A Clinical Trial of Cognitive Behavior Therapy for Psychiatric Comorbidity and Quality of Life with Cancer Patients during Chemotherapy (CPdC)

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Research Article

Abstract

Background

Cancer is a worldwide common illness, it evokes psychological distress at different stages, during chemotherapy patient perceives a variety of psychiatric symptoms due to various medication side-effects and psychological distress. Studies have shown a significant impact of CBT in the management of psychiatric symptoms during chemotherapy. This study aims to investigate the effectiveness of CBT for depression, anxiety, stress, death anxiety, satisfaction with life, and self-esteem among cancer patients during chemotherapy (CPdC).

Methods

Place and duration of the study: Department of Applied Psychology, Government College University Faisalabad in collaboration with Department of Oncology, Allied Hospital Faisalabad from November 20, 2020 and July 31, 2021. A total of 90 cancer patients were enrolled. 70 out of 90 met the eligibility criteria and 60 participants fulfilled all requirements. Participants were randomly allocated to four different groups. The pre-assessment screening was started along with the first trial of chemotherapy. The CBT-based treatment plan was formulated and one session per week was given to each patient for 3 to 4months. Participants' age range was 18–65 years (M ± SD = 47.51 ± 12.36. Demographic form, DASS, DAS, SWLS, and RSES measures were used. Descriptive, t-test, and repeated measure ANOVA statistics were used to investigate the findings.

Results

Results indicated significant mean difference on the variable of depression, anxiety and stress across four conditions (i.e. $F_{(2, 56)} = 39.55$, $p < .000$, $\eta^2 = .679$; $F_{(2,56)} = 73.32$, $p < .000$, $\eta^2 = .797$; $F_{(2,56)} = 119.77$, $p < .000$, $\eta^2 = .865$ respectively). On death anxiety significant difference across four conditions was found ($F_{(2,56)} = 22.71$, $p < .000$, $\eta^2 = .549$) with large effect size. Furthermore, findings indicated significant mean difference on the variable of satisfaction with life and self-esteem across four conditions was found ($F_{(2,56)} = 22.05$, $p < .000$, $\eta^2 = .542$; $F_{(2,56)} = 36.19$, $p < .000$, $\eta^2 = .660$) with large effect size.

Conclusion

It is concluded that CBT played a very effective role to reduce depression, anxiety, and stress-related psychiatric symptoms. CBT reduces the level of death anxiety and improving the quality of life and level of self-esteem among CPdC.

Trial Registration: The study trial was registered in the Thai Clinical Trial Registry-TCTR (TCTR20201113002).

Introduction

Cancer is a life-threatening disease and a major leading cause of death globally. Cancer mortality rate is increasing, approximately7.6 million deaths happened in 2008 and this mortality rate reached to 19.3 million in 2020 (1). In Africa, Asia, Central, and South America, more than 60% of cases and 70% deaths reported because of cancer (WHO, 2012). In 2020, a recent estimate reported 0.18 million new cases were reported in Pakistan, and approximately 0.12 million deaths happened out of 220 million population (International Agency for Research on Cancer, 2020). In Pakistan, the breast cancer rate is estimated at 31.5%, comparatively 2.5% higher than in Iran and India (2). In Pakistan, women are at high risk of breast cancer and men with prostate cancer (3). Around 50% of women ignore their physical health status, do not get proper health examinations timely, and die due to increased severity (Public Health, 2014). In 2015-16, around 40% of breast cancer cases were reported in hospitals; among the women screened for breast cancer, the highest incidence was between 30–50 years of age (4).

Cancer comorbidity is common (5) with depressive disorder (6), sleep disorders (7), anxiety-related disorder (8), and other psychiatric disorders (9). Psychiatric symptoms (i.e. anxiousness, fear, worries, restlessness, fatigue, and low mood, sleep, and appetite problems) are reported higher in CPdC(10). Studies have been proven; psychological treatment is effective to treat emotional and psychiatric problems among CPdC (11). Cognitive behavior therapy (CBT) is a more promising approach to treat psychiatric problems and emotional vulnerabilities of CPdC (12). CBT interventions address enormously depressive symptoms in cancer patients during chemotherapy (13). CBT work starts from psycho-education and remained continue till the process of recovery (14). Further, CBT creates an insight, address cognitive and behavioral problems and provides skills training to CPdC (15).

