*International Journal of Basic and Applied Medical Sciences ISSN: 2277-2103 (Online)*
*An Open Access, Online International Journal Available at http://www.cibtech.org/jms.htm*
*2014 Vol. 4 (2) May-August, pp. 24-35/ Bajaj and Malhotra*
***Research Article***

# EFFICACY OF COGNITIVE BEHAVIOUR THERAPY IN THE TREATMENT OF GENERALIZED ANXIETY DISORDER: A RANDOMIZED TRIAL

***Manoj Kumar Bajaj[1] and Sunita Malhotra[2]**
*[1]Department of Clinical Psychology, Department of Psychiatry, Level V Block D*
*Government Medical College & Hospital, Chandigarh (U.T.)*
*[2]Department of Psychology, Dean, Faculty of Social Sciences*
*Maharishi Dayanand University, Rohtak (Haryana)*
**Author for Correspondence*

## ABSTRACT
Aim of this study was to study the efficacy of cognitive behaviour therapy (CBT) compared to pharmacotherapy (PT) and combination of cognitive behaviour therapy and pharmacotherapy (CBT+PT) in the treatment of adults suffering from generalized anxiety disorder (GAD). A sample of ninety (90) patients fulfilled the criteria for GAD and agreed to participate in the study. A randomized multi-group pre to post acute (12 sessions) intervention research design was employed. Participants were randomly allocated to three intervention groups. CBT Group received cognitive behaviour therapy alone, PT Group received pharmacotherapy alone and CBT+PT Group received combination of both CBT and Pharmacotherapy for consequently three months each. Material Used: MINI International Neuropsychiatric Interview (Sheehan & Lecrubier, 2004) for the confirmation of diagnosis and exclusion of psychiatric co-morbidity. Beck's Anxiety Inventory (Beck *et al.*, 1988) was used as primary outcome measure. The Cognition Checklist (CCL) Beck *et al.*, 1987; Automatic Thoughts Questionnaire*(Kendall and Hollon, 1980 revised in 2006); Dysfunctional Attitude Scale (Weissman & Beck, 1978, revised in 2006) were used as secondary outcome measures. Statistical analysis: chi square and one way ANOVA was administered at pre treatment and Paired t test were employed for testing the hypotheses from pre to post intervention. Independent t test and effect size (Cohen'd) were calculated to see the differences between the groups at post intervention. CBT alone and CBT+PT combination groups were significantly more efficacious than PT alone group in the treatment of GAD. Largest effect size (.77) was found for the CBT and CBT+PT groups while comparing to PT group. CBT alone and CBT+PT in combination interventions were more effective than PT alone. CBT is an effective and cost effective treatment as compare to pharmacotherapy alone in adults suffering from generalized anxiety disorder. Although CBT and Pharmacotherapy may be combined for the treatment of GAD but it may have no additional advantage over CBT.

***Keywords*:** *CBT, GAD, Pharmacotherapy, Randomization*

## INTRODUCTION
A range of treatment approaches exist for the anxiety disorders, such as insight-oriented therapy and hypnosis. However, the treatments with empirically validated support include two main approaches: (1) pharmacotherapy (drug therapy) and (2) cognitive behavioural therapy (CBT), a form of psychotherapy. Although a few studies have compared these approaches to other treatments (e.g., analytic psychotherapy), these alternative approaches have generally not been especially effective compared to CBT and medication (Borkovec and Whisman, 1996). The review of treatment studies discusses the relative and combined effectiveness of pharmacological and cognitive-behavioural approaches in the treatment of anxiety disorders. Effective pharmacological treatments include anti-anxiety medications (i.e., benzodiazepines), antidepressants, and several other types of medication. In addition, a variety of psychological strategies have been shown to be useful for treating anxiety. A review of studies of cognitive-behavioural therapy (CBT) for generalized anxiety disorder, panic disorder with and without agoraphobia, and social phobia shown that CBT was consistently more effective than waiting-list and

placebo control groups. In general, CBT has proved more beneficial than supportive therapy as well. Comparisons with active behavioral treatments provide more variable results. Converging evidence suggests that cognitive change may be a strong predictor of treatment outcome, but that such change may be produced by a number of therapeutic approaches. Pretest–posttest change with CBT is depicted in meta-analytic summary form for each disorder. Myriam *et al.,* (2000) studied that individuals suffering from Generalized Anxiety Disorder (GAD) hold dysfunctional beliefs about worry and found that dysfunctional beliefs were significantly reduced after treatment compared to a waiting list control group. This result supports the importance of assessing and targeting beliefs about worry in the treatment of GAD patients.

