CHAPTER IV

PRESENT STUDY
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SUBJECTS

Out of a pool of 68 patients, initially accepted for the study, ultimately 45 patients completed the entire process of therapies and follow-up. All the patients reported to the psychiatry out patient departments of the local Medical Colleges & Hospitals, Calcutta for the treatment. From there, they were referred to the present investigator, when the patients met the DSM III - R diagnostic criteria for GAD. The diagnosis was made by the chief psychiatrist of the department and was corroborated by another psychiatrist. When both the psychiatrists made the same diagnosis, the patient was taken up for the study.

The inclusion criteria were
a) Presence of illness for at least two years.

b) Scoring 2 SD above the mean in Trait Anxiety Inventory.

c) Education of at least Xllth. Standard, so that the patients can follow the questionnaires or do the homework writing assignments, as needed in cognitive therapy.

d) Age between 25 to 40 years.

e) Continuing the entire course of treatments along with the 6 months follow up.

The exclusion criteria were
a) Who have other psychiatric illness prior to the outset or in addition to GAD.

b) Who have any kind of medical complication.

c) If a change is made in the original diagnosis of the patients, after including him up for the study.

After the patients met the inclusion criteria, they were explained the conditions of the treatment. When the patients accepted the conditions of the treatment they were included for the main study.

Thus, likewise 68 patients were accepted for the study, and were randomly assigned to any one of the three treatment conditions. After the acceptance, 2 were excluded and 21 patients dropped out either during the therapies or during the follow ups and 45 patients, 15 in each of the three groups completed the entire course of therapy and six-
months follow up. In the initial one and a half month (i.e. within the first 10 sessions of CT and BFBK), 3 dropped out from cognitive therapy, and 4 dropped out from the biofeedback group. In both the cases, the patients were wanting some rapid changes in this condition and they dropped out as they were not finding adequate changes from the therapies. During this period, two patients from pharmacotherapy were excluded from the study, because of irregular intake of medicines. In the next half of the therapeutic period, 1 patient dropped out from the cognitive therapy group (due to shifting to a different city) and 2 patients from the biofeedback group (for not finding adequate change) and 2 patients from the pharmacotherapy group (not willing to continue for not finding the desired change). After the end of the study, in the follow up session, 1 patient dropped out from the cognitive therapy group, 2 from the biofeedback group and 6 from the pharmacotherapy group. The drop out from PhT group in the time of follow up was much more than the other two groups, because patients found it difficult to remain without drugs during the entire period of follow up. The patients who found the difficulty unbearable were referred to different psychiatrists and were excluded from the main study.

In each of the three groups, there were 5 females (33.33%) and 10 males (66.7%). The mean age of the patients were 31.2 years and S. D. of 4.97 years. The duration of illness ranged from 2 years to 11 years, with a mean of 4.56 years and S. D. of 2.64 years. 48.9% of the patients had history of previous treatment. All the patients belonged to the middle and upper middle class socio-economic status.

As the patients were randomly assigned to the three groups, chi square of some of the significant demographic variables were conducted to see whether the three groups differ in respect to distribution of age, family type (nuclear or joints), history of previous treatment and family history of mental illness.

Thus below, the distributions and the chi squares would be given.

(1) **Age:**

<table>
<thead>
<tr>
<th></th>
<th>Below 30 years</th>
<th>31 - 35 years</th>
<th>36 - 40 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>5</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>BFBK</td>
<td>4</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>PHT</td>
<td>3</td>
<td>7</td>
<td>4</td>
</tr>
</tbody>
</table>

\[
\chi^2 = 0.75 \quad \text{Not significant}
\]
So there was no significant difference among the three groups in respect to distribution of age of the patients.

(2) Family type:

<table>
<thead>
<tr>
<th></th>
<th>Joint Family</th>
<th>Nuclear family</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>BFBK</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>PhT</td>
<td>4</td>
<td>11</td>
</tr>
</tbody>
</table>

$\chi^2 = 2.69$. Not significant.

Thus there was no significant difference amongst the three groups in respect to family type of the patients.

(3) Previous Psychiatric treatment:

<table>
<thead>
<tr>
<th></th>
<th>No Previous treatment</th>
<th>Had previous treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>BFBK</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>PHT</td>
<td>7</td>
<td>8</td>
</tr>
</tbody>
</table>

$\chi^2 = 2.31$. Not significant.