Studies on the cancer patients related to their psychiatric problems are already rare and no one study is conducted in Pakistan on cancer patients in order to treat their psychiatric problems particularly during the phase of chemotherapy. The general aim of this study was to investigate the impact of CBT to treat mental health problems, to improve patients' quality of life and adherence to treatment.

Methodology

This clinical trial was approved by the Institutional Review Board (IBR), Government College University Faisalabad (Ref.No.GCUF/ERC/1996). Later on, study protocol was approved by the Thai Clinical Trial Registry-TCTR on November 13, 2020 (TCTR20201113002). After approval from the registry participants' enrollment period was from November 20, 2020 to July 31, 2021. In this study, all methods were performed in accordance with the relevant guidelines and regulations. Written inform consent was obtained from all the participants. All patients read the consent form and signed it before the enrolment in the study. Thereafter, patients were allocated to intervention (i.e. stage-I = 15 & stage-II = 15) and control (i.e. stage-I = 15 & stage-II = 1) groups.

The study recruited 90 cancer patients from Department of Clinical Oncology, Allied Hospital Faisalabad between November 2020 and July 2021. 70 out of 90 participants met the inclusion and exclusion criteria. Participants' attrition rate was 67.78% and rest of the 32.23% was excluded. For example, patients who refused to participate in the study were 11.12%, excluded due to comorbidity problems were 6.67%, patients moved to other hospitals were 2.23%, shifted to different cities were 2.23%, missed various follow-up sessions were 5.56%, and not participated in post-assessment were 4.45% (see Fig. 1). Participants' age range was 25–65 years (M = 47.51, SD ± 12.36).

Inclusion and exclusion criteria

All the patients were screened and diagnosed by the consultant oncologist. In this study, only cancer patients of stage I and II were included. Participants with other medical comorbidity, having any physical or intellectual disability were excluded. Those patients who initially meet the inclusion criteria but later they face significant health decline were also excluded.

Instruments: Demographic form and history taking form were used for personal information and history of the problem. Then Urdu version *Depression Anxiety and Stress Scale (DASS),* a 42 item self-report measure was used (16,17). The DASS is a 4-point Likert scale with a response category ranging from "did not apply to me all=0" to "applies to me most of the time=3". Further, DASS provides ranges of severity from *normal* to *extremely severe*. The internal consistency of depression is 0.91, and of anxiety is 0.84, and stress has 0.90. Urdu version of Satisfaction with Life Scale (SWLS) was used (18,19). SWLS is a 7 point Likert scale. Each item is scored from "strongly agree =7" to "strongly disagree=1". SWLS describes ranges from extremely satisfied to extremely dissatisfied. SWLS has a sound internal consistency of 0.74 (Cronbach's alpha). Urdu version of *Death Anxiety Scale (DAS), a* 15 items scale was used (20). The DAS investigates the level of death anxiety among cancer patients. Each statement is scored with a "yes" or "no" response. Score range from 9-5 indicates-high level of death anxiety, and a range of 4-8 indicates medium level. Scale test-retest reliability coefficient is 0.83, with an internal consistency coefficient of 0.76. In addition, Urdu version of *Rosenberg Self-Esteem Scale (RSES)* was used (21,22). RSES consists of 10 items which are 4 points Likert scale from "strongly agree=3" to "strongly disagree=0". High scores indicate a high level of self-esteem. Scale has good reliability estimation 0.87.

Intervention

CBT is an evidence-based approach to treat psychological problems of cancer patients (23, 24). Structured treatment plan was formulated with set agendas, and all goals were achieved in therapeutic sessions. The 1st agenda was to "*psycho-educate*" the patients about the nature of their problem. Through 2nd agenda, *cognitive restructuring*, they were educated that how they can address their cognitive errors and negative beliefs (which are causing emotional disturbance in them). The 3rd agenda was to teach the patient about *"identification of thoughts and core beliefs"* that how patients can identify, evaluate, and respond to automatic though and core beliefs. The 4th agenda was *"stress and cancer crisis management"*. The therapist trained the patients using various techniques to address stressors and crisis interventions (25). The 5th agenda based on *"motivation/boosters"* to sustain during and after treatment to earn positive outcomes and hopes. The 6th agenda based on *"problem-solving skills"*, cancer patients usually find themselves unable to manage stress, and hence it is important to strengthen their positive ways of managing stress (26). The 7th agenda was to engage the patients in *"leisure activities"* to maintain a pleasant environment, pleasure activities, family gathering, and frequent social involvement (27). The 8th agenda of the therapy was to boost up patients' *"coping strategies"* to overcome the psychological vulnerabilities. The 9th agenda involved the patients in therapy on regular bases performing various regular *"exercises and homework assignments"* to process therapy outcomes faster. The 10th agenda of the therapy was *"lapse-relapse prevention"*.