Clark (2006) developed a report for the Department of Health in support of the submission to the Comprehensive Spending Review Effective Psychological Treatments for Anxiety Disorders and following a review of published randomized controlled trials, National institute for clinical excellence (NICE) has issued clinical guidelines for four of the anxiety disorders (panic disorder, generalized anxiety disorder, posttraumatic stress disorder, and obsessive-compulsive disorder). Each guideline indicates that cognitive-behaviour therapy (CBT) is an effective treatment. Norton *et al.,* (2007) done a meta analysis examined the efficacy of CBT across the anxiety disorders. One hundred eight trials of CBT for an anxiety disorder met study criteria. Cognitive therapy and exposure therapy alone, in combination, or combined with relaxation training, were efficacious across the anxiety disorders, with no differential efficacy for any treatment components for any specific diagnoses. CBT effects were superior to those for no-treatment and expectancy control treatments, although tentative evidence suggested equal effects of CBT when compared with relaxation-only treatments. Hofmann & Smits (2008) conducted systematic review of randomized control trials of treatment outcome studies of anxiety disorders between the 1st available year to March 1, 2007 and concluded CBT is efficacious for adult anxiety disorders. However considerable room for improvement and more studies need to include intent-to-treat analyses in the future.

Christian (2011) done a Meta analysis and concluded that despite some weaknesses of the original studies, the quantitative literature review of randomized placebo-controlled trials and of trials in naturalistic treatment settings provides strong support for both the efficacy and effectiveness of CBT as an acute intervention for adult anxiety disorders. At the same time, the results also suggest that there is still considerable room for further improvement of study and analysis methods. Thus, the exact magnitude of effect is currently difficult to estimate.

Despite a large literature supporting the use of medications and CBT, there is still much debate among clinicians and researchers from different etiological perspectives regarding the relative and combined efficacy of medications and CBT. Investigators from biological and psychological perspectives rarely collaborate on treatment studies and rarely read one another's work, except to criticize it.

Biological and psychological treatment studies tend to be conducted at different sites, use different assessment and outcome measures, and get published in different journals. Over time, more investigators and clinicians have been willing to consider multidimensional approaches to understanding and treating anxiety disorders, but there is still much work to be done to educate practitioners and researchers about the nature of anxiety disorders and their treatment.

Since the CBT used in the different trials included a variety of cognitive and behavioral techniques, it is difficult to know which the effective ingredients were. Cognitive factors influencing treatment outcome (dysfunctional cognitions, negative automatic thoughts) are highlighted in view of the empirically supported mediating role of these variables in accounting for treatment responsiveness. Potential effects of anxiolytic medication on cognitive change in CBT are postulated.

The review indicates that the current body of research generally supports cognitive mediation, but is considerably more mixed for cognitive specificity. However, some evidence suggests that cognitive changes associated with pharmacotherapy are more superficial than those associated with cognitive therapy.

Therefore, current research is taken up with the problem to investigate the efficacy of CBT and causal role of cognitions in the form of negative automatic thoughts, dysfunctional attitudes, cognitions pertaining to anxiety at pre to post intervention and to clarify that whether these factors are responsive to a specific intervention or not. From the current literature review and keeping the research problem in mind present study was conducted with the following aim, objectives and hypotheses.

Aim of this study was to study the efficacy of cognitive behaviour therapy as compared with pharmacotherapy and cognitive behaviour therapy along pharmacotherapy (combination therapy) in adults suffering from generalized anxiety disorder (GAD) and examining the causal role of cognitions in relation to treatment outcome.

The present investigation has been taken up with these objectives:

1) To assess the baseline anxiety (BAI), automatic thoughts frequency (ATQ-F) automatic thoughts-beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS) in patients suffering from GAD.
2) To study the efficacy of the intervention bringing the maximum reduction in anxiety (BAI), automatic thoughts-frequency (ATQ-F) automatic thoughts-beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS).

Hypotheses:

1. There would be significant reduction in anxiety (BAI), automatic thoughts frequency (ATQ-F) automatic thoughts beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS) in those intervention groups, which include cognitive behaviour therapy alone or in combination.
2. There would be no significant reduction in anxiety (BAI), automatic thoughts frequency (ATQ-F) automatic thoughts beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS) in Pharmacotherapy alone intervention group.
3. Cognitive behavior therapy alone and in combination of pharmacotherapy would be more efficacious and superior intervention than pharmacotherapy alone in anxiety reduction in adults suffering from GAD.

## MATERIALS AND METHODS

### *Methodology*

*Design*

For testing the hypotheses formulated above, a randomized multi-group pre to post acute intervention research was conducted to compare the interventions such as cognitive behaviour therapy alone, cognitive behaviour therapy plus pharmacotherapy and pharmacotherapy alone from pre to post in adults suffering from GAD.

*Sample*

Purposive sampling technique was used to select the participants. One hundred eighteen (118) patients (both male and females) were selected from OPDs of Department of Psychiatry and Department of Neurology, Dayanand Medical College & Hospital, Ludhiana. Patients, who gave the written and informed consent were literate minimum $10^{th}$, from 20-45 years of age from any social-economical and religious background, diagnosed with new onset of GAD as per the ICD-10 (WHO) research and diagnostic criteria and have not received any form of treatment either pharmacological or psychological in the past and were not having the co-morbidity of any severe medical, neurological and Axis-II disorder were recruited in the study.

