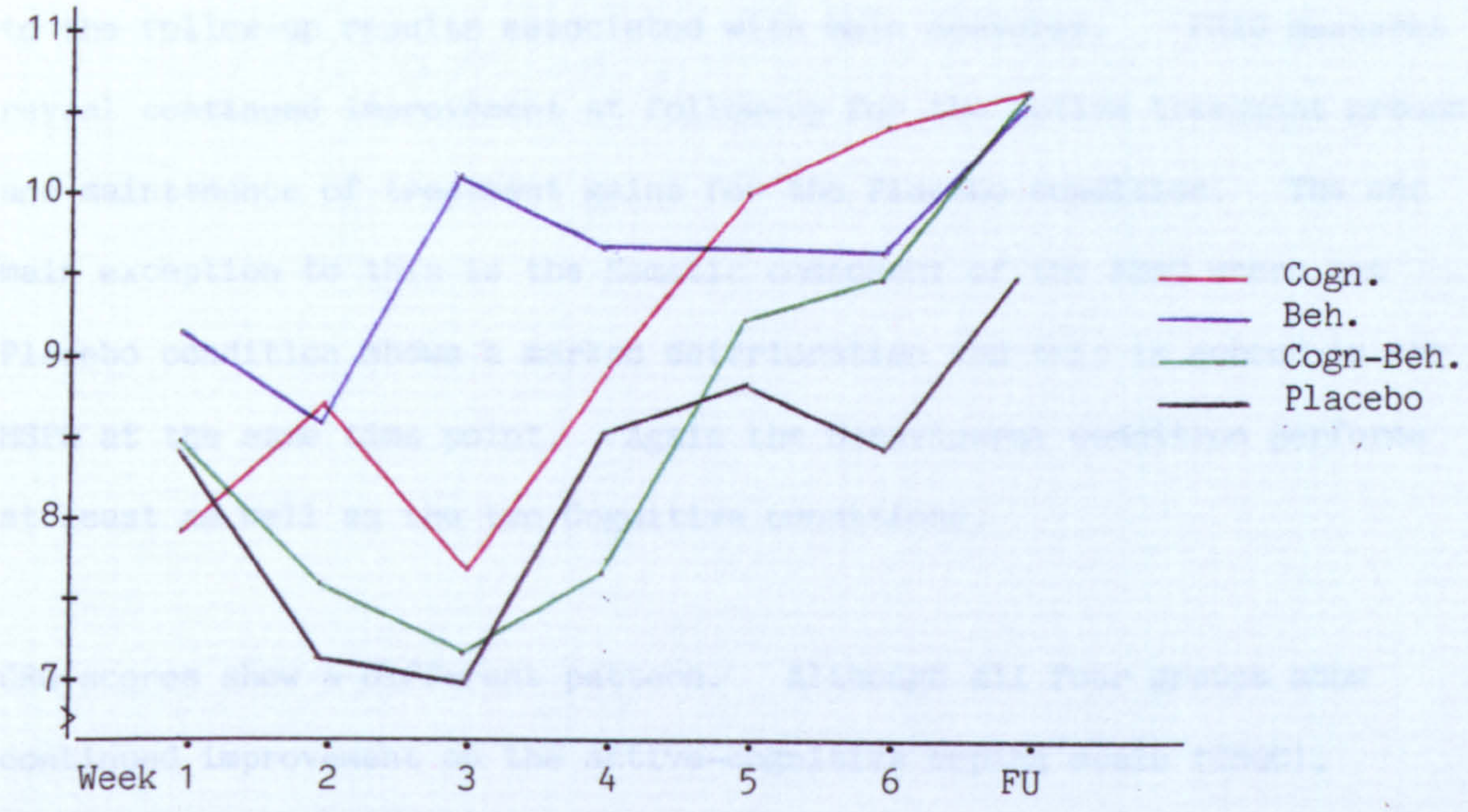

Figure 34. Comparison across treatment conditions of mean scores across the experimental period and at six month follow-up for CRQ : Active-Behavioural Coping scale.

iii. **Avoidance Coping**

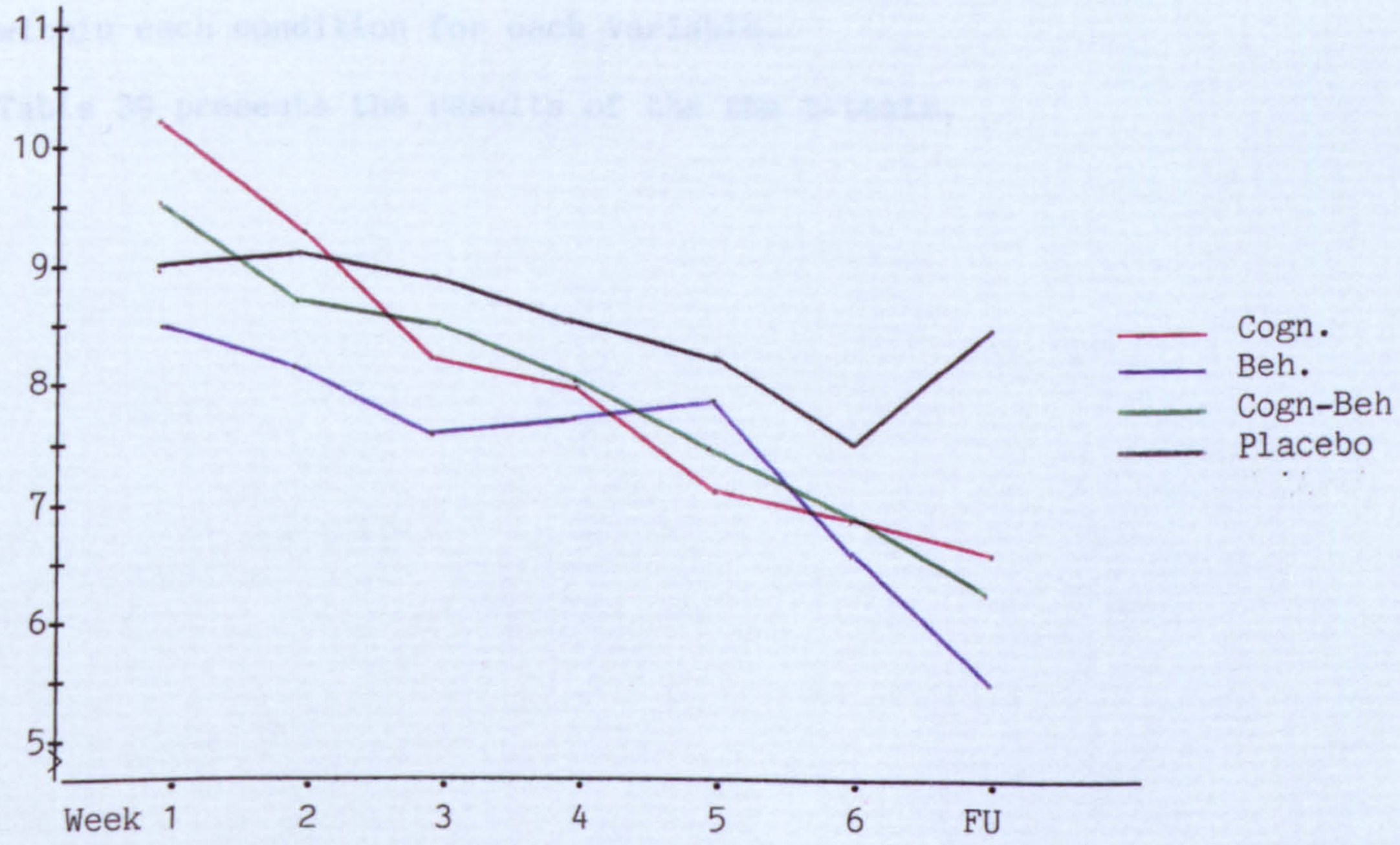

Figure 35. Comparison across treatment conditions of mean scores across the experimental period and at six month follow-up for CRQ : Avoidance Coping scale

Inspection of Table 38 and Figures 28 to 35 reveals a similar picture to the follow-up results associated with main measures. FSAQ measures reveal continued improvement at follow-up for the active treatment groups and maintenance of treatment gains for the Placebo condition. The one main exception to this is the Somatic component of the FSAQ where the Placebo condition shows a marked deterioration and this is echoed in the MSPQ at the same time point. Again the Behavioural condition performs at least as well as the two Cognitive conditions.

CRQ scores show a different pattern. Although all four groups show continued improvement on the active-cognitive coping scale (CRQC), the Cognitive condition merely maintains treatment gains on the active-behavioural (CRQB) and avoidance (CRQA) coping scales while the three other conditions show enhanced improvement.

PAIRED T-TESTS were conducted on post-treatment and follow-up scores within each condition for each variable.

Table 39 presents the results of the the t-tests.

TABLE 39. T-Test comparison (post-therapy - follow-up) of FSAQ and CRQ variables for each of the treatment conditions. (* p < .05, ** p < .01, *** p < .001)

TREATMENT VARIABLE.	T	d.f.	Probab.	Signif. level.
COGNITIVE CONDITION				
FSAQ				
Cognitive component	2.56	30	.016	*
Behaviour "	1.36	30	.183	NS
Somatic "	1.53	30	.136	NS
Mood "	3.15	30	.004	**
Total score	2.78	30	.009	**
CRQ				
Active-Cognitive coping	-2.99	30	.006	**
Active-Behaviour "	-0.37	30	.714	NS
Avoidance "	14.71	30	.000	***
BEHAVIOURAL CONDITION				
FSAQ				
Cognitive	2.73	30	.011	*
Behaviour	1.87	30	.071	NS
Somatic	3.73	30	.001	***
Mood	4.47	30	.000	***
Total Score	3.96	30	.000	***
CRQ				
Active-Cognitive coping	-4.06	30	.000	***
Active-Behaviour "	-1.63	30	.114	NS
Avoidance "	11.81	30	.000	***
COGNITIVE-BEHAVIOURAL CONDITION				
FSAQ				
Cognitive	2.37	25	.026	*
Behaviour	0.58	25	.570	NS
Somatic	1.57	25	.129	NS
Mood	2.01	25	.050	*
Total Score	2.08	25	.048	*
CRQ				
Active-Cognitive coping	-1.76	25	.091	NS
Active-Behaviour "	-1.66	25	.109	NS
Avoidance	13.98	25	.000	***

	T	d.f.	Probab	Signif. level.
PLACEBO CONDITION				
FSAQ				
Cognitive	0.50	9	.627	NS
Behavioural	-0.19	9	.850	NS
Somatic	-2.40	9	.040	*
Mood	-0.02	9	.981	NS
Total Score	-0.42	9	.683	NS
CRQ				
Active-Cognitive coping	-0.84	9	.421	NS
Active-Behavioural "	-0.92	9	.382	NS
Avoidance	5.44	9	.000	***

T-Tests show the continuation of significant change in the active treatment conditions. In particular, the Behavioural condition shows impressive change on the FSAQ measures in comparison with the two other active treatments.

There is a significant relapse on the Somatic component of the FSAQ in the Placebo condition.

ONEWAY ANOVAs across treatments were conducted on change scores from post-therapy to follow-up. Two significant effects appear. Cognitive, Behavioural, and Cognitive-behavioural conditions are significantly different from the Placebo condition on the Somatic component of the FSAQ [F (3,94) = 4.8, P = .005].

The Behavioural condition is significantly different to the Placebo condition on the Avoidance coping scale of the CRQ [F (3,94) = 2.66, P = .026].

b) SD values.

In order to assess variability in process measures during the follow-up period, Table 40 presents SD values.

TABLE 40. Comparison across treatment conditions of SD scores pre- and post-treatment and follow-up, and percentage change in post-therapy to follow-up values and in pre-therapy to follow-up values for process variables. (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
FSAQ				
Cognitive component				
pre	20.5	18.5	20.7	20.8
post	24.2	27.5	27.8	24.6
follow-up	20.8	20.1	24.0	27.2
% change (post-f.u.)	-14.0	-26.9	-13.7	+10.6
% change (pre-f.u.)	+1.5	+8.6	+15.9	+30.8
Behavioural component				
pre	22.1	23.2	19.6	24.0
post	21.0	23.3	18.1	23.5
follow-up	16.8	21.2	18.4	23.0
% change (post-f.u.)	-20.0	-9.0	+1.7	-2.1
% change (pre-f.u.)	-24.0	-8.6	-6.1	-4.2
Somatic component				
pre	14.7	16.8	17.0	14.6
post	14.9	18.2	16.3	18.8
follow-up	14.0	12.4	13.5	17.7
% change (post-f.u.)	-6.0	-31.9	-17.2	-5.9
% change (pre-f.u.)	-4.8	-26.2	-20.6	+21.2
Mood component				
pre	20.8	19.0	20.7	24.5
post	22.0	23.9	23.3	29.4
follow-up	20.7	17.5	19.0	23.3
% change (post-f.u.)	-5.9	-26.8	-18.5	-20.7
% change (pre-f.u.)	-0.5	-7.9	-8.2	-4.9
Total score				
pre	64.4	68.2	67.1	60.0
post	68.2	80.0	71.6	89.6
follow-up	58.9	59.1	65.0	81.4
% change (post-f.u.)	-13.6	-26.1	-9.2	-9.1
% change (pre-f.u.)	-8.5	-13.3	-3.1	+35.7

	Cognitive	Behavioural	Cogn-Beh.	Placebo
CRQ				
Active-Cognitive Coping				
pre	4.3	5.3	5.2	3.7
post	4.1	5.4	4.9	4.9
follow-up	3.9	4.7	5.1	3.2
% change (post-f.u.)	-4.9	-25.9	+4.1	-34.7
% change (pre-f.u.)	-9.3	-11.3	-1.9	-13.5
Active-Behavioural Coping				
pre	4.7	2.9	5.1	2.9
post	5.5	4.2	4.9	3.8
follow-up	5.4	4.1	3.9	3.6
% change (post-f.u.)	-1.8	-2.4	-20.4	-5.3
% change (pre-f.u.)	+14.9	+41.4	-23.5	-24.1
Avoidance coping				
pre	3.7	2.3	3.6	5.5
post	3.6	3.7	3.3	7.2
follow-up	2.5	2.6	2.3	5.1
% change (post-f.u.)	-30.6	-29.7	-30.3	-29.2
% change (pre-f.u.)	-32.4	+13.0	-36.1	-7.3

Table 40 presents evidence of generally decreased variability in scores at the follow-up compared with both pre- and post-therapy scores although the pattern is, by no means, uniform. In particular the Cognitive component of the FSAQ shows increases in variability at follow-up as compared with pre-therapy for all conditions, although decreased variability in the active treatment conditions when follow-up is compared with post-thrapy.

As with previous descriptive analysis of SD scores, further analyses will bedeferred until later.

3). GENERALISATION EFFECTS AND GLOBAL RATINGS

In this section, attention will be directed to:

a) Global anxiety ratings made by the patient and, independently, by the patient's spouse/relative.

b) Global rating of 'coping (Patient only).

c) Retrospective judgements concerning the credibility and expectation factors associated with Stress Control and contrast to pre-treatment judgements.

d) Compare the number of consultations with patients' G.P. 6 months prior to and six months following Stress Control.

e) For those patients using benzodiazepines, compare prescription numbers over the same time period.

a) Global ratings of anxiety.

Table 41 presents mean and SD values of global ratings of anxiety (SCQ 1 and 6), at pre- and post-therapy and follow-up, percentage change in post to follow-up values and in pre to follow-up values across treatment conditions.

TABLE 41. Comparison across treatment conditions of mean and SD values pre- and post-therapy and follow-up and percentage change scores for post to follow-up values and for pre to follow-up values for patients and spouse global ratings of anxiety. (SCQ1 and 6 : + = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
PATIENT (Mean)				
pre	7.9	7.6	7.2	8.4
post	4.8	5.1	4.7	6.0
follow-up	4.6	5.2	4.2	6.0
% change (post-f.u.)	-4.2	+1.9	-10.6	0
% change (pre-f.u.)	-41.8	-31.6	-41.7	-28.6
PATIENT (SD)				
pre	2.2	1.9	2.1	2.3
post	1.6	1.8	1.8	2.5
follow-up	1.8	1.7	1.8	2.7
% change (post-f.u.)	+12.5	-5.6	0	+8.0
% change (pre-f.u.)	-18.2	-10.5	-14.3	+17.4
SPOUSE (Mean)				
pre	7.3	8.5	9.1	9.6
post	5.4	5.7	4.7	6.9
follow-up	5.5	6.4	4.9	6.6
% change (post-f.u.)	+1.9	+12.3	+4.3	-4.3
% change (pre-f.u.)	-24.6	-24.7	-46.2	-31.2
SPOUSE (SD)				
pre	3.0	2.2	1.7	2.9
post	1.7	1.5	1.5	2.3
follow-up	2.0	1.5	1.8	2.6
% change (post-f.u.)	+17.6	0	+20.0	+13.0
% change (pre-f.u.)	-33.3	-31.8	+5.9	-10.3

Table 42. T-TEST comparisons (pre-follow-up; post-follow-up), for each of the treatment conditions, of patient and spouse global ratings of anxiety (* p < .05, ** p < .01, *** p < .001, NS = non-significant).

	T	d.f.	Probab.	Signif. level.
PATIENT				
COGNITIVE CONDITION				
post-fu	-0.74	30	.465	NS
pre-fu	7.31	30	.000	***
BEHAVIOURAL CONDITION				
post-fu	0.35	30	.727	NS
pre-fu	6.31	30	.000	***
COGN-BEH. CONDITION				
post-fu	-1.09	25	.287	NS
pre-fu	6.18	25	.000	***
PLACEBO CONDITION				
post-fu	-0.10	9	.923	NS
pre-fu	3.15	9	.012	*
SPOUSE				
COGNITIVE CONDITION				
post-fu	-0.59	30	.561	NS
pre-fu	3.57	30	.001	***
BEHAVIOURAL CONDITION				
post-fu	3.01	30	.005	**
pre-fu	7.05	30	.000	***
COGN-BEH. CONDITION				
post-fu	0.66	25	.514	NS
pre-fu	8.66	25	.000	***
PLACEBO CONDITION				
post-fu	-0.45	9	.661	NS
pre-fu	4.44	9	.002	**

Table 42 produces only one significant difference post-therapy to follow-up where spouse ratings in the Behavioural condition show deterioration in the folow-up period. All conditions show significant change pre-therapy to follow-up for both patient and spouse ratings with highly significant change being associated with the active treatment conditions.

Tables 41 and 42 thus demonstrate, generally, maintenance of improvement. It is interesting to note that spouses continue to rate patients as being more anxious than patients rate themselves. Patients' ratings (on a 12 point scale) suggest that they retain a definite degree of anxiety at follow-up.

b) Global ratings of coping

As before, data from the Coping Questionnaire were collapsed to form a global rating of everyday coping ability. Table 43 presents mean and SD values at pre- and post-therapy and at follow-up, percentage change in post to follow-up values and in pre to follow-up values across treatment conditions.

TABLE 43. Comparison across treatment conditions of mean and SD values pre- and post-therapy and follow-up, and percentage change scores for post to follow-up values and for pre to follow-up values for patient global ratings of 'coping' (Coping Questionnaire : + = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn-Beh.	Placebo
MEAN				
pre	5.2	4.8	4.7	5.3
post	7.2	7.0	7.1	6.8
follow-up	7.8	7.5	7.8	7.4
% change (post-fu)	+8.3	+7.1	+9.9	+8.8
% change (pre-fu)	+50.0	+56.2	+65.9	+39.6
SD				
pre	1.4	1.2	1.3	1.2
post	1.4	1.4	0.9	1.4
follow-up	1.6	1.2	1.0	1.4
% change (post-fu)	+14.3	-14.3	+11.1	0
% change (pre-fu)	+14.3	0	-23.1	+16.7

Table 44 presents PAIRED T-TESTS results for within group change on the above scores.

TABLE 44. T-TEST comparisons (pre-follow-up; post-follow-up), for each of the treatment conditions of global ratings of 'coping' (* p < .01, ** p < .01, *** p < .001, NS = non-significant).

	T	d.f.	Probab.	Signif. level.
COGNITIVE CONDITION				
post-fu	-2.08	30	.050	*
pre-fu	-7.17	30	.000	***
BEHAVIOURAL CONDITION				
post-fu	-1.22	30	.240	NS
pre-fu	-7.16	30	.000	***
COGN-BEH. CONDITION				
post-fu	-2.54	25	.029	*
pre-fu	-8.55	25	.000	***
PLACEBO CONDITION				
post-fu	0.20	9	.855	NS
pre-fu	-8.22	9	.000	***

ONEWAY ANOVA across conditions reveals no significant differences.

As with global ratings of anxiety, there is ample evidence of significant improvement in terms of everyday coping across conditions. Post-therapy to follow-up reveals not only maintenance of improvement during therapy but enhncement of this improvement. Although all treatment conditions improve significantly for pre-therapy to follow-up, the active treatment conditions show a larger degree of improvement than the Placebo condition.

c) Credibility and expectation ratings.

i Credibility ratings.

As noted in Table 5, the three pre-therapy credibility ratings from the SC questionnaire achieved a satisfactory level across treatment conditions. Table 45 compares mean values and SD values of these ratings at pre- and post-therapy and at follow-up across conditions.

TABLE 45. Comparison across treatment conditions of mean scores and SD scores (in parenthesis) of credibility ratings (SCQ 2 - 4).

	Cognitive	Behavioural	Cogn.Behavioural	Placebo
QUESTION 2				
How appropriate is (was) the booklet in explaining stress?				
Pre	10.84 (1.0)	11.06 (1.0)	9.38 (1.7)	10.90 (0.9)
post	10.90 (1.0)	11.50 (0.8)	11.30 (0.8)	11.00 (0.9)
follow-up	10.57 (1.2)	11.19 (0.8)	11.13 (0.8)	10.89 (1.0)
QUESTION 3				
How well does (did) the booklet explain your own problem?				
pre	9.51 (1.9)	10.10 (3.2)	8.58 (3.7)	9.40 (2.5)
post	9.34 (1.8)	9.97 (2.0)	10.30 (1.8)	10.50 (1.4)
follow-up	8.80 (1.9)	10.00 (1.8)	10.32 (1.8)	10.33 (1.3)
QUESTION 4				
How sensible does (did) this treatment seem to you?				
pre	9.58 (1.1)	10.29 (1.4)	9.44 (2.8)	10.30 (1.3)
post	10.41 (1.2)	10.63 (1.4)	10.91 (0.9)	9.70 (2.6)
follow-up	9.97 (1.1)	10.39 (1.2)	10.48 (1.0)	9.44 (1.4)

As there is clear evidence of high levels of credibility on these measures across conditions, no formal statistical tests were applied. Of interest is the initial lower ratings reported by the Cognitive-behavioural condition and the higher ratings reported by this group at post-therapy and follow-up. It should be noted that the Placebo condition's credibility ratings are at the same levels as the active condition at all three data points.

ii. Expectation ratings.

Question 5 in the SC questionnaire "How well do you think this treatment will work for you?" showed the same reasonably high level across conditions at the pre-therapy point. Table 46 contrasts pre-therapy expectation with post-therapy and follow-up

TABLE 46. Comparison across treatment conditions of mean scores and SD scores (in parentheses) of expectation of (pre) and actual, treatment outcome (post and follow-up)

QUESTION 5

How well do you think (did) this treatment work for you?

	Cognitive	Behavioural	Cogn.Behaviural	Placebo
pre	8.30 (2.0)	8.63 (1.3)	7.32 (2.6)	8.80 (2.0)
post	7.52 (2.1)	8.10 (1.8)	8.57 (1.9)	7.70 (2.6)
follow-up	7.91 (2.3	8.50 (1.9)	8.90 (1.6)	6.78 (1.8)

PAIRED T-TESTS revealed two significant differences. The Cognitive-behavioural condition significantly differs, pre-therapy to follow-up [T = 2.41 (d.f.25), Probability = .024] and the Placebo condition significantly differs over the same period [T = 2.71 (d.f. 9) Probability = .024]. ONEWAY ANOVA, using pre-follow-up change scores significantly differentiates the Cognitive-behavioural condition from the other three conditions [F (3,94) = 5.22, P = .002].

The results clearly indicate not only that expectations of therapy were reasonably high across all conditions but also that patients' rating at outcome both at post-treatment and 6 month follow-up appear to correlate highly with pre-treatment expectation ratings for the active therapy groups. It is interesting that patients in the Cognitive-behavioural condition do better than they expect pre-therapy and also that Placebo patients who start with the highest expectations end up with the lowest outcome ratings.

d) G.P. consultations pre- and post-therapy

Table 47 compares mean and SD (in parentheses) number of consultations for the six month periods pre- and post-therapy and percentage change in these values.

TABLE 47. Comparison across treatment conditions of G.P. consultation rates for the six month pre- and post-therapy (+ = increase in score; - = decrease in score).

	Cognitive	Behavioural	Cogn.Behavioural	Placebo
pre-therapy	6.6 (3.5)	4.7 (3.2)	5.2 (3.0)	5.3 (2.6)
post-therapy	3.0 (2.4)	2.5 (2.8)	3.0 (2.2)	3.0 (2.1)
% change	-54.5(-31.4)	-46.8(-12.5)	-42.3(-26.7)	-43.4(-19.2)

Table 48 presents PAIRED T-TEST results for within-group change.

TABLE 48. Comparison across treatment conditions of PAIRED T-TESTS (pre- and post-therapy) of GP consultations. (* p < .0, ** p < .01, *** p < .001).

	T	d.f.	Probab.	Signif. level.
Cognitive Condition	3.94	22	.001	***
Behavioural Condition	3.22	22	.004	**
Cogn.Beh.Condition	4.00	18	.001	***
Placebo Condition	2.56	6	.043	*

ONEWAY ANOVA revealed no differences between conditions. While the Placebo result should be viewed with caution in view of the small number of patients in the above analysis, the overall results show an impressive decrease in consultations across the treatment conditions.

e) Benzodiazepine use pre- and post-therapy.

Patients using benzodiazepine drugs agreed to maintain levels during therapy. Diary booklets recording use of these drugs shows that they did so. On completion of treatment, these patients, with G.P. approval, were given a self-help booklet on tranquilliser withdrawal written by the present author and co-therapist (M.K.) and based on the Stress Control booklet. Table 49 compares men and SD values (the latter in parenthesis) of benzodiazepine prescriptions issued during the six month periods pre- and post-therapy and percentage change in these values. The values relate only to the sub-group of patients using benzodiazepines prior to therapy (see Table 4 for further information).

TABLE 49. Comparison of mean and SD scores (the latter in parenthesis) across treatment conditions of benzodiazepine prescriptions issued during the six month periods pre- and post-therapy and percentage change in these values.

	Cognitive	Behavioural	Cogn-Beh.	Placebo
pre-therapy	4.0 (2.2)	3.3 (2.7)	3.4 (2.5)	3.2 (2.2)
post-therapy	1.3 (1.8)	1.5 (2.5)	1.7 (2.2)	1.3 (1.7)
% change	-67.5(-18.2)	-54.5(-7.4)	-50.0(-12)	-59.4(-22.7)

Table 50 presents PAIRED T-TESTS results for within-group change.

TABLE 50. PAIRED T-TEST comparisons (pre- and post-therapy) of benzodiazepine prescriptions issued for each of the treatment conditions. (* p < .05, ** p < .01, *** p < .001)

	T	d.f.	Probab.	Signif. level.
Cognitive Condition	5.27	17	.000	***
Behavioural Condition	2.87	12	.015	*
Cogn-Beh. Condition	3.09	11	.010	**
Placebo Condition	3.38	5	.020	*

ONEWAY ANOVA revealed no difference across conditions.

As with G.P. consultation rates, all treatment conditions evidence a large degree of change. Although the degree of change associated with the Cognitive condition is of the greatest magnitude, this may simply reflect the higher baseline for this group. Whether the significant differences are due to Stress Control or whether they are due to possible unrelated factors, e.g. changes in G.P. prescribing practice will be discussed later.

4). COMPONENT ANALYSIS

Patients, 9 months to 1 year, after completion of therapy, completed a components questionnaire and were asked to rate how useful each component was on a scale of 1 to 100 where 1 represents "no use at all" and 100 "extremely useful". Of the 12 items on the questionnaire, 9 were general to all conditions and 3 specific to each condition. Table 51 presents mean values for each item across treatment conditions with in parenthisis, the ranking with (1) representing highest rating. Items 10-12 represent the specific items and, thus, all 4 versions are reproduced.

TABLE 51/

TABLE 51. Comparison across treatment conditions of mean ratings on general (1-9) and specific (10-12) items of components questionnaire with rankings in parentheses. (C = Cognitive, C-B = Cognitive-behavioural, B = Behavioural, Pl = Placebo).

		Cognitive	Behavioural	Cogn-Beh.	Placebo
1.	Hearing the psychologists talk about 'Stress Control'	83.6 (1)	89.9 (1)	84.6 (1)	76.7 (2)
2.	The booklet	81.9 (2)	84.1 (2)	82.3 (3)	82.5 (1)
3.	Being in a group and meeting others with similar problems	69.4 (5)	80.0 (4.5)	70.8 (7)	68.2 (5)
4.	The chance to practise the skills taught during the sessions.	63.7 (8)	59.3 (11)	61.7 (11)	63.2 (7)
5.	Trying out the skills "in real life".	60.4 (11)	65.9 (7)	70.4 (8)	58.2 (9)
6.	Watching the video(s)	47.8 (12)	50.6 (12)	44.2 (12)	47.7 (11)
7.	Learning to control panic.	75.8 (4)	80.0 (4.5)	80.4 (5)	70.8 (3)
8.	Learning to control depression.	63.6 (9)	61.0 (10)	65.8 (9.5)	58.5 (8)
9.	Learning to prevent relapse.	61.5 (10)	63.1 (8)	65.8 (9.5)	46.8 (12)
10.	Learning about 'automatic thoughts' (C)	67.8 (6)			
	Using your relaxation tape (B + C-B)		80.7 (3)	81.3 (4)	
	Learning about the sub-conscious mind (Pl)				51.0 (10)
11.	Using positive thinking (C)	76.6 (3)			
	Learning about avoidance and controlling your actions (B + C-B)		72.5 (6)	74.6 (6)	
	Using the generalised anti-anxiety tape (Pl)				64.0 (6)
12.	Learning to break anxiety up into stages (C)	63.8 (7)			
	Learning about, and changing, your body language (B)		62.2 (9)		
	Using positive thinking (C-B)			84.2 (2)	
	Using the specialised anti-anxiety tapes (Pl)				69.0 (4)

The components perceived as being of greatest use, across conditions, appear to be the general components of "Hearing the psychologists talk about Stress Control" and "The booklet". The Cognitive and Cognitive-behavioural conditions rate "Using positive thinking" highly and the Behavioural and Cognitive-behavioural conditions rate "Using your relaxation tape" highly. In addition, all conditions rate "Learning to control panic" as being of use.

In order to test whether patients rated, overall, general components higher than specific components, these items were grouped and compared (General = 1-9 v Specific = 10-12) within each condition and across conditions. Table 52 presents mean and SD values across conditions.

TABLE 52. Comparison across treatment conditions of mean scores and SD scores (in parentheses) of general and specific items of the Components Questionnaire.

	Cognitive	Behavioural	Cogn-Beh.	Placebo
General Items	67.5 (20.3)	70.4 (18.5)	69.6 (13.1)	63.6 (19.9)
Specific Items	69.4 (21.2)	71.8 (20.5)	80.0 (13.5)	61.3 (26.7)

PAIRED T-TESTS within conditions produced one significant result. The Cognitive-behavioural condition rated specific items more highly than general items [T = 2.91 (d.f.11) Probab. = .014]. ONEWAY ANOVAs across conditions produced no significant differences.

Although,in general, there is little difference between general and specific items when combined, it is striking that patients in all conditions should confer such high ratings to individual general items. The fact that these "non-specific" factors are rated highly may help when we attempt to explain the overall improvements made by patients across conditions. In essence, it may that non-specific factors are of considerable importance in the production of the significant change identified so far.

* * * * * * *

Having now completed the main analyses of all measures to follow-up, there is now considerable support for the benifits of Stress Control both during therapy and in the six months follow-up period. There is an accumulating amount of information to allow us to put together a picture of the process and nature of change. However, the nature of the raw data has revealed a distinct variability in outcome measures (as noted in SD scores). Thus the global analyses reported may not be capable of yielding a comprehensive picture of the effects of Stress Control. For this reason, the following chapters will attempt to discern possible explanations to account for the variability.

PART 3

WITHIN GROUP ANALYSES

CHAPTER 14

THE EFFECT OF THE PRESENCE OF PANIC ON TREATMENT OUTCOME

INTRODUCTION

The preceding chapters suggest that, generally, Stress Control is an effective treatment for GAD. While trends favour the Cognitive and Behavioural conditions, all treatments appear to have a clear impact on anxiety reduction. However attention has been drawn to the variability which exists both before and after therapy. This suggests that a more complex picture may underlie the generally positive results. This section will look in greater detail both within and between conditions to obtain a better picture of the effects of the treatments. In particular, attention will focus on :

1) The effect of the presence of panic on treatment outcome.

2) Consonant vs non-consonant treatment.

3) Syncronous vs desynchronous change and their relationship to treatment outcome.

4) Clinical vs statistical significance.

5) Predicting response to Stress Control.

6) A comparison of treatment responders and non-responders.

THE EFFECT OF THE PRESENCE OF PANIC ON TREATMENT OUTCOME.

1. INTRODUCTION

As noted in Chapter 1, due to alterations introduced in DSM-III-R, the diagnosis of GAD now allows for the presence of panic. No studies have as yet looked at the effect of the presence of panic on treatment outcome. Due to the considerable current interest in GAD and PD, it may be of use to consider if GAD patients who experience panic, although not at a frequency or severity to warrant a diagnosis of PD, differ from those GAD patients who do not experience panic. Henceforth these two groups will be referred to as GAD (panic) and GAD (no panic) respectively.

a). Baseline Measures.

All patients in the four treatment conditions were allocated to either the GAD (panic) or GAD (no panic) group based on information obtained during the individual assessment interview using ADIS-R. T-TESTS were conducted, analysing all demographic and clinical baseline data. Twenty-nine variables were subjected to the tests. Only one variable - AGE - showed a significant difference between groups [T = 2.35 (d.f. 106) Probability = .020], GAD (panic) patients having a mean age of 36 while GAD (no panic) have a mean age of 41.

b). Effect of panic within active treatment conditions.

In order to determine whether any interesting interactions exist between the presence of panic and treatment type, the data were not collapsed. Instead patients within the three active treatment conditions were allocated to either GAD (panic) or GAD (no panic). Thus six conditions were created. Numbers in each condition were as follows:

1). Cognitive therapy (panic) n = 15

2). Cognitive therapy (no panic) n = 16

3). Behaviour therapy (panic) n = 13

4). Behaviour therapy (no panic) n = 18

5). Cognitive-behavioural therapy (panic) n = 10

6). Cognitive-behavioural therapy (no panic) n = 16

Due to the small number of patients in the Placebo condition sub-groups (4 (panic) and 6 (no panic)), it was decided to exclude this group from all subsequent analysis.