Thus the three groups were not differing amongst themselves in respect to the experience of previous psychiatric treatments.

(4) Family History of mental illness:

<table>
<thead>
<tr>
<th></th>
<th>Family history present</th>
<th>Family history absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>BFBK</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>PHT</td>
<td>2</td>
<td>13</td>
</tr>
</tbody>
</table>

$\chi^2 = 0.33$. Not significant.

Thus the three groups were not differing amongst themselves in respect to the family history of mental illness.
So, it appears that the patients in the three groups were grossly similar in respect to their demographic variables viz. age, sex, socio-economic status, family type, history of previous psychiatric treatment and history of mental illness in the family.

**MEASURES USED**

3. Skin Conductance on Galvanic skin response monitor (SC).
4. Beck Depression Inventory (BDI) (Beck et al, 1986) Appendix - C.
5. Cognitive Style Test (CST) (Blackburn et al, 1986) - Appendix - D.
6. Dysfunctional Attitude Scale (DAS) (Weissman & Beck, 1978) - Appendix - E.
8. Internal - External Locus of Control (LOC). (Valecha et al, 1980) - Appendix -G.

**PROCEDURE**

To conduct the study, as a first step consents were obtained from the local hospitals and medical college authorities. Liaison was made with the psychiatry departments of these hospitals and the nature and need of this investigation was explained.

Patients meeting the D.S.M. III-R diagnostic criteria for GAD, and reporting to the outpatient division of the psychiatry departments for their treatments, were referred to the present investigator. The diagnosis was made by the chief psychiatrist and was again reviewed by another psychiatrist. When both the psychiatrists were at consensus, the patients were referred. After the referrals, the present investigator found out whether these patients met the inclusion & exclusion criteria. The patients not meeting the criteria were referred back to the concerned psychiatrists. The patients meeting the criteria, were explained about the terms and conditions of the treatments. They were also explained that the nature of treatment would get decided by randomization, and after treatments they need to stay for follow up for six months. When the patients were ready to accept all the terms and conditions, they were accepted for study. If the patients had shown any particular preference for any type of treatment, they were not included for the present study and were referred elsewhere, according to their preferences. So, before the starting of the study, it was ensured that the patients were
not particularly inclined for any particular kind of treatment, as this factor could influence the outcome obtained from the treatments.

If the patients were already on any medication for their anxiety, they were kept on a drug wash out period of one month (Woods & Dennis, 1988). If the patients were not ready to remain in wash out and reported difficulty in withdrawing from drugs, they were kept out of the study.

After the acceptance of the patients in the study, the present investigator filled up the detailed case history proforma with demographic details, following Mayer-Gross, Slater & Roth (1986). This case history proforma helped in getting all the details of the patient and his / her illness and also helped in forming the basic rapport with the patient.

Once all the details of the case history were obtained, the patients were sent for pre-treatment assessment. Pre-treatment assessment was done on eight measures by an experienced psychologist independently, and the present investigator remained blind to the scores obtained from these various measures. Assessment was conducted in a laboratory room of the psychology department of Calcutta University and was spreading over three sessions each approximately comprising of one and a half hours of duration. The sessions were held on consecutive days. At the starting of each session, first a recording of basal skin conductance was taken for 10 minutes. Method of recording this measure and the precautions taken were already elaborated in the last chapter. After the recording of basal skin conductance, questionnaires were administered. The questionnaires were filled up in presence of the assessor, so that any clarification could be done immediately. The rating of anxiety on HARS was done by the assessor herself as she was quite experienced in doing so.

After the pre-treatment assessment, the patients were randomly assigned to either of the three groups, viz. CT, BFBK and PHT, and the treatments were started.

In each of the three groups, the initial session of the treatments was spent on explaining the following issues:
(a) Giving information about the anxiety and the nature of problems it creates.
(b) Explaining the rationale of the treatment, which the patient had to undergo and how it would help him / her in reducing the anxiety.
CT and BFBK were conducted by the present investigator herself. In these two groups, the patients were seen individually over the twenty sessions, twice a week for the initial two months and later on, once a week for the third month. So the treatment period for each patient ranged for three months.