Statistical Analysis

Data was scrutinized and prepared for statistical analysis. Descriptive statistics and repeated measure ANOVA statistics were used to formulate the results. An alpha of .05 was used to perform all analyses with *p*-value < .05 using IBM SPSS Statistics (Version 24).

Results

There were no significant discrepancies in baseline demographics characteristics and psychological testing results between experimental and control groups (age 44.85±10.87 vs. 45.60±13.55 years, total age 47.73±12.53 years, p=.>.05; age at diagnosis 43.99±10.68 vs. 44.73±12.9, total 46.86±12.10 years p=.>.05; depression 20.12±5.0 vs. 18.34±5.24, p=.>.05; anxiety 19.94±6.38 vs. 16.14±5.42, p=.>.05; stress 24.97±6.17 vs. 21.94±6.51, p=.>.05; death anxiety 11.20±3.22 vs. 10.40±3.19, p=.>.05; satisfaction with life 13.37±13.52 vs. 13.52±2.97, p=.>.05; self-esteem 14.52±3.49 vs. 16.94±5.32, p=.>.05) respectively (Table 1).

Table 1

Comparison of participants' demographic characteristics groups wise and overall

Note: M/F= Males/Females; S/M= Single/Married; M= Mean; SD= Standard Deviation

Table 2

Mean (standard deviation) and mixed-design ANOVA of clinical scores during pre- and post-test interventions

Group				
Characteristics		Experimental	Waitlist Control	Total
		M(SD)	M(SD)	M(SD)
Age		44.85(10.87)	45.60(13.55)	47.73(12.53)
Age at diagnosis		43.99(10.68)	44.73(12.90)	46.86(12.10)
Gender M/F (n/%)		9(25.7)/26(74.3)	24(86.6)/11(31.4)	33(47.1)/37(52.9)
Marital Status S/M (n/%)		9(25.7)/26(74.3)	18(51.4)/17(48.6)	27(38.6)/43(61.4)
Monthly income		22142.86(17148.39)	27342.86(19060.19)	24742.86(18187.18)
Residence Rural/Urban%		12(34.3)/23(65.7)	10928.6)/25(71.4)	22(31.4)/48(68.6)
Education	Below Metric (n/%)	09(25.7)	15(42.9)	24(34.3)
	High school (n/%)	12(34.3)	07(20.0)	19(27.1)
	Intermediate (n/%)	05(14.3)	06(17.1)	11(15.7)
	Graduation & above (n/%)	09(25.7)	07(20.0)	16(22.9)
Occupation	Currently working (n/%)	13(37.1)	11(31.4)	25(35.7)
	Not working (n/%)	10(28.6)	12(34.3)	27(38.6)
	Dependent on family (n/%)	12(34.3)	12(34.3)	18(25.7)
Types	Brest cancer	18(51.4)	10(28.6)	28(40.0)
of cancer	Lungs cancer	10(28.6)	01(2.90)	11(17.5)
	Leukemia	04(11.4)	14(40.0)	18(25.7)
	Carcinoma	03(08.6)	10(28.6)	13(18.6)
Depression scale		20.12(5.00)	18.34(5.24)	19.23(5.17)
Anxiety scale		19.94(6.38)	16.14(5.42)	18.04(6.18)
Stress scale		24.97(6.17)	21.94(6.51)	23.46(6.48)
Death anxiety scale		11.20(3.22)	10.40(3.19)	10.80(3.21)
Satisfaction with life scale		13.37(2.68)	13.52(2.97)	13.44(2.81)
Self-esteem scale		14.52(3.49)	16.94(5.32)	15.73(4.63)