TWO-WAY ANOVA was conducted (with treatment type and panic as factors), this time across the conditions using the same demographic and clinical baseline variables. No significant results emerged.
It was decided to initially study the main measures in detail by means of the descriptive and statistical analyses previously employed. No hypotheses are forwarded.

2. DESCRIPTIVE STATISTICS.

In order to provide a preliminary examination of the data, Table 53 presents mean values, SD values (in parentheses) and percentage changes in these values for all main measures at pre- and post-therapy and at follow-up across conditions. In contrast to the results presented in Chapter results here combine pre-, post- and post-follow-up data in the interests of simplification as this is an exploratory analysis.

TABLE 53. Comparisons across the three active treatment conditions (sub-divided into panic and no panic groups) of mean scores and SD scores (in parentheses) at pre- and post-therapy and at follow-up along with percentage change scores (pre-post; pre-fu) for each of the mean measures (+ = increase in score, - = decrease in score).

	Cognitive		Behavioural		Cogn-Beh.	
	Panic	No Panic	Panic	No Panic	Panic	No Panic
STAI:A-State						
pre	54.3 (13.2)	56.6 (10.2)	55.5 (12.1)	57.1 (13)	51 (15)	49.6 (11.7)
post	41.5 (11.8)	39.8 (12.2)	43.7 (15.7)	38.5 (10.9)	48.4 (11)	37.4 (11.1)
follow-up	37.8 (10.3)	36.8 (11.3)	37.5 (9.1)	32.7 (6.6)	36.1 (10.5)	36.2 (11.7)
% change (pre-post)	-24 (-11)	-30 (+20)	-21 (+30)	-33 (-16)	-5 (-27)	-25 (-5)
% change (pre-fu)	-30 (-22)	-35 (+11)	-32 (-25)	-43 (-49)	-30 (-30)	-27 (0)
STAI:A-Trait						
pre	56.6 (9)	59.5 (9)	58.5 (12.3)	60.3 (9.8)	56.5 (10.3)	53.7 (11.5)
post	48.5 (8.6)	48.9 (13.2)	56.8 (11.7)	48.2 (12.6)	54.1 (9.7)	44.7 (12.6)
follow-up	46 (8.7)	44.7 (13.6)	48 (9)	43.4 (9.4)	45.1 (10.1)	45 (11.3)
% change (pre-post)	-14 (-4)	-18 (+47)	-3 (5)	-20 (+29)		
% change (pre-fu)	-19 (-3)	-25 (+51)	-18 (-27)	-28 (-4)	-20 (-2)	-16 (-2)
DAS						
pre	100.3 (23.8)	98.1 (19.1)	101.7 (17.5)	97.6 (26.9)	93.9 (21.7)	96.9 (21.2)
post	113.6 (24)	110.9 (26.1)	109.2 (24.6)	108.5 (23.1)	102.5 (21.6)	103.9 (24.4)
follow-up	115.1 (25.3)	120.5 (26.9)	110.1 (21.8)	118.6 (17.2)	115.4 (26.2)	101.4 (21.9)
% change (pre-post)	+13 (+1)	+3 (+37)	+7 (+41)	+11 (-14)	+9 (-1)	+7 (+15)
% change (pre-fu)	+15 (+6)	+23 (+41)	+8 (+25)	+22 (-36)	+23 (+21)	+5 (+3)
FSS						
pre	94.3 (39.5)	113.7 (51.1)	101.8 (44.3)	109.9 (40.5)	127.8 (46.7)	91.7 (43.9)
post	63.7 (39.7)	88.9 (48.8)	78.6 (47.3)	69.4 (34.9)	105.1 (49.6)	66.3 (40.6)
follow-up	67.5 (37.1)	75.4 (46)	75.5 (43.8)	64.1 (35.1)	87.4 (34.9)	74.5 (38)
% change (pre-post)	-32 (+1)	-22 (-5)	-23 (+7)	-37 (-14)	-18 (+6)	-28 (-8)
% change (pre-fu)	-28 (-6)	-34 (-10)	-26 (-1)	-42 (-13)	-32 (-25)	-19 (-13)
BDI						
pre	14.7 (7.8)	22.1 (7.4)	19.3 (10)	20.5 (9.1)	17.8 (9.2)	16.6 (11.2)
post	9.3 (6.7)	12 (5.4)	12.7 (8.5)	10.5 (6.3)	14.5 (11.2)	9.4 (8.6)
follow-up	7.4 (7.3)	8.3 (7.4)	8.9 (6.2)	8.3 (4.8)	9.6 (11.1)	10.3 (7.9)
% change (pre-post)	-37 (-14)	-46 (-27)	-34 (-15)	-49 (-31)	-18 (+22)	+43 (-23)
% change (pre-fu)	-50 (-6)	-62 (0)	-54 (-38)	-60 (-47)	-46 (+21)	-38 (-29)

	Cognitive		Behavioural		Cogn-Beh.	
	Panic	No Panic	Panic	No Panic	Panic	No Panic
MSPQ						
pre	35.6 (16.7)	33.1 (10.8)	36.4 (14.3)	32.9 (13.3)	31.7 (17.4)	27.7 (9)
post	20.6 (9.6)	25.9 (12.7)	27.9 (13.9)	20.8 (13.6)	29.2 (17.7)	17.4 (11.9)
follow-up	19.7 (14.3)	18.4 (12.5)	18.1 (10.3)	13.2 (6.3)	13.7 (8.2)	11.9 (8.3)
% change (pre-post)	-42 (-43)	-22 (+18)	-23 (-3)	-37 (+2)	-8 (+2)	-37 (+32)
% change (pre-fu)	-45 (-14)	-45 (+16)	-50 (-28)	-60 (-53)	-57 (-53)	-57 (-8)

Table 53 shows considerable improvement across conditions on all of the main variables with the partial exception of DAS when the Behavioural (panic) and Cognitive-behavioural (no panic) groups show only slight improvement. There is no concomitant consistency in SD changes either within or across conditions.

Considering the changes at post-therapy, two contradictory trends emerge. On DAS, FSS and MSPQ, the Cognitive (panic) condition shows greater improvement than the Cognitive (no panic) condition while the Behavioural and Cognitive-behavioural (no panic) conditions either show greater or equal improvement to their respective (panic) conditions. However, on STAI:A-State , A-Trait and BDI the emerging picture is one of the no panic groups consistently showing greater improvement than the panic groups across conditions.

At follow-up, these trends disappear and are replaced with a fairly consistent picture of the Cognitive and Behavioural (no panic) conditions showing a trend to greater improvement than their panic counterparts. In the Cognitive-behavioural condition, however, the panic group either shows a better or equal performance as compared to the no panic group.

3. STATISTICAL ANALYSIS

As in the previous chapters, the statistical analysis will firstly look at pre-post change and then at change during the follow-up period.

a). Pre-Post Main Effects.

Table 54 presents the results of MANOVAs for the meain measures.

TABLE 54. Repeated measures analysis of main measures across the active treatment conditions (sub-divided into panic and no panic) using MANOVA during pre-post therapy (* p < .05; ** p < .01; *** p < .001; NS = non-significant).

SOURCE OF VARIATION	Pillai	Hyp.D.F.	Error D.F.	F ratio	F probab.	Signif. level.
STAI:A-State						
Group		5		1.43	.222	NS
Time	.498	2	80	39.77	.000	***
Group x Time	.239	10	162	2.19	.020	*
STAI:A-Trait						
Group		5		1.65	.155	NS
Time	.369	2	80	23.37	.000	***
Group x Time	.163	10	162	1.44	.167	NS
DAS						
Group		5		0.30	.911	NS
Time	.403	2	80	27.00	.000	***
Group x Time	.045	10	162	0.38	.955	NS
FSS						
Group		5		1.18	.324	NS
Time	.592	2	80	58.82	.000	***
Group x Time	.098	10	162	0.85	.585	NS
BDI						
Group		5		2.14	.068	NS
Time	.526	2	80	44.99	.000	***
Group x Time	.165	10	162	1.48	.151	NS
MSPQ						
Group		5		1.24	.297	NS
Time	.385	2	80	25.38	.000	***
Group x Time	.147	10	162	1.30	.235	NS

As expected, highly significant time main effects are apparent for all of the main variables. No group main effect exists for any variable while only one group x time significant effect is to be found on STAI:A-State where, at post-therapy, the Behavioural (no panic) group are significantly

different compared to the Cognitive-behavioural (panic) group. (F = 2.34, D.f (5,81), F probab. .048). This difference, however, disappears at follow-up. Further treatment within time analyses will not be pursued. However, in light of the significant time main effects, the simple effects of time within treatment group will now be considered.

b). Pre-Post Time within Treatment Group Sub-effects.

Table 55 provides information, separately for each of the six conditions and illustrates the magnitude of effect of treatment upon each of the main measures.

TABLE 56. Time within Treatment Group simple effects and sub-effects at mid- and post-therapy presented separately for each of the six conditions (panic and no panic). (* p < .05; ** p < .01; *** p < .001; NS = non-significant.)

TREATMENT VARIABLE	Pillai	F probab.	Mid-therapy	Post-therapy
COGNITIVE (panic)				
STAI:A-State	.244	8.488	*	***
STAI:A-Trait	.187	6.064	NS	**
DAS	.222	7.530	NS	***
FSS	.256	9.157	NS	***
BDI	.176	5.710	NS	**
MSPQ	.326	12.917	NS	***
COGNITIVE (no panic)				
STAI:A-State	.361	14.913	*	***
STAI:A-Trait	.325	12.687	NS	***
DAS	.278	10.144	NS	***
FSS	.240	8.444	NS	***
BDI	.386	16.777	**	***
MSPQ	.223	7.658	NS	**
BEHAVIOUR (panic)				
STAI:A-State	.254	8.978	***	***
STAI:A-Trait	.176	5.628	NS	NS
DAS	.076	2.172	NS	NS
FSS	.149	4.678	NS	**
BDI	.208	7.017	*	***
MSPQ	.284	10.593	NS	**
BEHAVIOUR (no panic)				
STAI:A-State	.478	24.091	*	***
STAI:A-Trait	.384	16.392	*	***
DAS	.286	10.544	NS	**
FSS	.373	15.882	**	***
BDI	.383	16.555	*	***
MSPQ	.367	15.489	NS	***

TREATMENT VARIABLE	Pillai	F probab	Mid-therapy	Post-therapy.
COGN-BEH. (panic)				
STAI:A-State	.192	6.278	NS	NS
STAI:A-Trait	.166	5.229	NS	NS
DAS	.204	6.751	NS	NS
FSS	.201	6.723	NS	**
BDI	.175	5.664	NS	NS
MSPQ	.237	8.293	NS	NS
COGN-BEH. (no panic)				
STAI:A-State	.188	6.110	*	***
STAI:A-Trait	.142	4.374	NS	**
DAS	.067	1.882	NS	*
FSS	.163	5.205	NS	***
BDI	.186	6.087	NS	***
MSPQ	.150	4.702	NS	NS

Table 56 clearly demonstrates marked improvement across all six conditions. There appears to be little difference between the panic and no panic groups within the Cognitive condition, both groups showing a large degree of change by post-therapy. Within the Behavioural condition, the no panic groups shows significant change on all variables. Although significant change is associated with the panic group on most variables, this change is not produced on those variables measuring more stable factors i.e. A-Trait and DAS. This discrepancy within an active treatment condition is very clearly illustrated in the Cognitive-behavioural condition. While the no panic group show significant change on all variables except for the MSPQ, the panic group show significant change only on the FSS measure.

c). Follow-up.

Paired T-TESTS were conducted on post-therapy and follow-up measures within each conditionf or each of the main measures. Table 57 presents the results of the t-tests.

TABLE 57. T-TEST comparisons (post-therapy - follow-up) of the main measures for each of the active treatment conditions (panic and no panic). (* p < .05; ** p < .01; *** p < .001; NS = non-significant.)

TREATMENT VARIABLE	T.	D.F.	Probability	Signif. level.
COGNITIVE (panic)				
STAI:A-State	1.26	14	.227	NS
STAI:A-Trait	1.78	14	.097	NS
DAS	0.90	14	.384	NS
FSS	0.51	14	.618	NS
BDI	2.00	14	.066	NS
MSPQ	0.26	14	.797	NS
COGNITIVE (no panic)				
STAI:A-State	1.49	15	.158	NS
STAI-A:Trait	1.57	15	.140	NS
DAS	2.32	15	.036	*
FSS	1.15	15	.269	NS
BDI	2.87	15	.012	*
MSPQ	1.71	15	.109	NS
BEHAVIOURAL (panic)				
STAI:A-State	1.76	12	.104	NS
STAI:A-Trait	3.05	12	.010	**
DAS	0.67	12	.517	NS
FSS	0.93	12	.317	NS
BDI	2.43	12	.032	*
MSPQ	3.53	12	.004	**

TREATMENT VARIABLE	T.	D.F.	Probability	Signif. level.
BEHAVIOURAL (no panic)				
STAI:A-State	1.92	17	.071	NS
STAI:A-Trait	1.79	17	.091	NS
DAS	2.31	17	.033	*
FSS	0.34	17	.737	NS
BDI	1.86	17	.080	NS
MSPQ	2.24	17	.039	*
COGN-BEH. (panic)				
STAI:A-State	3.09	9	.013	*
STAI:A-Trait	3.62	9	.006	**
DAS	4.80	9	.001	***
FSS	1.73	9	.117	NS
BDI	1.89	9	.092	NS
MSPQ	4.44	9	.002	**
COGN-BEH. (no panic)				
STAI:A-State	0.84	15	.413	NS
STAI:A-Trait	0.13	15	.897	NS
DAS	0.36	15	.722	NS
FSS	1.34	15	.202	NS
BDI	0.11	15	.916	NS
MSPQ	1.89	15	.079	NS

Having examined the within subject effects, between subjects effects were analysed using TWO-WAY ANOVAs conducted on change scores from post-therapy to follow-up. No significant results emerged.

Table 57 suggests little significant change in the follow-up period. The exception to this is the Cognitive-behavioural (panic) group which produces significant change on four of the six variables. It is interesting to note that this group showed least change from pre- to post-therapy so that, in some ways, the post to follow-up change allows the group to "catch up" on the other groups.

d). Conclusions.

In general, the results of dividing the active treatment conditions into panic and no panic sub-groups does not seem to help explain the variability detected earlier. Similarly, the results do not suggest that the presence of panic significantly alters treatment outcome across conditions one way or another although examination of the descriptive statistics associated with the Cognitive and Behavioural conditions does suggest one interesting finding. With the exception of the BDI, the difference between percentage change scores (pre-therapy to follow-up) between the panic and no panic sub-groups in the Behavioural condition is generally twice as great as those in the Cognitive condition. Thus, it could be very tentatively suggested that some form of cognitive explanation/therapy may be of value where panic is present. This possibility should be cautiously assessed however as the clinical utility, as previously noted, of dividing GAD patients into those who experience panic and those who do not appears to be limited.

CHAPTER 15

CONSONANT VERSUS NON-CONSONANT TREATMENT

CONSONANT vs NON-CONSONANT TREATMENT.

1. INTRODUCTION

Although there is only weak support for the hypothesis that maximum treatment effectiveness will occur when patients are treated with a technique that matches the most prominent system of reactions (see Chapter for review of literature), no studies have yet looked at 'tailored' therapies for GAD. It is therefore apropriate to do so now.

Deciding on criteria for what constitutes a e.g. 'cognitive responder' is arbitrary. As no other study of GAD patients is available and as the measures used in the present study are restricted to self-reports, the FSAQ was selected. As this questionnaire contains the four sub-scales of cognitive, behavioural, somatic and mood, patients can be selected on the basis of their sub-scale scores.

Before deciding on criteria, mean scores at baseline on the FASQ sub-scales were calculated for the four treatment groups combined. These are as follows:

Cognitive scale	:	59.9
Behaviour scale	:	46.9
Somatic scale	:	46.2
Mood scale	:	57.1

The discrepancy between mean scores on the four scales will be taken into account in defining the criteria.

Looking at the raw data reveals that, where a discrepancy exists between baseline FSAQ sub-scale scores, the vast majority show increased cognitive scale scores compared to the other three. It was thus

decided that only a cognitive-responder condition could be extracted. It will be compared to a generic non-cognitive responder condition. It was also decided that the main distinction should exist between cognitive and somatic sub-scales as these appear to be of greater importance in non-phobic anxiety states than the behavioural scale. The criteria are as follows:

A patient can be classified as a cognitive responder if:

1). The cognitive scale is higher than any of the three other scales and

2). The cognitive score is at least 50% higher than the somatic score.

A patient can be classified as a non-cognitive responder if:

1). Any of the other scales is higher than the cognitive score.

These criteria now led to the creation of six conditions. (Due to the small numbers involved, the Placebo condition is excluded from these analyses):

Cognitive therapy	(1) cognitive responders	(n = 10)
	(2) non-cognitive responders	(n = 14)
Behaviour therapy	(3) cognitive responders	(n = 11)
	(4) non-cognitive responders	(n = 11)
Cogn.-beh. therapy	(5) cognitive responders	(n = 8)
	(6) non-cognitive responders	(n = 8)

Within the non-cognitive responder conditions, the highest scales were as follows:

1) **Cognitive therapy** : Somatic = 8, Mood = 6.

Behaviour therapy : Somatic = 6, Mood = 3, Behaviour = 2.

Cogn-beh. therapy : Somatic = 3, Mood = 4, Behaviour = 1.

Three separate analyses will be carried out:

1. **An initial comparison of cognitive vs all non-cognitive responders** by conducting T-TESTS or TWO-WAY ANOVAs on baseline variables.
2. Comparison of cognitive and non-cognitive responders within the cognitive-therapy condition.
3. Comparison of the cognitive responders and non-cognitive responders across the three active treatment conditions.

****

2). <u>BASELINE MEASURES</u>.

Cognitive and non-cognitive responders were collapsed across conditions. T-Tests were applied on all demographic and clinical baseline measures. Twenty-nine variables were subjected to the tests. Five variables show a significant difference:

1). FSAQ : Cognitive scale [T = 3.56 (d.f. 62), P < .000]

Cognitive > Non-cognitive.

2). FSAQ : Somatic scale [T = 4.35 (d.f. 62), P < .000]

Non-cognitive > Cognitive.

3). CRQ : Active cognitive coping [T = 3.18 (d.f. 62), P < .001]

Cognitive > Non-cognitive.

4). CRQ : Active behavioural coping [T = 4.34 (d.f. 62), P < .000]

Cognitive > Non-cognitive.

5). STAI:A-Trait : [T = 2.08 (d.f. 62), P < .05]

Cognitive > Non-cognitive.

The first two measures differ due to the selection process. The third measure is probably indirectly related to this. The other measures may simply be due to chance although, given the cognitively orientated nature of the questions, the A-Trait difference again may be an indirect result of the selection criteria

Therefore, in general, no demographic and few clinical variables differentiate the groups. Both groups appear to experience anxiety to the same degree if not in the same patterning.

A similar set of T-TESTS were conducted upon baseline variables comparing the cognitive- and non-cognitive - responders within the Cognitive therapy condition - as expected similar differences emerged on the FSAQ Cognitive and Somatic scales and the CRQ scale.

TWO-WAY ANOVAs were carried out on baseline variables comparing cognitive- and non-cognitive-responders within the three active treatment conditions. Significant effects were found between cognitive- and non-cognitive-responders on the FSAQ Cognitive and Somatic scales.

3). <u>COMPARISON OF THE COGNITIVE- AND NON-COGNITIVE RESPONDERS WITHIN THE COGNITIVE THERAPY CONDITION.</u>

As this is an exploratory investigation, no h ypotheses are forwarded and, as in the case of the analyses concerned with investigating the role of the presence of panic, only the main measures will, at this stage, be assessed.

a) Descriptive Statistics

Table 58 presents mean values, SD values (in parentheses) and percentage change in these values at pre-therapy, post-therapy and follow-up across the two groups.

TABLE 58. Comparison of the cognitive- and non-cognitive responders within the Cognitive therapy condition of mean scores and SD scores (in parentheses) at pre-therapy, post-therapy and follow-up along with percentage change scores (pre-post; pre-fu) for each of the mean measures (+ = increase in score, - = decrease in score).

	COGNITIVE THERAPY.			
	Cognitive Responders		Non-Cognitive Responders.	
STAI:A-State				
pre	62.2	(13.3)	50.3	(9.3)
post	39.3	(13.7)	43.6	(11.6)
follow-up	33.3	(9.5)	38.6	(10.6)
% change (pre-post)	-36.8	(+3)	-13.3	(+12.7)
% change (pre-fu)	-46.5	(-28.6)	-23.2	(+13.9)
STAI:A-Trait				
pre	60.3	(9.6)	55.8	(10)
post	48.4	(12.9)	50.5	(7.8)
follow-up	46	(12.4)	45.6	(6.2)
% change (pre-post)	-19.7	(+13.4)	-9.5	(-22)
% change (pre-fu)	-23.7	(+29.2)	-18.3	(-38)
DAS				
pre	92.1	(19.3)	105	(21.9)
post	102.3	(24.8)	112.9	(23)
follow-up	109.1	(24.9)	122.5	(19.9)
% change (pre-post)	+11.1	(+28.5)	+7.5	(+5)
% change (pre-fu)	+18.5	(+29)	+16.7	(-9.1)
FSS				
pre	120.5	(26.9)	99.9	(58.2)
post	89.1	(32.3)	77.8	(54.2)
follow-up	98.6	(49.7)	62.5	(29.6)
% change (pre-post)	-26	(+20)	-22.1	(-6.9)
% change (pre-fu)	-18.2	(+84.8)	-37.4	(-49.1)

	COGNITIVE THERAPY			
	Cognitive Responders		Non-Cognitive Responders	
BDI				
pre	21.5	(5.2)	15.3	(8.3)
post	11.3	(5.4)	10.8	(5.8)
follow-up	8.9	(7.8)	6	(4.7)
% change (pre-post)	-47.4	(+3.8)	-29.4	(-30.1)
% change (pre-fu)	-58.6	(+50)	-60.8	(-43.4)
MSPQ				
pre	28.1	(12.3)	34.6	(11.9)
post	17.8	(6.6)	27.5	(12.7)
follow-up	19.0	(10.6)	17	(8.9)
% change pre-post	-36.6	(-46.3)	-20.5	(+6.7)
% change (pre-fu)	-32.4	(-13.8)	-50.9	(-25.2)

In the previous section, evidence was presented showing that cognitive- and non-cognitive responders, although having anxiety to the same degree, experience that anxiety in different ways. Further evidence for this is contained in Table 58 where the cognitive responders, at baseline, experience greater levels of stress as measured by cognitively orientated questionnaires - the STAI scales, DAS and BDI while the non-cognitive responders experience higher levels of somatic anxiety as measured by the MSPQ. The behavioural measure (the FSS) shows greater dysfunction in the cognitive-responder group.

Table 58 also shows the cognitive responders outperforming the non-cognitive responders on all variables at post-therapy. In particular the two STAI scales, the BDI and the MSPQ show the greatest discripancy. Although the non-cognitive responders may be showing a floor effect on the STAI: A-State, the same finding cannot be used to explain the difference on the MSPQ.

However, at follow-up these differences, with the exception of the STAI-A-State, mainly disappear. Indeed a reversal of fortunes is found on the FSS and MSPQ where the cognitive responders suffer slight set-backs while the non-cognitive responders substantially accelerate progress. It is of interest that the same pattern is not found on the more cognitively orentated questionnaires.

b). Statistical Analysis.

As in the previous chapter, the statistical analysis will initially look at pre-post change and then at change during the follow-up period.

i. Main effects.

Table 59 presents the results of MANOVAs for the main measures.

TABLE 59./

TABLE 59. Repeated measures analysis of main measures across the cognitive-and non-cognitive responder groups within the Cognitive therapy condition using MANOVA during pre- post-therapy (* p < .05; ** p < .01; *** p < .001; NS = non-significant).

Source of Variation.	Pillai	Hyp.D.F.	Error D.F.	F ratio	F probab.	Signif. level.
STAI:A-State						
Group		1		0.19	.662	NS
Time	.716	2	21	26.43	.000	***
Group x Time	.359	2	21	5.88	.009	**
STAI:A-Trait						
Group		1		0.01	.935	NS
Time	.457	2	21	8.87	.002	**
Group x Time	.145	2	21	1.77	.194	NS
DAS						
Group		1		2.36	.139	NS
Time	.271	2	21	3.92	.036	*
Group x Time	.017	2	21	0.18	.838	NS
FSS						
Group		1		1.51	.233	NS
Time	.632	2	21	18.09	.000	***
Group x Time	.190	2	21	2.47	.109	NS
BDI						
Group		1		1.36	.255	NS
Time	.342	2	21	5.47	.012	*
Group x Time	.107	2	21	1.25	.306	NS
MSPQ						
Group		1		3.57	.072	NS
Time	.671	2	21	21.38	.000	***
Group x Time	.184	2	21	2.36	.119	NS

Significant time main effects are apparent for all of the variables but with the exception of STAI:A-State no group x time effect nor group main effect achieves significance. The cognitive responders show significant improvement compared to the non-cognitive responders on the STAI:A-State

both at mid-therapy [T = 2.4 (d.f. 22), P < 0.05] and at post-therapy [T = 3.22 (d.f. 22)), P < 0.01]. Further treatment within time analyses will not be pursued.

ii. Time within treatment group sub-effects.

Table 60 provides information, separately for the cognitive- and non-cognitive responders within the cognitive therapy condition and illustrates the magnitude of effect upon each of the main measures.

TABLE 60./

TABLE 60. Time within Treatment Group simple effects and sub-effects at mid- and post-therapy presented separately for the cognitive- and non-cognitive responders within the Cognitive Therapy condition (* p < .05; ** p < .01; *** p < .001; NS = non-significant.)

TREATMENT VARIABLE	Pillai	F probab.	Mid-therapy	Post-therapy.
COGNITIVE RESPONDERS				
STAI:A-State	.699	24.353	***	***
STAI:A-Trait	.429	7.881	NS	***
DAS	.181	2.319	NS	NS
FSS	.558	13.266	NS	***
BDI	.325	5.048	NS	**
MSPQ	.597	15.543	NS	***
NON-COGNITIVE RESPONDERS				
STAI:A-State	.308	4.672	NS	**
STAI:A-Trait	.142	1.734	NS	NS
DAS	.137	1.667	NS	NS
FSS	.368	6.108	NS	**
BDI	.087	0.996	NS	NS
MSPQ	.391	6.729	NS	**

Table 60 appears to confirm the impression gained from the descriptive statistics. There is a clear trend favouring greater improvement at post-therapy in the cognitive responder group. Before assessing the clinical significance of this finding, follow-up scores will be considered.

iii. Follow-up.

Table 61 presents the results of PAIRED T-TESTS conducted on post-therapy and follow-up scores.

TABLE 61. T-TEST comparisons (post-therapy - follow-up) of the main measures for the cognitive- and non-cognitive responders within the Cognitive therapy condition (* p < .05; ** p < .01; *** p < .001; NS = non-significant.)

TREATMENT VARIABLE	T	d.f.	Probability	Signif. level.
COGNITIVE RESPONDERS				
STAI:A-State	1.58	9	.148	NS
STAI:A-Trait	0.71	9	.495	NS
DAS	-1.23	9	.250	NS
FSS	-1.29	9	.231	NS
BDI	1.72	9	.120	NS
MSPQ	-0.45	9	.661	NS
NON-COGNITIVE RESPONDERS				
STAI:A-State	2.42	13	.031	*
STAI:A-Trait	3.03	13	.010	**
DAS	-3.79	13	.002	**
FSS	1.25	13	.233	NS
BDI	4.65	13	.000	***
MSPQ	3.56	13	.003	**

T-TESTS demonstrate no between group differences at follow-up.

****

Having noted, by reviewing the descriptive statistics, that the cognitive responders appear to improve to a greater degree than the non-cognitive responders during therapy, statistical analyses also elicited a clear trend in this direction. Thus we can suggest that over the course of therapy, matching cognitively responding patients to a cognitive therapeutic approach appears to enhance treatment effects. However,

why the differences should disappear at follow-up is potentially of great clinical interest.

Before concluding that consonant treatment, at least during the course of therapy, is beneficial, further analyses have to be carried out. In particular, it may be that cognitive responders will out-perform non-cognitive responders on a range of therapies. If so, support for the idea of consonant therapy will be diminished. Thus at this point a comparison will be made of cognitive-responders and non-cognitive responders in the Cognitive, Behavioural and Cognitive-behavioural conditions.

4. COMPARISON OF THE COGNITIVE-AND NON-COGNITIVE RESPONDERS IN THE COGNITIVE, BEHAVIOURAL AND COGNITIVE-BEHAVIOURAL CONDITIONS.

As before, no hypotheses are forwarded in this exploratory investigation only main measures will be assessed.

a) Descriptive Statistics.

Table 62 presents mean values, SD values (in parentheses) and percentage changes in these values at pre-therapy, post-therapy and follow-up across the six conditions.

TABLE 62/

TABLE 62. Comparisons of the Cognitive- and non-cognitive-responders within the three active therapy conditions of mean scores and SD scores (in parentheses) at pre-therapy, post-therapy and follow-up along with percentage change scores (pre-post; pre-fu) for each of the mean measures (+ = increase in score; - = decrease in score).

	COGNITIVE THERAPY				BEHAVIOUR THERAPY				COGN-BEH.THERAPY			
	Cogn.		Non-Cogn.		Cogn.		Non-Cogn.		Cogn.		Non-Cogn.	
STAI:A-State												
pre	62.2	(13.3)	50.3	(9.3)	52.8	(11)	56.2	(13.1)	54.7	(14.7)	46.9	(16.2)
post	39.3	(13.7)	43.6	(11.6)	41.1	(11)	36.7	(14.8)	41.7	(17.7)	39.4	(11.7)
follow-up	33.3	(9.5)	38.6	(10.6)	34.4	(7.8)	33.4	(9)	32.3	(10.6)	35.1	(11.6)
% change (pre-post)	-36.8	(+3)	-13.3	(+24.7)	-22.2	(0)	-34.7	(+13)	-23.8	(+20.4)	-16	(-27.8)
% change (pre-fu)	-46.5	(-28.6)	-23.3	(+13.9)	-34.8	(-29)	-40.6	(-31.3)	-40.9	(-27.9)	-25.2	(-28.4)
STAI:A-Trait												
pre	60.3	(9.6)	55.8	(10)	61	(11.9)	56.8	(11.4)	58.4	(9.7)	47.7	(13.2)
post	48.4	(.12.9)	50.5	(7.8)	54.3	(10.4)	51.9	(15)	49.1	(13.9)	42.7	(12.1)
follow-up	46	(12.4)	45.6	(6.2)	49.7	(8.3)	43	(11.4)	42.8	(9.9)	41.3	(13.5)
% change (pre-post)	-19.7	(+34.4)	- 9.5	(-22)	-11	(-12.6)	- 8.6	(+31.6)	-15.9	(+43.3)	-10.5	(-8.3)
% change (pre-fu)	-23.7	(+29.2)	-18.3	(-38)	-18.5	(-30.2)	-24.3	(0(	-26.7	(+2)	-13.4	(+3.1)
DAS												
pre	92.1	(19.3)	105	(21.9)	105.8	(20.5)	102	(21.8)	91.3	(16.5)	108.1	(25.5)
post	102.3	(24.8)	112.9	(23)	110.4	(22.4)	111.2	(24.8)	99	(16.7)	115.7	(28.6)
follow-up	109.1	(24.9)	122.5	(19.9)	114.5	(20.2)	109.2	(22.5)	107.3	(19.7)	118.1	(29.4)
% change (pre-post)	+11.1	(+28.5)	+ 7.5	(+5)	+ 4.3	(+9.3)	+ 9	(+13.8)	+ 8.4	(+1.2)	+ 7	(+12.2)
% change (pre-fu)	+18.5	(+29)	+16.7	(-9.1)	+ 8.2	(-1.5)	+ 7.1	(+3.2)	+17.5	(+18.6)	+ 9.3	(+15.3)
FSS/												

	COGNITIVE THERAPY				BEHAVIOUR THERAPY				COGN.-BEH.THERAPY			
	Cogn.		Non-Cogn.		Cogn.		Non-Cogn.		Cogn.		Non-Cogn.	
FSS												
pre	120.5	(26.9)	99.9	(58.2)	94.9	(44.6)	121.3	(41.9)	97.9	(42.7)	89.1	(55.8)
post	89.1	(32.3)	77.8	(54.2)	67.5	(31.4)	87.4	(50.6)	76	(38.5)	74.4	(61.6)
follow-up	98.6	(49.7)	62.5	(29.6)	67.2	(35.2)	95.5	(44.2)	79	(32.8)	67.3	(39.9)
% change (pre-post)	-26	(+20)	-22.1	(-6.9)	-28.9	(-29.6)	-27.9	(+20.8)	-22.4	(-9.8)	-16.5	(+10.4)
% change (pre-fu)	-18.2	(+84.8)	-37.4	(-49.1)	-29.2	(-21)	-21.3	(+5.5)	-19.3	(-23.2)	-24.5	(-28.6)
BDI												
pre	21.5	(5.2)	15.3	(8.3)	21.4	(9.8)	18.1	(10.3)	19.3	(11.6)	14	(12.8)
post	11.3	(5.4)	10.8	(5.8)	13.6	(7.3)	9.9	(8.2)	11	(9.2)	9.9	(14.1)
follow-up	8.9	(7.8)	6	(4.7)	10.7	(5.6)	7.9	(5.5)	9.3	(8.4)	10.3	(12.9)
% change (pre-post)	-47.4	(+3.8)	29.4	(-30.1)	-36.4	(-25.5)	-45.3	(-20.4)	-43	(-20.7)	-29.3	(+10.2)
MSPQ												
pre	28.1	(12.3)	34.6	(11.9)	29.4	(13.2)	36.9	(16.4)	26.1	(12)	28	(17.7)
post	17.8	(6.6)	27.5	(12.7)	23.3	(12.1)	26.2	(18)	13.1	(12.1)	27.1	(21.4)
follow-up	19.0	(10.6)	17	(8.9)	15	(8.7)	16.9	(11.5)	8.4	(6.9)	14.8	(9.1)
% change (pre-post)	-36.6	(-46.3)	-20.5	(+6.7)	-20.7	(-8.3)	-29	(+9.8)	-49.8	(+1)	- 3.2	(+21)
% change (pre-fu)	-32.4	(-13.8)	-50.9	(-25.2)	-49	(-34)	-54.2	(-29.9)	-67.8	(-42.5)	-47.1	(-48.6)

Table 62 suggests some interesting possibilities. Again there appears to be no great difference in severity of anxiety as rated by the main measures across the conditions at baseline with the clear exception of the non-cognitive responders in the Cognitive-behavioural condition who, on all measures except the MSPQ, are less dysfunctional. Thus interpretation of the results involving this group should take this into account.