In the pharmacotherapy group, the treatment was rendered by a trained and experienced psychiatrist, and the patients reported to him once a week. To maintain regular compliance, medicines were supplied to the patients. Medicines were given for one week, and were asked to return the unused pills, if any on the next session. The present investigator remained along with the psychiatrist during the PhT sessions, and collected information regarding the compliance of the dosage of medicine prescribed. Information were collected both from the patient and the patient's family. In case of irregular intake of medication the patient was kept out of the study. In PhT, care was taken that there was no emphasis on the patient therapist interaction. Thus the frequency and length of the PhT sessions remained limited. As the active ingredient was supposed to be performed by the medication, here the doctor's role remained only in administering the drugs with enough clarity of direction and encouragement to ensure the compliance. Like CT & BFBK, the treatment period of PhT group also continued for 3 months.

For the purpose of control, all the three types of therapies were conducted in the same therapeutic set up, i.e. in a pleasant, comfortable and a quiet room. The room consisted of a table and some comfortable chairs to carry out discussions as needed in the therapies. In one corner of the room, the S.C. biofeedback instrument was kept, with a reclining chair, to conduct the BFBK. On the other end, the relaxation bed was kept, which was used in CT.

After the pre-treatment assessment (Phase I) assessments on the same eight measures were again conducted at the mid treatment period i.e. after one and a half month of treatment (Phase II), and at the post treatment period i.e. after the total completion of three months of treatment (Phase III). Assessments were done independently by the same psychologist, who conducted the initial assessment. Attempts were made to keep
her blind to the patient's treatment conditions as much as possible. For this the patients were instructed not to discuss the mode of therapy with the assessor, to avoid biasness. The therapist i.e. the present investigator, however remained totally blind to the scores obtained, to avoid any kind of biasness.

After the end of the three months, patients were put on a follow up period for six months. During this period, assessments were conducted three times. First two months after the termination of the treatments (Phase IV); Second, four months after the termination of the treatments (Phase V); and lastly, six months after the termination of the treatments (Phase VI). Each time during assessments, measures were taken on all the eight variables and the questionnaires were filled up in direct supervision of the assessor. Care was also taken to see that there was no sequential effect in administration of the psychological tests.

During the entire period of follow up, no contact was kept with the therapist in the CT and BFBK group. Patients visited the assessor only for assessment. But in PhT group, to avoid withdrawal symptoms and reappearance of anxiety as a part of withdrawal symptoms, drugs were tapered off gradually, each week 2.5 mg lower than the previous week's dose. Thus for monitoring of the treatment and for collecting the medicines, the patients were required to meet the psychiatrist for the next one and half month after the treatment got over. But effort was taken to cut down any kind of therapeutic interaction, except administration of the drugs.

After the drugs were completely withdrawn, patients only visited the assessor for assessment. So during the follow up period, all the patients remained without any active treatment. If within this period, the patients expressed any unwillingness or real difficulties to continue in this manner, then they were referred back to the psychiatry department, from where they were originally taken up. If the patients had dropped out from the follow-up period, they were replaced through randomization and the entire process of therapy and assessments were conducted on them. Thus in the end, it was taken care, that there were fifteen patients in each of the groups, who had completed the entire process of therapy and follow up of six months.
**Therapist**

The therapist on the present investigator, who conducted cognitive therapies and biofeedback therapies was a trained clinical psychologist (M.Sc., M.Phil) obtaining training of cognitive therapy and biofeedback from National Institute of Mental Health and Neurosciences, Bangalore, India. Before the starting of the present study, she had three years of post training experience in conducting cognitive therapy and biofeedback on several patients, as an independent practitioner. The therapy sessions were also occasionally supervised by the supervisor of this Ph.D. work, who himself is a trained clinical psychologist, having experience of more than 20 years.

**Assessor**

The assessor was an experienced psychologist (M.A.) having two years experience of conducting psychological assessments, independently.

**Psychiatrist**

The psychiatrist who prescribed the medicine for the PhT group, was a trained psychiatrist (MBBS, MD(Psy.)) with experience of independent practice of two years.

**ANALYSIS**

The data obtained from the present study will be analyzed and presented in three sections.

(A) The first section would deal with the changes that occur within a group and between the groups due to the administration of different therapeutic modalities. These changes are analyzed by the use of appropriate statistical techniques and interpreted.