	Groups									Partial
	Experimental				Waitlist Control					Squared
	Stage-I		Stage-II		Stage-I		Stage-II			Eta
	Baseline	Post-Test	Baseline	Post-Test	Baseline	Post-Test	Baseline	Post-Test		η_p^2
	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)	F	
DEPS	23.29(3.87)	5.00 (2.91)	19.25(4.10)	6.25(2.29)	18.98(5.24)	18.40(6.95)	16.93(5.22)	17.74(7.23)	39.55***	.679
ANXS	21.72(5.61)	5.07(2.97)	20.75(6.06)	4.93(2.91)	15.87(5.36)	16.67(6.00)	14.34(6.44)	15.34(6.16)	73.32***	.797
STSS	29.21(4.12)	6.86(2.18)	22.32(6.11)	8.50(2.25)	21.13(6.36)	22.20(6.76)	22.14(6.20)	22.47(6.17)	119.77***	.865
DAS	11.85(1.61)	3.14(0.87)	11.06(4.24)	4.38(1.93)	11.00(2.83)	9.67(2.36)	9.74(3.22)	9.34(2.56)	22.71***	.549
SWLS	12.36(2.93)	22.15(3.66)	14.40(2.64)	24.06(5.63)	13.47(3.14)	13.93(2.66)	13.60(2.83)	14.20(3.43)	22.05***	.542
SES	13.57(3.44)	20.00(2.26)	15.63(3.85)	22.13(1.86)	15.40(2.83)	15.07(2.83)	16.87(5.72)	17.27(4.84)	36.19***	.660

Note: DEPS= Depression Scale; ANXS= Anxiety Scale; STSS= Stress Scale; DAS= Death Anxiety Scale; SWLS= Satisfaction with Life Scale; SES= Self-Esteem Scale; M= Mean; SD= Standard Deviation

Results (Table 2) indicated significant mean difference on the variable of depression, anxiety and stress across four conditions (i.e. $F_{(2, 56)} = 39.55$, p<.000, η^2= .679; $F(2,56)$= 73.32, p<.000, η^2= .797; $F(2,56)$= 119.77, p<.000, η^2= .865 respectively) with large effect size. Results reveal that depression, anxiety and stress related symptoms significantly reduced after CBT treatment in stage-I (M±SD=5.0±2.91; 5.07±2.97; 6.86±2.18) and stage-II (M±SD=6.25±2.29; 4.93±2.91; 8.50±2.25) as compared to control group in stage-I (M±SD=18.40±6.95; 16.67±6.0; 22.20±6.76) and stage-II

(M±SD=17.74±7.23; 15.34±6.16; 22.47±6.17). The paired wise comparisons indicated that there are significant means differences between experimental and control groups on depression, anxiety and stress related symptoms. On death anxiety significant difference across four conditions was found (F (2,56)= 22.71, p<.000, η^2= .549) with large effect size. Result reveals that death anxiety significantly reduced after CBT treatment in stage-I (M±SD= 3.14±0.87) and stage-II (M±SD= 4.38±1.93) as compared to control group in stage-I (M±SD= 11.00±2.83) and stage-II (M±SD= 9.34±2.56). The paired wise comparisons indicated that there are significant means differences between experimental and control groups death anxiety. Furthermore, findings indicated significant mean difference on the variable of satisfaction with life and self-esteem across four conditions was found (F(2,56)= 22.05, p<.000, η^2= .542; F(2,56)= 36.19, p<.000, η^2= .660) with large effect size. Result reveals that satisfaction with life and self-esteem significantly improved after CBT treatment in stage-I (M±SD= 22.15±3.66; 20.0±2.26) and stage-II (M±SD= 24.06±5.63; 22.31±1.86) as compared to control group in stage-I (M±SD= 13.93±2.66; 15.07±2.80) and stage-II (M±SD= 14.20±3.43; 17.27±4.84). The paired wise comparisons indicated that there are significant means differences between experimental and control groups on the variable of satisfaction with life and self-esteem.

Graphical presentation of the results reveals that CBT produced substantial improvement on post-testing scores in the experimental group of stage-I and II. Similarly, participants with stage-I and II significantly reduced the level of depression, anxiety, stress and death anxiety and significantly improved the level of satisfaction with life and self-esteem scale as compared to control group of stage-I and II among CPdC (see Figure 2).