In the main results section, we found few differences between the Cognitive and Behavioural conditions yet in assessing the cognitive responders in both conditions there is a clear trend favouring the cognitive responders in the Cognitive condition on all measures except the FSS at post-therapy and, with the exception of the FSS and MSPQ, at follow-up. Why it should be the measures of behavioural and somatic anxiety which show least change in a condition which does not target these symptoms is of interest and will be discussed elsewhere. The same trend is not found where cognitive responders in the Cognitive and Cognitive-behavioural conditions are compared either at post-therapy or at follow-up.

Comparing cognitive- and non-cognitive responders, an interesting pattern appears to emerge. At post-therapy, the cognitive responders in the Cognitive and Cognitive-behavioural condition out-perform the non-cognitive responders (although the difference in DAS is negligible). At follow-up, the difference, as we saw in the previous section, disappears in the Cognitive condition, but in the Cognitive-behavioural condition, with the exception of the FSS, remains. However, as the

mean scores at this point are roughly equal, the difference is possibly related to floor effects for the non-cognitive responders. In the Behavioural condition an opposite effect is seen. At post-therapy the non-cognitive responders out-perform the cognitive responders on 4 of the 6 variables, while minor differences exist on the other two. At follow-up, the trend, although weaker, remains.

Thus the descriptive analysis seems to be suggesting that the matching of an individual's characteristics and a therapy which targets those characteristics results in enhanced therapeutic effects and that therapies which do not target those characteristcs result in less effective outcome. It is hoped that statistical analysis can clarify these speculations.

b). Statistical Analysis

The statistical analysis will again initially look at pre-post change and then at change during the follow-up period.

i. Main effects.

Table 64 presents the results of MANOVAs for the main measures.

TABLE 64/

TABLE 64. Repeated measures analysis of main measures across the cognitive- and non-cognitive responders within the three active treatment conditions using MANOVA during pre-post-therapy (* p < .05; ** p < .01. *** p < .001; NS = non-significant).

SOURCE OF VARIATION	Pillai	Dyp.D.F.	Error D.F.	F ratio	F Probab	Signif. level.
STAI:A-State						
Group		5		0.21	.956	NS
Time	.600	2	55	41.38	.000	***
Group x Time	.197	10	112	1.23	.282	NS
STAI:A-Trait						
Group		5		1.17	.336	NS
Time	.331	2	55	13.63	.000	***
Group x Time	.131	10	112	0.78	.640	NS
DAS						
Group		5		0.84	.529	NS
Time	.380	2	55	16.87	.000	***
Group x Time	.133	10	112	0.80	.628	NS
FSS						
Group		5		0.83	.537	NS
Time	.613	2	55	43.59	.000	***
Group x Time	.152	10	112	0.92	.518	NS
BDI						
Group		5		0.43	.824	NS
Time	.510	2	55	28.14	.000	***
Group x Time	.323	10	112	2.12	.028	*
MSPQ						
Group		5		2.10	.079	NS
Time	.430	2	55	20.82	.000	***
Group x Time	.234	10	112	1.48	.155	NS

Significant time effects are apparent for all of the variables. No group main effects are significant. Only BDI achieves a significant group x time interaction where, at mid-therapy the non-cognitive responders in the Cognitive-behavioural condition are significantly worse than the other five groups (F (5,56) = 3.189, F prob .013). Further treatment within time analyses will not be pursued.

ii. Time within treatment group sub-effects.

Table 65 provides information, separately for the cognitive- and non-cognitive rsponders in the Cognitive, Behavioural and Cognitive-behavioural conditions.

TABLE 65. Time within Treatment group simple effects and sub-effects at mid- and post-therapy presented separately for the cognitive- and non-cognitive-responders within each of the three active treatment conditions (* p < .05; ** p < .01; *** p < .001; NS = non-significant).

TREATMENT VARIABLE	Pillai	F Probab.	Mid-therapy	Post-therapy
COGNITIVE THERAPY COGNITIVE RESPONDERS				
STAI:A-State	.368	16.048	**	***
STAI:A-Trait	.188	6.362	NS	***
DAS	.140	4.480	NS	*
FSS	.261	9.687	NS	***
BDI	.189	6.288	NS	***
MSPQ	.202	6.982	NS	**
COGNITIVE THERAPY. NON-COGNITIVE RESPONDERS				
STAI:A-State	.114	3.536	NS	**
STAI:A-Trait	.055	1.612	NS	NS
DAS	.109	3.366	NS	*
FSS	.162	5.324	NS	**
BDI	.045	1.261	NS	NS
MSPQ	.094	2.842	NS	*

BEHVIOUR THERAPY/

TREATMENT VARIABLE	Pillai	F Probab.	Mid-therapy	Post-therapy
BEHAVIOUR THERAPY / COGNITIVE RESPONDERS.				
STAI:A-State	.172	5.704	NS	***
STAI:A-Trait	.045	1.309	NS	NS
DAS	.023	0.653	NS	NS
FSS	.193	6.556	NS	***
BDI	.103	3.095	NS	**
MSPQ	.077	2.300	NS	NS
BEHAVIOUR THREAPY / NON-COGNITIVE RESPONDERS				
STAI:A-State	.354	15.078	*	***
STAI:A-Trait	.038	1.087	NS	NS
DAS	.120	3.760	NS	NS
FSS	.324	13.193	NS	***
BDI	.205	6.970	NS	***
MSPQ	.246	8.991	NS	***
COGN-BEH. THERAPY / COGNITIVE RESPONDERS				
STAI:A-State	.183	6.157	*	***
STAI:A-Trait	.106	3.268	NS	*
DAS	.047	1.357	NS	NS
FSS	.174	5.807	NS	**
BDI	.152	4.844	NS	**
MSPQ	.199	6.816	**	***
COGN.-BEH. THERAPY / NON-COGNITIVE RESPONDERS				
STAI:A-State	.075	2.231	NS	NS
STAI:A-Trait	.106	3.264	NS	NS
DAS	.206	7.147	*	NS
FSS	.215	7.544	NS	**
BDI	.350	14.521	***	**
MSPQ	.037	1.047	NS	NS

Note BDI significance level at mid-therapy in the Cognitive-behavioural non-cognitive responder group represents a significant relapse.

Table 65 appears to confirm the impression gained from the descriptive analysis. Before assessing these findings further, follow-up scores will be considered.

iii. Follow-up.

Table 66 presents the results of PAIRED T-TESTs conducted on post-therapy and follow-up scores.

TABLE 66. T-TEST comparisons (post-therapy - follow-up) of the main measures for the cognitive- and non-cognitive responders within the three active treatment conditions (* p < .05;** p < .01; *** p < .001; NS = non-significant.).

TREATMENT VARIABLE	T	D.F.	Probab.	Signif. level.
COGNITIVE THERAPY COGNITIVE RESPONDERS				
STAI:A-State	1.58	9	.148	NS
STAI:A-Trait	0.71	9	.495	NS
DAS	-1.23	9	.250	NS
FSS	-1.29	9	.231	NS
BDI	1.72	9	.120	NS
MSPQ	-0.45	9	.661	NS
COGNITIVE THERAPY NON-COGNITIVE RESPONDERS				
STAI:A-State	2.42	13	.031	*
STAI:A-Trait	3.03	13	.010	**
DAS	-3.79	13	.002	**
FSS	1.25	13	.233	NS
BDI	4.61	13	.000	***
MSPQ	3.56	13	.003	**

BEHAVIOUR THERAPY/

TREATMENT VARIABLE	T	D.F.	Probab.	Signif. level.
BEHAVIOUR THERAPY / COGNITIVE RESPONDERS				
STAI:A-State	1.79	10	.104	NS
STAI:A-Trait	1.60	10	.140	NS
DAS	-1.86	10	.092	NS
FSS	0.11	10	.914	NS
BDI	1.98	10	.076	NS
MSPQ	2.31	10	.044	*
BEHAVIOUR THERAPY / NON-COGNITIVE RESPONDERS				
STAI:A-State	1.26	10	.235	NS
STAI:A-Trait	2.83	10	.018	*
DAS	0.44	10	.671	NS
FSS	0.29	10	.233	NS
BDI	1.19	10	.262	NS
MSPQ	2.50	10	.030	*
COGN-BEH. THERAPY / COGNITIVE RESPONDERS				
STAI:A-State	1.54	7	.168	NS
STAI:A-Trait	1.35	7	.218	NS
DAS	£."$	'	.014	*
FSS	-0.21	7	.837	NS
BDI	0.46	7	.659	NS
MSPQ	1.41	7	.203	NS
COGN-BEH. THERAPY / NON-COGNITIVE RESPONDERS				
STAI:A-State	2.67	7	.032	*
STAI:A-Trait	1.01	7	.347	NS
DAS	-0.47	7	.653	NS
FSS	0.29	7	.783	NS
BDI	-0.28	7	.789	NS
MSPQ	2.66	7	.033	*

TWO-WAY ANOVAS produce no significant differences between the groups.

The statistical analysis substantiates the interpretations made from the descriptive statistics. In general, it appears that cognitive-responders do best in a cognitively orientated therapy at least up until post-therapy. They also appear to show most change on cognitively orientated measures and least on somatic and behaviourally orientated measures. Cognitive responders seem to do less well in a behaviourally orientated therapy than non-cognitive responders. It should be made clear that this latter group cannot be said to be 'matched' with behavioural therapy.

At follow-up, non-cognitive responders catch up with cognitive responders in Cognitive therapy although the same pattern does not obtain in Cognitive-behavioural therapy. Cognitive responders in this first group show mild relapse on the non-cognitive measures. In addition, the relatively poor performance of the cognitive-behavioural condition as outlined in the main results section may have been affected by the scores of the non-cognitive responders who appear to be quite different from the other five conditions. Inspection of the cognitive-responders' scoring in the Cognitive-behavioural condition shows that, on average, their scores are similar to the other conditions both at post-therapy and at follow-up. Inspection of the SD changes also suggests, overall, that the marked variation found in the main analysis can, to a certain extent, be more clearly understood by the division into cognitive-and non-cognitive-responders.

These findings will be discussed at greater length elsewhere and the question of whether these statistical findings are of clinical relevance.

CHAPTER 16

SYNCHRONOUS vs DESYCHRONOUS CHANGE AND THEIR RELATIONSHIP TO TREATMENT OUTCOME

SYNCHRONOUS vs DESYNCHRONOUS CHANGE AND THEIR RELATIONSHIP TO TREATMENT OUTCOME.

Rachman and Hodgson (1974), in drawing attention to patterns of fear mechanisms, hypothesised that desynchrony between the response systems (in particular the cognitive and somatic systems) during treatment may be of use as a prognostic. Although no empirical studies of GAD have been carried out, Vermilyea et al (1984) have shown that, in agoraphobia, synchronous patients showed more improvement than desynchronous patients on physiologically assessed heart rate although not on cognitive measures.

The present study will assess the role of synchrony/desynchrony using the main elements of the definitions of Rachman and Hodgson (1974) which were also used in the Vermilyea et al (1984) study. These definitions were, however, imprecise and have been operationalised to a greater degree here. Again, as in the case of dividing patients into cognitive and non-cognitive responders, the FSAQ was used and, in particular, the cognitive and somatic scales compared. Thus patients were dichotomised by use of the following definitions:

A synchronous patient was defined as one who showed concordant changes in the cognitive and somatic scales of the FSAQ across at least two of three time phases (pre- mid-therapy; mid- post-therapy; pre- post-therapy). In particular if the difference between the cognitive and somatic change scores was less than 33% across at least 2 time phases, the patient was defined as synchronous.

If the difference between the change scores exceeded 33% on at least 2 of the 3 time phases, the patient was defined as desynchronous.

This resulted in the following dichotomies:

Cognitive-therapy : 21 synchronous patients, 10 desynchronous

Behaviour therapy : 20 synchronous patients, 11 desynchronous

Cognitive-behaviour therapy : 16 synchronous patients, 10 desynchronous.

Due to the small number of patients, the Placebo condition was omitted from this analysis.

Prior to embarking on the main analysis, two issues will be dealt with.

1). Relationship with cognitive and non-cognitive responders.

One function of the criteria employed in determining cognitive and non-cognitive responders was to identify patients who showed a discordant relationship between cognitive and somatic FSAQ scales at pre-therapy. (Cognitive responders). If patients thus identified also are those identified as desynchronous then the interpretation of any subsequent analyses will be fraught with difficulty. Table 67 presents the number of patients in each condition who are identified as both cognitive responders and desynchronous.

TABLE 67/

TABLE 67. Comparison across conditions of patients meeting the criteria for cognitive responders, desynchrony status.

	Cognitive responders	Desynchronous	Joint
Cognitive therapy	10	10	4
Behaviour therapy	11	11	5
Cogn.-beh. therapy	8	10	3

Table 67 suggests that although the relationship between cognitive responders (by definition, discordant at pre-therapy) and desynchronous patients (by definition, discordant over time) is both unclear and incomplete, caution should be applied in interpreting the results in the following analyses.

2. Baseline Measures.

Synchronous and desynchronous patients in the three active treatment conditions were compared by conducting TWO-WAY ANOVAS analysing all demographic and clinical baseline variables. Twenty-nine variables were included in the test. Only two significant differences emerged. T-Tests, using Bonferroni adjustment to limit the possibility of Type 1 errors, demonstrated significant differences on the BDI where synchronous patients in the Cognitive, Behavioural and Cognitive-behavioural conditions show higher levels of depression than the desynchronous patients in the Cognitive-behavioural condition. Similarly, both Cognitive and Behavioural synchronous patients show significantly higher levels of anxiety as measured by the STAI:A-State.

3). Analysis of treatment outcome.

No hypotheses are forwarded and, as in previous sections, only main measures will be assessed.

a). Descriptive Statistics.

Table 68 presents mean values, SD values (in parentheses) and percentage changes in these values at pre-therapy, post-therapy and follow-up across the six conditions.

TABLE 68. Comparisons across the three active treatment conditions of patients classified as either synchronous or desynchronous of mean scores and SD scores at pre- and post-therapy and at follow-up along with percentage change scores (in parentheses) (pre-post; pre-fu) for each of the main measures. (+ = increase in score, - = decrease in score).

	COGNITIVE THERAPY				BEHAVIOUR THERAPY				COGN-BEH.THERAPY			
	Synchronous		Desynchronous		Synchronous		Desynchronous		Synchronous		Desynchronous	
STAI:A-State												
pre	54.4	(10.8)	57.7	(13.6)	58	(12.8)	53.5	(11.9)	54.5	(13.4)	43.2	(8.4)
post	39.9	(12.4)	42.9	(10.8)	43.4	(14.2)	35.8	(9.7)	45.7	(11.3)	35.8	(11.6)
follow-up	37.5	(11.9)	37.1	(7.7)	36.1	(9.3)	33.1	(5.6)	38.3	(11.4)	31.2	(8.6)
% change pre-post	-26.7	(+14.8)	-25.6	(-20.6)	-25.2	(+11)	-33.1	(-18.5)	116.1	(-15.7)	-17.1	(+38)
% change pre-fu	-31.1	(+10.2)	-35.7	(-43.4)	-37.8	(-27.3)	-38.1	(-52.9)	-29.7	(-14.9)	-27.8	(+2.4)
STAI:A-Trait												
pre	58.5	(7.7)	57.3	(11.7)	61.4	(10)	56.3	(11.9)	58.3	(10.7)	49.2	(9.3)
post	48.3	(11.5)	49.6	(9.7)	54.4	(12.5)	47	(12.5)	52.9	(11.5)	41.6	(10.4)
follow-up	46	(12)	44.1	(9.7)	45.6	(10.9)	45.3	(7)	48.1	(9.1)	37.8	(10.6)
% change (pre-post)	-17.4	(+49.4)	-13.4	(-171.)	-11.4	(+25)	-16.5	(+5.1)	- 9.3	(+5.6)	-(15.4)	(+11.8)
% change (pre-fu)	-21.4	(+55.8)	-23	(-17.1)	-25.7	(+9)	-19.5	(-41.2)	-17.5	(-15)	-23.2	(+14)
DAS												
pre	96.5	(19.3)	105.4	(25.3)	96.8	(24.7)	103.9	(20.4)	89	(21.4)	106.5	(38.6)
post	114.1	(23.8)	106.6	(28.3)	107	(24.8)	111.9	(21.2)	97.8	(23.9)	112.4	(18.4)
follow-up	119.9	(26.6)	116	(22.4)	110.8	(20.9)	120.7	(16.3)	104.7	(27.3)	114.2	(14.2)
% change (pre-post)	+18.2	(+23.3)	+ 1	(+11.9)	+10.5	(+1)	+ 7.7	(+3.9)	+ 9.9	(+11.7)	+ 5.5	(-52.3)
% change (pre-fu)	+24.2	(+37.8)	+10	(-11.5)	+14.5	(-15.4)	+16.2	(-20)	+17.6	(+27.6)	+ 7.2	(-63.2)

FSS/

	Synchronous		Desynchronous		Synchronous		Desynchronous		Synchronous		Desynchronous	
FSS												
pre	100.9	(40)	111.6	(58.9)	109.8	(41.1)	100.6	(43.9)	122.9	(45.3)	77.9	(33.6)
post	69.1	(36.7)	93.5	(62.3)	75	(45.2)	69.7	(30)	99.6	(49.3)	55.2	(30.7)
follow-up	71.5	(43.7)	71	(37.3)	68.9	(41.2)	70.7	(37.7)	87	(35.9)	62.7	(34.7)
% change (pre-post)	-31.5	(-8.3)	-16.2	(+6)	-31.7	(+10)	-30.7	(-31.7)	-19	(+8.8)	+13.6	(-20.5)
% change (pre-fu)	-29.1	(+9.3)	-36.4	(-36.7)	-37.2	(0)	-29.7	(-14.1)	-29.2	(-20.8)	-19.5	(-10.1)
BDI												
pre	20	(7.7)	15.5	(9.4)	20.5	(9.4)	19	(9.9)	21.3	(9.5)	10.2	(7.7)
post	10.7	(6.5)	10.3	(5.7)	11.6	(8.5)	11.1	(4.3)	15.7	(10)	4.6	(4.3)
follow-up	8.6	(7.7)	6.2	(6.3)	8.3	(6.3)	9	(3.8)	11.5	(9.6)	6.2	(7.2)
% change (pre-post)	-46.5	(-15.6)	-33.5	(-39.4)	-43.4	(-9.6)	-41.6	(-56.6)	-26.3	(+5.3)	-54.9	(-44.2)
% change (pre-fu)	-57	(0)	-60	(-33)	-59.5	(-32.9)	-52.6	(-61.6)	-46	(0)	-39.2	(-6.5)
MSPQ												
pre	37.8	(14.1)	27	(10.4)	34.1	(14.6)	34.9	(12.2)	29.5	(15.3)	24.1	(7.8)
post	25.4	(11.8)	17.3	(8)	23	(15.3)	24.8	(11.8)	26.3	(15.7)	15.6	(13.2)
follow-up	20.1	(14.8)	17	(9.8)	13.5	(9.3)	18.6	(6.5)	14.1	(8.5)	9.2	(6.3)
% change (pre-post)	-32.8	(-16.3)	-35.9	(-23)	-32.6	(+4.8)	-28.9	(-3.3)	-10.8	(+2.6)	-35.3	(+69.2)
% change (pre-fu)	-46.8	(+5)	-37	(-5.8)	-60.4	(-36.3)	-46.7	(-46.7)	-52.2	(-44.4)	-61.8	(-19.2)

Inspection of Table 68 suggests that synchronous and desynchronous groups present, at pre-therapy, with fairly similar patterns of scoring on the main measures. However, the exception to this is the desynchronous group in the Cognitive-behavioural condition who, on all variables, are less dysfunctional than the other groups across conditions and this finding should be kept in mind in the interpretation of the results.

At post-therapy there is a faint pattern favouring enhanced performance of synchronous patients in the Cognitive condition particularly in DAS scoring. There is no clear pattern in the other two conditions. At follow-up the advantage for Cognitive synchronous, with the exception of the DAS, disappears as the desynchronous patients catch up. There is some evidence for synchronous patients in the Behavioural condition to out-perform their desynchronous counterparts particularly on the FSS and MSPQ. No clear pattern exists for the Cognitive-behavioural condition.

b). Statistical Analysis

i. Main effects.

Table 69 presents the results of MANOVAs for the main measures.

TABLE 69/

TABLE 69. Repeated measures analysis of main measures across the active treatment conditions of patients classified as either synchronous or desynchronous using MANOVA during pre-post therapy (* p < .05; ** p < .01; *** p < .001; NS = non-significant)

Source of Variation	Pillai	Hyp. d.f.	Error d.f.	F ratio	F probab.	Signif. level.
STAI:A-State						
Group		5		2.081	.076	NS
Time	.504	2	81	41.214	.000	***
Group x Time	.114	10	164	.993	.451	NS
STAI:A-Trait						
Group		5		2.372	.046	*
Time	.330	2	81	19.934	.000	***
Group x Time	.080	10	164	.683	.739	NS
DAS						
Group		5		1.017	.413	NS
Time	.285	2	81	16.168	.000	***
Group x Time	.161	10	164	1.461	.169	NS
FSS						
Group		5		1.518	.193	NS
Time	.555	2	81	50.626	.000	***
Group x Time	.149	10	164	1.321	.223	NS
BDI						
Group		5		2.644	.029	*
Time	.490	2	81	38.497	.000	***
Group x Time	.190	10	164	1.703	.084	NS
MSPQ						
Group		5		2.244	.057	NS
Time	.367	2	81	23.452	.000	***
Group x Time	.216	10	164	.216	.058	NS

Significant Time effects are found on all variables. Significant Group effects are found for A-Trait and BDI. As no significant interactions are found, treatment within time analyses will not be pursued.

ii. Time within treatment group sub-effects

Table 70 provides information separately for the synchronous and desynchronous patients in the Cognitive, Behavioural and Cognitive-behavioural conditions.

TABLE 70. Time within Treatment group simple effects and sub-effects at mid- and post-therapy presented separately for each of the six groups (synchronous and desynchronous across treatment conditions). (* p < .05;, ** p < .01; *** p < .001; NS = non-significant.)

TREATMENT VARIABLE	Pillai	F. Prob.	Mid-Therapy	Post-therapy
COGNITIVE CONDITION: Synchronous patients.				
STAI:A-State	.295	16.922	*	***
STAI:A-Trait	.202	10.260	NS	***
DAS	.319	18.962	NS	***
FSS	.355	22.246	NS	***
BDI	.260	14.117	NS	***
MSPQ	.227	11.905	NS	***
COGNITIVE CONDITION desynchronous patients.				
STAI:A-State	.117	5.369	*	**
STAI:A-Trait	.046	1.944	NS	NS
DAS	.003	0.116	NS	NS
FSS	.056	2.381	NS	*
BDI	.037	1.529	NS	NS
MSPQ	.112	5.087	NS	**
BEHAVIOURAL CONDITION synchronous patients				
STAI:A-State	.220	11.454	*	***
STAI:A-Trait	.068	2.976	NS	*
DAS	.131	6.085	NS	**
FSS	.329	19.861	NS	***
BDI	.244	12.923	NS	***
MSPQ	.238	12.676	NS	***
BEHAVIOURAL CONDITION desynchronous patients				
STAI:A-State	.207	10.565	**	***
STAI:A-Trait	.070	3.066	NS	*
DAS	.029	1.197	NS	NS
FSS	.152	7.252	NS	***
BDI	.096	4.236	NS	**
MSPQ	.069	2.986	NS	*

	Pillai	F. Prob.	Mid-Therapy	Post-therapy
COGN.BEH. CONDITION synchronous patients				
STAI:A-State	.097	4.348	NS	*
STAI:A-Trait	.048	2.023	NS	NS
DAS	.069	3.003	NS	*
FSS	.138	6.513	NS	***
BDI	.121	5.520	NS	**
MSPQ	.001	0.053	NS	NS
COGN.BEH. CODNITION desynchronous patients.				
STAI:A-State	.071	3.118	NS	*
STAI:A-Trait	.108	4.924	NS	*
DAS	.047	2.000	NS	NS
FSS	.187	9.338	NS	***
BDI	.262	14.185	**	***
MSPQ	.098	4.412	*	**

The information contained in Table 70 makes clearer the evidence contained in the descriptive analysis. There is a clear pattern of enhanced improvement associated with the synchronous patients in the Cognitive, and to a lesser extent, the Behavioural conditions. If anything, a mirror image pertains in the Cognitive-behavioural condition although given the pre-therapy differences already alluded to, this result should be treated with caution.

iii. Follow-up.

Table 71 presents the results of PAIRED T-TESTS conducted on post-therapy and follow-up scores.

TABLE 71. T-TEST comparisons (post-therapy - follow-up) of the main measures for each of the six groups (synchronous and desynchronous across treatment conditions).
(* $p < .05$; ** $p < .01$; *** $p < .001$; NS = non-significant.)

TREATMENT VARIABLE.	T	d.f.	Probab.	Signif. level.
COGNITIVE THERAPY Synchronous				
STAI:A-State	1.16	20	.258	NS
STAI:A-Trait	1.52	20	.143	NS
DAS	-1.75	20	.096	NS
FSS	-0.39	20	.702	NS
BDI	2.46	20	.023	*
MSPQ	1.49	20	.151	NS
COGNITIVE THERAPY desychronous				
STAI:A-State	1.74	9	.116	NS
STAI:A-Trait	2.12	9	.063	NS
DAS	-2.29	9	.047	*
FSS	1.41	9	.191	NS
BDI	2.55	9	.031	*
MSPQ	1.31	9	.169	NS
BEHAVIOURAL THERAPY synchronous				
STAI:A-State	2.78	19	.012	*
STAI:A-Trait	4.08	19	.001	***
DAS	-1.00	19	.329	NS
FSS	0.99	19	.335	NS
BDI	2.64	19	.016	*
MSPQ	3.51	19	.002	**
BEHAVIOURAL THERAPY desynchronous				
STAI:A-State	.81	10	.434	NS
STAI:A-Trait	.51	10	.622	NS
DAS	-2.07	10	.065	NS
FSS	-0.30	10	.773	NS
BDI	1.40	10	.193	NS
MSPQ	1.95	10	.079	NS

	T	d.f.	Prob.	Signif. Level.
COGN. BEH.THERAPY synchronous				
STAI:A-State	2.42	15	.029	*
STAI:A-Trait	1.77	15	.098	NS
DAS	-3.63	15	.002	**
FSS	1.78	15	.095	NS
BDI	2.44	15	.028	*
MSPQ	4.54	15	.000	***
COGN.-BEH.THERAPY desychronous.				
STAI:A-State	1.83	9	.101	NS
STAI:A-Trait	1.47	9	.176	NS
DAS	-0.36	9	.727	NS
FSS	-1.69	9	.125	NS
BDI	-0.95	9	.368	NS
MSPQ	1.82	9	.102	NS

TWO-WAY ANOVAs produce no significant differences between the groups.

Results of the t-tests help to clarify the relationship between treatment outcome and synchrony/desynchrony. There is no great difference between the two groups in the Cognitive therapy condition between post and follow-up thus leaving the general trend favouring the synchronous group.

In the Behavioural and Cognitive-behavioural conditions, the synchronous groups show enhanced performance during the follow-up period over the desynchronous groups.

Thus, at the follow-up point, there is statistical evidence suggesting that synchronous changes in the cognitive and somatic scales of the FSAQ is related to enhanced performance. The implications of this finding will be discussed later.

CHAPTER 17

CLINICAL vs STATISTICAL SIGNIFICANCE

CLINICAL SIGNIFICANCE

As statistically significant change may not reflect clinically significant change and because of the variability of outcome noted in previous sections, there is a need to determine the proportion of patients who benefitted from Stress Control. Various studies have attempted to assess 'clinical significance' although as Jacobsen et al (1984) point out, there is little consensus as to what the term means and thus the various criteria imposed as either arbitrary or highly subjective. Jacobsen et al (1984) suggest standardised criteria, the most stringent of which is that the level of functioning at post-therapy should fall outside the range of the dysfunctional population (i.e. pre-therapy) where range is defined as extending to two standard deviations above (in the direction of functionality) the mean for that population. This criterion should be combined with a measure of "reliable change index" which is equivalent to the difference score (post-pre) divided by the standard error of measurement.

While the above attempt to standardise the definition of clinically significant change is worthwhile, the present study will reject it on the following grounds:

1). 'Clinical significance' should not employ a strict cut-off point. Indeed, Jacobsen et al (1984) suggest that a less stringent cut-off of one SD could suffice. This suggests an almost random definition of clinical significance.

2). 'Clinical significance' has to be seen through the eyes of the patient. Someone starting off with severe anxiety and ending with moderate anxiety may still be in the dysfunction population but may still feel that therapy has been of great benefit. This may be particularly

true in GAD where trait anxiety may have been high for many years prior to treatment.

Thus the present study does not set arbitrary or subjective criteria for clinically significant change but instead employs a simple method for assessment of clinical change. Tables and bar charts displaying percentage change pre- to post-therapy and again for pre-therapy to follow-up will be presented. This method allows visual inspection of the amount of change which has taken place and obviates the need to determine cut-off points - a concept which, in clinical terms, has little merit.

Given the large number of possible variables which could be used, attention will be paid to those which may be of greater significance to the patient i.e. those global measures of anxiety and coping. Two main measures will be presented:

1). Anxiety global rating.

This measure is taken from the SC questionnaire (SCQ) - Question 1. **"How anxious have you been over the last week?"**

2). Coping global rating.

This measure was taken from the Coping Questionnaire (CQ). Question 7. **"How well are you generally coping with life?".**

In addition a third measure will be presented:

3). Treatment Outcome global rating.

The post-therapy and follow-up responses to Question 5 in the SCQ will be presented (**"How well did this treatment work for you?"**)

While it is accepted that these measures, even more than other questionnaire ratings, may be open to demand influences, it is argued

that, in combination, the measures allow us to assess clinical significance from the point of view of the patient who, irrespective of the clinician's view, is the final arbiter of whether therapy is successful or not. As clinical significance cannot employ a strict cut-off point it is argued that change should be presented not in a dichotonous fashion but rather as a continuum.

1). <u>ANXIETY global rating</u>.

Table 72 presents percentage changes (pre-therapy - post-therapy and pre-therapy - follow-up) on ANXIETY global ratings across the foud treatment conditions.

TABLE 72/

TABLE 72. Comparison across the four treatment conditions of percentage changes (pre-therapy-post-therapy and pre-therapy-follow-up) of ANXIETY global ratings (SCQ1). (DECREASE represents decrease in anxiety).

		Cognitive		**Behavioural**		**Cogn-Beh.**		**Placebo**	
		Post	FU	Post	FU	Post	FU	Post	FU
	n=	**29**	**25**	**30**	**26**	**23**	**21**	**10**	**9**
INCREASE		3	4	6	11	9	0	0	0
DECREASE	**0-19**	21	20	27	11	26	24	50	33
	20-39	28	32	27	42	30	24	20	33
	40-59	29	20	30	16	9	24	10	11
	60-79	15	16	10	20	17	19	20	23
	80-99	4	8	0	0	9	9	0	0

In order to permit inspection of each condition separately, Figures 36-39 employ bar charts which should also facilitate a more meaningful comparison across conditions.

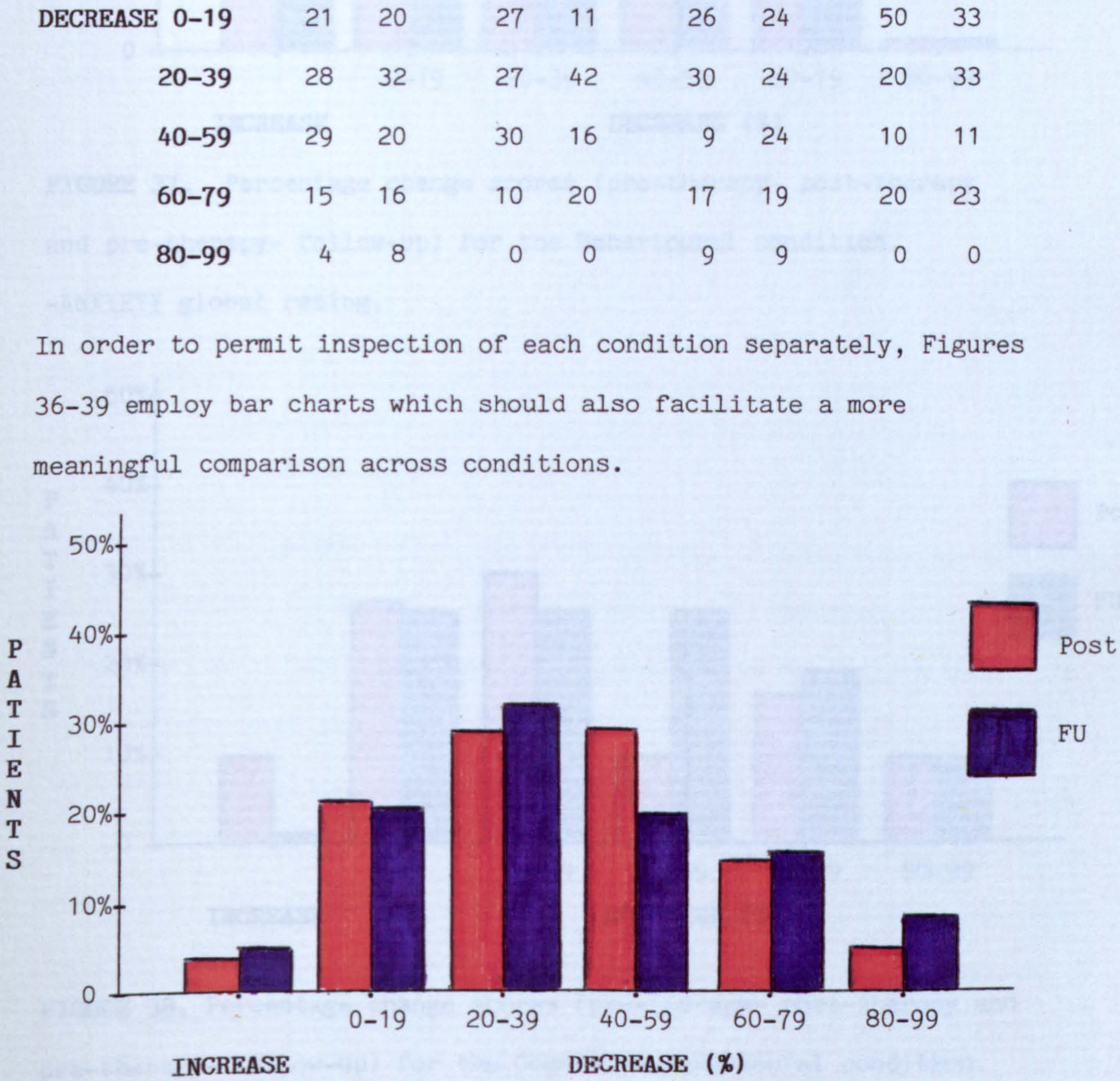

FIGURE 36. Percentage change scores (pre-therapy- post-therapy and pre-therapy-follow-up) for the Cognitive condition. ANXIETY global rating.