### *Material Used*

*MINI International Neuropsychiatric Interview (Sheehan & Lecrubier, 2004)*

The M.I.N.I was designed as a brief structured interview for the major axis 1 psychiatric disorders in DSM IV and ICD-10. Validation and reliability studies have been done comparing the MINI to the SCID-P for DSM III R and the CIDI (a structured interview developed by the WHO for lay interviewers for ICD-10). The results of these studies show that the M.I.N.I. has acceptably high validation and reliability

scores, but can be administered in a much shorter period of time (mean 18.7 ±11.6 minutes, median 15 minutes) then the above referenced instruments. It can be used by clinicians, after brief training sessions.

Beck's Anxiety Inventory (Beck *et al.,* 1988)

BAI is a 21 items self report instrument designed to measure the severity of physiological and cognitive anxiety symptoms (e.g. numbness or tingling; feeling hot; wobbliness in legs; fear of worst happening) over the preceding week including the day of administration. Subject responses to each item are required on a 4 point scale consisting of the points: not at all, mildly, moderately, severely corresponding to individual score of 0-3. Total score is achieved by summating the ratings of individual; symptom item.

Automatic Thoughts Questionnaire*(Kendall and Hollon, 1980 revised in 2006)

The ATQ is a 30-item instrument that measures the frequency of automatic negative statements about the self. Such statements play an important role in the development, maintenance and treatment of various psychopathologies, including depression. ATQ taps 4 aspects of these automatic thoughts: personal maladjustment and desire for change (PMDC), negative self-concepts and negative expectations (NSNE), low self esteem (LSE), and Helplessness. Items are rated on the frequency of occurrence from "not at all" to "all the time". Total scores are the sum of all 30 items. A high total score indicates a high level of automatic negative self-statements.

*2nd version: Asks respondents to rate the degree of belief of each of the 30-items. A high total score indicates greater believability in negative thoughts. Reliability of the instrument has excellent internal consistency with an alpha coefficient of.97. Validity: The items significantly discriminated depressed from non-depressed subjects. Has good concurrent validity, correlating with 2 measures of depression, the Beck Depression Inventory and the MMPI Depression scale.

The Cognition Checklist (CCL) Beck *et al.*, 1987

The CCL was developed to measure the frequency of automatic thoughts relevant to anxiety and depression. The CCL has a 12-item subscale of anxious cognitions and a 14- item subscale of depressed cognitions rated on a 5-point scale. The measure contains irrational cognitions related to danger, thought to be a characteristic of anxiety, plus irrational cognitions related to depression to test explicitly the content-specificity hypothesis of the Beck model. Patients diagnosed with anxiety disorders had higher mean CCL anxiety scores while patients diagnosed with depressive disorders had higher mean depression scores supporting the validity of the CCL.

Dysfunctional Attitude Scale (Weissman & Beck, 1978, revised in 2006)

The DAS is a 40-item instrument that is designed to identify and measure cognitive distortions, particularly distortions that may relate to or cause depression. The items contained on the DAS are based on Beck's cognitive therapy model and present 7 major value systems: Approval, Love, Achievement, Perfectionism, Entitlement, Omnipotence, and Autonomy. Scoring: Any items that are missing, assign a zero. To obtain the overall score, simply add the score on all items (ranging from 1 to 7). When no items are omitted, scores on the DAS range from 40 to 280. Lower scores represent more adaptive beliefs and fewer cognitive distortions. Practitioners can also examine other areas where respondents may be emotionally vulnerable or strong as indicated by their responses to other specific items. Treatment can then be targeted to those areas. Reliability of the DAS is reported to have very good internal consistency, with alphas ranging from.84 to.92. The DAS also has excellent stability, with test-retest correlations over 8 weeks of.80 to.84. It has excellent concurrent validity, significantly correlating with several other measures of depression. The DAS was also found to be sensitive to change following clinical intervention with depressed outpatients.

*Procedure*

The new onset generalized anxiety disorder patients (n=118) evaluated clinically and referred by the psychiatrist and neurologists were weighted against the specified inclusion and exclusion criteria. These patients were interviewed for their willingness and suitability to participate in the study. Further the diagnosis of generalized anxiety disorder was confirmed by administering the Mini International Neuropsychiatric Inventory (M.I.N.I.) and comorbidity of any other Axis-1 disorder were excluded. Eighteen (18) patients did not agree for participation due to their personal constraints as inability to come

for weekly sessions. Ten (10) patients were excluded as they did not meet the inclusion exclusion criteria of the study. Finally ninety (90) patients fulfilled the criteria and agreed to participate in the study. Treatment conditions were informed and explained to the patients who gave their consent to participate. They were randomly allocated to three intervention groups. Intervention was randomly assigned Group I received CBT alone (CBT Group), Group-II received Pharmacotherapy (PT group) alone and Group-III received combination of both ; CBT+ Pharmacotherapy (CBT+PT group) for consequently three months each.