Thus, the obtained result of the eight measures for the three groups, each on six phases were analyzed statistically. The means and standard deviations of each of the measures were computed separately for the three groups each on six phases. To study the significance of differences within a specific group, over the various phases, one way analysis of variance for repeated measures was used. This analysis was used to test the significance of difference among the means of the six phases viz. I (pre-treatment assessment), II (mid treatment assessment) III (post treatment assessment), IV (Follow up after 2 months) V (Follow up after 4 months) and VI (follow up after 6
months), for each group and on each measure. Subsequent to F-test for repeated measure, Duncan’s Multiple Range Test was attempted to find out the differences between each of the two means of the six phases. Next, to study the significance of differences among the three groups, one way analysis of variance for independent sample was used. This analysis was done to test the significance of differences among the means of the three groups on each of the phases separately. Subsequent to ANOVA for independent samples, multiple comparison of the means were again attempted by using the appropriate Duncan’s Multiple Range Test.

(B) The second section would deal with the clinical improvements in subjects. No doubt, it is important to established statistically significant changes in a group comparison study (as done in section A.) But there are two major limitations of this approach, it provides no information on the effects of therapy for individual clients (Barlow, 1981; Garfield, 1981, Ost, Jerremaim & Johansson, 1981;) and it applies a statistical criterion for determining a treatment effect that may have little clinical relevance (Jacobson, Follette & Revenstorf, 1984). Thus, to evaluate the clinical significance of the reported results, it was felt necessary to consider the additional indices of change. Hereby in the present study also two such indices were used. Both these indices had been reported with sufficient frequency in the other relevant studies (Borkovec, et al, 1987; Butler et al, 1987; 1991; Power et al, 1989; 1990) and were used in the present study to enable comparisons with them.

The two indices used in this study are elaborated below:

(1) STANDARDIZED CRITERIA FOR A RETURN TO NORMATIVE FUNCTIONING - A variety of criteria are used in different studies. In the present study, the criterion for normative functioning was operationally defined, as follows (i) a score of less than 10 on the Hamilton Anxiety Rating Scale and (ii) two standard deviation below the mean of the basal skin conductance of the pre-treatment level.

In the present study, to avoid any ambiguity, criteria for normative functioning was based on two measures, HARS, a subjective measure and SC, a totally objective measure. The former, though a subjective measure, is a widely used tool and have been used as a criterion for most of the previous researchers (Power et al 1990, Butler et al 1991). Generally a cut off point is defined as a score more than 2 standard deviations
from the mean of dysfunctional distribution. (Jacobson, et al 1984). This definition was used to fix up the criterion of S.C, but the same could not be used for HARS, as in the present study the score of 2SD below the pre-treatment mean, was still very much within the dysfunctional range. Thus, a score of less than 10 on HARS was used, as this brings an individual within the normal range. The same criterion was previously used by Butler et al, 1991.

(2) DEGREE OF CHANGE - To assess improvement percentage change from the pre-treatment value to post treatment and 6 months follow up were calculated. Analysis was restricted only to two measures. (i) State - Trait Anxiety Inventory - Trait Version and (ii) Hamilton Anxiety Rating Scale. Both these measures have been variously used in the recent studies, and thus allow to have data for comparison.

The first two sections of the Result (A & B) attempted to investigate the objective no 1 & 2 as given in Chapter 1 (Introduction). The detail of Section C is elaborated below.

(C) The third section of the results attempted to elicit whether the four clinical characteristics of the patients (severity of anxiety, duration of illness, loading of depression and history of previous treatment) have any role in influencing the outcome of a specific therapy. This was done to study the possibility of predicting a response to a particular therapy, prior to the starting of it based on the clinical characteristics of the patients. This part also studied the role of locus of control on the outcome of a therapy.

Therapeutic outcomes were studied on two occasions:

(i) When the therapy was getting terminated (i.e. phase III).
(ii) at 6 months after the therapy got terminated (i.e. phase VI).

Outcome of the therapy was divided into two categories:

(i) Responded well.
(ii) Did not respond well.

'Responded well' were those patients who reached the criteria of normative functioning, specified in section B.
For the present analysis 2 x 2 tables were formed based on two categories of therapeutic outcomes and two categories of patients, classified on the basis of their clinical characteristics. Fisher's exact probability test was used for each of the clinical characteristics for the different therapeutic modalities separately, assessed at phase III and phase VI of the study.

In the same way 2 x 2 tables were formed based on two categories of therapeutic outcomes and two categories of locus of control ('towards internal' and 'towards external') and Fisher's exact probability test was to find out the significance of locus of control on therapeutic outcome.

The section C of the results attempted to study the objective no 3 & 4 as given in Chapter1 (Introduction).