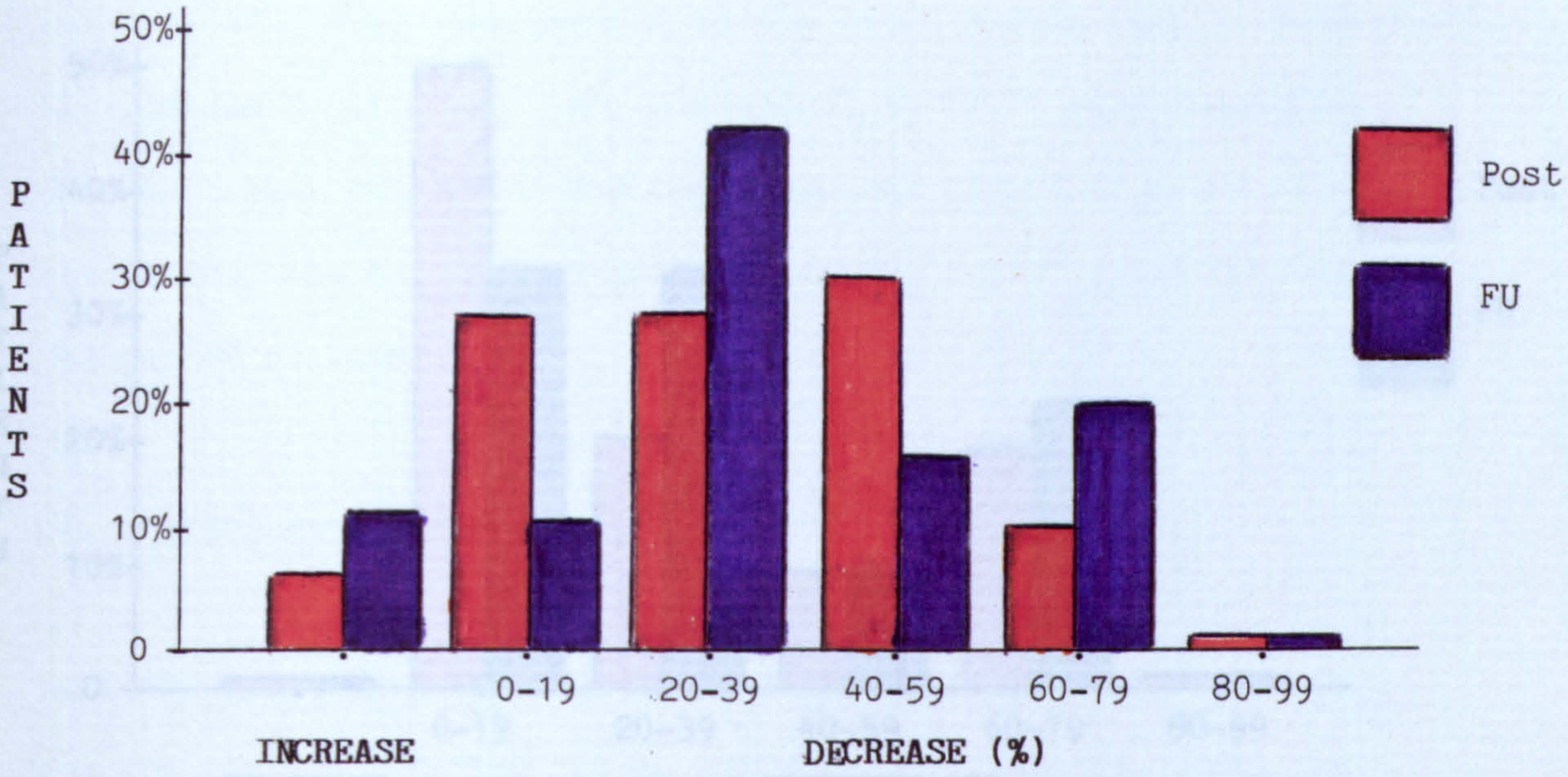

FIGURE 37. Percentage change scores (pre-therapy- post-therapy and pre-therapy- follow-up) for the Behavioural condition.

-ANXIETY global rating.

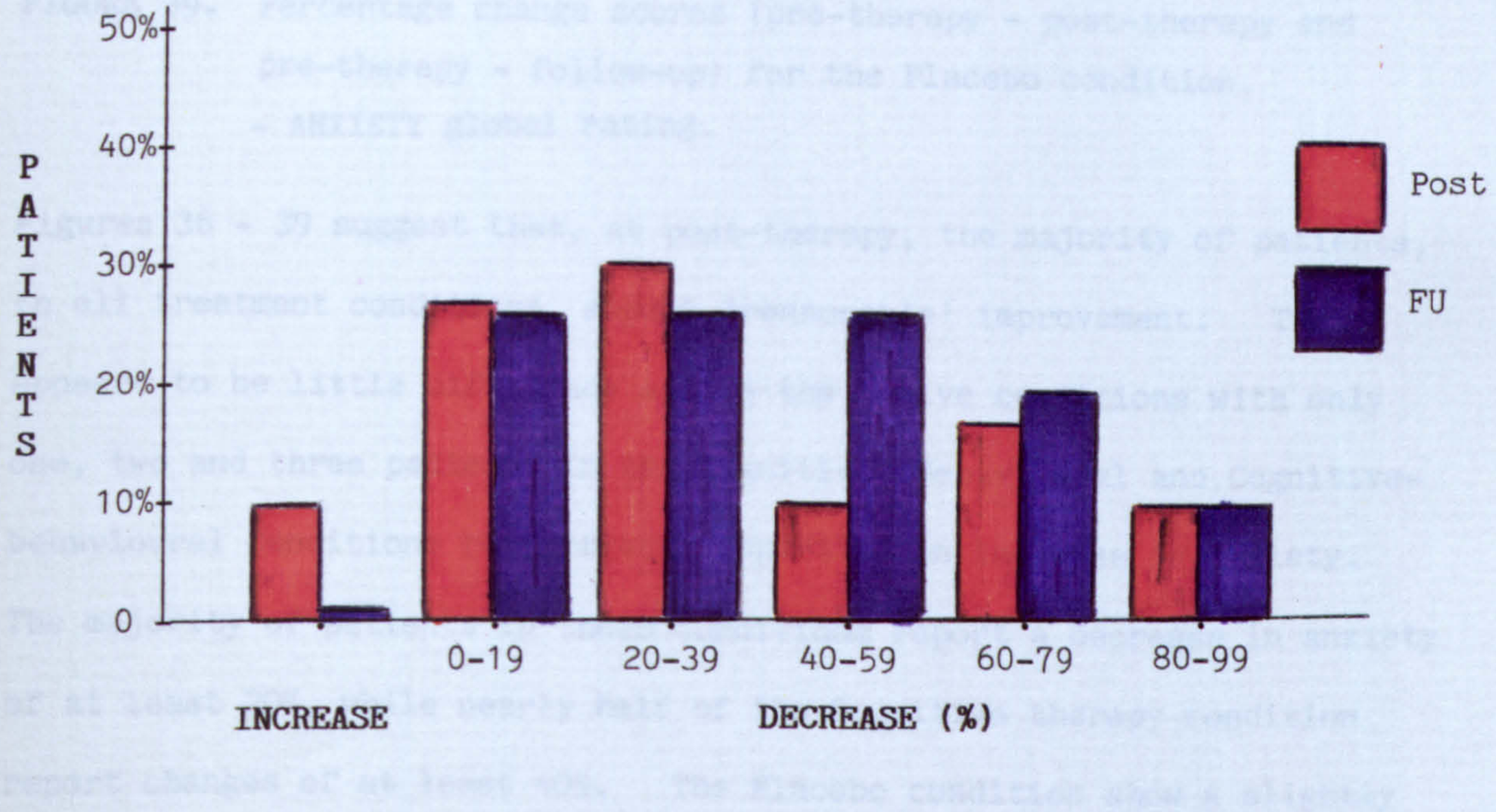

FIGURE 38. Percentage change scores (pre-therapy- post-therapy and pre-therapy- follow-up) for the Cognitive-Behavioural condition.

-ANXIETY global rating.

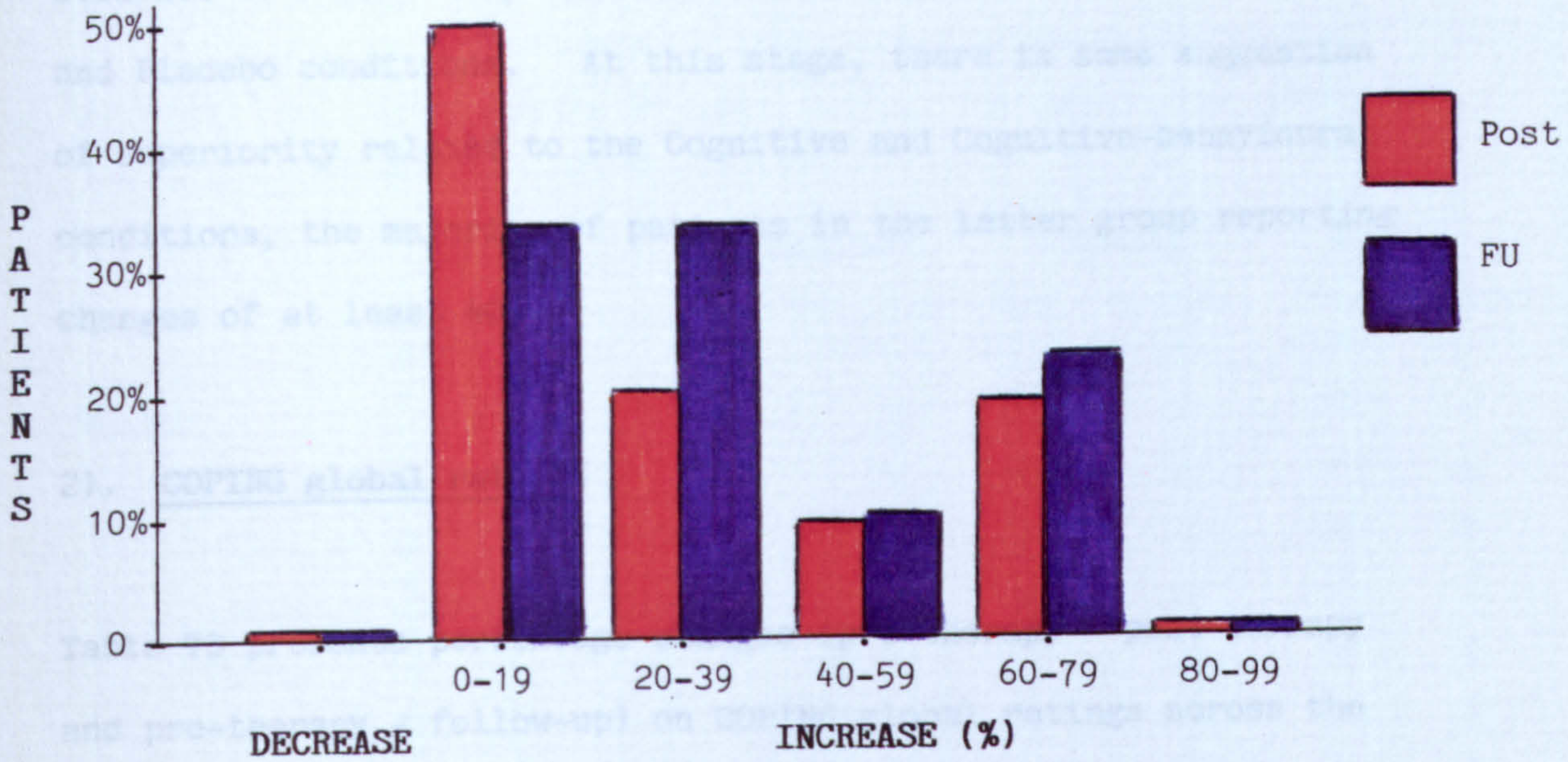

FIGURE 39. Percentage change scores (pre-therapy - post-therapy and pre-therapy - follow-up) for the Placebo condition. - ANXIETY global rating.

Figures 36 - 39 suggest that, at post-therapy, the majority of patients, in all treatment conditions, report 'reasonable' improvement. There appears to be little difference across the active conditions with only one, two and three patients in the Cognitive, Behavioural and Cognitive-behavioural conditions respectively reporting an increase in anxiety. The majority of patients in these conditions report a decrease in anxiety of at least 20%, while nearly half of the Cognitive therapy condition report changes of at least 40%. The Placebo condition show a slightly lower magnitude of improvement although no-one reports an increase in anxiety. At follow-up, this improvement is generally maintained with

evidence of further improvement in the Behavioural, Cognitive-behavioural and Placebo conditions. At this stage, there is some suggestion of superiority related to the Cognitive and Cognitive-behavioural conditions, the majority of patients in the latter group reporting changes of at least 40%.

2). <u>COPING global rating</u>.

Table 73 presents percentage changes (pre-therapy - post-therapy and pre-therapy - follow-up) on COPING global ratings across the four treatment conditions.

TABLE 73/

TABLE 73. Comparisons across the four treatment conditions of percentage change (pre-therapy - post-therapy and pre-therapy - follow-up) of COPING global ratings (CQ7). (INCREASE represents an increase in coping ability.

	Cognitive		Behavioural		Cogn-Beh.		Placebo	
	Post (n=29)	Follow-up (n=25)	Post (n=30)	Follow-up (n=26)	Post (n=23)	Follow-up (n=21)	Post (n=10)	Follow-up (n=9)
DECREASE	0	0	0	0	13	0	10	0
INCREASE 0-49	42	37	20	15	27	26	50	63
50-99	19	25	38	28	4	10	0	25
100-149	23	17	21	28	32	26	40	0
150-199	4	4	7	5	9	11	0	12
200+	12	17	14	24	15	27	0	0

Figures 40 - 43 employ bar charts to facilitate comparisons across conditions.

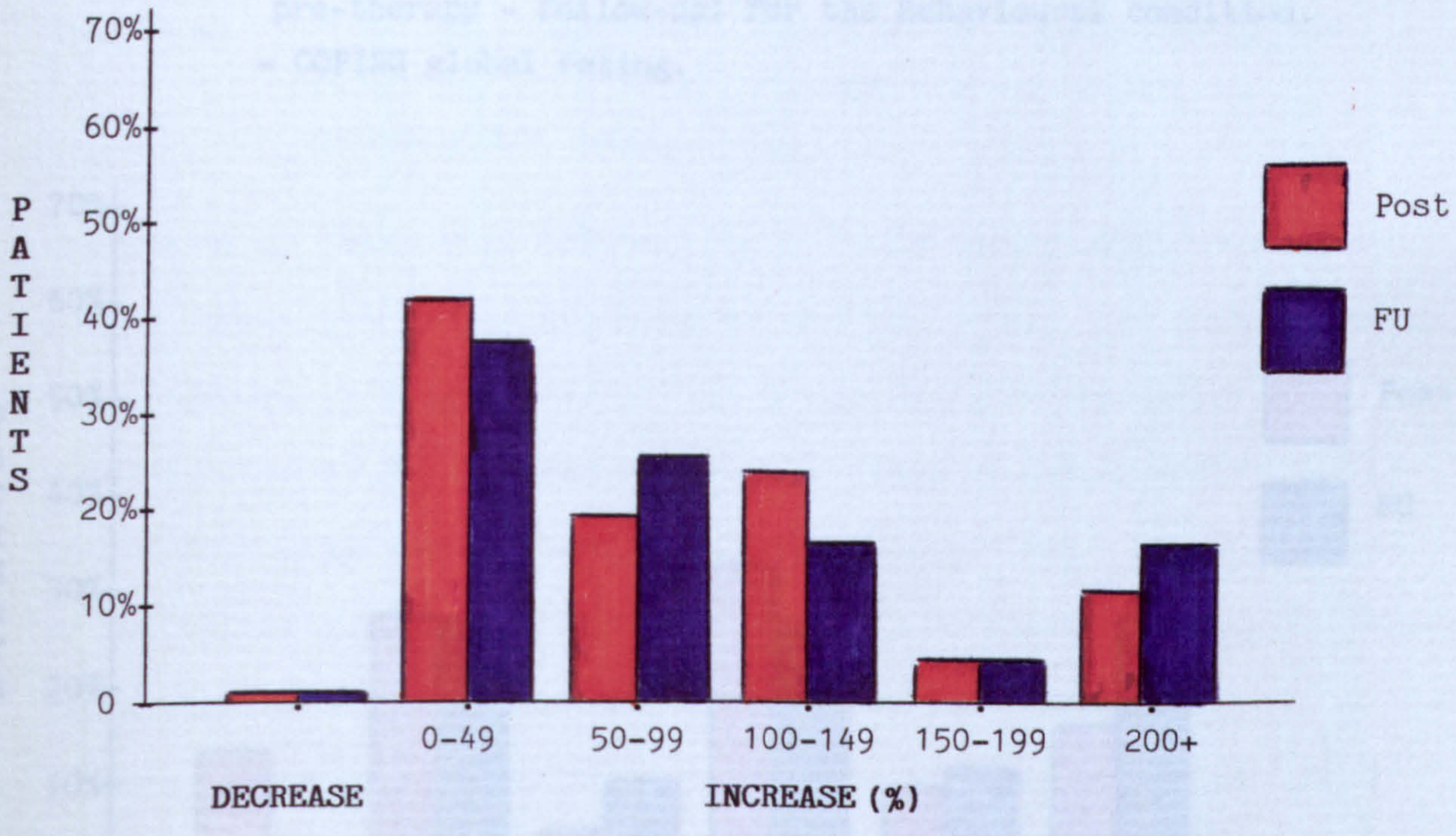

FIGURE 40. Percentage change scores (pre-therapy - post-therapy and pre-therapy - follow-up) for the Cognitive condition.
-COPING global rating.

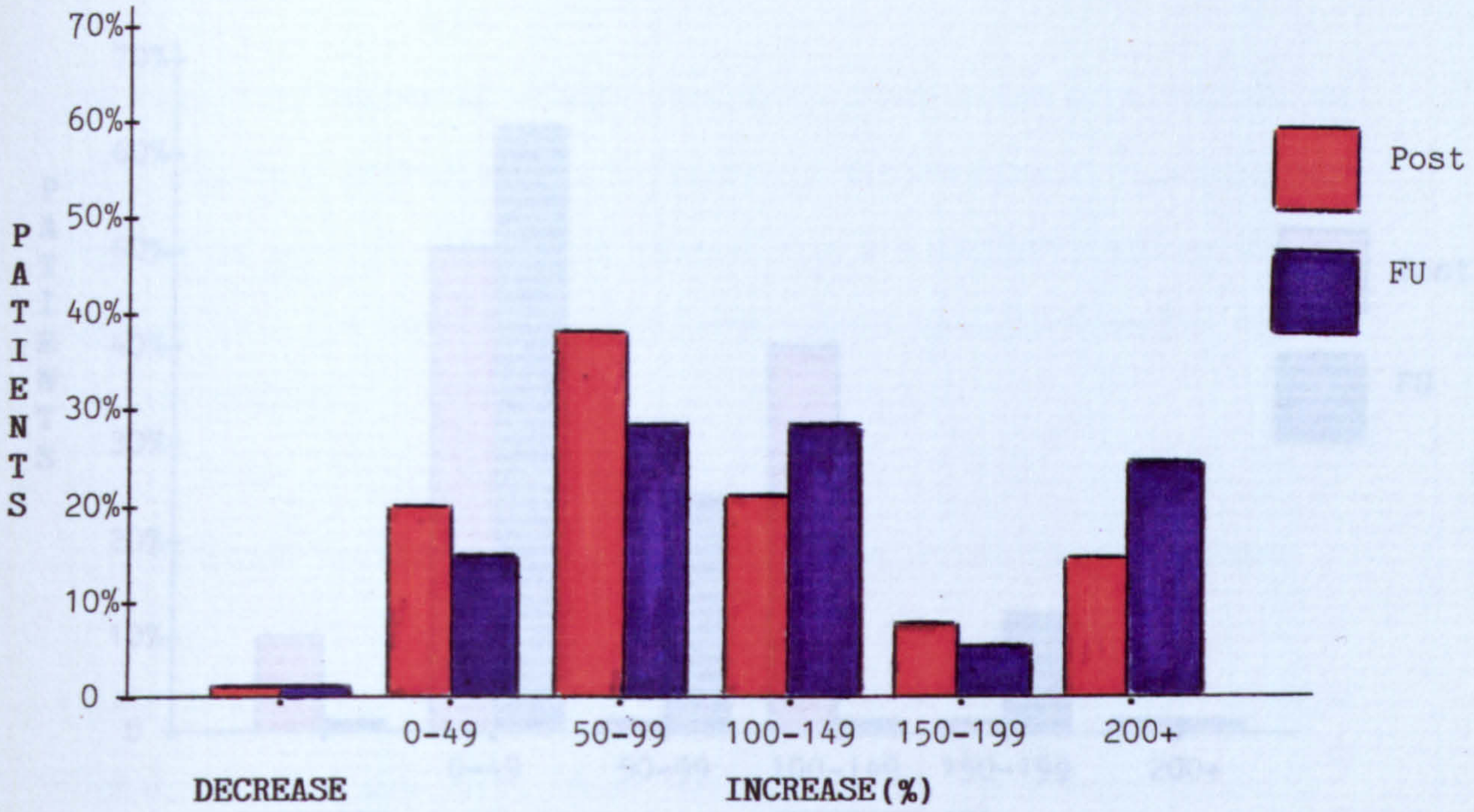

FIGURE 41. Percentage change scores (pre-therapy - post therapy and pre-therapy - follow-up) for the Behavioural condition.
- COPING global rating.

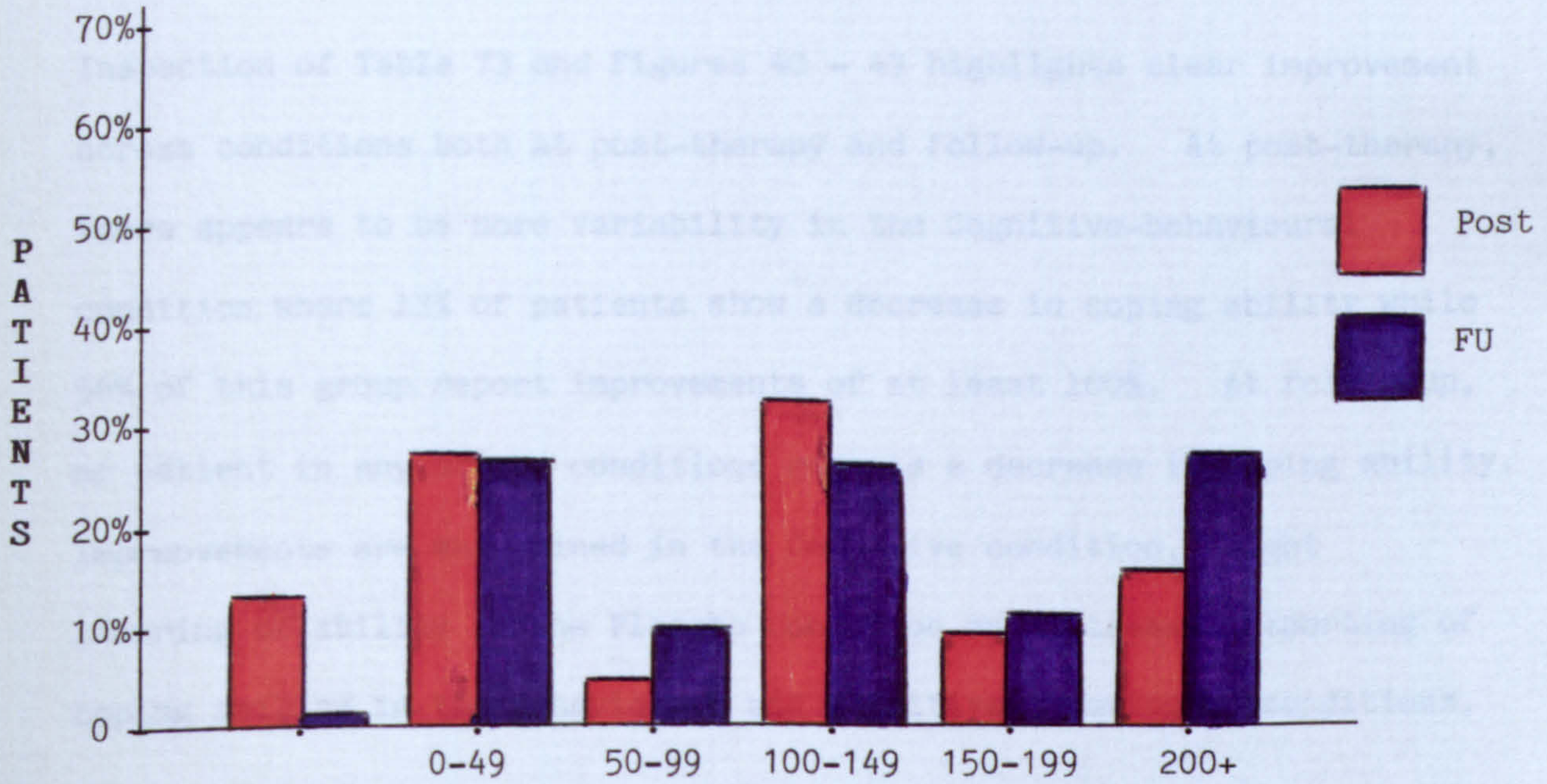

FIGURE 42. Percentage change scores (pre-therapy - post therapy and pre-therapy - follow-up) for the Cognitive-Behavioural condition.
-COPING global rating.

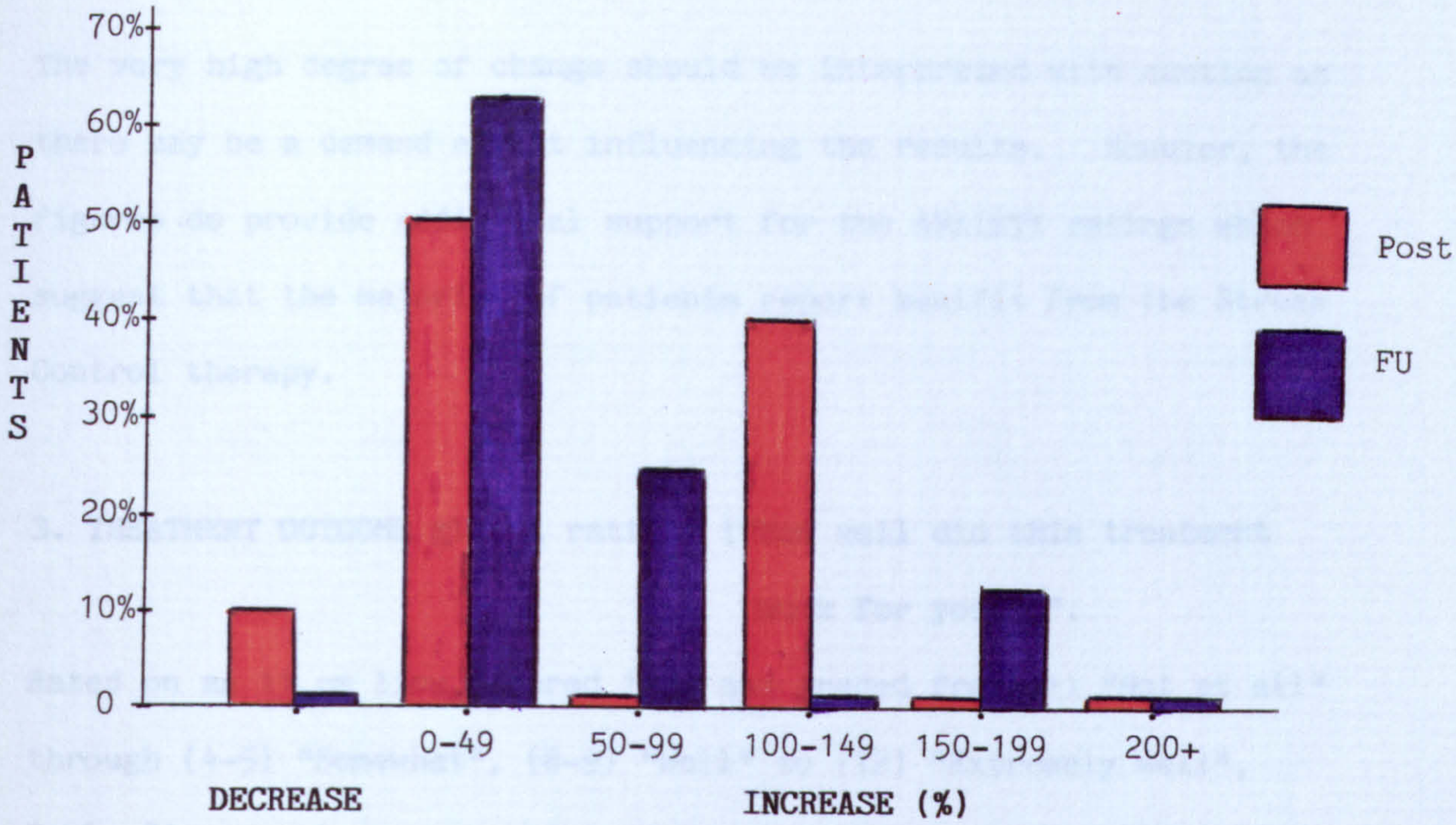

FIGURE 43. Percentage change scores (pre-therapy - post-therapy and pre-therapy - follow-up) for the Placebo condition.

_COPING global rating

Inspection of Table 73 and Figures 40 - 43 highlights clear improvement across conditions both at post-therapy and follow-up. At post-therapy, there appears to be more variability in the Cognitive-behavioural condition where 13% of patients show a decrease in coping ability while 56% of this group report improvements of at least 100%. At follow-up, no patient in any of the conditions reports a decrease in coping ability. Impreovements are maintained in the Cognitive condition, slight lowering of ability in the Placebo condition and increased reporting of coping ability in the Behavioural and Cognitive-behavioural conditions.

The very high degree of change should be interpreted with caution as there may be a demand effect influencing the results. However, the figures do provide additional support for the ANXIETY ratings which suggest that the majority of patients report benifit from the Stress Control therapy.

3. TREATMENT OUTCOME global rating. ("How well did this treatment work for you ? ".

Rated on an 11 cm line, scored 1-12 and graded from (1) "Not at all" through (4-5) "Somewhat", (8-9) "Well" to (12) "Extremely well", Table 74 presents scores obtained at post-therapy and at follow-up across the four treatment conditions.

TABLE 74/

TABLE 74. TREATMENT OUTCOME global ratings across the four treatment conditions at post-therapy and follow-up.

Gradings	Cognitive		Behavioural		Cogn-Beh.		Placebo	
	Post	FU	Post	FU	Post	FU	Post	FU
1	-	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-	-
3	-	4	-	-	-	-	-	-
4	4	4	3	4	-	-	-	-
5	25	8	10	12	4	5	40	45
6	7	20	3	0	14	5	-	-
7	18	4	14	16	4	14	10	11
8	11	12	21	12	38	14	-	33
9	17	20	35	12	8	24	20	-
10	7	8	7	32	14	14	10	11
11	7	16	-	8	4	19	20	-
12	4	4	7	4	14	5	-	-

Figures 44 - 47 employ bar charts to facilitate comparison across conditions.

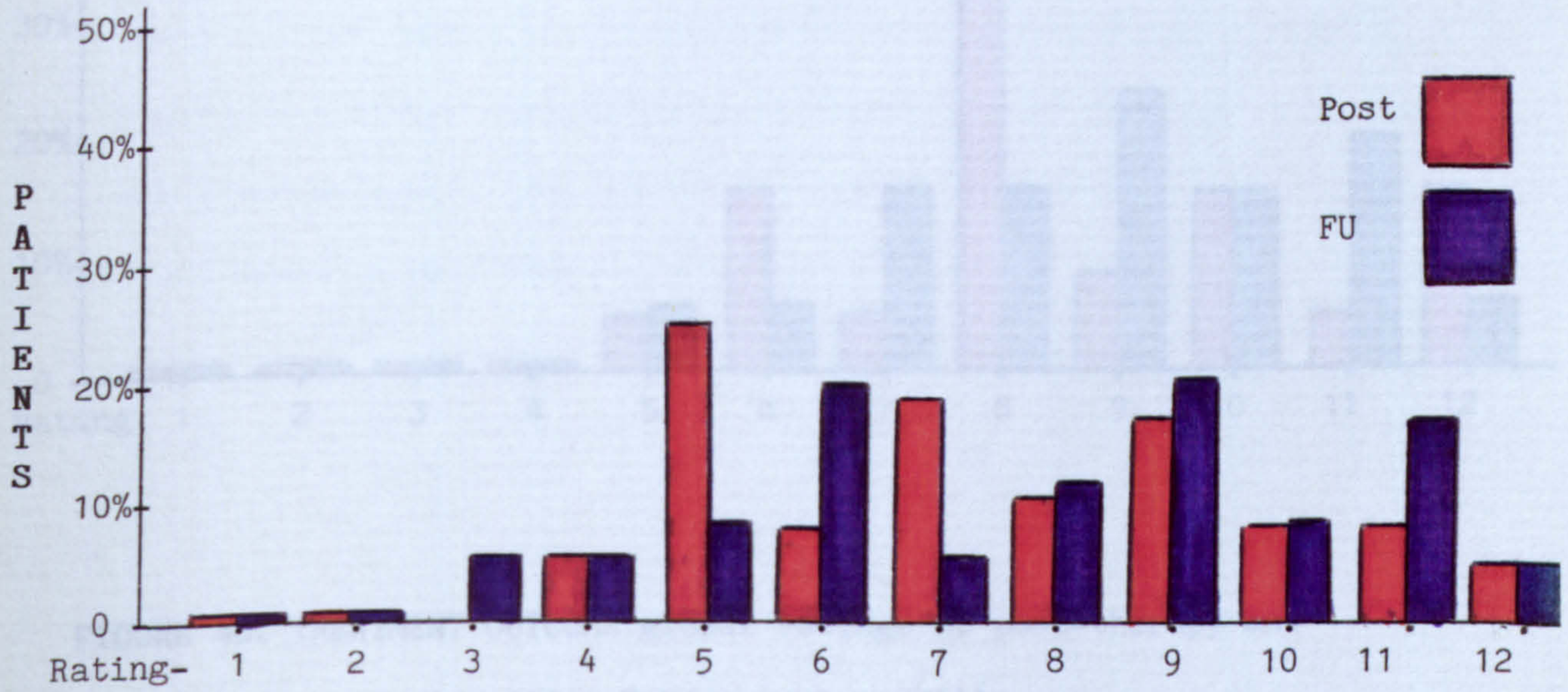

FIGURE 44. TREATMENT OUTCOME global ratings at post-therapy and follow-up for the Cognitive condition.