Group who received CBT (n=30) was given Cognitive behaviour therapy for 12 weeks, patients in the PT group were prescribed only anti- anxiety medicine by the psychiatrist in adequate and stable doses for three months and the patients in the CBT+PT group (n=30) was given cognitive behaviour therapy (12 weekly sessions) along with Pharmacotherapy for three months. Assessment of the ninety patients was carried out at baseline. Total (n= 75) patients completed the treatment, 26 in CBT group; 21 in PT group and 28 in CBT+PT group. Four patients dropped out from CBT group, 9 from pharmacotherapy group and 2 from CBT+PT group till the completion of the study. The cognitive behaviour therapy and assessments (pre-post) were carried out by the investigator. Finally the data collected from the assessments are analyzed with the help of statistical techniques.

Therapy process and assessments:

Assessment was carried out at the beginning of the therapy (pre treatment) and at the $12^{th}$ week for all the three groups. Total 2 assessments were carried out in 3 months. Although all patients were also assessed (monthly or during the sessions) on visual analogue scale for the response to treatment but data is analysed on the basis of proposed scales from pre to post. Only those, who have completed the therapy (n=75) for three months were analyzed in this study.

For the CBT and CBT + Pharmacotherapy group individualized or tailored varieties of cognitive and behavioural techniques were utilized.

Session wise agenda and format of Cognitive behaviour therapy

*First Two Intake Sessions*:

- ❖ Psycho-education
- ❖ Therapeutic alliance
- ❖ Relationship between thoughts, behaviour and emotions
- ❖ Explaining the developing model (idiomatically)
- ❖ Explaining the model to his/ her development of illness
- ❖ Therapeutic contract:
- ❖ Duration of treatment
- ❖ Strategies, techniques and compliance
- ❖ Assessment of cognitive state
- ❖ Administration of the base line primary and secondary outcome measures
- ❖ Home work assignment maintaining the thoughts records was done

*Sessions 3-11*

Implementation of the cognitive and behavioural techniques mentioned below as per the requirement of the patient current state. Review of home work assignments and monitoring symptomatic improvement was the agenda of every session.

Cognitive techniques: Cognitive techniques were aimed at delineating and testing the patient's specific misconceptions and maladaptive assumptions. This approach consists of highly specific learning experiences designed to teach the patient the following operations: 1) to monitor his negative, automatic thoughts (cognitions); 2) To recognize the connections between cognition, affect and behaviour; 3) To examine the evidence for and against his distorted automatic thoughts; 4) To substitute more reality oriented interpretations for these biased cognitions and; 5) To learn to identify and alter the dysfunctional beliefs which predispose him to distort his experience. Following is the list of techniques which were commonly used in the CBT intervention groups.

- ❖ Pie Chart

- Down ward arrow
- Re-attribution
- Thought Action fusion
- Attorneys –judge
- Alternative thoughts

*Behavioural techniques:*

- Activity scheduling
- Behavioral experiment
- Behavioral rehearsal
- Graded task assignment
- Exposure and response prevention and
- Relaxation techniques

*In Final session*: Re-assessment of the cognitive state, administration of the primary and secondary outcome measures was administered. Booster and follow up sessions once in a month and once in three months were planned to know the relief sustainability.

*Pharmacotherapy group* was administered antidepressant and benzodiazepine as anti-anxiety drugs in stable and adequate doses by the consultant psychiatrist. They were also assessed at baseline and at three months. Total three follow up sessions were attended by the patients in this group (once monthly) during the treatment. It has been stated that anti- anxiety drugs achieves the level within three months. Monitoring of the side effects of the medicine was done by the consultant psychiatrist to the patients. The name of the drugs was not mentioned by the investigator and conventional benzodiazepine and antidepressant were used these were named as anti-anxiety drugs.

The *statistical analysis* of the data was done with the help of Statistical Package for Social Science research (SPSS version 18). The descriptive statistical methods of frequency and percentage and non parametric test chi square were used in categorical variables and student t test in continuous variables for comparing the groups. One way ANOVA was administered at pre treatment and Paired t test were employed for testing the hypotheses at post intervention. Independent t test and effect size (Cohen'd) were calculated to see the differences between the groups at post intervention.

*Ethical Consideration*: This treatment investigation was conducted with the prior approval of Institutional Ethics Committee (IEC) and author has maintained necessary ethical standards while conducting the present research. No harm was given to the participants and written and informed consent was obtained. They were all informed about their participation which is voluntary and they can refuse to participate any time during the investigation. The possible treatments available for the treatment of GAD was also explained in their vernacular language and they were assured that refusal to participation will not cause any discrimination in the treatment. They were not given any incentive or no grant has been received for conducting this research.

## RESULTS AND DISCUSSION

The main aim of present investigation was to study the efficacy of Cognitive Behaviour Therapy (CBT) as compared to Pharmacological Therapy (PT) and combined treatment of Cognitive Behaviour Therapy along with Pharmacological Therapy (CBT+PT) for adults suffering from GAD. The results are presented in the tables 1, 2, 3, & 4.