Discussion

Overall findings appear to be in the same direction as those found in the literature regarding the high efficacy of CBT in the treatment of cancer patients during chemotherapy to manage psychological symptoms (27). CPDC experienced illness stress which leads to anxiety and depressive symptoms. It was appraised that CBT addresses depressive symptoms of low mood, lack of interest, sleeping, and appetite problems in cancer patients positively. CBT interventions reduced the severity of overall clinical symptoms and increased patients' will-power and confidence to face the illness' adverse effects and restructure thoughts(28).

In therapy our emphasis was to train the patients in term of "*psycho-education, identification of thoughts and core beliefs, cognitive restructuring, inoculation of motivational thoughts/beliefs*, and development of new skills; *stress and cancer crisis management, problem-solving, coping strategies, leisure activities*" (29). Studies have shown positive impact of CBT to address daily life stressors, identification of cognitive errors and thought re-structuring, coping skills and leisure activities will help to manage the outcomes (30). When a therapist provided psychoeducation and awareness to patients about the nature of the illness, patients started to overcome the emotional problems through coping mechanisms(31). The outcomes were evident of decrease in the level of psychological distress and increase in will-power with high motivations; the stability of mood; and the ability to cope with stress throughout treatment (32).

The cognitive intervention proved beneficial to minimize anxiety symptoms. The CPdC patients, who received CBT interventions, exhibited ability to manage death-related anxiety (33). The therapist properly educated the patients using different techniques and skill training; they reduced fear of death anxiety and psychological distress. It was observed CBT interventions reduced the intensity of anxiety disorders at the early stage of diagnosis as well as the early detection of anxiety-related symptoms, while the undetected symptoms will lead to severe anxiety disorders in later life (23).

CBT treatment significantly improved the level of life satisfaction and self-esteem among CPDC. Patients during chemotherapy usually experience some somatic complaints and adverse side-effects, which elevate patients' mood swings and dissatisfaction with life (14) and other associated extraneous factors (34). Further, individuals with low self-esteem perceived high scores on depression and low scores on life satisfaction during cancer treatment because of less responsible, lower need for achievement, and poor motivation while patients with high scores on self-esteem perceived low degree of depression and anxiety because they can control emotions and motivations to bear the pain during treatment (12). Thus CBT focuses on the development of illness acceptance and self-management to improve treatment efficacy and lower psychological disturbance(35). CBT played a supporting role along with the chemotherapy trial to manage and overcome psychiatric symptoms; psychological distress was reduced and there were improvements in patient's quality of life(36). To our knowledge, it was the first CBT trail in Pakistan which was applied on cancer patients during chemotherapy.

Conclusion

In conclusion, we found CBT an evidence-based intervention with statistically significant efficacy and feasibility to treat psychiatric symptoms, reduce fears / apprehensions, improves mood stability, self-image, and satisfaction with life. CBT efficiently works to address maladaptive schemas and beliefs they trigger due to emotional disturbance and affect physical and mental health during chemotherapy.

Limitations And Recommendations

This study was the first initiative in Pakistan to develop an evidence-based treatment model of CBT with cancer patients during chemotherapy. This is recommended along with chemotherapy as an additional and supportive treatment to produce better outcomes. Further study should carry out to find its efficacy with cancer patients at all stages, focusing on other psychological problems except depression and anxiety. Patients were not familiar with psychological interventions; therefore, the termination rate was high, and some patients did not practice these interventions properly due to lack of awareness about its efficacy. It has been observed that their belief system gives them courage to fight even with terminal illness, like cancer. So, it is recommended to include meditation, Quranic Verses, Hadith or religious inscriptions as part of this treatment model.

Clinical Implications: This study provides a rationale background to practitioners that they can apply psychological interventions as supportive treatment modalities along with chemotherapy and it will increase treatment adherence of the cancer patients. Psychoeducation program, awareness program and psychological interventions are the most relevant treatment strategies which significantly address psychological problems, increase patients will-power and supportive role with chemotherapy to produce better outcomes.