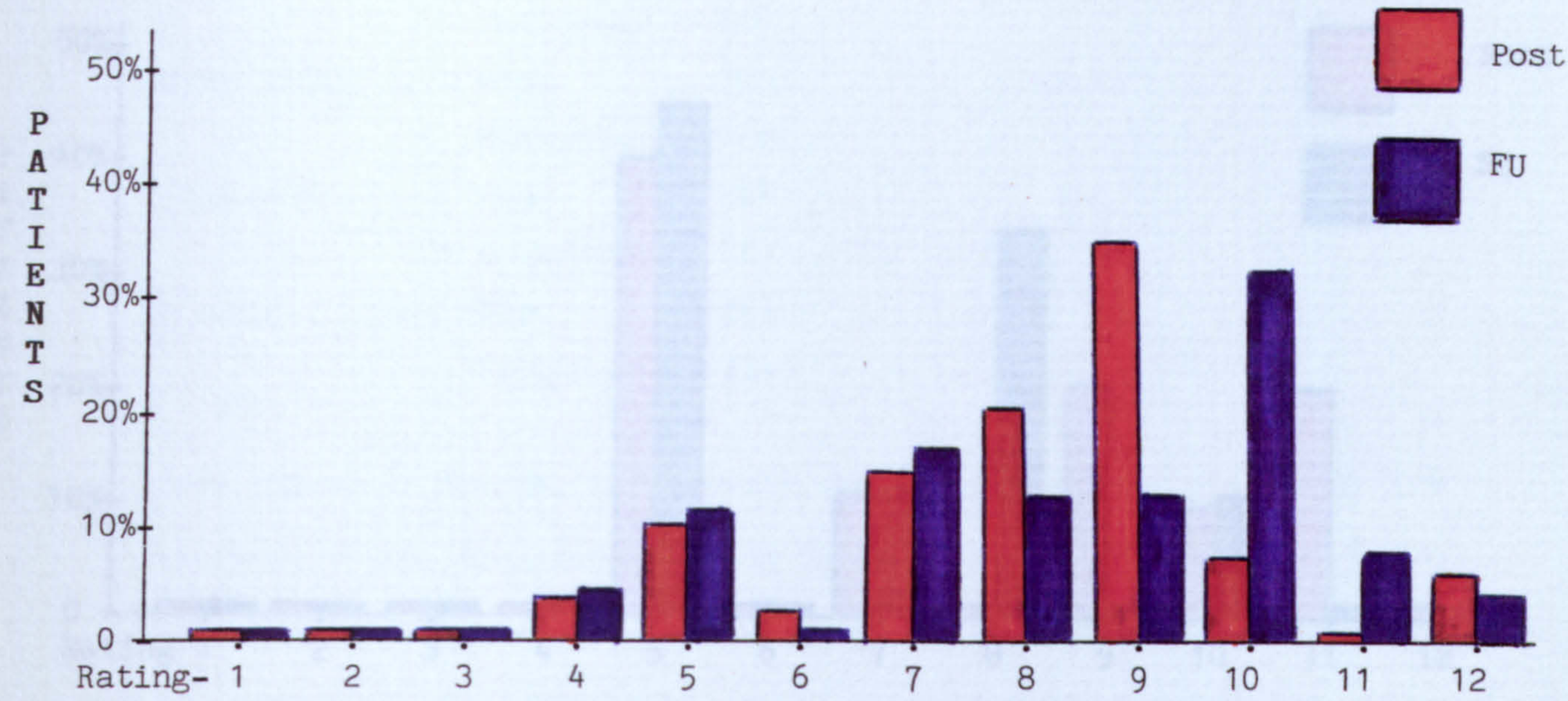

FIGURE 45. TREATMENT OUTCOME global ratings at post-therapy and follow-up for the Behavioural condition.

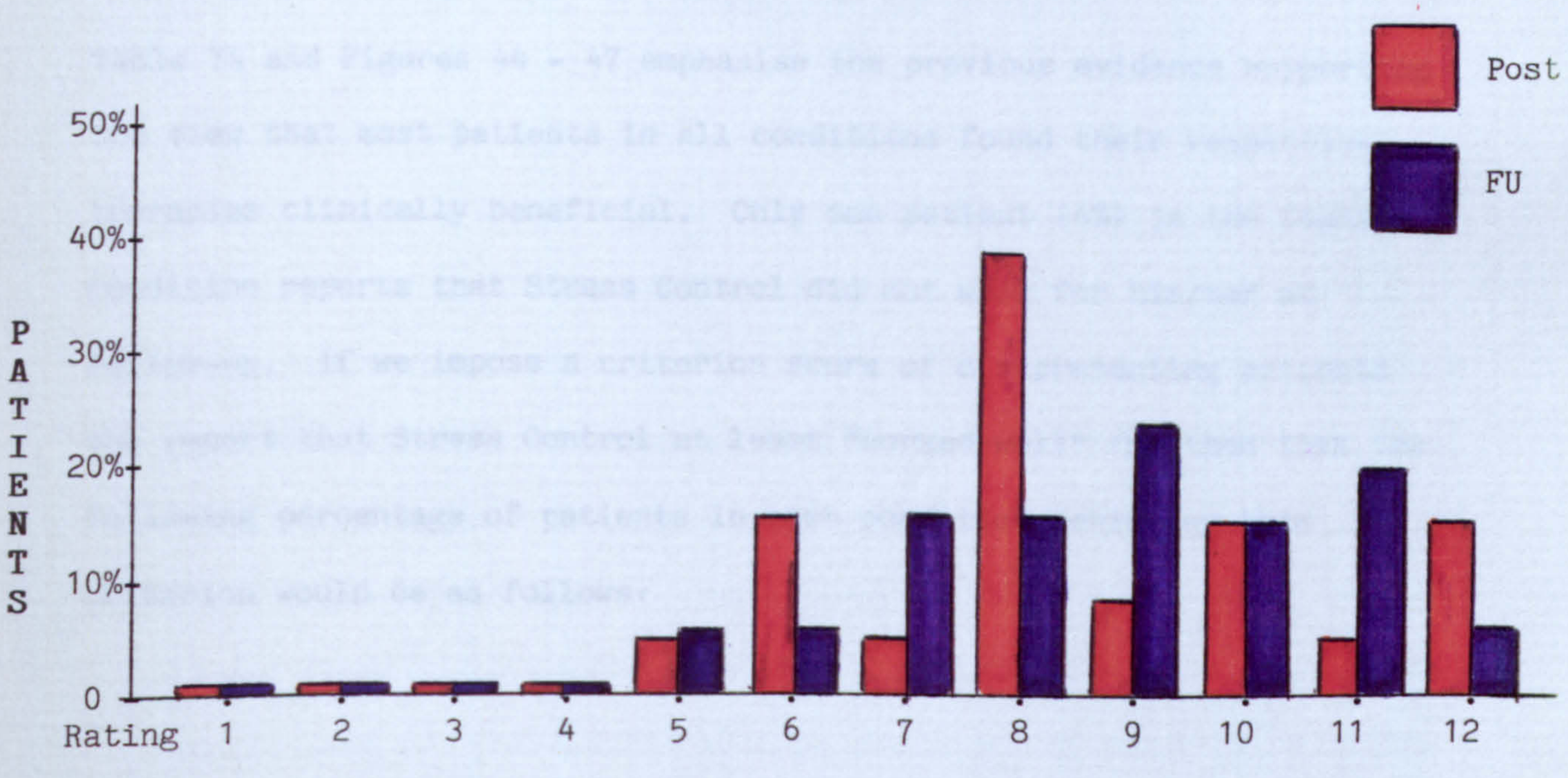

FIGURE 46. TREATMENT OUTCOME global ratings at post-therapy and follow-up for the Cognitive-Behavioural condition.

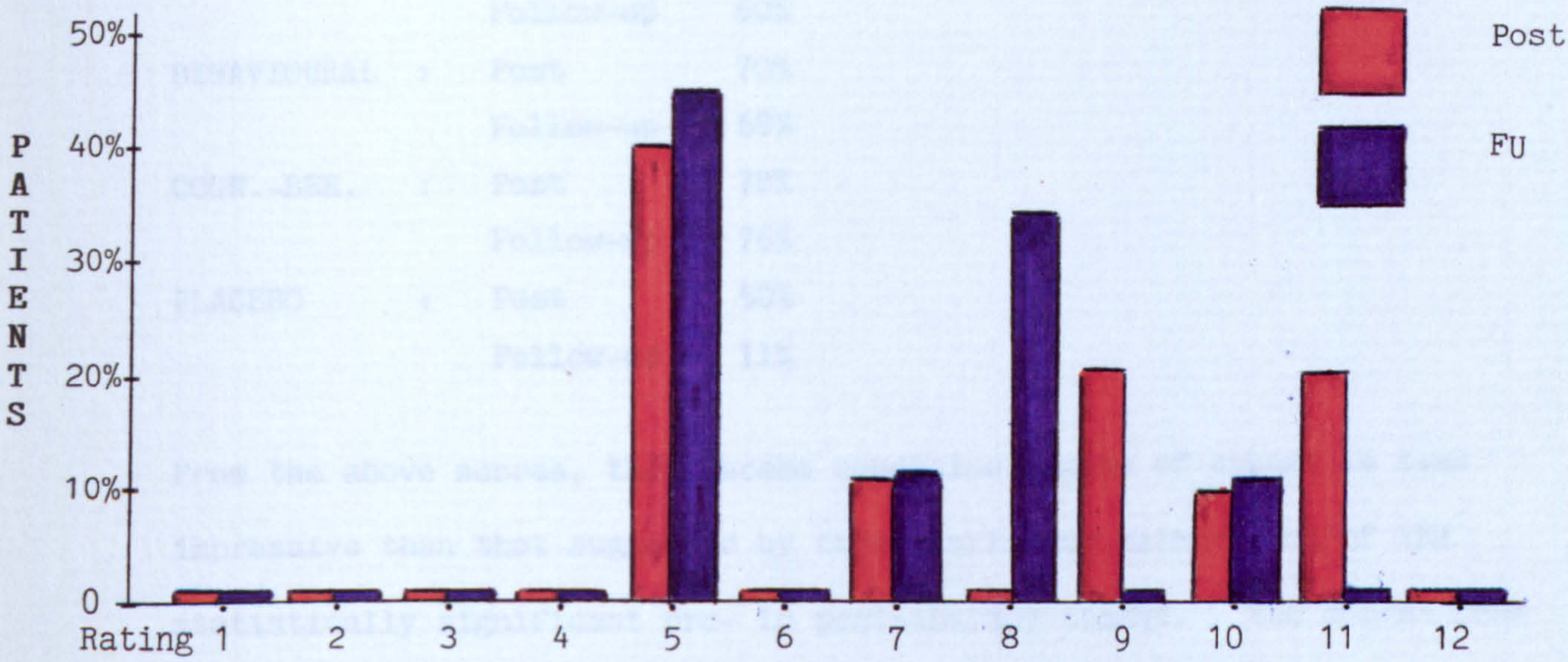

FIGURE 47. TREATMENT OUTCOME global ratings at post-therapy and follow-up for the Placebo condition.

Table 74 and Figures 44 - 47 emphasise the previous evidence supporting the view that most patients in all conditions found their respective therapies clinically beneficial. Only one patient (4%) in the Cognitive condition reports that Stress Control did not work for him/her at follow-up. If we impose a criterion score of 8 representing patients who report that Stress Control at least "worked well" for them then the following percentage of patients in each condition achieving this criterion would be as follows:

COGNITIVE	:	Post	46%
		Follow-up	60%
BEHAVIOURAL	:	Post	70%
		Follow-up	68%
COGN.-BEH.	:	Post	78%
		Follow-up	76%
PLACEBO	:	Post	50%
		Follow-up	11%

From the above scores, the Placebo condition degree of change is less impressive than that suggested by their follow-up maintenance of the statistically significant pre- to post-therapy change. The scores from the active therapy conditions are in line with the statistical significant results previously noted although now suggest that the Cognitive-behavioural condition benefitted somewhat more than the Behavioural condition and, surprisingly, the Cognitive condition - a finding quite contrary to that found in the statistical analysis.

Caution should be applied before reading too much into these findings although it does emphasise the importance of looking at the clinical meaning of statistically significant improvement. We have seen from the components analysis presented in Chapter 13 that patients, in rating which aspects of Stress Control they found most useful, disagree with what theory suggests should be most useful. Similarly, as in the case of the Cognitive-behavioural condition, subjective perception of improvement may not necessarily correlate highly with improvement as measured by questionnaires. This point will be discussed in detail at a later point.

CHAPTER 18

PREDICTING RESPONSE TO STRESS CONTROL

PREDICTING RESPONSE TO STRESS CONTROL

1. INTRODUCTION.

Previous studies, e.g. Butler et al (1987) and Durham and Turvey (1987) have noted that although cognitive-behavioural treatments for GAD are now reasonably successful, a substantial number of patients remain essentially unchanged after therapy, e.g. the former study, out of a total sample of 38, identified 18 of those patients as 'non-responders'. If it were possible to predict response to treatment prior to commencement of that treatment not only could a more economical use of scarce resources be achieved but the information gathered could potentially be used in the design of an appropriate therapy for the non-responding group.

A two-stage approach is adopted. An initial attempt at prediction utilises a PEARSON CORRELATION co-efficient to identify the relationship between base-line and change scores (pre-post and pre-follow-up) across each of the therapy conditions, i.e. to identify any relationship between the starting level and the magnitude of change.

If this initial exploration seems fruitful, a second stage will be embarked upon. MULTIPLE REGRESSION analysis will attempt to identify clinically significant predictors again, for magnitude of change. Both stages will attempt to identify predictors at post-therapy and follow-up. As this is a retrospective analysis, no hypotheses are forwarded. In addition, due to the sample sizes involved, particularly the Placebo condition (n = 10), caution is indicated in the interpretation of results.

2. PEARSON CORRELATION

Predictive variables involved all clinical pre-treatment variables and the change score (pre-post; pre- follow-up) on that variable. Results are presented for variables achieving significance of at least 0.01.

a. Post-Therapy

Table 75 presents the results for post-therapy.

TABLE 75/

TABLE 75. Predictor variables and their relationship with the change score on the same variable at post-therapy (pre - post) across the four treatment conditions. Pearson co-efficients and probability values (* p < .01; ** p < .001) are displayed.

	Cognitive	Behavioural	Cogn.Beh.	Placebo
Main Measures				
STAI:A-State		.621*		
STAI:A-Trait				
DAS				
FSS				
BDI	.700**	.754*	.712*	
MSPQ				
DIARY				
Anxiety	.741**		.861**	
Time	.818**		.715*	.876*
Cope	.640**			
FSAQ				
Cognitive				
Behavioural				
Somatic				
Mood	.559*			
Total				
SCQ				
SC1 +a	.756**			
SC5 +b	.521*			
SC6 +c	.816**		.909**	
COPING QUESTIONNAIRE				
Q7 +d		.774**	.863**	.920*

a "How anxious have you been over the last week"?
b "How well do you think this treatment will work for you"?
c "How would you rate your relative's/spouse's anxiety"?
d "How well are you generally coping with your life"?

CRQ and IMAGINAL TEST variables produced no significant correlations and are omitted from the table.

Table 75 suggests that the BDI is a useful predictor for the active therapy groups and that the Diary measures help predict for the Cognitive and Cognitive-behavioural conditions. SC6,and CQ7 also appear to be of promise. There appears, with the exception of the BDI, to be no pattern across conditions.

b. <u>Pre-therapy - Follow-up</u>

In the hope that a pattern becomes clearer at follow-up, Table 76 presents significant pre-therapy and follow-up relationships.

TABLE 76/

TABLE 76. Predictor variables and their relationship with the change score on the same variable at follow-up (pre - follow-up) across the four treatment conditions. Pearson co-efficients and probability values (* p < .01; ** p < .001) are displayed.

	Cognitive	Behavioural	Cogn.Beh.	Placebo
Main Measures				
STAI:A-State	.661**	.846**		
STAI:A-Trait	.524*	.746*		
DAS				
FSS				
BDI	.746**	.899**		
MSPQ	.688**	.782*		
DIARY				
Anxiety	.741**		.895*	
Time	.818**			
Cope	.634*			
FSAQ				
Cognitive	.750**			
Behavioural	.669**			
Somatic	.690**			
Mood	.755**			
Total	.746**			
SCQ				
SC1 +a	.782**	.761*	.827*	
SC5 +b	.613*	.545*		
SC6 +c	.716**			
COPING QUESTIONNAIRE				
Q7 +d	.663**	.874**		
CRQ				
Cognitive	.562*			
Behavioural Avoidance				

+a "How anxious have you been over the last week"?
+b "How well do you think this treatment will work for you"?
+c "How would you rate your relative's/spouse's anxiety"?
+d "How well are you generally coping with your life"?

Table 76 presents an intriguing picture. The treatment conditions are now clearly distinguished. The Placebo condition contains no significant correlations while the Cognitive-behavioural condition contains only two. While the Behavioural condition achieves significant correlations on four of the six main measures, the Cognitive condition achieves significant correlations on 85% of the variables. Across the active therapy conditions, SCl (global anxiety rating) is the only consistent predictor.

Table 76 is of potential importance. The results suggest that, in comparison with the other conditions, Cognitive therapy produces significant change on a wide range of measures of affective distress. Thus by having an impact on various dimensions of anxiety, it may produce more comprehensive results than those achieved by other therapeutic interventions.

The results of the correlational study suggest that this initial exploration has been of value. In order to carry out a more precise analysis to ascertain whether certain variables can be extracted to provide the best predictors and to analyse the amount of variance accounted by these predictors, MULTIPLE REGRESSION can now be used to explore these matters further.

3. STEPWISE MULTIPLE REGRESSION.

As in the correlational study, the influence of the pre-treatment level of distress was removed by the use of change scores (pre - post; pre - fu) in the analyses. Due to the small number of patients in the Placebo condition (n = 10), this group was excluded. Caution should also be applied, however, in assessment of the active treatment conditions due to the relatively small sample sizes.

a. Measures

i. Independent variables.

These variables were chosen on the clinical grounds as representing important dimensions of anxiety and related affective distress. The six main measures were utilized as these reflect a comprehensive assessment of anxiety. In particular STAI:A-State and A-Trait represent current distress and predisposition respectively; DAS, FSS and MSPQ reflect the three systems assessment of cognitive, behavioural and somatic symptoms and BDI measures associated depression. Each of these variables can be seen as reflecting a unique dimension of affective distress.

In addition, three clinical variables were added - DURATION (of symptoms), PSYCHPRE (previous psychiatric treatment) and EXPECTATION (of treatment success).

ii. Outcome variables.

As no single outcome measure can be said to encapsulate a criterion measure of improvement, the degree of change produced on all six main measures are presented.

b. Results

The results are presented in accordance with the recommendations made by Robins (1987). Thus, tables will report the value and significance of the F test for the effect of adding each variable, over and above the effects of variables already in the equation. This is given as F change and Significance of F change. Where the regression analysis involves more than one step, the overall values for the entire equation are presented in bold type.

i. Cognitive therapy condition.

Table 77 presents the contribution of each of the predictor variables for the Cognitive condition (n = 31) at post-therapy.

TABLE 77/

TABLE 77. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre - Post) for the Cognitive condition (n = 31) at post-therapy (* p < .01; ** p < .01; *** þ < . 001)

Outcome Variable (pre-post)	Independent Variable	r^2(%)§	St. reg. coeff +	F/ F change	F probab.	Signif F/ Signif F change
STAI:A-State	STAI:A-State	24.6	.496	9.45	.004	**
	DAS	11.2	.361	4.87	.036	*
	BDI	10.0	.349	4.97	.034	*
	PSYCHPRE	9.1	.313	5.26	.030	*
		54.9		7.91	.000	***
STAI:A-Trait	PSYCHPRE	19.1	.437	6.83	.014	*
DAS		No variable reaches criterion for entry.				
FSS	PSYCHPRE	3.4	.447	7.65	.009	***
	BDI	14.0	.374	4.74	.037	*
		32.4		6.74	.004	**
BDI	BDI	44.5	.666	23.24	.000	***
	FSS	8.4	-.334	4.99	.034	*
	STAI:A-Trait	7.7	.339	5.35	.028	*
		60.6		13.89	.000	***
MSPQ	MSPQ	40.1	.633	19.39	.000	***

§ Amount of variance explained

+ Standard regression coefficient.

Table 78 presents the same analyses for follow-up data

TABLE 78/

TABLE 78. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre-fu) for the Cognitive condition at follow-up (* p < .05; ** p < .01; *** p < .001)

Outcome Variable (pre-fu)	Independent Variable	r^2(%) §	St. reg. coeff +	F/ F change	F probab.	Signif F/ Signif F change.
STAI:A-State	STAI:A-State	29.9	.549	12.38	.001	***
STAI:A-Trait	STAI:A-Trait	14.7	.383	4.99	.033	*
DAS		No variable reaches criterion for entry.				
FSS	BDI	20.0	.447	7.25	.001	*
BDI	BDI	29.6	.544	12.24	.002	**
	FSS	10.3	-.371	4.82	.037	*
		39.9		9.34	.001	***
MSPQ	MSPQ	25.2	.502	9.79	.004	**
	SCS	11.6	.355	5.16	.031	*
		36.8		8.17	.002	**

§ Amount of variance explained

\+ Standard regression coefficient

Tables 77 and 78 produce for all variables with the exception of DAS, significant F values and mainly clinically significant amounts of explained variance particularly at post-therapy. Previous psychiatric treatment at post-therapy and expectation at follow-up enter the analyses although generally the best predictor of change on each variable is the pre-treatment value of that variable.

ii. Behaviour therapy condition.

Table 79 presents the contribution of each of the predictor variables for the Behavioural condition (n = 31) at post-therapy.

TABLE 79. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre-post) for the Behavioural condition (n = 31) at post-therapy. (* p < .05; ** p < .01; *** p < .001).

Outcome Variable (pre-post)	Independent Variable	r^2(%) §	St. reg. coeff. +	F/ F change	F probab	Signif F/ Signif F change
STAI:A-State	STAI:A-State	28.9	.538	11.82	.001	***
	BDI	13.1	.549	6.32	.018	*
		42.0		10.16	.000	***
STAI:A-Trait	STAI:A-Trait	14.7	.383	4.99	.033	*
DAS		No variable reaches criterion for entry				
FSS	FSS	17.2	.414	6.02	.020	*
	MSPQ	11.8	.428	4.68	.039	*
		29.0		5.73	.008	**
BDI	BDI	39.4	.627	18.82	.000	***
MSPQ	STAI:A-State	18.0	.424	6.37	.017	*

§ Amount of variance explained

\+ Standard regression coefficient

Table 80 presents the same analyses for follow-up data.

TABLE 80/

TABLE 80. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre-fu) for the Behavioural condition (n = 31) at follow-up.
(* p < .05; ** p < .01; *** p < .001)

Outcome Variable (pre-fu)	Independent Variable	r^2(%) §	St. reg. coeff. +	F/ F change	F probab.	Signif F/ Sifnif F change.
STAI:A-State	STAI:A-State	52.4	.723	31.94	.000	***
STAI:A-Trait	STAI:A-Trait	36.2	.601	16.44	.000	***
	DURATION	14.1	-.388	7.92	.008	**
		50.3		14.14	.000	***
DAS	DAS	20.4	.452	7.46	.011	*
	DURATION	16.5	-.431	7.35	.011	*
		36.9		8.22	.002	**
FSS	No variable reaches criteria for entry					
BDI	BDI	56.1	.769	37.09	.000	***
	DURATION	12.4	-.371	11.07	.002	**
		68.5		30.52	.000	***
MSPQ	MSPQ	40.8	.638	19.97	.000	***

§ Amount of variance explained.

+ Standard regression coefficient.

Tables 79 and 80 again show, in general, highly significant amounts of variance explained by the pre-treatment score on the change score of the particular variable. Prediction seems more certain at follow-up with DURATION of symptoms being entered at Step 2 in three of the equations, in each case the longer the duration the less change occurring. Unlike the cognitive condition, change on A-Trait and MSPQ are best predicted by A-State at post-therapy. Again DAS produces no predictor at this stage.

iii. Cognitive behavioural condition.

Table 81 presents the contribution of each of the predictor variables for the Cognitive-behavioural condition (n = 26) at post-therapy.

TABLE 81. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre-post) for the Cognitive Behavioural condition (n = 26) at post-therapy (* $p < .05$; ** $p < .01$; *** $p < .001$).

Outcome Variable (pre-post)	Independent Variable	r^2(%) §	St. reg. coeff. +	F/ F change	F probab.	Signif F/ Signif F change
STAI:A-State	STAI:A-State	24.3	.493	7.69	.010	**
	FSS	14.5	-.390	5.47	.028	*
		38.8		7.30	.004	**
STAI:A-Trait		No variable reaches criterion for entry.				
DAS	DURATION	15.3	-.391	4.34	.047	*
FSS		No variable reaches criterion for entry				
BDI		No variable reaches criterion for entry				
MSPQ		No variable reaches criterion for entry.				

§ Amount of variance explained.

\+ Standard regression coefficient.

Table 82 presents the same analyses for follow-up data.

TABLE 82/

TABLE 82. Stepwise multiple regression analyses showing the contribution of each variable to prediction of change (pre-fu) for the Cognitive behavioural condition (* p < .05; ** p < .01; *** p < .001).

Outcome Variable (Pre-fu)	Independent Variable	r^2(%) §	St. reg. coeff.	F/ F change	F probab	Signif F/ Signif F change.
STAI:A-State	STAI:A-State	34.1	.583	12.42	.007	**
	DAS	16.4	.433	7.62	.011	*
		50.5		11.73	.000	***
STAI:A-Trait		No variable reaches criterion for entry.				
DAS	FSS	19.0	-.436	5.64	.025	*
FSS	FSS	32.6	.571	11.60	.002	**
	STAI:A-Trait	11.3	.368	4.62	.042	*
	PSYCHPRE	11.3	.349	5.94	.023	*
	DURATION	7.5	.332	4.33	.049	*
		62.7		9.08	.000	***
BDI	BDI	17.4	.417	5.07	.033	*
MSPQ	MSPQ	63.9	.799	42.64	.000	***

§ Amount of variance explained

+ Standard regression coefficient.

Table 81, in contrast to all other results, shows only two of the equations producing significant prediction and, of these, only A-State producing a clinically significant result. At follow-up, A-State, FSS and MSPQ in particular account for highly significant clinical and statistical change. DAS produces, at post-therapy, DURATION and, at follow-up, FSS, as significant predictors. As in Tables 77 and 78, lower scores on these variables at pre-therapy are associated with greater magnitude of change.

c. Summary.

Table 83 summarises the amount of variance explained by the predictor variables across conditions.

TABLE 83. Summary of stepwise multiple regression analyses showing the amount of variance explained by the predictor variables across conditions at post-therapy and at follow-up. (* denotes two or more predictor variables in the equation).

Outcome Variable		Amount of Variance Explained - r^2(%) Cognitive (n = 31)	Behavioural (n = 31)	Cogn.-Behavioural (n = 26)
STAI:A-State	: post-therapy	55*	42*	39
	: follow-up	30	52	51
STAI:A-Trait	: post-therapy	19	15	-
	: follow-up	15	50*	-
DAS	: post-therapy	-	-	15
	: follow-up	-	37*	19
FSS	: post-therapy	32*	29*	-
	: follow-up	20	-	63
BDI	: post-therapy	61*	39	-
	: follow-up	40*	69*	17
MSPQ	: post-therapy	40	18	-
	: follow-up	37*	41	64

Figures 48 and 49 employ bar-charts to facilitate comparison of the significant prediction across conditions both at post-therapy and at follow-up.

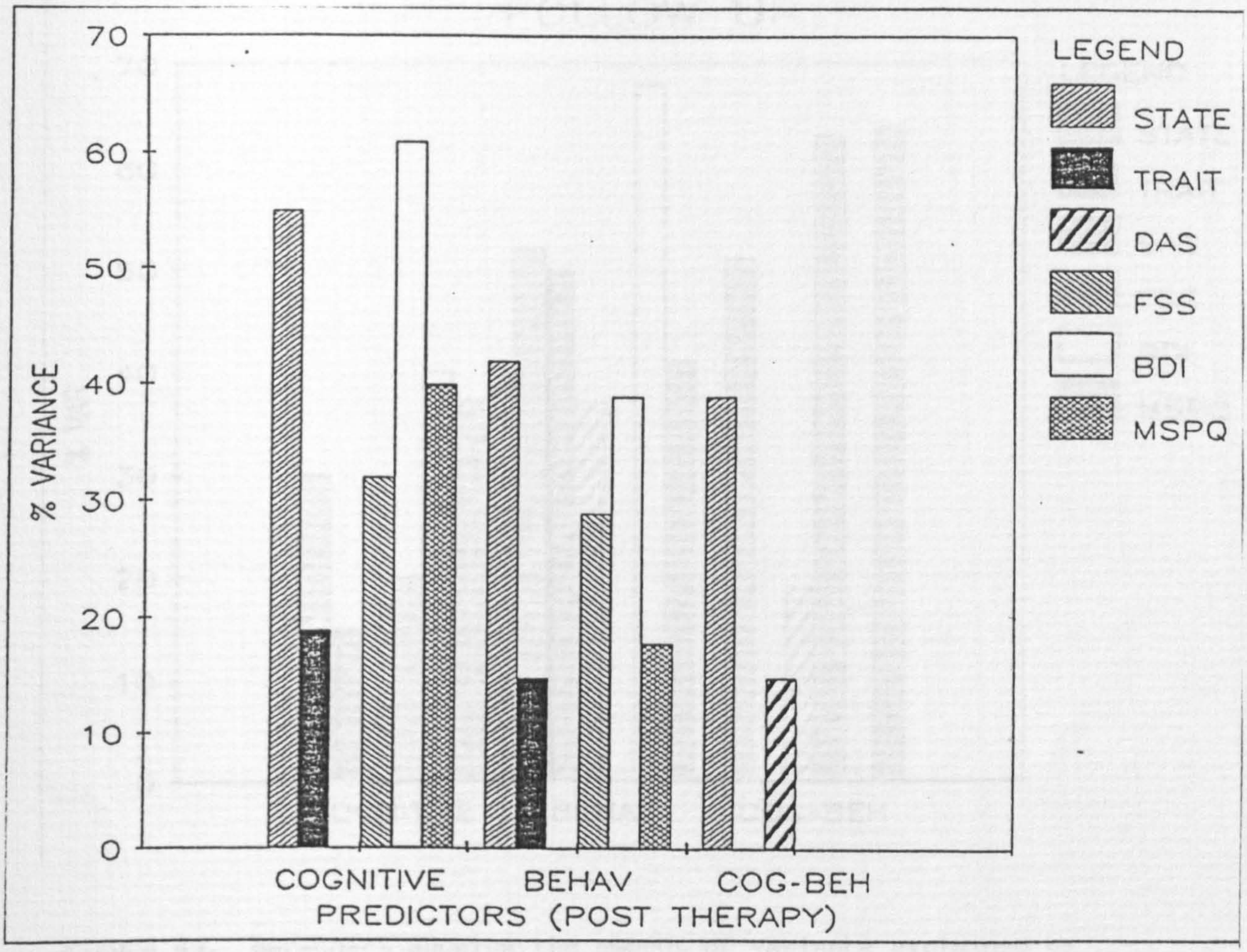

Figure 48. Bar-chart showing the amount of variance explained by the predictor variables across conditions at post-therapy.

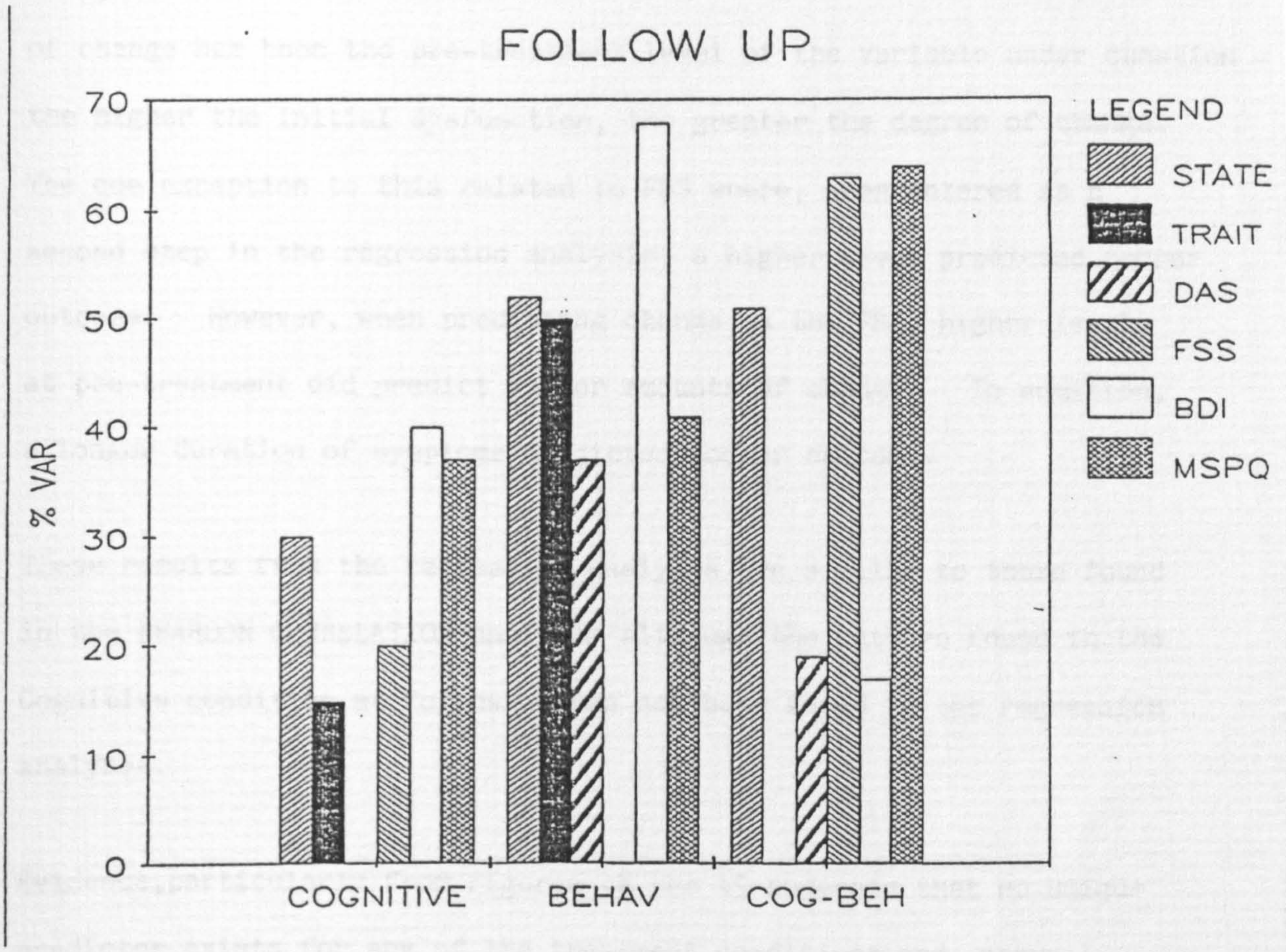

Figure 49. Bar-chart showing the amount of variance explained by the predictor variables across conditions at follow-up.

4. CONCLUSION.

The aim of this chapter has been to look for clinically significant prediction of outcome. The preceding evidence suggests that this attempt has been reasonably successful. In general, the best predictor of change has been the pre-treatment level of the variable under question - the higher the initial dysfunction, the greater the degree of change. The one exception to this related to FSS where, when entered as a second step in the regression analysis, a higher level predicted poorer outcome. However, when predicting change on the FSS, higher levels at pre-treatment did predict larger amounts of change. In addition, a longer duration of symptoms predicted poorer outcome.