The participants having the GAD as principal diagnosis majority of them were in the age range of 20 to 30 years of age suggests that majority of people are affected from anxiety disorders in second to third decade of their lives. Almost half of participants were men and half of the participants were married, majority of the participants were college educated, Hindu and from urban background and having the nuclear families. They were students, housewives and private job workers in regards to their occupational status. To test the differences in the socio-demographic and clinical characteristics of the participants among CBT group (n=26), PT group (n=21) and CBT+PT group (n=28) F test for continuous variables and chi square for categorical variables were computed. From the Table 1 it is evident that F value for the

age and duration of illness was.23 and.06 respectively which is insignificant indicate, there was no significant difference in age and duration of illness in three groups, suggest all groups were equal in respect to their age and duration of illness. There were no significant differences between the groups in respect to their specified socio-demographic and clinical details. On the other way three groups were similar in relation to their socio demographic characteristics. It is very important in intervention studies that groups should be similar or homogeneous on background variables so the effect of these variables can be controlled. To study and compare the differences at base line on following measures one way ANOVA was computed (Table 2) in which F values for BAI, ATQ-F, ATQ-B, CCL-A, CCL-D and DAS were.53,.39,.13,.14,.73 and.04 respectively. All the F values were insignificant suggestive of no significant differences found between the groups on these measures' scores. Therefore, no significant differences at baseline in all intervention groups in respect to cognitions and anxiety severity were found and this fulfil the criteria for the an intervention research in which all the groups should be similar at base line to see the effect of intervention more precisely.

**Table 1: Socio-demographic and clinical details' frequencies, percentage, mean and SD of the patients of CBT, PT and CBT+ PT groups with their chi square, F test with significance and P values**

| Socio demographic and Clinical variables | CBT group (n=26) Frequency (%) | Pharmacotherapy group (n=21) Frequency (%) | CBT+ Pharmacotherapy group(n=28) Frequency (%) | Chi square/ F value | Significance |
|---|---|---|---|---|---|
| Age in Years | | | | .23 | Insignificant |
| Mean | 28.69 | 27.33 | 27.28 | | |
| (SD) | (6.54) | (7.95) | (9.31) | | |
| Duration of illness in months | | | | .06 | Insignificant |
| Mean | 7.30 | 6.85 | 7.92 | | |
| (SD) | (5.43) | (5.56) | (5.57) | | |
| Education status | | | | 0.52 | Insignificant |
| School educated | 8 (30.76) | 8(38.09) | 8(28.57) | | |
| College educated | 18 (69.24) | 13(61.91) | 20(71.43) | | |
| Gender | | | | .33 | Insignificant |
| Male | 14(53.84) | 11(52.38) | 13(46.42) | | |
| Female | 12 (46.16) | 10(47.62) | 15(53.58) | | |
| Marital status | | | | 3.74 | Insignificant |
| Unmarried | 13 (50.00) | 5(23.80) | 9(32.14) | | |
| Married | 13(50.00) | 16(76.20) | 19(67.86) | | |
| Occupation | | | | .18 | Insignificant |
| Govt. or Pvt. Service & Business | 12 (46.15) | 11(52.38) | 14 (50.00) | | |
| Students, house wife | 14(53.85) | 10(47.62) | 14(50.00) | | |
| Religion | | | | .52 | Insignificant |
| Hindu | 16(61.53) | 15(71.42) | 18(64.28) | | |
| Sikh + others | 10(38.47) | 6(28.58) | 10(35.72) | | |
| Family type | | | | .28 | Insignificant |
| Joint | 5(19.23) | 5(23.80) | 5(17.85) | | |
| Nuclear | 21(80.77) | 16(76.20) | 23(82.15) | | |
| Drop out | 4(13.33) | 9(30) | 2(6.66) | 17.34*** | Significant |

**(p <.05), ** (p <.01), *** (p <.001)*

**Table 2: Summary Table of one way ANOVA at pre treatment for three groups**

| Measures | | Sum of Squares | df | Mean Square | F | P value | Significance |
|---|---|---|---|---|---|---|---|
| BAI | Between Groups | 39.82 | 2 | 19.91 | .53 | .588 | Insignificant |
| | Within Groups | 2679.06 | 72 | 37.20 | | | |
| | Total | 2718.880 | 74 | | | | |
| ATQ-F | Between Groups | 133.59 | 2 | 66.79 | .39 | .674 | Insignificant |
| | Within Groups | 12110.99 | 72 | 168.20 | | | |
| | Total | 12244.58 | 74 | | | | |
| ATQ-B | Between Groups | 55.43 | 2 | 27.71 | .13 | .870 | Insignificant |
| | Within Groups | 14362.34 | 72 | 199.47 | | | |
| | Total | 14417.78 | 74 | | | | |
| CCL-A | Between Groups | 12.71 | 2 | 6.35 | .14 | .862 | Insignificant |
| | Within Groups | 3086.27 | 72 | 42.86 | | | |
| | Total | 3098.98 | 74 | | | | |
| CCL-D | Between Groups | 19.98 | 2 | 9.99 | .73 | .485 | Insignificant |
| | Within Groups | 983.96 | 72 | 13.66 | | | |
| | Total | 1003.94 | 74 | | | | |
| DAS | Between Groups | 35.93 | 2 | 17.96 | .04 | .961 | Insignificant |
| | Within Groups | 32313.74 | 72 | 448.80 | | | |
| | Total | 32349.68 | 74 | | | | |