These results from the regression analyses are similar to those found in the PEARSON CORRELATION analyses although the pattern found in the Cognitive condition at follow-up has not been found in the regression analyses.

Evidence,particularly from Figures 48 and 49 suggests that no unique predictor exists for any of the treatment conditions and, overall, A-State, BDI and MSPQ appear to be of promise as clinically relevant predictors. DAS pre-treatment values and EXPECTATION appear to be of little value.
These findings will be discussed at a later point.

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CHAPTER 19

A COMPARISON OF TREATMENT RESPONDERS AND NON-RESPONDERS

A COMPARISON OF TREATMENT RESPONDERS AND NON-RESPONDERS.

a). Introduction.

The aim of this chapter is to compare treatment responders and non-responders - in particular to assess whether this division can be accurately predicted on the basis of pre-treatment information. Only status at six month follow-up will be considered as although improvement at post-therapy is clearly of great significance, the maintenance of improvement is of greater importance.

b). Criteria for 'treatment non-responders'.

A treatment non-responder, hereafter referred to as a 'failure' was classified as such if he or she met at least two of the following three criteria:

a). **Global anxiety rating** (SC1) "How anxious have you been over the last week"?

: a follow-up rating that represents less than a 20% reduction on the pre-therapy rating.

b). **Global coping rating** (CQ7) "How well are you generally coping with life"?

: a follow-up rating that represents less than a 50% increase on the pre-therapy rating.

c). **Global outcome rating** (SC5) "How well did this treatment work for you"?

: a follow-up rating equal to or less than 6 on a 12 point scale where 1 represents "Not at all" and 12 "Extremely well".

The above three measures are the variables used in assessing 'clinically significant change' although in that assessment no attempt was made to dichotomise patients.

Anyone not achieving these criteria was regarded as a 'success'. Patients were excluded from the two categories if data were missing at either pre-therapy or follow-up. The classifications resulting from the implementation of these criteria are presented in Table 84.

TABLE 84. Classification of patients, at follow-up, into successes and failures across the active therapy conditions.

	Treatment Success	Treatment failure	Unallocated
Cognitive condition	21	5	5
Behavioural condition	21	4	5
Cogn.-Beh. condition	15	6	5
Placebo condition	6	3	1

Table 84 immediately suggests that the majority of patients achieve 'treatment success'. Indeed given the relatively liberal criteria for failure, it is perhaps surprising that so few appear in the failure column particularly when compared to other GAD treatment outcome studies, e.g. Butler et al (1987b) identified 20 good responders and 18 poor responders (criteria not given). However, the low number of failures within each condition suggests that collapsing the data will achieve a more meaningful analysis of the data. In addition, given the relatively higher number of failures in the placebo condition, this group will now be dropped from the analysis: Thus the three active conditions are merged to give:

15 failures
57 successes.

Table 85 presents descriptive statistics involving the pre-therapy, follow-up and percentage change scores on the main measures for the two groups along with T-Tests applied on mean scores at pre-thrapy between successes and failures.

TABLE 85/

TABLE 85. Comparison of treatment successes and failures of mean scores at pre-therapy and follow-up along with percentage change scores for each of the main measures (+ = increase in score, - = decrease in score) along with T-TEST comparisons of pre-therapy mean scores (one-tailed)

	Success	Failure.	
STAI:A-State			
Pre	55.2	49.3	(T = 1.76, p = 0.04)
Fu.	34.4	37.7	
% change	-37.7	-23.5	
STAI:A-Trait			
Pre	59.5	50.8	(T = 2.74, p = 0.005)
Fu	43.0	48.0	
% change	-27.7	-5.5	
DAS			
Pre	96.9	105.3	(T = 1.19, p = 0.125)
Fu	116.4	112.3	
% change	+20.1	+6.6	
FSS			
Pre	107.8	108.4	(T = 0.05, p = 0.48)
Fu	65.8	94.6	
% change	-39.0	-12.7	
BDI			
Pre	20.1	13.1	(T = 3.22, p = 0.001)
Fu	7.6	10.9	
% change	-62.2	-16.8	
MSPQ			
Pre	33.8	23:9	(T = 2.52, p = 0.019)
Fu	13.9	20.4	
% change	-58.9	-14.6	

Inspection of Table 85 reveals that, with the exception of FSS, the pre-treatment scores of the successes are considerably higher than those of the failures. Indeed T-TESTS show significant differences on all measures except FSS and DAS. At follow-up, the situation is reversed

with the failures now more dysfunctional than the successes thus suggesting that the results are not simply reflecting the Law of Initial Values.

c). Stepwise Discriminant Analysis.

Stepwise discriminant analysis can be carried out on the successes and failures in the collapsed active therapy condition. The predictor variables used in the regression analyses are again employed. Table 85 provided mean scores at pre-therapy for the main measures. DURATION (of symptoms) for the successes is 6.5 years and, for the failures, 12.3 years ($T = 3.88$, $p = 0.001$). Successes have a higher positive expectation of treatment outcome compared to the failures - 8.4 v 6.8 ($T = 2.42$, $p = 0.02$). Around 25% of patients in both groups have had previous psychiatric treatment.

It is interesting that although less dysfunctional at pre-treatment, the failures have a significantly longer duration of symptoms and a more pessimistic view of treatment success.

Table 86 presents the results of the Stepwise discriminant analysis.

TABLE 86/

TABLE 86. Stepwise discriminant analysis of treatment success and failures (* p < .05; ** p < .01; *** p < .001)
(bold type represents overall analysis)

STEP	VARIABLE ENTERED	EIGENVALUE	WILKS' LAMBDA	PROBAB.	SIGNIF.
1	DURATION		.841	.0008	***
2	BDI		.767	.0002	***
3	SC5		.740	.0002	***
4	A-Trait		.715	.0003	***
5	MSPQ	.429	.699	.0004	***

Table 86 strongly suggests that the discriminant analysis, based on the eigenvalue, has excellent discriminating value. The overall Wilks' lambda, at Step 5, indicates that differences between the successes and failures account for 30% of the variance in the predicting variables.

Table 87 assesses the percentage of cases that are classified correctly.

TABLE 87. Number and percentage of cases classified into treatment success or failure by STEPWISE DISCRIMINANT ANALYSIS.

ACTUAL GROUP	NO. OF CASES	PREDICTED GROUP	
		Success	Failure
Success	57	46 (81%)	11 (19%)
Failure	15	4 (27%)	11 (73%)

Percent of 'grouped' cases correctly classified : 79%

Table 87 shows that, overall, patients divided into successes and failures at follow-up can be fairly accurately predicted on the basis of five pre-treatment variables. In general, DISCRIMINANT ANALYSIS, taken together with the REGRESSION ANALYSES, suggest that reasonable predictive ability for Stress Control therapy exists and the implications of this will be discussed later.

Table 89 shows that, overall, patients divided into successes and failures at follow-up, can be fairly accurately predicted on the basis of three pre-treatment variables : Duration of symptoms, BDI and SC5 (expectation). Only four treatment success patients are misclassified using these variables. However 9 treatment failures - 60% in all are misclassified - a result which stands in stark contrast to that of the success group.

It is possible that given the relatively small number of patients in the failure category, and given the relatively liberal criteria imposed in defining failure, this group may be rather heterogeneous in nature and that a more conservative set of 'failure' criteria would help boost the number of correct classifications. However, the numbers involved are too small to permit this.

In general, DISCRIMINANT ANALYSIS, taken together with the REGRESSION ANALYSES carried out earlier, suggest that reasonable predictive ability for Stress Control Therapy exists and the implications of this will be discussed later.

PART 4

CHAPTER 20

DISCUSSION

Discussion of the results of the present study will be organised around a number of themes and each theme will form a section of this chapter. The areas of interest are as follows:

A. Psychological treatments and their effects.

B. Within group analyses.

C. Impressions of Stress Control.

D. Comparison with other treatment outcome studies.

E. Non-specific effects.

F. Suggestions for future investigations.

A. PSYCHOLOGICAL TREATMENTS AND THEIR EFFECTS.

In reviewing the reasons for the present study, eleven questions were posed (see page 196). We are now in a position to address these questions.

1) Does a multi-dimensional group therapy package result in improvements in GAD patients treated in primary care?

The present study hoped to provide a treatment which could not only be a practical alternative to benzodiazepines but would also be a clinical- and cost-effective resource in primary care psychology.

The evidence presented in Parts 2 and 3 overwhelmingly suggests that this aim has been achieved. In terms of an economical use of scarce therapist time, Stress Control, treating up to twenty-four patients by two psychologists in twelve hourse is clearly of great potential for busy out-patient clinical work. In terms of clinical outcome, the highly significant statistical (and clinical) change during the course of therapy again suggests that a reasonable compromise between quantity of patients treated and quality of service provided has been achieved.

2) Are treatment gains maintained at six month follow-up?

As Zielinski (1978) comments, failure to achieve maintenance of gain becomes "an exercise in futility". The results presented in Chapter 13 provide evidence not only of maintenance but of enhancement of post-therapy gains in all of the active therapy conditions and,

against expectation, maintenance of gain for the Placebo condition. Evidence for this is consistent both for self-report and objective indices of change. It does appear that the obje ctive of "turning the patient into his/her own therapist" to help prevent relapse has been achieved.

The results from the present study, at least for the active therapy conditions, parallel those found by Mathews et al (1981) in a therapist-administered bibliotherapy study of agoraphobia where half as much change took place after the completion of therapy as took place during therapy.

3) **Are there any outcome difference between Cognitive, Behavioural, Cognitive-behavioural, Placebo and Waiting list conditions?**

and

4) **Do patients in each treatment condition show a different process of change - specifically in terms of the three systems of anxiety?**

It may be useful to combine these questions and summarise the results by assessing change on each of the measures employed in the study. These measures can be subsumed under three categories:

a) **Main measures.**

b) **Process measures.**

c) **Generalisation and global measures.**

a) Main measures.

STAI:A:State

At post-therapy, all four treatment conditions are significantly different to the Waiting list condition. Both the Cognitive and Behavioural conditions show significant change over pre-therapy by mid-therapy and all treatment conditions show highly significant change ($p < .001$) at post-therapy. By six month follow-up, this trend continues with the three active therapy conditions displaying significant improvement over post-therapy scores. The Cognitive and Behavioural conditions, with change from pre-therapy to follow-up of 36 - 38%, show the greatest magnitude of change. It is clear, however, that all treatments show marked reductions in state anxiety.

STAI:A-Trait

At post-therapy, the three active treatment conditions are significantly different to the Waiting list condition. The Cognitive and Behavioural conditions show greatest change from pre-therapy ($p < .001$) and the Cognitive-behavioural and Placebo conditions also attain significant change ($p < .01$ and .05 respectively). Improvement continues in all therapy conditions during the follow-up period with the Cognitive and Behavioural conditions demonstrating significant change from post-therapy scores. These two conditions show 13 and 14 point reductions in A-Trait scores respectively. These large differences in an apparently stable measure of anxiety proneness are the largest changes so far reported in the GAD treatment outcome literature.

Dysfunctional Attitude Scale (DAS)

Although it was hypothesised that the two cognitive conditions would show the greatest reduction in dysfunctional attitudes, the Behavioural condition along with the Cognitive condition show the largest magnitude of change at post-therapy ($p < .001$) although only the Cognitive condition is significantly different to the Waiting list condition at this point. The pattern of continued improvement to follow-up is noted for the active treatment conditions. The 16% change in the Behavioural group compares reasonably well with the 20% change achieved by the Cognitive condition and suggests that cognitive approaches are not essential in order to alter dysfunctional attitudes.

Fear Survey Schedule - FSS-III

As with A-Trait, the three active conditions, at post-therapy, are significantly different to the Waiting list condition and all treatment conditions show significant change over time ($p < .001$). A non-significant trend towards further improvement exists for the three active treatment conditions while the Placebo condition maintains treatment gains. Again, greatest gains are recorded by the Cognitive and Behavioural groups suggesting, in the case of the former condition, that reliance upon behavioural techniques is not necessary in changing reactions to fear-related stimuli.

Beck Depression Inventory -BDI

All treatment conditions are significantly different to the Waiting list condition at post-therapy and significant change over time exists for

all treatment conditions ($p < .01$). This trend continues for all conditions to follow-up and the Cognitive and Behavioural conditions achieve significant change from post-therapy ($p < .05$). As with all variables so far studied, greatest improvement is associated with these two groups.

Modified Somatic Perception Questionnaire - MSPQ

All treatment conditions are significantly different to the Waiting list condition at post-therapy. Surprisingly the Cognitive-behavioural condition does not show significant change over time at this point although highly significant change occurs between post-therapy and follow-up ($p < .001$). Indeed, at follow-up a different picture to that found on other main measures begins to emerge. The Placebo condition relapses and is significantly different to the Cognitive-behavioural condition which, with the Behavioural condition, shows change over pre-therapy of between 53 - 55%. Although the Cognitive condition shows highly significant change of 44% over the same period, these results do suggest that the inclusion of progressive muscular relaxation techniques may be of value in terms of their impact on somatic symptoms of anxiety.

Overview of main measures

The measures show unanimity in terms of the significant improvements associated with all treatment conditions. The results from the Waiting list condition demonstrate unequivocally that spontaneous remission does not account for treatment effects in this study. Of the four treatment conditions, the Cognitive and Behavioural conditions produce the most

significant change closely followed by the Cognitive-behavioural and Placebo condition. Against expectation, there is no evidence favouring the cognitive therapies. Of interest is the continuation of improvement following therapy thus suggesting that patients have learned more appropriate methods of coping and are actively using these coping techniques during the follow-up period. The similarity between conditions and, in particular, the impressive results associated with the Placebo condition, begins to help orient us towards possible explanations for this change. A review of the process measures should provide further help in this endeavour.

b) Process measures.

Diary measures : i "How anxious have you been today?" (ANXIETY)

ii "How much time have you spent thinking or worrying about your problems today?" (TIME)

iii "How well have you coped today?" (COPE)

The diary measures produce distinct patterns of change across conditions. The Placebo condition demonstrates marked changes in all three variables early in therapy followed by marked relapse during the latter part of therapy. In the case of COPE and TIME, the three active conditions are significantly different to the Placebo conditions at this time. In contrast, the change associated with the Behavioural and Cognitive-behavioural conditions appears more smooth- the latter showing highly significant change from baseline from Week 2 of therapy onwards. The Cognitive condition shows, in ANXIETY and TIME, significant worsening in the early stages of therapy. Significant improvement over baseline

only becomes apparent during the final week of therapy. It appears reasonable to suggest that the therapy itself has caused the Cognitive condition to react in this way and possible reasons will be discussed later.

As expected, there is an inverse relationship between the ANXIETY and TIME variables and COPE, the latter improving as therapy goes on and the first two variables showing decreases over time. Unlike the results found in the main measures, the Cognitive-behavioural condition generally does at least as well as the Cognitive and Behavioural conditions even although the former group starts off with lower ratings of distress.

Four Systems Anxiety Questionnaire - FSAQ

Cognitive component

The three active therapy conditions improve to almost the same statistically significant degree over the course of therapy ($p < .001$). Neither the Placebo and Waiting list show significant change over time although a non-significant trend towards improvement exists for the former group. All treatment conditions are significantly different to the Waiting list by the final week of therapy.

Of greater interest, however, is the process of change. Against expectation, no differential pattern of change exists between the conditions although the Behavioural and Cognitive-behavioural conditions show some evidence of relapse at Weeks 4 and 2 respectively. Significant improvement continues to follow-up for the active treatment conditions ($p < .05$) and a non-significant trend towards improvement exists for

the Placebo condition. Again the Cognitive-behavioural condition performs as well as the other active treatment groups by follow-up, showing 46% reduction in pre-therapy scores.

Behavioural component

Again the active conditions are significantly discriminated from the Waiting list by the end of therapy and (non-significantly) from the Placebo condition at follow-up. Highly significant change over time is associated with the active conditions from mid-therapy onwards ($p < .001$). Only in the final week of therapy does the trend.. towards improvement in the Placebo condition become statistically significant. Although the Behavioural condition shows the greatest degree of change from pre-therapy (42%), it does not greatly differ from the Cognitive or Cognitive-behavioural conditions. As with the cognitive component, the pattern and magnitude of change appears similar across conditions.

Somatic component

All active treatment conditions and, in particular, the Cognitive-behavioural condition, evidence a large degree of change from pre-therapy to follow-up (35 - 44%). Improvement continues in the follow-up period (significant in the case of the Behavioural condition). All treatment conditions are significantly superior to the Waiting list condition by the end of therapy. At follow-up, the active conditions are significantly superior to the Placebo condition ($p < .005$). The latter group shows significant relapse between post-therapy and follow-up ($p < .04$) although, overall, shows a 14% improvement over baseline score.

This result, as we would expect, echoes that of the MSPQ reported earlier. There appears to be no important differences in the process of change associated with the three active therapy conditions.

Mood component

Although descriptive statistics note a reduction at post-therapy of between 19 - 31% in the three active treatment conditions and record no change in either the Placebo and Waiting list conditions, no significant differences emerge either within or between conditions. It is noticeable that the SDs associated with this variable are generally larger than those associated with the other FSAQ variables. Between post-therapy and follow-up, however, significant improvement is noted in all active therapy conditions ($p < .05$) while the Placebo condition relapses slightly. Once again, the pattern of change across active treatment conditions appears similar.

Total scores.

As an amalgam of the four components, the Total scores produces expected results. All four treatment conditions show highly significant differences when compared to the Waiting list condition from Week 3 onwards ($p < .001$) and highly significant reductions in anxiety from baseline ($p < .01$). The active therapies show significant gains over post-therapy scores at follow-up ($p < .05$) while the Placebo condition maintains gain. The similarity across conditions in terms of process of change is apparent although it again displays the relapse in the Cognitive-behavioural condition during Week 2 which occurs in all components.

Thus all FSAQ measures demonstrate significant changes over time associated with all treatment conditions, although the Placebo condition, on all variables, produces a smaller degree of change than the active treatment conditions which, as with the Diary measures but unlike the main measures, show the Cognitive, Behavioural and Cognitive-behavioural conditions performing at an equally high level.

Coping Responses Questionnaire - CRQ

Active-Cognitive coping

Although no between group differences exist during therapy and although the active treatment conditions show clear improvement, the Cognitive condition alone produces significant change over time ($p < .01$ at post-therapy). Significant improvement from post-therapy to follow-up is found in the Cognitive condition ($p < .01$) and in the Behavioural condition ($p < .001$). The other two conditions show a non-significant trend towards improvement.

In terms of the process of change, both the cognitively orientated conditions show an initial worsening in coping ratings - a pattern similar to that found in the Diary - ANXIETY and TIME ratings. Thereafter these two conditions display consistent incremental change similar to that displayed throughout by the Behavioural and Placebo conditions.

Active-Behavioural coping

Against expectation, the Behavioural condition does relatively badly as compared to the other active treatments and, indeed, shows no significant change across time even although, by the final week of

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therapy, all active therapy conditions are significantly improved compared to the Waiting list. By follow-up, although all treatment conditions show a continuation of improvement, significant change is particularly associated with the Cognitive condition which shows a 34% improvement over pre-therapy scores.

In terms of process changes, all treatment conditions, over the first few weeks of therapy, show relapse from pre-therapy scores. The second half of treatment shows reasonably consistent improvements across conditions.

Avoidance coping

All of the active treatment conditions show significant improvement over time ($p < .001$) and from as early as Week 2, show significant differences to the Waiting list. The Placebo condition is significanly discriminated from the Waiting list from Week 4 onwards although displays no significant change between Week 1 and end of therapy. Significant improvement from post-therapy is found for all of the active treatment conditions at follow-up ($p < .001$) while the Placebo relapses slightly.

As with the other variables in the CRQ, the process of change seems fairly similar across treatment conditions. Overall it appears that changes in coping strategies are strongly associated with symptomatic improvement. Milne (1987) suggests that the former causes the latter. The present study, however, cannot go beyond the evidence of correlation.

(The Imaginal test will be dealt with in a later section).

Overview of Process measures.

As with the main measures, all process measures show significant change associated with the active therapy conditions and, to a lesser extent, the Placebo condition. Unlike the main measures, the Cognitive-behavioural condition generally produces as much change as the Cognitive and Behavioural conditions. There is evidence from the CRQ, possibly reflected in the Diary COPE variable, that patients have altered their coping strategies and this may be of importance to the continuation of improvement during the follow-up period.

In terms of the process of change, the results are less illuminating than was hoped for. In general, a similar process of change exists across conditions. The only notable difference is seen most clearly in the ANXIETY and TIME Diary and CRQ-C measures where the Cognitive condition shows an initial exacerbation in anxiety.

Generalisation effects and Global ratings

Global anxiety - patient and spouse ratings.

With rating decreases between 32 - 38% ($p < .001$), patients in the active therapy conditions outperform, to a degree, Placebo patients who show a 28% reduction ($p < .05$). These improvements are maintained by the Behavioural and Placebo groups at follow-up while the other conditions show an enhancement of post-therapy improvement.

Spouse ratings show a similar trend. At post-therapy, all treatment conditions show significant change ($p < .001$) and, with the exception

of the Behavioural condition which shows significant relapse ($p < .01$), maintain improvement. Overall, all conditions at post-therapy record improvement on patients ratings in the range 29 - 42% and on spouse ratings in the range 24 - 46%.

Global coping (patients only)

Active therapies produce significant increases in global coping skills at post-therapy in the range 39 - 50% ($p < .001$) compared to the 29% ($p < .05$) increase reported by the Placebo condition. Active therapy conditions enhance this change between post-therapy and follow-up and now report change in the range 50% (Cognitive) to 66% (Cognitive-behavioural) with the Placebo condition enhancing improvement at 39%. Thus, as with the process measures, the global ratings suggest that the Cognitive-behavioural condition does at least as well as the other two active therapy conditions.

G.P. consultations - 6 month pre- and post-therapy.

Significant decreases in consultations are noted in all treatment conditions in the range 42 - 54%. This 'hard' evidence compliments the self-report data presented earlier and provides evidence that Stress Control not only helps relieve patients subjective distress but also relieves pressure on other NHS resources.

Benzodiazepine use - 6 month pre- and post-therapy.

Significant decreases in the range of 50 - 67% across conditions again supports the earlier evidence of substantial change occurring as a result of the various Stress Control conditions. However, whether this evidence is as important is doubtful. The present study took place at a time of

increasing dissatisfaction with benzodiazepines both within the medical profession and from the general public. Thus the results may reflect changes in GP prescribing practice rather than being simply due to treatment gains.

Overview of measures.

The measures show a very clear pattern. The Waiting list condition shows no improvement on a wide range of measures. The Placebo condition, again on a wide range of measures and against expectation, demonstrates significant improvement during therapy and, by and large, maintains that improvement at follow-up. The active treatment conditions show greater improvements during therapy and generally enhance that improvement at follow-up. .. . The main measures suggest that particular improvement is associated with the Cognitive and Behavioural conditions. The process measures and global ratings, however, show the Cognitive-behavioural condition improving to the same degree.

Thus there is overwhelming evidence that Stress Control is an effective treatment for GAD. All active therapy and, to a lesser extent, Placebo, conditions, produce significant change.

Use of self-report measures.

Of necessity, the present study relied, almost exclusively, on the use of self-report measures. Self-report was used to assess the cognitive, behavioural and physiological systems of anxiety.

Hugdahl (1981) questions whether a verbal report can be taken as an accurate perception of the physiological and behavioural systems.

Self-report has been criticised on the grounds that responses are subject to response bias, demand or expectancy and social desirability (Jayaratne and Levy, 1979). However, it is not only self-reports that are subject to demand characteristics. Miller and Bernstein (1972) provide evidence of high demand instructions influencing approach behaviour in a behavioural avoidance test (BAT) while Odom and Nelson (1977) provide evidence of high demand influencing heart rate during a BAT.

While self-report is the only measure of cognitive activity, physiological measurement, as reported in Chapter 5, can run across the complications produced by individual response stereotypy and stimulus response specificity. Use of the FSAQ helps diminish these problems by including 15 items which assess various somatic symptoms in different parts of the body. As this questionnaire also includes items on cognitive, behavioural and mood indices of anxiety, it results in a flexibility which, otherwise, in large group therapy, could not be considered. The FSAQ, in Cone's (1979) terminology, uses the same method of measurement (self-report) to assess the level of anxiety in the four different content areas - a method previously used by Lehrer and Woolfork (1982) who were thus able to point out that desynchrony and discordance could not be attributed to the methodological differences in assessing the level of anxiety in the different systems. Confirmation of the validity of this method requires the findings of high correlations between direct measures of physiological arousal and overt behaviour and the corresponding components of the measure.

Ost et al (1982), in a social phobia treatment outcome study, produced evidence of parallel changes in the Autonomic Perception Questionnaire and in heart rate. Douglas et al (1988), in a social anxiety assessment study, showed a strong relationship between the MSPQ and pulse rate. Similarly there was a high correlation between the cognitive self-report questionnaire (SASSC) and the cognitive fear thermometer. By contrast, the behavioural self-report questionnaires did not show clear correlations with rated verbal and non-verbal behaviour in the performance test. However, it has been suggested by Thorpe (1989) that this finding is weakened due to a confounding of 'question asked' and 'response mode' - the assumption being that if the same "question" is asked throughout each response system, the intercorrelations among the systems will be much higher.

Thus evidence supporting the use of self-report is available and its use in the present study is defended as a realistic and, above all, pragmatic method of assessment.

5) Does cognitive change (in terms of positive- and negative- self-statements) differ between the therapy conditions?

The Imaginal test was used as a method of accessing automatic thoughts and of monitoring changes in belief in these thoughts. Both the descriptive and statistical analyses suggest the following:

1) Patients across conditions, as evidenced by the imaginal ratings, had little difficulties in imagining the anxiety provoking scenes presented to them.

2) Patients across conditions reported reasonably high levels of anxiety experienced during the presentation of the scenes.

3) Patients across conditions were able to rate level of belief in the eight positive- and eight negative- self-statements without apparent difficulty.

From the above, it appears reasonable to conclude that the Imaginal test is a valid test. There is also clear evidence to show that the test does discriminate between the conditions in terms of changes in beliefs in nagative- and positive- self-statements.

Although no significant between group differences occurred, there is a clear trend favouring increased belief in positive self-statements in the Cognitive and Cognitive-behavioural conditions (see Figure 19). These trends in the within group analyses reach significance early in therapy in both of these conditions and, by the final session, are significantly different from Session 1 in the Cognitive condition ($p < .001$) and in the Cognitive-behavioural condition ($p < .05$). The rate of increase in beliefs in positive self-statement scores is relatively smooth in these two conditions with the exception of Session 4 when both relapse somewhat. This point will be considered later. In contrast, the Behavioural and Placebo conditions, although overall showing a non-significant trend towards increasing belief in the statements, show

a much more erratic process of change. Thus there is evidence favouring the cognitive approaches in increasing belief in positive self-statements and that, by Session 6, the 'purer' the cognitive content, the larger the increase.

In all four conditions, the change in belief of negative self-statements is a mirror image of belief in positive self-statements - as one increases, the other decreases and, as such, the same inverted pattern exists - for the Behavioural and Placebo conditions no significant improvement exists. Indeed the Behavioural condition shows significant worsening from Session1 at Sessions 3 and 5 ($p < .01$) at which points it is significantly poorer than the Cognitive and Cognitive-behavioural conditions ($p < .001$). Again, significant change between Sessions 1 and 6 is produced by the Cognitive ($p < .001$) and the Cognitive-behavioural ($p < .01$) conditions with the more consistent significant change from Session 1 being found in the latter condition. As with the positive self-statements, there is an increase in negative self-statement belief at Session 4 in both conditions. The results again suggest, certainly in terms of pre- post functioning, that the 'purer' Cognitive condition is associated with greatest change. Thus, different effects have been found for different kinds of therapies.

While Ingram and Wisnicki (1988) stress the importance of assessing positive self-statements, Kendall et al (1979) found that while the presence of positive self-statements did not help patients undergoing cardiac catheterization to cope, an absence of negative cognition was related to positive adjustment. Schwartz and Michelson (1986), however,

suggest that it is the ratio of positive to negative thinking that is critical in determining psychological dysfunction. The present study provides evidence of a reliable relationship between negative and positive self-statements. Within sessions, positive and negative self-statements are significantly negatively correlated during each of the six Imaginal tests for the three active treatment conditions and in five of the six tests for the Placebo condition. Correlations do not, of course, suggest direction of causality.

Thus the results of the Imaginal test suggest that the Cognitive and Cognitive-behavioural conditions, by significantly altering self-statements should, in accordance with cognitive theories of change, improve to a greater degree. However, looking at the Imaginal test in relation to other indices of therapeutic improvement this does not appear to be the case. Outcome measures do not discriminate between conditions and particularly not between the Cognitive and Behavioural conditions. Thus the possibility exists that althought the two cognitive therapies do produce self-statement change and significant symptomatic improvement, the two may, to some extent at least, be unrelated. It may also be possible to suggest that self-statement change does lead directly to symptomatic improvement but that improvement in the Behavioural and Placebo conditions is achieved via different pathways.

While the implications of this finding may be of great importance, caution should be urged given the nature of the test itself. The following criticisms can be made:

1). The self-statements to be rated were provided and were thus not elicited by the individuals themselves. Although they were based on the self-statements commonly found in GAD patients, patients in the present study may not have produced such statements in a more open-ended assessment.

2). Martzke et al (1987), in reviewing self-statement tests, suggest that performance may be subject to patients' post hoc re-appraisals of their thoughts. Demand characteristics may be of importance - it is possible that cognitive therapy patients knew what was expected of them and behaved accordingly. While this possibility is difficult to disprove, Figures 18 and 19 clearly show an increase in negative self-statements and decrease in positive self-statements in both the Cognitive and Cognitive-behavioural conditions during Session 4. If demand factors are in operation, we should not expect to see this. The relapse was also noted in other measures and has been alluded to earlier.

3). Even if the changes during the Imaginal test are 'real', we cannot be sure if they reflect changes occurring outwith the test, i.e. in "real life". However, reviewing cognitive 5 column diaries does suggest that patients in the cognitive conditions were increasingly using, and using effectively, rational re-appraisal in a host of situations.

One other possibility should be noted. While the test was designed specifically to measure self-statement change, it may inadvertently become part of the treatment process by acting as an exposure technique. Mathews (1984) suggests that anxiety arousal may be an important feature of more successful treatments. It may be possible that the patients

in the Cognitive and Cognitive-behavioural conditions were able to successfully put into effect their rational re-appraisals while in an anxious state thus leading to decrements in negative self-statement belief. In the absence of such preparation, the other two conditions were unable to alter their self-statement belief during the test.

In addition, Glogower et al (1978), reviewing studies of self-statement change, suggest that, although some treatment interventions do not directly alter such self-talk as measured by a variety of tests, spontaneous changes in self-statements may yet underlie improvement in a variety of treatments.

In conclusion, the present study suggests, bearing in mind the various alternative explanations referred to above, that changes in self-statement belief may not be essential to therapeutic improvement. While it may be that such changes represent one pathway to improvement, it does open up the possibility that more general, non-specific factors are of considerable importance and will help to explain why the differential effects found in this test have not been found in the other indices of improvement. An attempt to uncover these factors will follow in this discussion.

B. WITHIN GROUP ANALYSES

6) Does the presence of panic affect outcome within and/or between the therapy conditions?

Table 53 displays descriptive information regarding patients who did, and did not, experience panic within each of the three active conditions. No significant pre-therapy differences exist. This contrasts to Butler et al (1986b) who found that of the GAD patients who experienced panic in their sample, A-State scores were significantly higher than for those patients who did not panic.

In terms of treatment outcome, few consistent differences remain at follow-up - all sub-groups showing significant change. One finding is perhaps of interest. With the exception of BDI, the differences between the panic and no panic groups in the Behavioural condition are generally twice as greatas for thosegroups in the Cognitive condition. Why the no panic group should show greater change is unclear although it could be tentatively suggested that some form of cognitive explanation (omitted from the Behavioural condition) may be of value. Rapee (1986) found that none of his PD group felt that hyperventilation alone produced a panic attack and Gorman et al (1984) found that only 3 of 12 PD or agoraphobic patients panicked following fifteen minutes of voluntary hyperventilation. These findings highlight the importance of cognitive factors in the production of panic (see also Barlow, 1988d) and may lend credence to the importance of cognitive techniques being involved in treatment.

Van der Hout et al (1988) produce evidence that expectation and suggestion play a crucial role in the effects of controlled breathing approaches to hyperventilation thus the absence of the critical cognitive interventions

during the panic control session may have worked against the panic group in the Behavioural condition.

This point should not, however, be overemphasised. In comparison to the sub-group in the other conditions, the Behavioural panic sub-group achieve relatively large decreases in symptomatology and, in general, the present study does not provide evidence favouring distinctions being made in terms of treatment for those GAD patients who panic and those who do not. This accords with the findings of Butler et al (1987a) who noted similar improvement and maintenance of improvement in their sample of GAD panic and no panic patients.

7) Does matching the patient (i.e. consonant therapy) improve outcome?

Chapter 15 presented the results of consonant vs non-consonant treatment. As it was possible only to extract a cognitive responder group, this group was initially compared to the non-cognitive responders within the Cognitive condition. Evidence was presented showing that the two groups experience anxiety in different ways in terms of pre-therapy loadings on the main measures - cognitive responders showing higher levels of distress as measured by the cognitively orientated questionnaires, non-cognitive responders experiencing higher levels of distress as measured by behavioural and somatic orientated questionnaires.

At post-therapy there is clear evidence favouring enhanced improvement in the consonant patients - particularly on the STAI measures, BDI and MSPQ. At follow-up, however, these differences, with the exception of A-State, disappear due to continuing improvement in the non-cognitive responders.

These results are of interest. One possibility may be that the cognitive responders, finding techniques they could readily apply to their own symptoms during therapy, are helped to quicker improvement by post-therapy. In contrast, the non-cognitive responders may have to develop or adapt the techniques to make them more relevant but cannot do this until the relatively less important cognitive symptoms can be controlled by direct application of the cognitive techniques. This process would, of necessity, be more prolonged and thus significant change retarded until the follow-up period.

The analysis was then extended to compare cognitive- and non-cognitive responders across the active treatment conditions. Again at post-therapy, cognitive responders do very well in the Cognitive-behavioural condition particularly on the cognitive measures although less well within the Behavioural condition. At follow-up, the same pattern exists within the Behavioural condition where, although showing a significant degree of improvement, the cognitive responders do not perform as well as the non-cognitive responders. Although the latter group are not matched with the therapy, it seems plausible to suggest that the therapeutic procedures involved in this condition are more appropriate and thus perhaps more readily absorbed and applied.