*BAI- Beck's Anxiety Inventory, ATQ-F- automatic thoughts questionnaire -frequency, ATQ-B- automatic thoughts questionnaire -beliefs, CCLA- cognition check list-anxiety, CCLD- cognition check list-depression, DAS- Dysfunctional Attitude Scale.*

**Table 3: Mean and paired t test (pre to post) values for the three intervention groups on all measures of anxiety and cognitions**

| **Measures** | **CBT group (n=26)** | | | **CBT+PT group (n=28)** | | | **PT group (n=21)** | | |
|---|---|---|---|---|---|---|---|---|---|
| | Pre Mean | Post Mean | t value | Pre Mean | Post Mean | t value | Pre Mean | Post Mean | t value |
| **BAI** | 41.0 | 15.96 | 15.126*** | 42.25 | 15.92 | 19.711*** | 42.76 | 32.95 | 7.286*** |
| **ATQ-F** | 109.76 | 44.38 | 18.931*** | 112.14 | 45.67 | 13.86*** | 112.14 | 94.23 | 7.379*** |
| **ATQ-B** | 88.3 | 32.0 | 14.402*** | 86.5 | 36.32 | 17.216*** | 86.5 | 46.33 | 10.243*** |
| **CCL-A** | 41.8 | 15.65 | 18.512*** | 41.35 | 23.32 | 8.046*** | 41.35 | 35.38 | 7.593*** |
| **DAS** | 178.53 | 52.61 | 23.392*** | 178.78 | 93.17 | 7.468*** | 178.78 | 153.9 | 7.316*** |

*P> 0.0001 (very significant)*

**Table 4: t-values and Cohen'd between three groups at post intervention on BAI scores**

| Beck's Anxiety Inventory | | N | Mean | Mean Difference | t values | Cohen's d |
|---|---|---|---|---|---|---|
| Comparison 1 | CBT | 26 | 15.96 | -16.99 | -8.506*** | .77 |
| | PT | 21 | 32.95 | | | |
| | CBT | 26 | 15.96 | .03 | .019(ns) | .003 |
| Comparison 2 | CBT+PT | 28 | 15.92 | | | |
| | PT | 21 | 32.95 | 17.02 | 8.526*** | .77 |
| Comparison 3 | CBT+PT | 28 | 15.92 | | | |

**p<.05; **p<.01; ***p<.001; ns (non significant)*
*CBT- Cognitive Behaviour Therapy, PT-Pharmacotherapy*

Further to achieve the aim of the study, hypotheses were made. The first hypothesis was "there would be significant reduction in anxiety (BAI), automatic thoughts frequency (ATQ-F) automatic thoughts beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS) in those intervention groups, which include cognitive behaviour therapy alone or in combination". The findings from table 3 of the present study suggest that the above hypothesis is accepted. The mean scores and paired t test values are statistically significant from pre to post in the interventions groups which included CBT. This means CBT alone and CBT+PT combination treatment were very effective in the treatment of GAD in adults. Results of the present investigation were very enlightening and in consistent with the findings of Gillian *et al.,* (1991) in which they reported the consistent pattern of change favored the CBT, was evident in measures of anxiety, depression, and cognition. Similar findings by Myriam *et al.,* (2000) reported that individuals suffering from Generalized Anxiety Disorder (GAD) hold dysfunctional beliefs about worry and found that dysfunctional beliefs were significantly reduced after treatment compared to a waiting list control group. Therefore, findings were supported that means combination treatment was also found to be effective treatment in bringing the significant changes in anxiety severity; Automatic thoughts- frequency and beliefs; cognitions and dysfunctional attitudes in patients suffering from generalized anxiety disorders. These findings were consistent with the findings of Lindsay, 1987 and Micheal, 2000 in which CBT + PT was found to be an effective treatment for anxiety disorders.

The second hypothesis of the study was, there would be no significant reduction in anxiety (BAI), automatic thoughts frequency (ATQ-F) automatic thoughts beliefs (ATQ-B), cognitions related to anxiety (CCL-A) and dysfunctional attitudes (DAS) in Pharmacotherapy (alone) intervention group. Findings suggests hypothesis is rejected as the mean scores from pre to post and paired t test values were found to be statistically significant from pre to post intervention in the PT intervention group. These findings were in contrary to the previous studies in which efficacy of the pharmacological treatment was investigated. Although this change is significant but while comparing to the previous studies the difference pre to post intervention should be larger enough the patients do not further met the diagnosis of anxiety disorder. Therefore the effects sizes were calculated to further substantiate the findings and to see the superiority of the treatment in bringing the maximum reduction in anxiety levels at post intervention.

Finally the third hypothesis was tested that "cognitive behaviour therapy alone and in combination of pharmacotherapy would be more efficacious than pharmacotherapy alone in anxiety reduction in adults suffering from GAD". The t value between the CBT and PT group on anxiety (BAI) were found to be –8.506 which was significant at ($p<.000$). These findings were in support of the study hypothesis that Cognitive behaviour therapy (CBT) would be more efficacious than pharmacotherapy (PT) in anxiety reduction.

The t value between the CBT+PT and PT was 8.526 which was significant at ($p<.000$) suggestive of CBT+PT group was significantly more efficacious than PT group in the treatment of anxiety. This is again in support of the hypothesis that Cognitive behaviour therapy plus pharmacotherapy (CBT+PT) would be more efficacious than pharmacotherapy (PT) in anxiety reduction.

Between CBT and CBT+PT groups t value on BAI were.019 which was insignificant. This is in favour of the hypothesis in which Cognitive behaviour therapy plus pharmacotherapy (CBT+PT) and CBT would be more efficacious than PT alone in anxiety reduction.

To substantiate further, effect sizes were calculated by using the Cohen's d formula. Largest effect size (.77) was found between the CBT and PT and CBT+PT and PT (Table 4) suggest that CBT and CBT+PT interventions were more effective than PT, again in support of the hypotheses.

To addition to above dropout rate were calculated. 30% participants were dropped from the pharmacotherapy group; 13.33% from the CBT group and the 6.66 % were from the combination group (see Table 1). There were significant differences between the groups (Chi Square=17.34; $p<.0001$) in respect to drop out rate.

Findings of the t test and effect size between the groups indicate CBT group, CBT+PT group were more effective in treating the anxiety symptoms compare to PT group. These findings were in consistent with the findings of Gillian; 1991, Blowers *et al.,* 1987, Breatholtz *et al.,* 2001, Linden *et al.,* 2005, Gosselin *et*

*al.*, 2006, Micheal, 2006, Clark, 2006, Norton *et al.*, 2007, Hoffmann & Smith, 2008, Christian, 2011 that CBT is efficacious for adult anxiety disorders as compare to pharmacotherapy. But there were also the findings in which CBT combining with the Pharmacotherapy will not have additional benefits but remains the choice of treatment between the physicians treating these disorders (Gosselin *et al.*,2006, Micheal ; 2006, Clark; 2006, Norton *et al.*, 2007, Hoffmann & Smith; 2008). Linden and colleagues (2005) concluded that the CBT an effective treatment for GAD with an effect size comparable or larger than those reported for antidepressant medication.

To substantiate further, Beck's anxiety inventory was the primary outcome measure in this study therefore effect sizes were calculated by using the Cohen's d formula. Largest effect size suggests that CBT and CBT+PT interventions were more efficacious than PT in bringing the maximum reductions in anxiety. However all interventions were found to be significantly effective in reducing the anxiety symptoms from pre to post, but the maximum reduction in anxiety symptoms were achieved by the CBT or CBT+PT intervention groups (Bretholtz; 2002, Gosselin *et al.*, 2006, Micheal; 2006, Clark; 2006, Norton *et al.*, 2007, Hoffmann & Smith; 2008, Christian; 2011) supporting the superiority of psychological treatment especially cognitive behaviour therapy in the treatment of generalized anxiety disorder in adults.

***Conclusion***

From this study it can be concluded that CBT is an effective and cost effective treatment in the management of generalized anxiety disorder in adults as compare to pharmacotherapy alone. Although pharmacotherapy may be combined for the treatment of GAD but it may have no additional advantage over CBT.

*Implications of Present Findings:*

1. The status of CBT as gold standard psychological intervention for treating generalized anxiety disorder has been strengthened.
2. On the basis of present findings CBT identified as an efficacious intervention for the treatment of GAD as compare to pharmacotherapy.
3. CBT can be recommended as first line treatment in GAD.

Suggestions for future research:

1. The inclusion of no specific treatment or placebo group is suggested to be included in further comparison studies.
2. Mechanism of change especially in CBT need to be further studied in future research.

**REFERENCES:**

**American Psychological Association (2010).** *Publication Manual* (Washington, D.C: American Psychological Association) 6th edition.

**Beck A (1993).** *Cognitive Therapy and the Emotional Disorders* (NY: Penguin).

**Beck AT and Emery G (1985).** *Anxiety Disorders and Phobias: A Cognitive Perspective* (New York: Basic Books).

**Beck AT, Epstein N and Brown G (1988).** An inventory for measuring clinical anxiety: Psychometric properties. *Journal of Consulting and Clinical Psychology* **56** 893–897.

**Blowers C, Cobb J and Mathews A (1987).** Generalized anxiety: A controlled treatment study. *Behavior Research Therapy* **25** 493–502.

**Borkovec TD and Costello E (1993).** Efficacy of applied relaxation and cognitive–behavioral therapy in the treatment of generalized anxiety disorder. *Journal of Consulting and Clinical Psychology* **61** 611–619.

**Borkovec TD and Whisman MA (1996).** Psychosocial treatment for generalized anxiety disorder. In: *Anxiety Disorders: Psychological and Pharmacological Treatments* edited by Mavissakalian M & Prien R (Washington, DC: American Psychiatric Press).