The results involving the Cognitive-behavioural condition are interesting. In the main results chapers, e.g. Tables 8 and 35, the Cognitive-behavioural condition, both at post-therapy and at follow-up, lagged behind the other two active therapy conditions in terms of degree of symptomatic change. Inspection of Table 62 points to an intriguing explanation for this unexpected finding. As was noted in Chapter 15, the non-cognitive responders in this condition were clearly less dysfunctional and showed,

possibly due to floor effects, less change. In comparison, the cognitive responders show marked change, e.g. the A-Trait score shows a drop of 15.6 points (pre-therapy - follow-up), a difference larger than mean changes in any of the therapy conditions noted in Table 35 and, incidentally, easily the largest change score so far reported in the GAD literature. Changes in all main measures suggest that this group functioned as well as the Cognitive and Behavioural conditions and, as such, the relatively poorer performance of the Cognitive-behavioural condition as a whole may have been biased by the non-cognitive responding sub-group within that condition who, prior to treatment, were dissimilar to the other patients across conditions. If so, then the effects of all of the three active treatments may be more distinct from the effects of the Placebo condition than was initially apparent.

It is important to assess the clinical relevance of the above finding. Although the findings at post-therapy are of interest, in clinical terms, it is the follow-up results that should command more attention. These results suggest that cognitive therapy will produce essentially the same effects for cognitive- and non-cognitive-responders although the two groups will have reached this end by apparently different routes. Behaviour therapy, even at follow-up, favours, to a degree, non-cognitive responders. However, the difference seems of little importance. The more tantalising findings are contained in the Cognitive-behavioural condition where cognitive responding sub-group perform notably better than the condition as a whole. Due to the pre-therapy differences in the non-cognitive responders, the effects of combined therapy are not as clear as we would have wished. However as, Stress Control, due to the large number of

patients involved, would be unlikely to be able to contain only, e.g. cognitive-responders, it may be that the Cognitive-behavioural condition, parsimoniously, is the most clinically relevant form of Stress Control, as, although this must be speculative, it may discriminate less against either cognitive- or non-cognitive-responders as it includes relevant techniques for both groups.

Studies of tailored therapy reported in Chapter 5 provided only weak evidence favouring consonant treatment and the present study's findings are, generally, in accordance with those studies. In the preceding results and discussion, evidence has been accumulating to suggest that patients may not be responding to therapy-specific factors as much as non-specific factors common across therapies. Although more time will be devoted to this, it does somewhat negate the view that tailored therapy, at least in the form of large group therapy, can be readily identified.

8) Does the presence of desynchronous change affect outcome?

Chapter 16 reports on the results of sub-dividing each of the active treatment conditions into synchronous and desynchronous sub-groups. The results suggest that synchronous patients in the Cognitive conditions show enchanced gain at post-therapy as compared to their desynchronous counter-parts and then maintain this superiority at follow-up. Similar, although not as pronounced, results emerge from the Behavioural condition. By follow-up, the synchronous patients in the Cognitive-behavioural condition have, on most main measures, caught up with the enhanced performance of the desynchronous group evidenced at post-therapy and maintained at

follow-up. This latter finding is difficult to explain given the notably less dysfunctional nature of the Cognitive-behavioural desychronous group.

Although differences have been found, examination of Tables 68, 69 and 70 shows statistically and clinically significant change associated with all synchronous and desynchronous groups. Thus there is no evidence that desynchrony necessarily predicts treatment failure. However, it should be noted that this prediction is based on the continued manifestation of anxiety in one of the response systems. Although desynchronous, significant change was generally found in both systems used in the present study - improvement in both systems occurs at different rates. As the only study yet on synchrony/desynchrony in GAD, the results are in accordance with a treatment outcome study of agoraphobia by Craske et al (1987) (see Chapter 5) who found that desynchronous responses did not predict treatment failure.

9) Can treatment outcome be predicted from pre-treatment variables?

Although PEARSON CORRELATION (Tables 75 and 76) suggested strongly that, in comparison to the other treatment conditions, a wide range of pre-treatment variables were significantly related to the amount of change in those variables at post-therapy and at follow-up in the Cognitive condition, STEPWISE MULTIPLE REGRESSIONproduced evidence of clinically useful predictors across conditions. As with the correlational analyses, the pre-treatment value of the variable under question generally emerges as the best predictor of change on that variable both at post-therapy and at follow-up - the higher the initial dysfunction, the greater the degree of change. It does appear that the amount of statistically

significant amount of variance explained is of clinical relevance.

Initial levels of STAI:A-State, BDI and MSPQ appear to be the best predictors of change and as these variables taken together represent important dimensions of affective distress they are of clinical utility.

Two GAD treatment outcome studies have attempted to predict outcome. Durham and Turvey (1988) used stepwise multiple regression techniques to predict outcome from their 1987 treatment outcome study. Using initial levels of anxiety and depression and the duration of symptoms as predictor variables, Durham and Turvey failed to account for a significant amount of variance and the authors suggest that regression techniques may be inappropriate given their relatively small sample.

Butler and Anastasiades (1988) presented evidence for three reliable predictors of individual therapy outcome - these variables reflecting anxiety, depression and demoralisation. Lower levels of anxiety and demoralisation combined with higher levels of depression predicted a better outcome.

The present study does not replicate these findings. In general, higher levels of affective distress predicted higher levels of change. It may be that the results of the regression analyses simply suggests that the Law of Initial Value is in operation. This can be looked at in greater detail in the next section.

10) Can treatment responders and non-responders be reliably discriminated?

Using relatively liberal criteria to define treatment non-responders, the present study identified, in the three active treatment conditions, 15 non-responders and 57 responders. Table 85, comparing these 'failures'

and 'successes', displayed evidence suggesting that treatment failures recorded significantly lower levels of dysfunction at pre-therapy. The relatively smaller degree of improvement on main measures may therefore have been, in the failure group, influenced by the Law of Initial Values although Table 85 also shows higher follow-up scores in the failure group as compared to the successes. Failures also had a much longer duration of symptoms - 12 years vs 6 years thus suggesting that, in combination with the failures' lower expectation of treatment success, this group may regard their problems in trait terms and perhaps feel more demoralised in terms of their ability to change. It is interesting that the stepwise discriminant analysis entered DURATION, BDI and SC5 (expectation) as the first 3 (of 5) steps with the equation as a whole accounting for a highly significant 30% of the variance.

The concept of demoralisation has been advanced by Butler and Anastasiades (1988) to explain treatment failure in GAD and, by Fairburn et al (1987) in bulimia. Butler and Anastasiades suggest that patients become demoralised when they fail to cope with their symptoms and this can thus be seen as a mirror image of 'learned resourcefulness' (Rosenbaum, 1980).

This demoralisation which, plausibly, increases over time, would therefore predict poorer outcome. From a clinical standpoint, it may be beneficial to incorporate, at an early stage, techniques to combat demoralisation - perhaps as in cognitive-behavioural approaches to depression, simple behavioural techniques aimed at producing early treatment success and, hopefully, inculcating a high degree of resourcefulness and thus expectation of improved outcome.

suggesting that, in combination with the failures lower expectation of treatment success, this group may regard their problems in trait terms and perhaps feel more demoralised in terms of their ability to change. It is interesting that the stepwise discriminant analysis (Table 88) entered these two variables (A-Trait and SC5) prior to the entry of pre-therapy BDI score with the equation as a whole accounting for a highly significant 26% of the variance. Table 89 showed that although these variables allowed 93% of success patients to be correctly classified, only 40% of failures were classified correctly.

This promotes caution in advancing explanations for treatment failure as, given the liberal criteria used for failure, this relatively small group may be heterogeneous in nature. However, the concept of demoralisation has been advanced by Butler and Anastasiades (1988) to explain treatment failure in GAD and in bulimia nervosa by Fairburn et al (1987).

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11) Are the results also of clinical as well as statistical significance?

Jacobsen et al (1984) criticise reliance on group means and statistical significance tests in the evaluation of treatment effects and the corresponding lack of emphasis on data highlighting variability and clinical significance. Although statistically significant results are of interest, it must be borne in mine that statistical significance, even when properly interpreted, bears no relation to the importance of, or the size of, the effect. As Barlow et al (1984) point out, one of the problems lies in the word significant. A statistically significant result can be very trivial indeed and be very far from the usual meaning of the word significant.

The present study has been carried out from essentially a clinical perspective. That perspective will always emphasise the individual and statistical significance says nothing about improvement in an individual patient undergoing that treatment. In addition, Pocock (1983) highlights the situation where, as in the present study, more than two treatments are compared and notes that the power to detect treatment differences depends on the number of patients per treatment, not the total number of patients in the trial.

Tables 72 - 74, presenting evidence more attuned to clinical rather than statistical significance, strongly suggest that the majority of patients, particularly in the active treatment conditions, achieve reasonable levels of clinically significant change. The results suggest that patients in the Cognitive-behavioural condition improve to a greater degree than the

descriptive and statistical analyses earlier suggested and the evidence suggests little difference between the active conditions - all of which are superior to the Placebo condition ratings.

The results of the clinically significant change approach does, in fact, lend additional credance to the significant statistical results which have been presented in some detail.

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Having now looked in detail at the results of the present study, it may be helpful to consider therapists and patients impressions of Stress Control.

C. IMPRESSIONS OF STRESS CONTROL

General.

Stress Control, run by two psychologists and involving up to twenty-four patients, proved surprisingly straightforward to manage. It seems reasonable to suggest that the combination of appropriate pre-therapy preparation and a very directive therapy are essential ingredients in the management of the course.

It is of crucial importance to set accurate expectations regarding treatment and appropriate role behaviours. Mayerson (1984) points out that patients may approach group therapy with fears relating to having to speak, possibly about emotive issues, in front of strangers or, possibly worse, in front of people who may be known to them, e.g. neighbours. They may, therefore, have concerns about confidentiality in addition to fears that they may get worse having to listen to other people's problems and may have concerns that their own problems will not be paid attention to. There may also be the fear that they will be in a group with mentally ill people. Given the social concerns of GAD patients, it seems likely that many will fear, e.g. making a fool of themselves, being the centre of unwanted attention, etc.

In view of these concerns, Stress Control was planned as a radical form of group therapy which, in some senses, breaks cardinal rules, e.g. patients are explicitly told that they do not have to talk - around 50% of patients, in fact, do not and, more importantly, patients are told they are not to bring up personal problems in the group. Patients readily complied with this. Thus whether Stress Control should be

seen as a group therapy as 'traditionally' defined is open to argument. However, the obvious therapeutic nature of the course possibly makes this point somewhat superfluous.

The booklet, given at the assessment interview to patients, is of great importance not only in guiding expectations but also in reducing anticipatory anxiety. As was seen in the components analysis (see Table 51), it appears, across conditions, that the provision of information - both via the booklet and via psychologists - is rated extremely highly. Many patients also noted that, if their anxiety started to rise at any point during the follow-up period, reading the booklet helped them 'decatastrophise' even without them carrying out any specific stress management technique. The booklet as talisman may not be an absurd concept.

Patients generally appeared tense during the first half of the first session. Informal discussion later in the course suggests that at this early stage, patients are content to listen to the psychologists reviewing the booklet and discussing the course in detail. It is noticeable that prior to this first session beginning and again at the tea-break, most patients read their booklets or engage in other solitary activities. Many patients turn up at exactly 7 pm and are likely to look for seats in the peripheral areas of the room. During the second half of the session, patients are able to relax somewhat in the smaller sub-groups. The use of the video (assessment of a GAD individual) proves useful as patients readily identify with the man and through verbal comments or non-verbal cues from other members of the group, appear to begin the development of the cohesion, and identification of common

problems and goals, which, by the end of the course, is strong. Reassurance may come both from meeting others with similar problems and from seeing that they are 'normal'.

It is also noticeable that from early in the course there is a good deal of goodwill directed towards the therapists. This is presumably helped by the knowledge that the therapiests wrote the booklet which often led to patients commenting on how well we understand what is going on inside their head. This is aided substantially by the wealth of therapeutic experience distinct from theoretical expertise, that the psychologists bring into Stress Control. These skills (or, possibly, 'tricks') may not be possessed by recently qualified therapists who, although possibly highly qualified and knowledgeable, may be unlikely to possess much 'therapist-craft'. This point will be taken up later.

By emphasising the uniqueness of Stress Control as an approach to therapy and the experimental nature of the study, it was hoped to keep the therapy from becoming, in the therapist's eys, routine, and, in the patient's eyes, for them to feel part of the project instead of passive guinea pigs. This may help to explain the relatively high rate of questionnaire returns both during the course and at follow-up.

It also seems likely that theunique therapists-patients relationship is beneficial. Although, in theory, the patient must play an active role in a collaborative cognitive or behavioural treatment, it seems highly likely that most patients, faced with a high status professional, often of a different socio-economic status, adopt a relatively subserviant role while most therapists, in the guise of a democratic role, in fact,

practice a form of benign dictatorship.

Stress Control cannot foster such relationships. It is made clear - almost harshly so - that the approach is offered on a take it or leave it basis, i.e. patients are told explicitly that although the therapists provide the necessary information, only they can implement the approaches taught. If they fail to do so, no improvement will take place and they will not get another chance. Far from discouraging patients, this approach may well be therapeutically sound. Given that patients have been prepared for Stress Control by:

a) clearly defining appropriate behaviour and goals and

b) setting positive self-efficacy and appropriate expectations of success, patients feel that the course has given them the "tools for the job" and has given them the confidence to use the tools to actively work on more appropriate coping skills.

It may be that 'selling' Stress Control as an 'evening class' instead of a 'group therapy' helps in this respect.

As the course proceeds, patients become more socially confident - conversations take place before the session begins, at tea-break, etc. More questions are asked, more comments made. A cohesiveness develops quickly and, if necessary, a protectiveness towards the therapists when, e.g. a member of the group says he/she is not feeling any better.

On several occasions, particularly in the sub-groups, patients will suggest that it is the fault not of the course or therapists but of the individual and generally offer advice on better ways of coping.

The use of humour, both by therapists and patients, is therapeutic. Put simply, when able to laugh at some aspect of their anxiety problem, the patient is standing back, distancing himself from the problem and thus more able to deal objectively with a problem that no longer envelopes him. It may be that Stress Control, by adopting the very directive didactic approach wherein patients are, from the very onset, having to take on responsibility for improvement and thus have to find, within themselves, resources which may help to lead them to expose themselves to a variety of novel coping techniques. These patients are, as Butler et al (1987) note, avoiding in a subtle but widespread manner and the directiveness of the Stress Control approach may be seen as an exposure technique. Although didactic, Stress Control must be seen as an intense, purposeful therapy which may be as emotionally laden as any other therapeutic approach. This may help stimulate patients betweeen sessions to carry out the homework assignments and, of great importance, to keep thinking about, and acting upon, the information and techniques learned on the course.

It may be that, rather than a disadvantage, the large number of patients in each group, is a distinct advantage. A small group of six patients and one therapist would possibly result in patients remaining relatively passive and unable to work as independently as Stress Control forces them to. Given the large numbers involved in Stres Control and, consequently, the lack of personalised help from the therapists, patients, rather than carrying out the therapy in the way the therapist suggests/ dictates instead mould/modify the techniques around their particular problem and this adaptation, although perhaps not theoretically defensible,

is likely of greater relevance and help to individual patients than the rather blanket prescriptions suggested by a superficial review of Stress Control.

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Having now looked at general impressions of Stress Control, we can now look at the five experimental conditions in order to assess factors specific to those conditions.

Specific.

i. Waiting list condition.

The eleven members of this condition, following inclusion into the study after the assessment interview, completed the measures sent by post to them. Very little missing data accrued and all members subsequently joined the second Cognitive Therapy group. As Chapters 11 and 12 demonstrate, little or no improvement occurs during the waiting time. Thus inclusion into a therapy condition is justified. Had improvement been noted, the data from the subsequent therapy condition would have been confounded by this pre-therapy change.

The results in the present study echo those from other outcome studies using waiting list conditions (Barlow et al, 1984; Butler et al, 1987; Blowers et al, 1987) where waiting list patients show no evidence of

improvement over periods of between 10 - 14 weeks compared to the six weeks in the present study. That no changes resulted from the simple passage of time should not be surprising given the lengthy duration of symptoms noted in the present sample and in the recalcitrant nature of the disorder.

Although there has been a recent decision by many outcome researchers to refrain from using either waiting list or no treatment control groups in cognitive therapy replication studies, the use of a waiting list condition in the present study is defended as, due to the novel aspects of Stress Control therapy, the condition was included to make clearer the results of the therapy conditions.

ii. Cognitive therapy condition.

Chapter 2, reviewing the treatment outcome studies suggesting that given the cognitive distortions in GAD identified by various workers (e.g. Hibbert, 1984; Rapee, 1985) and assuming that these distortions are crucial to the maintenance of anxiety, strongly indicated the need for techniques directly aimed at modifying these distortions. The cognitive approaches in the present study were designed to achieve this end.

Bedrosian and Beck (1985) suggest that during 'traditional' one to one cognitive therapy, three key epistemological principles are conveyed to the patient:

1) perceptions or interpretations of reality are not identical to reality itself.

2)/

2) interpretations of reality are dependent upon cognitive processes, which are themselves inherently fallible.
3) beliefs are hypotheses which are subject to disconfirmation and modification.

In order to adopt these principles, the authors argue against a purely didactic effort on the part of the therapist. The present study, however, using a didactic intervention to stimulate patients into altering cognitions largely without the collaborative relationship which is generally seen to be an integral part of therapy.

There appears to be reasonable evidence that cognitive therapy techniques can be transmitted in this way and significant reductions in distress achieved. The suggestion has been made before (e.g. Arnkoff, 1981; Haaga, 1986) that flexible approaches should be compared to the highly structured individual therapies associated particularly with Beck. The present study produces some evidence that flexible administrations of cognitive techniques is both feasible and effective.

The successful results for this condition also argues against the views of Woodward and Jones (1980), who suggested that cognitive techniques are not effective for highly aroused generally anxious patients. Although no attempt was made to directly reduce arousal levels, cognitive therapy produced a 44% reduction (pre-therapy - follow-up) in MSPQ ratings (although this was less than the 55% reduction recorded in the Behavioural condition where progressive relaxation techniques may have added to the improvement). Thorpe et al (1976) also suggest that as cognitive

techniques rely, to an extent, on patient insight, it may be too difficult a treatment for some patients. Assuming that the level of intelligence among the present sample is representative of patients in general, there is no suggestion that cognitive therapy should be restricted to higher intelligence groups.

The results from the Cognitive condition (and, to a lesser extent, the Placebo condition) counter the suggestion made by Borkovec and Mathews (1988) that all outcome change reported in the literature may be solely due to relaxation training.

An interesting finding on several variables (e.g. DAS, Diary ANXIETY and TIME, CRQ-C) is a worsening during the first few weeks of therapy or at mid-therapy. This affected particularly the Cognitive and, to a lesser extent, the Cognitive-behavioural conditions. In general, the former condition was initially less responsive than the non-cognitive conditions during the first half of therapy. Two possibilities exist to explain this:

1) Unlike the other treatment conditions, active therapeutic procedures were not instituted until Session 3 when rational re-appraisal (positive thinking) was taught. Prior to this, only information was presented and assessment of automatic thinking attempted.

2) Perhaps of greater importance is the finding that assessment of automatic thinking may have increased anxiety. Many individuals found these early sessions stress-provoking partially due to the relative complexity of accessing habitual thinking patterns but also because

there was the feeling that teaching the nature of these thoughts may have opened up an aspect of their anxiety problem that some patients had not previously paid much attention to. Patients are not by nature 'cognitive theorists'. They will likely be very well aware of the somatic symptoms of stress - indeed it may be those symptoms which they first present to their G.P.; they will also be aware that they cannot relax and that their behaviour alters under stress. However, they will, generally, not be aware of specific cognitions associated with anxiety. Thus the result of the early sessions of Stress Control may be to impart the news. "The problem is deeper than you thought - look at this!". In comparison, the Behavioural condition concentrates on information probably already accessible to the majority of patients. Although this is speculative, informal discussions with patients at the end of therapy do seem to lend credence to this conjecture.

Course content.

Session 1, containing the overview of information contained in the cognitive booklet, was perceived as helpful and easy to assimilate. Session 2 begins with a description of tranquillisers. Although a substantial number of patients were not using benzodiazepines at the time (see Table 4), almost all had used them at some point in the past and thus found the information relevant and beneficial - possibly as an antidote to the many sensationalised accounts appearing in the mass media at the time.

Some difficulties were experienced at the stage of eliciting automatic thoughts in Sessions 2 and 3. There was, in many patients, an emotive

reaction to discovering this 'hidden' layer of symptoms and this has been dealt with in a previous section. It was also important to issue counter demand instructions to keep expectations realistic. Thus patients were told that initially the elicitation of automatic thoughts would prove difficult and that we expected the 3 column diaries to reflect these difficulties. It was emphasised that this would, with continued practice, pass and that, switching to positive demand instructions, patients would, before the end of the course, generally be able to get in touch with their throughts and to rationally re-appraise them. After the initial difficulties already alluded to, by Session 5, patients, on the evidence from the sub-group workshops and 5 column diaries suggest that most patients were coping reasonably well with these techniques.

The attempt in Session 4 to re-appraise these automatic thoughts seemed reasonably straightforward. Patients, in the smaller workshop groups, were sold the idea of using 'positive thinking' through the process of carrying out an 'as if' technique concentrating on the anxiety provoking thoughts and then rating anxiety level between 1 and 10. Patients then volunteered their self-rating and were instructed to re-run the scene except this time instead of concentrating on the anxiety provoking thoughts, they were to use positive thoughts elicited as appropriate (by each individual) during the intervening period. Anxiety level was rated again, and patients were asked to compare both ratings and volunteer the outcome. In virtually all cases anxiety ratings drop during the second scene. A case could then easily be made for the importance not only of the role of 'negative thinking' in the production of stress but of the role of 'positive thinking' as a useful technique for reducing anxiety.

An attempt to assess dysfunctional attitudes by giving feedback on DAS scores was probably of little help given the constraints on time and this section of the course should now be dropped as the results across conditions suggest that it is not a critical component.

The panic treatment section is, however, of great importance and was rated highly by patients (see Table 51), interestingly even by patients who do not panic. Although the panic treatments across conditions were kept as distinct as possible, this attempt probably failed. All of the active treatment conditions carried out the hyperventilation provocation test (HVPT). Cognitive patients then concentrated on re-appraising the cognitive symptoms, Behavioural patients concentrated on breathing control techniques while the Cognitive-behavioural condition did both. However, it seems likely that the Cognitive condition, perceiving that unpleasant sensations followed voluntary hyperventilation, made the obvious connection and perhaps attempted controlled breathing without therapist instruction. As Rapee (1986) has demonstrated, voluntary hyperventilation will not lead patients, in a clinical setting, to panic, it can be argued that the HVPT works very effectively as a method of improving group cohesion. It highlights a theatrical element to therapy in as much as therapists, through the use of slide projectors and verbal information 'build up' the atmosphere beforehand and the group, already experiencing some degree of anticipatory excitement/ anxiety, tended to become very animated, excited and talkative, comparing reactions, after the HVPT, with other group members. Perhaps the HVPT can be likened to a roller coaster ride in the way it builds

up apprehension and relieves that tension after successful completion of the event.

Session 6 looked at the associated problems of depression and insomnia. Again, due to time constraints, it is unlikely that this part of the course is of much value. The course review is of use and feedback from the groups tended to be very positive. The relapse prevention information, incorporating cognitive rehearsal appears to be of use, emphasising, as it does, the importance of putting into effect what has been learned on the course. Patients are explicitly told that failure to do so will result in the maintenance of anxiety and that, although hopefully they have already benefitted from the course, the course has aimed at training them to now deal with the anxiety condition themselves.

iii. Behavioural condition.

As we saw in Chapers 11 and 12, this condition showed significant improvement on all variables. Indeed the mean 14 point difference (pre-therapy - follow-up) on the STAI:A-Trait represents the largest degree of change reported in any GAD treatment outcome study to date. Highly significant time within treatment change is found for practically all main and process measures with the vast majority of patients showing clinically significant change. Progress is enhanced on all measures during the follow-up period.

These results compare favourably with other outcome studies and particularly well when compared to the Durham and Turvey (1987) (individual) behaviour therapy condition. In that study, behavioural

approaches were not associated with significant improvement with a trend for patients at follow-up to revert back towards pre-treatment levels. In the present study, the Behavioural condition produced decreases (pre-therapy - follow-up) of 55% in both MSPQ and BDI scores compared to decreases of 14% and 29% for these variables in the Durham and Turvey study. Thus there is strong evidence favouring the Stress Control Behavioural condition.

Although the use of progressive relaxation techniques can be theoretically justified in the treatment of GAD, the use of exposure techniques in a condition supposedly devoid of phobic avoidance is more difficult to justify. In fact, clinical experience shows that GAD patients do show marked levels of avoidance but in a diffuse pattern unlike the more focal patterning often found in phobic individuals. Empirical evidence for this is provided by Butler et al (1987b) who report 80% of their sample (n = 45) identifying some situational anxiety and 64% reporting avoidance - mainly of social and agoraphobic situations. Thus both functional analyses and exposure therapy seem justified on empirical grounds.

This being the case, we may have expected a greater magnitude of change relative to the other conditions on the FSS. In fact, little difference emerges between the Cognitive and Behavioural conditions. The possibility should however be examined that the FSS is not a suitable measure of the subtle forms of avoidance likely to be found in a GAD population. However much the same pattern emerges on the FSAQ: Behavioural component.

In general, however, the results of behavioural treatment were very similar to those of cognitive treatment and this result opens up various possibilities. It may suggest that, against expectation, deliberately focusing on the alteration of conscious appraisal may be unnecessary in therapy. It may also be that, with its convincing rationale, the Behavioural condition may have indirectly altered conscious appraisals as effectively as the Cognitive condition. This would appear the more satisfying conclusion as modifying appraisals may be of particular importance in Stress Control, the success of which may depend on the patients' preparedness to experiment actively with the novel coping strategies being presented to them within a context of increasing self-control.

Arnkoff (1986), comparing the coping and restructuring components of cognitive restructuring in an analogue study of test anxiety, found that subjects did not restrict their learning to the explicit treatment content and thus concluded that therapists cannot assume that the content of treatment dictates the processes affected by that treatment.

Course content.

Session 1 again was perceived as helpful and easy to cope with. It seems that patients may settle into the therapy without significant difficulties when the first session does not demand a great deal of involvement from them. There were no difficulties in teaching a behavioural model of anxiety maintenance and patients appeared to be able to fit their own problems into the general model.

Following the description of tranquillisers, the group carried out 'live' progressive muscular relaxation led by the present author. In order to keep expectations realistic, patients were told that they would be unlikely to relax on this first occasion. However, from past experience of group relaxation, following PMR, several patients enthused about the degree of relaxation achieved. This may act as a positive modelling experience and engender positive expectations about the technique. Few patients experienced any difficulties and reports of relaxation-induced anxiety (RIA) were, perhaps surprisingly, non-existent. The supply of taped relaxation for home use helps get patients actively involved in therapy at an early stage.

Session 3 involved a functional analysis of anxiety. Patients had no difficulty in identifying situations associated with heightened anxiety. Session 4 concentrated on targetting and hierarchy construction. Although generally able to do this, some patients could not see this as relevant to their problem.

The use of Behavioural Relaxation Training (BRT) was generally seen as a useful adjunct to PMR. Poppen (1988) suggests that PMR and BRT supplement each other. It may be, however, that Applied Relaxation (Ost, 1985) may be of greater use as a more systematic series of relaxation techniques for this group (see Clark, 1989 for a short description of A.R.).

Session 5 involved a description of 'body language' and the present author, after having patients try to identify mood from various body postures, modelled appropriate relaxed postures. Again, although of interest and probably entertaining, this component could be omitted from future courses.

As with the Cognitive condition, the treatment of panic attacks was rated highly. In this version of the treatment, no attempt was made to modify the cognitions associated with the overbreathing. Instead only controlled breathing, as found on the relaxation tape, was taught.

Session 6 involved behavioural approaches to depression (activity scheduling and graded assignment) and insomnia (stimulus control) were possibly more useful than cognitive approaches to these conditions due to their more 'concrete' basis which may have been of greater use in the short duration of time devoted to these problems. Behavioural rehearsal was taught as a relapse prevention technique.

Again, as in the Cognitive condition, patients were noticeably enthusiastic about the course and warm towards the therapists. As the results have clearly shown, their degree of improvement is impressive. This arises perhaps in spite of, rather than because of, the techniques taught. The relevance of some of the techniques is doubtful in GAD and, as in the Durham and Turvey (1987) study, this condition lacks the greater internal consistency of the Cognitive condition, appearing more as a rag-bag of techniques. Clearly it does not appear to have been seen as such by the patients and points us to look to factors other than the specific techniques when we look for reasons for the improvement. This will be done in a later section.

iv. Cognitive-behavioural condition.

As with the other treatments, particularly the active treatments, Cognitive-behavioural therapy produced highly significant improvement on all variables. Given the high levels of arousal combined with the

cognitive distortions found in GAD, a treatment which involves components aimed at each area could be hypothesised to be the treatment of choice for GAD. However, in comparison with the other treatment conditions, the combined condition, at least on main measures, did not produce as much improvement as either the Cognitive or Behavioural treatments. This pattern is not, however, so clear on process and other measures.

Rapee and Barlow (1988) comparing relaxation only, cognitive restructuring only and a combined approach, found similar results and speculated that GAD patients have difficulty incorporating a lot of new information and that the combined treatment, involving, as it does, more information than is contained in the other techniques, will thus produce less effective results. These authors also suggest that a combined approach involving relaxation and cognitive techniques is teaching two opposing techniques - relaxation, viewed as a form of distraction, teaching patients to cut off from their catastrophic thinking while cognitive approaches attempt to concentrate on the catastrophic thinking in order to then restructure their thoughts.

These views are speculative and given the significant improvements associated with all of the treatments, we might look more profitably at other factors. In addition, evidence was provided from the synchrony and consonant treatment sub-group analyses that the Cognitive-behavioural condition contained a sub-group who began therapy with lower levels of anxiety whose degree of change was, due to the Law of Initial Values, proportionately smaller than changes associated with patients in other conditions.

Course content

Session 1 contained an amalgam of cognitive and behavioural factors in the maintenance of anxiety and, as such, took slightly longer to transmit. Patients had no difficulties in coping with this session. Session 2 is identical to that of the Behavioural condition and similar reactions found. Session 3 abbreviated two sessions in the Cognitive condition and some problems were experienced particularly in accessing automatic thoughts. Although some time was generally devoted in subsequent sessions to cognitive techniques, it is clear that not enough time is available in this condition for the transmission of cognitive assessment and treatment.

Similarly, Session 4 attempts the equivalent of two Behavioural condition sessions with a functional analysis, targetting and hierarchy construction. Again, it seems likely that insufficient time is available. Session 5 attempts to "combine the skills" into a recognisable 3 systems framwork. Perhaps surprisingly, in view of the preceding criticisms, few patients reported any significant difficulties in putting into effect techniques already learned. In particular, the relaxation techniques are highly rated at this stage and 'positive thinking' is increasingly seen as a useful tool.

The treatment of panic emphasises both controlled breathing and re-appraisal of cognitions. This is probably the best form of panic control within the Stress Control framework but, as noted previously, the success of this session, particularly among those patients who do not experience panic,

may lie in reasons other than those suggested by theory. The final session combines the cognitive and behavioural elements noted previously.

Although this combined approach was thought to be the treatment of choice, it may be that radically revising the teaching and lengthening the course by perhaps 2 sessions would be of use in order to accommodate the increased volume of information. However, given the results from the Cognitive and Behavioural conditions, there would seem to be little clinical utility in doing so. An argument will be made in a subsequent section suggesting that alterations to this condition may not be necessary.

iv Placebo condition.

While the use of the Waiting list condition provides information regarding the natural history of the disorder, it cannot separate real treatment effects from placebo effects and the non-specific effects of demand and expectancy. In addition, no placebo condition had yet been included in a GAD treatment outcome study. Thus the inclusion of a Placebo condition in addition to a Waiting list condition was of great importance.

There are, however, significant problems associated with the development of placebo condition in psychotherapy (see Shapiro, 1971, for a comprehensive review of placebos). Lo Piccolo (1977) notes that if a placebo treatment is created which is truly therapeutically inert, patients are quite likely to realise that they are not receiving genuine treatment. On the other hand, if the placebo treatment is similar enough to real treatment to have credibility in the patient's eyes, it probably is not a placebo at all, but has some genuinely therapeutic elements. Even

if patients are deceived, the therapist is unlikely to be 'blind' and as therapist expectation for change has been shown to be a good predictor of patient improvement, this can be a serious problem (Martin and Stern, 1975; Lick and Bootzin, 1975). In addition, as O'Leary and Borkovec (1978) point out, the definition of placebo is that there should be no currently supported theoretical reason why the placebo would influence the behaviour under question. "In essence, it is a definition governed by ignorance" (page 823).

The Placebo condition in the present study 'Subconscious Reconditioning' has been evaluated by patients in that condition as being equally sensible and appropriate and engendered the same reasonably high levels of expectation as noted in the active therapy conditions. Thus we can conclude that patients did view the placebo as a credible approach. Although the therapist (JW) was not 'blind', having devised the approach, there was no difficulty carrying out the therapy due to patients' immediate enthusiasm for the approach. There was, as they had come to the first session having read the booklet, no need to 'sell' the technique.

Patients in the Placebo condition initially seemed much more convinced by their therapy than any of the active treatment patients and this belief was maintained throughout therapy. They also, in the first few weeks of therapy, reported powerful, indeed often dramatic, therapeutic change. At the end of treatment, no-one in the group expressed a need for individual 'traditional' therapy which was, for ethical reasons, offered. They were also pleased that this 'experimental therapy' had been successful and hoped that it would become widely available. There was a very

great sense of goodwill directed towards the therapist, very high compliance in returning questionnaires both during therapy and at follow-up. It was also noticeable that patients, returning questionnaires by post at post-therapy and at follow-up were more likely than patients in the active therapy conditions, to include thank-you letters and, as therapy ended in early December, Christmas cards.

Thus, the Placebo condition in the present study seems to have 'worked'. The question now must be posed as to whether the procedures used were, as anticipated, therapeutically inert.

Bearing in mind that 'subliminal anti-anxiety messages' were not, against patients' expectation, included on the audio tapes used, the inclusion of pleasant music, used to "distract the conscious mind" thus allowing the anti-anxiety messages access to the sub-conscious mind, may have had a therapeutic effect. Common sense suggests that listening to pleasant music may be beneficial in reducing stress. Certainly the emotional effects of music can be observed in all cultures (Hargreaves, 1986) and there has been an increased emphasis recently on studying the impact of music on mood. Clark (1983), Sutherland et al (1982) and Albersnagel (1988) amongst others have found music to be a better means of inducing affect (including anxiety) than emotive self-statements (Velten technique).

Recalling the debate on the relative status of affect and cognition (Rachman (1981) suggests "perhaps the most important goal... is to search for techniques that provide easy entry into the affective system...

We should expand behaviour modification to include affect modification" (P 285) and, in a later paper Rachman (1984) proposes "Given the imperfect influence of verbal operations on affect, attempts should be made to directly modify affective reactions using non-verbal means where possible, e.g. music". (P 582).

Viewing music as a higher-order or secondary unconditioned stimulus , Eiffert et al (1988) included positively evaluated (i.e. liked) music in every second treatment session involving in-vivo exposure for animal phobics. Overall results suggest that liked music invoked a positive affective state that increased the effectiveness of in-vivo exposure.

While a conditioning model is inappropriate in explaining any anxiety reduction mechanism which may have been contained in the use of music in the Placebo condition, it may have had a relaxation/distraction effect. However, patients had no say in the choiceof musical tracks used and, generally they reported that they had found the music reasonably enjoyable rather than relaxing. The classical pieces were rated as less enjoyable than the pop music.

Although we cannot rule out the mediational effects of music, it seems unlikely that the music, by iself, could produce the often dramatic effects noted in previous chapters with such a recalcitrant population. While some support for the inclusion of liked music in an in-vivo exposure treatment for simple phobics has been reported above, GAD clearly constitutes a more complex constellation of symptoms affecting the individual's life to a much greater degree than would be expected from phobia ofcane toads and green frogs. In addition, the review of

treatments in Chapter 2 strongly militates against the effectiveness of uni-dimensional techniques.

The clinical impression left from carrying out this therapy is that patients benefitted from much more complex reasons than simply from listening to relaxing music. The literature is replete with examples of bogus treatments producing symptomatic improvement. In the area of generalised anxiety, for example, Mathews and Shaw (1977) could find no differences between "thought stopping" and its antithesis "thought satiation". Ramm et al (1981) had patients rehearse either positive or negative self-statements ("I am going crazy" etc.) and again found little difference between the two groups. Smith (1976) found two bogus treatments "periodic somatic inactivity" and "cortically mediated stabilization" to be as effective as transcendental meditation. He suggested that improvement was obtained in these impressively titled therapies because of:

a) the treatments were taught by a person who believed them to be effective
b) the treatments were complex and highly structured
c) claims of effectiveness and a plausible and comprehensive theoretical rationale were supplied.
d) the person receiving the treatment received what he believed to be signs that the treatment was working for him.

The Placebo condition in the present study did not, however, involve all of these conditions. In fact, condition a) was met only after the therapist received very positive feedback at the start of Session 1, i.e. after patients had read the booklet. Condition b) was met - very precise

instructions for complying with therapy were given and the theoretical framework, although easily understood, was of a complex nature. Condition c) was not met. Patients were repeatedly told that Subconscious Reconditioning was an experimental therapy and therefore no expectation of outcome could be given. In fact this may paradoxically have had a beneficial effect inasmuch as patients began to regard their role as guinea pigs in a positive light and were very keen to know how I felt therapy was going and whether I would use it in the future. It was their strong view that it should be used again. Condition d) was met. Patients, on listening to the 'general anti-anxiety' tape during each session, regularly reported feeling much less anxious after listening to the tape. Several, in fact, reported being aware of the anti-anxiety messages being relayed to the sub-conscious mind although they were, as they expected, unable to actually distinguish what the messages were.

Although there is evidence that GAD patients may be more open to placebo effects in the psychological studies noted above and in medication studies (e.g. Silverstone and Turner, 1978; McCormick, 1983), the findings of the presnt study were, I believed, influenced by what might be termed a magical effect. Patients were intrigued by the functioning of their "deep dark mysterious subconscious mind" and by the apparently powerful method of altering its anxiety provoking functioning. The essential mystique of the therapy was very attractive to patients and may have elevated the degree of belief in the therapist as the originator of these techniques to a level much higher than that produced in the active therapy conditions where the role of the therapists was much different. In the latter, the therapists, working well within the cognitive-behavioural condition,

continually pushed reponsibility for improvement on to the patients who were given a very active role in their own treatment. In contrast, patients in the Placebo condition were essentially passive throughout therapy - their role being to simply allow the anti-anxiety messages to penetrate into the subconscious by simply quietly listening to a tape. By doing this, the "fight" to control the anxiety would be taking place without their awareness and, indeed, active participation. If this was indeed the case, and this can only be speculation, then it goes against what is generally seen to be of eminent importance in cognitive behavioural therapy - the collaborative relationship.

Ethical considerations.

O'Leary and Borkovec (1978) identify three sources of harm from placebo methodology:

1) Deception. Placebo conditions are inherently deceptive. Informed consent demands cannot be met with the use of placebos. Complete debriefing should follow completion of the study and the researcher should provide safeguards to insure that patients do not leave the experiment with remaining discomfort.

The Placebo condition in the present study was 'sold' as an experimental therapy and no expectation of success given. While consent was obtained, this consent obviously was not informed (although informed consent was obtained from referring agents). In addition, patients were not debriefed at the end of therapy. This was a clinical decision taken in view of the significant degree of improvement apparent in each patient in the condition. It was my view that debriefing would lead to relapse and would make patients

less likely to approach me for 'traditional' individual therapy which was offered, both verbally and in writing, if they felt that further therapy would be beneficial or if they felt that the Placebo treatment had not worked. The offer of immediate individual treatment was provided as a safeguard (G.P.s were also informed). It is significant that no patient at post-therapy or at follow-up felt this necessary.

2) Treatment deterrent. Placebos may deter patients from seeking active treatment during the course of the evaluation. When a patient discovers that he or she was given a placebo, he or she may feel angered that time was wasted at his or her expense.

In the present study, patients were not placed in the general waiting list and were thus offered therapy many months sooner than normally would have been the case. As, on average, patients had experienced the problem for four years prior to therapy, there was no immediate concern that alternative therapy could not be offered until after the completion of the six week course. Although patients were not debriefed and none realised that they had been given a placebo treatment, there can be little doubt that anger would have been likely if patients had realised this. This is of great ethical importance and was perhaps avoided in the present study more by luck than by anything else.

3) Minimal improvement. If a placebo is inert, significant clinical improvement will be unlikely to occur for most subjects. In such cases, harm to the subject in the form of increased frustration and lack of confidence in the helping professions may be a very serious consequence.

In the present study, this was not a problem. Each individual in the Placebo condition showed significant improvement on main, process and global measures. As compared to other active therapy studies, Placebo patients often showed as much change on these measures. As was noted earlier, the status of the therapist was probably deemed higher by Placebo than by other active therapy condition patients.

In general, every attempt was made to minimise the inherent ethical problems associated with placebo research. It was felt that on balance the benefits from this research outweighed the potential risks to patients.

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Having looked in detail at each of the experimental conditions, we can now turn to a comparison with other treatment studies.

D. COMPARISON WITH OTHER TREATMENT STUDIES.

Outcome measures.

Early in this study, Table 7 established that patients in the present study are comparable to those in other studies in terms of pre-therapy ratings of anxiety. At this stage, we can now compare treatment effectiveness across these (and other) studies. Table 90 shows percentage change scores on variables used in both the present and comparison studies.

TABLE 90/

TABLE 90. Comparison across studies of mean scores at pre-therapy and follow-up (6 months unless otherwise indicated) along with percentage change scores (+ = increase in score; - = decrease in scores; key to abbreviations displayed below table).

VARIABLE/ SOURCE	Treatment(s)	Pre	F.U.	% Change
STAI:A-State				
Butler et al (1987)	A.M.	58.0	43.9	-24
Eayres et al (1984)	Coping Skills	53.0	40.0	-25
	Relaxation	47.0	37.0	-27
Present Study	Cognitive	55.5	35.5	-36
	Behavioural	56.4	34.8	-38
	Cogn.-Beh.	50.2	36.2	-28
	Placebo	59.7	46.9	-21
* * *				
STAI:A-Trait				
Butler et al (1987)	A.M.	55.8	43.7	-22
Eayres et al (1984)	Coping Skills	51.0	40.0	-22
	Relaxation	55.0	47.0	-15
Jannoun et al (1982)	AMT.	50.1	39.4*	-21
Powell (1987)	AM	56.6	45.9	-19
Blowers et al (1987)	AMT	52.5	48.5	- 8
	ND	53.3	47.7	-11
Borkovec & Mathews (1988)	CT	54.0	43.4	-20
	ND	53.3	49.0	- 8
	CDS	54.4	44.8	-18
Present Study	Cognitive	58.1	45.4	-22
	Behavioural	59.5	45.4	-24
	Cogn.-Beh.	54.8	45.0	-18
	Placebo	59.3	50.4	-15
* * *				

VARIABLE/ SOURCE	Treatment(s)	Pre	F.U.	% Change
DAS				
Durham & Turvey (1987)	CT	70.1	86.7	+24
	BT	75.7	72.4	- 4
Present Study	Cognitive	99.2	118.7	+20
	Behavioural	99.3	114.8	+16
	Cogn.-Beh.	95.7	107.4	+12
	Placebo	99.1	112.4	+13
	* * *			
BDI				
Durham & Turvey (1987)	CT	14.3	9.5	-34
	BT	18.9	13.4	-29
Borkovec & Mathews (1988)	CT	14.5	8.7	-40
	ND	12.1	14.4	+19
	CDS	15.3	11.6	-24
Present Study	Cognitive	18.5	7.8	-58
	Behavioural	20.0	8.6	-57
	Cogn.-Beh.	17.0	10.0	-41
	Placebo	20.8	12.7	-39
	* * #			
FSS				
Woodward & Jones (1980)	SD	139.2	87.6d1	-37
	CT	148.9	136.7	- 8
	CBT	126.0	94.3	-25
Present Study	Cognitive	104.4	71.8	-31
	Behavioural	106.5	69.6	-35
	Cogn.-Beh.	105.6	80.0	-24
	Placebo	116.6	96.2	-18
	* * *			

VARIABLE/ SOURCE	Treatment(s)	Pre	F.U.	% Change
MSPQ				
Durham & Turvey (1987)	CT	25.7	14.2	-45
	BT	30.7	26.5	-14
Lindsay et al (1987)	CBT	36.1	20.8	-42
	AMT	52.4	30.3	-42
Present Study	Cognitive	34.3	19.1	-44
	Behavioural	34.4	15.4	-55
	Cogn.-Bch.	27.4	12.7	-54
	Placebo	29.2	26.0	-11

* * *

AM = Anxiety Management; AMT = Anxiety Management Training; ND = Non-directive;
CT = Cognitive Therapy; BT = Behaviour Therapy; CBT = Cognitive-behaviour therapy;
CDS = Coping desensitisation : * = 3 month follow-up; d1 = 1 month follow-up;
+ = group therapy.

In comparison with other individual and group therapy outcome studies, Stress Control, particularly the Cognitive and Behaviioural conditions, achieves at least as much improvement on all variables. Enhanced improvement is particularly associated with the MSPQ, BDI, A-State and A-Trait. The large changes associated with A-Trait are perhaps surprising given that the scale is intended as a stable measure of anxiety proneness. Of interest, is the degree of change evidenced by the Placebo condition. In many cases, the Placebo condition produces at least as much change as active therapy conditions in the comparison studies. The one exception to this is the relatively poor performance of this condition on MSPQ scores at follow-up.

As the present study is the only one to include a Placebo condition, there is reason to suspect that improvements in the active therapy conditions

across studies may be significantly influenced by factors other than therapy specific factors.

In general terms, comparison across studies indicates that Stress Control is at least as effective as a range of therapeutic approaches.

Amount of Therapist contact.

One of the aims of Stress Control was to produce an effective therapy which could be carried out within the constraints of NHS resources. Thus the issue of scarce therapist time is of considerable importance. Table 91 compares the degree of therapeutic time across studies. The Stress Control figure for the active therapies represents the average number of patients across conditions in a group and taken into account the fact that two therapists were involved with each group (with the exception of the Placebo condition). Contact time represents only therapeutic involvement and omits time taken in pre-therapy assessment across studies.

TABLE 91/

TABLE 91. Comparison across studies of mean amount of time in therapist/patient contact (* = average number of sessions).

SOURCE	NO. SESSIONS	LENGTH OF SESSION	NO. OF PATIENTS IN GROUP	CONTACT TIME PER PATIENT
<u>INDIVIDUAL THERAPY</u>				
Butler et al (1987)	8.7*	up to 60	-	Up to 8hr 40 min.
Blowers et al (1987)	10	45 min:	-	7h 30m
Durham & Turvey (1987)	16	60 min.	-	16 h
Borkovec & Mathews (1988)	12	60-105 min.	-	12 - 21h
<u>GROUP THERAPY</u>				
Woodward & Jones (1987)	8	75 min.	7	1h 26m
Eayres et al (1984)	8	90 min.	6	2h
Powell (1987)	6	90 min	8	1h 8 m
Present Study: active therapy conditions	6	120 min.	22	1h 5m
Placebo	6	120 min.	10	1h 12m

Stress Control, in terms of therapist-patient contact compares reasonably well with other group therapies and extremely well in comprison with individual therapy studies. Given the superior functioning of Stress Control particularly when compared to the above group therapies, Table 91 again suggests tht the economical use of time is justified on improvement indices.

Drop-out rates.

While Tables 90 and 91 have produced further support for the use of Stress Control in clinical practice, it is important to compare drop-out rates with the studies highlighted above. Table 92 explores this issue.

TABLE 92. Comparison across studies of average drop-out rates across treatment conditions within each comparison study. (Drop-out defined as those accepted for therapy but failing to attend/ complete therapy.

SOURCE		% Drop-out
INDIVIDUAL THERAPY		
Butler et al (1987)		7
Blowers et al (1987)		29
Durham & Turvey (1987)		12
Borkovec & Mathews (1988)		6
GROUP THERAPY		
Woodward & Jones (1980)		not given
Eayres et al (1984)		28
Powell (1987)		19
PRESENT STUDY:	Cognitive	7
	Behavioural	7
	Cogn.-beh.	8
	Placebo	0

Table 92 clearly demonstrates that Stress Control has an acceptably low drop-out rate when compared to other studies. Although there were only 10 patients in the Placebo condition, it is surprising that there were no drop-outs in this condition. The highest level of drop-out (Blowers et al and Eayres et al) both involved the use of nurse therapists and possibly highlights the importance of therapist characteristics, e.g. background knowledge and experience and this point will be looked at later.

To conclude this section, evidence has been produced to support the view that Stress Control, in comparison to other treatment outcome studies, is at least as effective, is well within the constraints of NHS resources and is associated with an acceptably low drop-out rate. The latter finding compares very favourably with the high drop-out rates often associated with primary care studies, e.g. Trepka (1986) reports on attrition rate of 40% from his primary care out-patient clinic. As the present study involves the largest sample yet reported in the GAD treatment literature, the findings give us greater confidence about the effectiveness of this approach.

E. NON SPECIFIC FACTORS

It is left to answer why distinctive treatments produced broadly similar results. In particular, on only one measure (MSPQ at follow-up) was there a significant difference between an active therapy (Cognitive-behavioural) and the Placebo. As the active therapies have not been shown to be significantly better than the Placebo, then logically we should conclude that they have not "worked". Based on the overwhelming evidence presented, this is clearly not the case but we can argue, as has been done in a previous section, that the Placebo condition was not, as anticipated, inert but rather that it contained effective therapeutic components and it may be of value to look for effective common components across conditions.

Although the Cognitive and Cognitive-behavioural conditions showed evidence of improved ability to alter belief in positive- and negative-self-statements during the Imaginal tests, on the whole, the results of the various process measures strongly advocates against different pathways to improvement. Instead the marked similarity in process change across conditions suggests a common pathway and it will be of value to assess some possibilities.

Firstly, it is clear that the present study fits in well with other comparative research studies. Smith et al's (1980) statistical meta-analysis of more than 500 treatment outcome studies failed to demonstrate

evidence for different types or degrees of benefit even although the content of these therapies are demonstrably not equivalent. (see also Luborsky et al, 1975; Kiesler, 1985; Sloane et al, 1975). Smith and Glass (1977) note "despite volumes devoted to the theoretical differences among different schools of psychotherapy, the results of research demonstrate negligible diferences in the effects produced by different therapy types" (p 760). Luborsky et al (1975) suggest that the verdict of the Dodo bird on the race in Alice's Advertures in Wonderland "Everybody has won and all must have prizes" captures the situation most vividly.

However, such studies can be criticised. Jones et al (1988) point to the complications involved in assessing patient change while Kazdin (1986) notes that sample sizes in comparative studies are modest (usually 20 or less subjects per group) and highlights various methodological issues in comparative research. Strupp (1983) suggests that the differential effects of two therapies would need to be robust indeed to over-ride the limitations imposed by the general nature of assessment devices, the typically brief duration of treatments and the small sample sizes.

Bearing these points in mind, evidence from a recent comparative outcome study is of particular relevance. Results from the National Institute of Mental Health's Treatment of Depression Collaborative Research Program suggest that cognitive therapy, interpersonal therapy and imipramine do not demonstrate differential success rates (Elkin, 1986). While the two psychological treatments share the elements of active and empathic therapeutic style, structure and therapist contact, they can be readily

discriminated by relatively naive raters (DeRubeis et al, 1982).

Thus it seems appropriate to look for common factors to explain the results of the present study. Goldfried (1980) suggests that as no one orientation will provide all the answers to all the theoretical problems, we should look at common strategies, not common theories or common techniques. The latter, in particular, would likely to be trivial. Examples of such clinical strategies would include:

a) providing patients with new, corrective experiences,

b) offering patients direct feedback,

c) inducing in patients the expectation that therapy can be helpful,

d) providing for participation in a therapeutic relationship between patient and therapist and

e) providing patients repeated opportunities to test reality.

As Haaga (1986) points out, each of these strategies could be implemented or explained in different ways; agreement on clinical strategies does not depend on common procedure or theory. Wilson (1982) argues that therapists of different orientations do not practice more similarly, even when more experienced. However, in the present study, the same therapists, both steeped in the cognitive-behavioural orientation, may have offered such common strategies across conditions.

Wilkins (1979) points out that the term "non-specific" is used loosely across a variety of contexts and that the label is a negative as the heterogeneity of events defined by the exclusion of a property ranges

from -

a) procedural and theoretical events presumed to be common to all therapies (e.g. placebo effects) to

b) events that are common to some therapies (e.g. face validity of procedures) to

c) events extraneous to the delivery of therapy that are common to no therapy (e.g. demand characteristcs of the situation and therapist bias.

While it is a truism that therapy cannot be administered free from all non-specific factors, they have been accorded a much lower priority than specific therapy components. The present study suggests that they warrant much more attention than contemporary research has given them.

Frank (1985) posits the view that "all psychotherapeutic methods are elaborations and variations of age-old procedures of psychological healing. These include confession, atonement and absolution, encouragement, positive and negative reinforcements, modelling and promulgation of a particular set of values" (pp 49 - 50) and although psychotherapies have distinguishing features from other forms of psychological healing and from each other, it does appear that features shared by all therapies account for an appreciable amount of the improvement observed in responding patients (Frank, 1973). It is his view that the integration into everyday life of a framework for perceiving and coping with problems that is understandable, personally relevant and broad range in its application is necessary in order to cope independently with life stresses especially when these have pervasive negative effects on general functioning as in anxiety.

A demoralisation hypothesis has been forwarded by Frank (1985). He suggests that patients seek help not for symptoms alone but for symptoms coupled with demoralisation. This may be characterised by, e.g. subjective incompetence, loss of self-esteem, alienation, hopelessness (feeling that no-one can help) or helplessness (feeling that other people could help but will not). Demoralisation may occur when, because of lack of certain skills or confusion of goals, an individual becomes persistently unable to master situations which both he and others expect him to handle or when he experiences continued distress which he cannot adequately explain or alleviate. While this will not account for all patients seeking therapy, Frank assumes that the majority of patients do fit into this model. He further suggests that much of the improvement stemming from psychotherapy lies in its ability to restore the patient's morale with, as a result, the diminuation of symptoms. Frank also notes that alleviation of symptoms may be the best way to restore morale.

While this demoralisation hypothesis remains speculative, it may be of value in the context of the present value and, in particular, help explain the often significant changes very early in therapy, at a stage where treatment effects would be expected to be minimal.

Bandura's self-efficacy theory may be of considerable importance. Stress Control may foster patients' belief that they can successfully execute specific behaviour. According to Bandura (1984), self-efficacy is not merely a cognitive estimate of future competence on the basis of past performance; self-perceptions of efficacy enhance performance rather than merely forecast degrees of success (Bandura and Cervone, 1983).

Although the conceptual and empirical status of self-efficacy theory has been challenged (e.g. Eastman and Marzillier, 1984), it seems reasonable to speculate that all the treatment conditions in the present study are, to some extent, diverse means to a common end, namely the enhancement of patients' self-efficacy beliefs. Tables 5 and 6 suggest that patients in all treatment conditions shared moderately high expectations and rated therapies as sensible. Although not consistently found as a good predictor of outcome, it suggests that the mobilisation of positive expectations (or hope) is an active ingredient in Stress Control for all conditions and may help explain the often dramatic gains made particularly by the Placebo condition in the first few weeks of therapy which cannot be adequately explained by therapy-specific effects. Early expectation effects may then have been bolstered by treatment-effect success which helps pull patients, particularly in the active therapy conditions, along by their enhanced expectation of further improvement.

It may also be useful to consider therapist-patient factors. With the exception of the Placebo condition which had only one therapist (JW), all the treatment groups were run by the same two psychologists. While the use of the same therapists limits our ability to generalise from the results, it does allow us to speculate that an important common factor of therapists across conditions may help explain the similar findings.

Both therapists, having jointly devised the Stress Control therapy and having successfully run four courses (cognitive-behavioural therapy) prior to the present study, were highly motivated, identified closely with the therapy and had, with the exception of the Placebo condition, reasonably high expectations of outcome for all versions of the therapy. The therapists

worked well together and, indeed, enjoyed carrying out Stress Control. These points were often remarked upon by patients and it seems reasonable to suggest that the sight of therapists who believe in the therapy they are offering and who appear to enjoy transmitting that therapy would be of benefit to the patients. Indeed it calls to mind the view that therapies work best when they are new (and when therapists are enthusiastic).

It was also frequently remarked upon that, particularly as the therapists had also written the booklet, we knew exactly how patients felt, indeed were often to make more sense of the problem than patients had been able to do, and this again may help bridge the gap between therapists and demoralised patients. In addition, although reviews of the triad of "necessary and sufficient" conditions of warmth, empathy and genuineness (Rogers, 1957) have returned a verdict of "not proven", in the case of Stress Control, it seems reasonable to propose that unless patients quickly believe in the therapy and, indirectly, in the therapists as the medium for that therapy, they are unlikely to adopt the necessary mantle of responsibility for putting the techniques into effect.

The literature appears to play down a particularly important aspect of therapist involvement, i.e. experience of the therapist. It is reasonable to assume that any two therapists, irrespective of the amount of experience they have, trained in the same theoretical and therapeutic tradition, will still work in distinct ways. It seems very likely that experienced therapists will work differently from inexperienced therapists particularly as experience may allow a diversity and flexibility not available to more

inexperienced therapists. Jones et al (1988) produce evidence that successful therapists modified the therapeutic model for the treatment of stress disorders in a direction required by the nature of their patients' difficulties. It is less likely that Ph.D students, 1st year graduate psychologists could do this. Yet such therapists are often employed in the U.S. studies (e.g. Borkovec and Mathews, 1988; Rapee and Barlow, 1988).

Similarly, the poorer results recorded by Blowers et al (1987) may have been influenced by the use of behaviour therapy nurses who may be less able to draw on a knowledge of various aspects of psychology - both normal and abnormal than would an experienced clinical psychologist by dint of his/her undergraduate and post-graduate training. This would be particularly useful when patients do not respond in the ways the manual suggests they should. In my experience, particularly in cognitive therapy, patients do not respond as they appear to do in the therapy transcripts included in the cognitive therapy manuals. Either this highlights my inexperience/incompetence in carrying out cognitive therapy or the transcripts are unrepresentative of typical therapy encounters. If the latter is, indeed, the more likely explanation, then the experienced therapist will probably be more able to draw on past experience to make therapy successful.

Blowers et al (1987) comment that the relatively small differences achieved between their two active treatment conditions may be explained by a finding amongst therapists that, despite different treatment procedures and rationale, responding patients often described the adoption of common strategies. They also suggest that patients may have been helped by

reconceptualising anxiety as a problem to be tackled rather than as a catastrophic and uncontrollable threat. Butler et al (1987b), similarly, comment that patients gave the impression that one of the main benefits of treatment was finding that they had the resources for dealing with the problems themselves. This was, of course, one of the main aims of Stress Control and, as in the Butler study, some of the factors contributing to successful outcome may have been : providing an explanation for the symptoms of anxiety; confirming that the strategies used are appropriate and likely to succeed if practised persistently; discouraging the use of unhelpful strategies (drugs, alcohol, avoidance, etc.).

Stress Control, perhaps surprisingly in view of the large number of patients involved in each group, the "therapeutic alliance" (see Luborsky, 1976; Marziali, 1984) was strong and, one can speculate, beneficial. It may be that the therapists, in all conditions, were able to establish a positive emotional bond and sense of mutual collaboration with receptive patients, even if these patients were treated as a "lump" rather than having individual attention bestowed upon them, and that this relationship carries a good deal of therapeutic weight.

The concept of "therapeutic alliance", deriving from the psychoanalytic tradition, puts forward the thesis that the specific tasks, techniques and theories attached to alternative therapies are relatively unimportant except as vehicles for enacting the therapeutic alliance. It should, however, be borne in mind that early symptom relief is likely to strengthen the therapeutic alliance so that the relationship to outcome may be bi-directional.

While the exact operation of patient and therapist contributions remains to be clarified, the existence of a good therapeutic relationship, the importance of which is recognised in both cognitive and behaviour therapy (cf Beck et al, 1979; Wilson and Evans, 1977), in conjunction with a set of techniques are both necessary and neither is sufficient for a good outcome.

It is important to note that although a range of therapies produced significant effects, with the exception of the Placebo, the active treatments were "dismantled" forms of an original Stress Control therapy. Therapies bore the hallmarks of cognitive-behavioural therapies - treatment was highly structured, the therapists assumed active roles, goals of therapy were circumscribed, treatment relates to the "here and now" and endorses the belief that maladaptive reactions can be altered without insight into the precise origin of the symptom. Thus the style of therapy may be of importance and it would be rash to suggest that, e.g. a dynamically orientated Stress Control with a distinctive style would produce similar results.

Stress Control emphasises self-monitoring and self-initiation of alternative methods of handling stress. It seems possible that as patients became more aware of the cognitive, behavioural and somatic systems of anxiety, they became more able to detect the origins of an anxiety cycle and to intervene at an earlier stage using the techniques learned. By doing so, self-control would increase while, naturally, lack of control would diminish.

The results of the present study do suggest that the movement towards integrating the psychotherapies is of value (e.g. Beitman et al, 1989; Haaga, 1986). Karasu (1986) identified over 400 different 'schools' of psychotherapy. Assuming that they cannot all be right, an attempt to bridge the boundaries often imposed by mutual distrust, antipathy and by the "dogma eats dogma" environment should be encouraged. In a profession in which 41% of survey respondents label themselves eclectic (Smith, 1982), the ability, in an empirically based eclecticism, to learn from other approaches would be of value. We should also pay more attention to clinical skills rather than theoretical purity as the important medium in producing symptomatic improvement for our patients. As Barlow et al (1984) note "few procedures are practised with theoretical purity to the great advantage of millions seeking help from psychotherapy" (p 34).

F. SUGGESTIONS FOR FUTURE INVESTIGATION.

The present study has shown that large group therapy in several formats is a successful approach in the treatment of GAD. The reasons why this approach is successful are not clear although speculation has suggested that non-specific factors are of great importance. It is appropriate now to employ Stress Control as a routine clinical practice. Research, however, should continue to investigate process of change and it may be of value to assess concepts such as self-efficacy, patient characteristics and, importantly, to attempt a replication study using different therapists. Further studies could also profitably look at the components of Stress Control, e.g. the utility of the booklet, the workshops, etc.

It has been recommended earlier that certain components used in the present study should now be dropped, e.g. the assessment of dysfunctional attitudes, Behavioural Relaxation Training. Based on clinical impressions as well as empirical findings, a synthesised version of Stress Control should now be developed.

Given the high priority placed upon "Hearing the psychologists talk about Stress Control" and "the booklet", it is suggested that the therapists should devote more attention to the didactic element of the therapy. In particular, more use of video and slide presentation would aid information transmission and retention. As Ley's work (e.g. 1976) demonstrates, patients are likely to be unable to retrieve significant amounts of information transmitted and information transmitted via a variety of media may boost retention.

Related to this, it is recommended that the booklet is enlarged. The sections on the cognitive techniques and the treatment of panic would benefit in particular from this while an increased use of case histories may help earlier identification. As many patients commented, at follow-up, that simply reading the booklet on a "bad day" often helped decrease anxiety, more attention should be paid to relapse prevention advice - perhaps a section entitled "What to do on a bad day" and involving simple, specific advice.

It is also proposed that the section on behavioural approaches should be redesigned. Rather than concentrating on hierarchy construction and targetting, it may be more useful to include behavioural 'tips' of the type commonly suggested in anti-Type A training : take one thing at a time, do not accept other peoples' targets, advice on avoidance, etc.

The use of relaxation in two of the conditions also seemed useful (although clearly not necessary). As relaxation has a high degree of face validity and, RIA notwithstanding, is a technique almost all GAD patients can readily carry out, it is proposed that its use should be extended to involve Applied Relaxation.

One other consideration with respect to the treatment of GAD must be assessed. It was noted that the Placebo condition, on many variables, showed the greatest degree of change in the first few weeks of therapy. By the latter part of therapy, this rate of progress slowed, their improvement overtaken by that of the active conditions. It is argued

that one reason for the often dramatic degree of early change (and corresponding enthusiasm of Placebo condition patients) was the appeal of the Placebo rationale, i.e. the use of hidden messages to thwart the anxiety-producing mechanisms buried deeply in the sub-conscious mind. Speculatively, I would propose harnessing the power of the Placebo to the power of the (synthesised) active Stress Control, i.e. combine placebo and cognitive-behavioural priciples in the one therapy. Thus the role of cognitive techniques could be sold as a way of tackling sub-conscious forces, subliminal messages could be inserted into progressive relaxation tapes (including white noise at beginning and end). Doing so may allow the powerful placebo reaction in the early stages of therapy and, in the latter stages, the developing impact of the active therapeutic ingredients could sustain and enhance the placebo effects, continuing into the months following treatment cessation.

The present study involved groups of up to 24 patients. Few difficulties were encountered with this number and an argument has been made suggesting that a larger number of patients may have definite benefits over a small group therapy. In terms of clinical utility, therefore, studies using larger groups of perhaps 40 patients should be attempted.

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With respect to the treatment of GAD, Stress Control has been shown to be an effective therapy. However, attempts should be made to adapt Stress Control to cope with other diagnostic categories. One group who

may readily benefit from Stress Control are Panic Disorder patients. Given the likelihood of generalised anxiety symptoms existing along with the Panic Disorder and with Stress Control already including a panic attack treatment, it seems likely that PD patients could be immediately fitted into existing Stress Control therapy.

Of greater interest would be to test the flexibility of Stress Control in the treatment of other diagnostic groups particularly those who also experience panic. Barlow (1988a) speculates that all currently identified anxiety disorders as well as some DSM-III-R disorders not included in the anxiety disorders grouping, may be basically panic disorders that differ only in terms of the pervasiveness of the antecedants, the perception of the cues and whether the panic is expected or not. Under this rubric would come such conditions as simple phobias, social phobias, panic disorder with- and without- agoraphobia and post-traumatic stress disorder.

Given that few services would be able to bring together, e.g. 25 PTSD patients at any one time, Stress Control could be adapted to provide a more generic approach to the treatment of various forms of anxiety disorder. The idea has immediate appeal to hard pressed therapists in busy clinics. It is possible to see immediate benefits in terms of, e.g. an agoraphobic patient using Stress Control not only as a treatment for a co-morbid generalised anxiety disorder but also as an appropriate target in an exposure-based programme. Similarly, a social phobic could use, e.g. the tea break with the target of initiating a conversation. Although simple phobia and PTSD may not fit as clearly into a Stress Control model,

it may be of value to devise a series of supplements to the Stress Control booklet. These would take the form of booklets devoted to specific problems but which can be integrated into the Stress Control therapy. These supplements (one, in the form of a tranquilliser reduction booklet was used in the present study) would be given following the individual assessment interview.

Thus, conceivably, a booklet on agoraphobia could be produced giving information on the condition - characteristics, symptoms, causes, maintenance etc., combined with a specific self-help exposure-based programme, e.g. have the patient create appropriate targets perhaps by means of self-help assessment techniques included in the booklet (or in the case of more severe problems, in concurrent individual therapy sessions).

It may also be possible to form sub-groups which could meet prior to the main therapy group and receive therapist help in creating targets. Possibly a "menu" of events could be created where patients could choose between alternative talks/workshops/video presentations during certain parts of the main Stress Control course.

If Stress Control proved adaptable in this respect, it may be appropriate to attempt to extend the range to envelope non-anxiety disorders and, in particular, unipolar depression. Cognitive therapies, in particular, have been shown to be effective in the treatment of this pervasive problem which, in primary care, is generally treated with the use of anti-depressants.

Evidence has been presented that after successful palliative treatment of the first depressive episode with anti-depressant there is a 78% relapse rate within 2 years. Cognitive therapy, however, shows a relapse rate over the same period of 32% (Blackburn et al, 1986). Thus a cognitive-behavioural treatment, retaining the style and format of Stress Control, could prove a feasible method of treating the very large numbers of uni-polar depressives presenting in primary care.

It would also be interesting to explore whether the use of a Stress Control approach would be of value in the area of prevention particularly for physical health. Johnston (1989) persuasively outlines the case for stress management techniques to be utilized in the prevention of coronary heart disease (CHD) and, in particular, with very high risk groups such as those patients who have already suffered a heart attack. It is his thesis that the classic risk factors for CHD - raised blood pressure, raised blood cholesterol and cigarette smoking - are, to a greater or lesser extent, behavioural and of greater importance, these risk factors are stress related and also interact positively with stress. Stress Control would seem to offer an appropriate treatment approach and thought should be given to an adaptation suited to the population.

One final adaptation of Stress Control should be considered and again it relates to the provision of information. Given the current dissatisfaction with benzodiazepines and the lack of evidence for the usefulness of nonbenzodiazepines, e.g. Buspirone (e.g. Rickels et al, 1988), G.P.s will have to look for alternatives for the anxiety disorders population which comprise 20% of all patient consultations (Espie and White, 1986) and take up 30% of all consultation time (Hassell and Stillwell, 1977).

As only a fraction of this number can reasonably be referred to specialist services, the possibility of adapting Stress Control into a complete self-help therapy should be considered. This would involve a package containing a self-help Stress Control booklet, assessment charts, applied relaxation tapes and, conceivably, a video, perhaps given a loan from the G.P. practice, of a therapist talking about stress, giving advice on ways of using the self-help package, etc. which would allow a degree of "therapist contact". This form of Stress Control would be designed as a preventative approach and, as such, would be flexible enough to cope with a wide range of stress-related conditions.

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If these proposals do have any therapeutic merit, they would allow psychologists to intervene in a much greater number of problems and with a much greater number of individuals than can currently be envisaged.

Earlier in this study, a view was expressed that psychologists, particularly those involved at the primary care level, should attempt to adapt existing strategies. The present study, hopefully, has provided some empirical support for this view and now offshoots of the basic idea can perhaps continue this development.