**Breitholtz BJ and Öst LG (2002).** Cognitions in generalized anxiety disorder and panic disorder patients. A prospective approach. *Behavioral and Cognitive Psychotherapy* **30** 227-231.

**Breitholz E, Westling B and O Èst LG (1998).** Cognitions in generalized anxiety disorder and panic disorder patients. *Journal of Anxiety Disorders* **12** 567-577.
**Christian O (2011).** Cognitive behavioral therapy in anxiety disorders: current state of the evidence. *Dialogues in Clinical Neuroscience* **13** 413–421.
**Clark DA, Beck AT and Alford BA (1999).** In *Scientific Foundations of Cognitive Theory and Therapy of Depression* (NY, USA: John Wiley and Sons) 36–76.
**Clark DM (1986).** A cognitive approach to panic. *Behavior Research Therapy* **24** 461–470.
**Clark DM, Ehlers A and Hackmann A (2006).** Cognitive therapy versus exposure and applied relaxation in social phobia: A randomized controlled trial. *Journal of Consulting and Clinical Psychology* **74** 568–578.
**Clark DM, Ehlers A, McManus F, Hackman A, Fennell M, Campbell H, Flower T, Davenport C and Louis B (2003).** Cognitive therapy versus fluoxetine in generalized social phobia: a randomized placebo-controlled trial. *Journal of Consulting and Clinical Psychology* **71** 1058–1067.
**Clark DM, Salkovskis PM and Chalkley AJ (1985).** Respiratory controls a treatment for panic attacks. *Journal of Behaviour Therapy and Experimental Psychiatry* **16** 23-30.
**Clark DM, Salkovskis PM and Hackmann A (1994).** A comparison of cognitive therapy, applied relaxation, and imipramine in the treatment of panic disorder. *British Journal of Psychiatry* **164** 759–769.
**Clark DM, Salkovskis PM, Hackmann A, Wells A, Ludgate J and Gelder M (1999).** Brief cognitive therapy for panic disorder: a randomized controlled trial. *Journal of Consulting and Clinical Psychology* **67** 583-589.
**Gillian B, Melanie F, Philip R and Michael G (1991).** Comparison of behavior therapy and cognitive behavior therapy in the treatment of generalized anxiety disorder. *Journal of Consulting and Clinical Psychology* **59**167-175.
**Gosselin P, Ladouceur R and Morin CM (2006).** Benzodiazepine Is continuation among adults with GAD: A randomized trial of cognitive–behavioral therapy. *Journal of Consulting and Clinical Psychology* **74** 908-919.
**Hofmann SG (2000).** Treatment of social phobia: potential mediators and moderators. *Clinical Psychology: Science and Practice* **7** 3–16.
**Hofmann SG (2004).** Cognitive mediation of treatment change in social phobia. *Journal of Consulting and Clinical Psychology* **72** 392-399.
**Hofmann SG and Smits JA (2008).** Cognitive-behavioural therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *Journal of Clinical Psychiatry* **69** 621-32.
**Ingram RE and Kendall PC (1987).** The cognitive side of anxiety. *Cognitive Therapy Research* **11** 523-536.
**Kendall PC and Hollon SD (1980).** Anxious self-talk: Development of the anxious self-statements questionnaire (ASSQ). *Cognitive Therapy Research* **13** 81-93.
**Linden M, Zubraegel D and Baer T (2005).** Efficacy of cognitive behaviour therapy in generalized anxiety disorders. Results of a controlled clinical trial (Berlin CBT-GAD Study). *Psychotherapy and Psychosomatics* **74** 36-42.
**Lindsay WR, Gamsu CV, McLaughlin E, Hood EM and Espie CA (1987).** A controlled trial of treatments for generalized anxiety. *British Journal of Clinical Psychology* **26** 3–15. doi: 10.1111/j.2044-8260.1987.tb00718.x
**Michael WO, Jasper AS and Hannah ER (2006).** Combined Psychotherapy and Pharmacotherapy for Mood and Anxiety Disorders in Adults: Review and Analysis. *Clinical Psychology: Science and Practice* **12** 72–86.
**Myriam L, Michel JD and Robert L (2000).** Changes in dysfunctional beliefs before and after a cognitive-behavioral treatment for people with generalized anxiety disorder. *Canadian Journal of Behavioural Science* **32** 91-96.
**Norton PJ and Price EC (2007).** A meta-analytic review of adult cognitive-behavioral treatment outcome across the anxiety disorders. *Journal of Nervous Mental Diseases* **195** 521–531.

**Sharma MP, Mao A and Sudhir PM (2012).** Mindfulness-based cognitive behavior therapy in patients with anxiety disorders: A case series. *Case Report* **34** 263-269.
**Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavas J, Weiller E *et al.*, (1998).** The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *Journal of Clinical Psychiatry* **59**(suppl.20) 22-33.
**Weissman AN and Beck AT (1978).** Development and validation of the Dysfunctional Attitudes Scale: a preliminary investigation. In: *Proceedings of the meeting of the American Educational Research Association. Toronto, ON.*