Abbreviations

CBT: Cognitive Behavior Therapy; CPdC: Cancer Patients during Chemotherapy; DASS: Depression Anxiety Stress Scale; DAS: Death Anxiety Scale; SwLS: Satisfaction with Life Scale; RSES: Rosenberg Self-Esteem Scale; ANOVA: Analysis of Variance; TCTR: Thai Clinical Trial Registration; WHO: World Health Organization; IBR: Institutional Review Board; M/F: Male/Female; M: Mean; SD: Standard Deviation; DEPS: Depression Scale; ANXS: Anxiety Scale; STSS: Stress Scale

Declarations

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Authors' contributions

Q.A. conceptualized the study, designing and applied for ethical approval, assisted in data collection, conducted therapeutic sessions, and drafted the manuscript for publication. N.A. prepared study protocol, collected data, scrutinized the data, and conducted therapeutic sessions. K.B. helped in trial registration, analyzed the data, interpreted the results, and did treatment planning. M.K. helped in data arrangements, manuscript write-up, and edited the manuscript. M.K. helped in patients' scrutiny, allocation, care, and supervision of medical treatment. M.S. helped in data collection, data preparation, and therapeutic sessions. All authors reviewed the manuscript.

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Availability of data and materials

The dataset generated and/or analyzed during the present study are not publically available because no permission was taken from the participants and the hospital administration where the study was conducted. The datasets are available from the corresponding authors on a reasonable request.

Ethics approval and consent to participate

Ethical approval was obtained from the Institutional Review Board (IRB), Government College University Faisalabad, and Allied Hospital Faisalabad (Ref.No.GCUF/ERC/1996). Then study protocol was approved by the Thai Clinical Trial Registry-TCTR (TCTR20201113002). Participants gave written informed consent before the process of enrollment and screening. All procedures including participant enrollment, screening, data collection, data scrutiny and analysis were performed in accordance with relevant guidelines.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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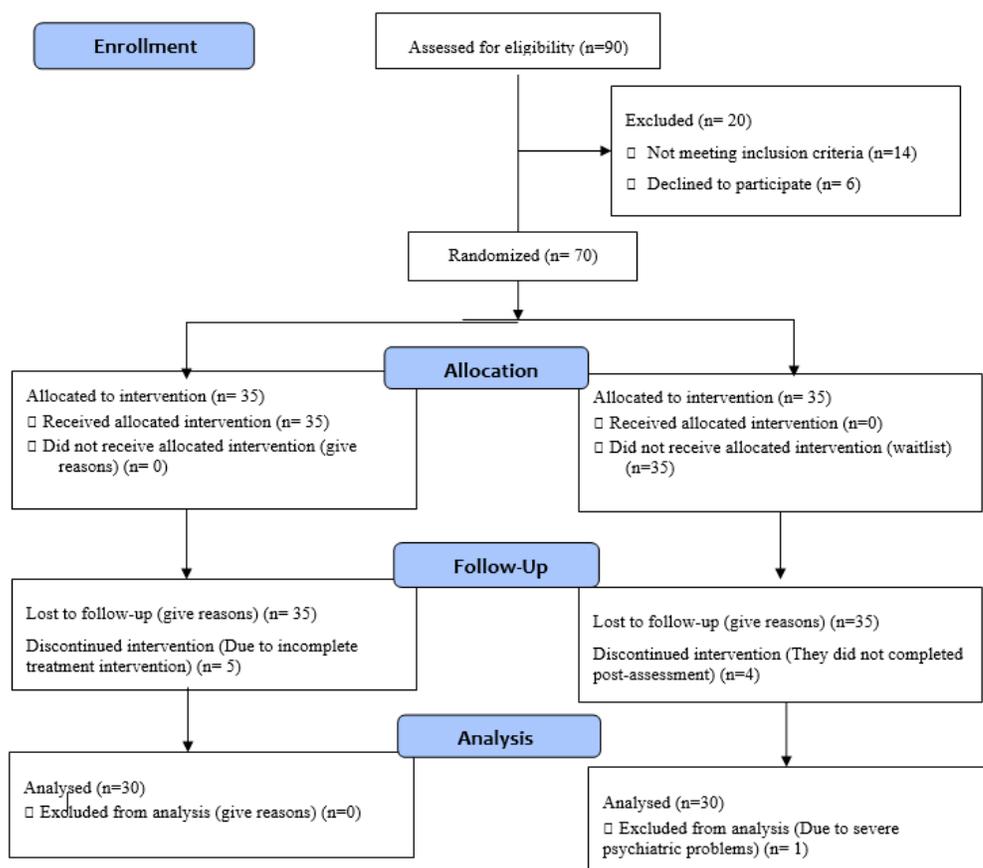
Figures

Figure 1

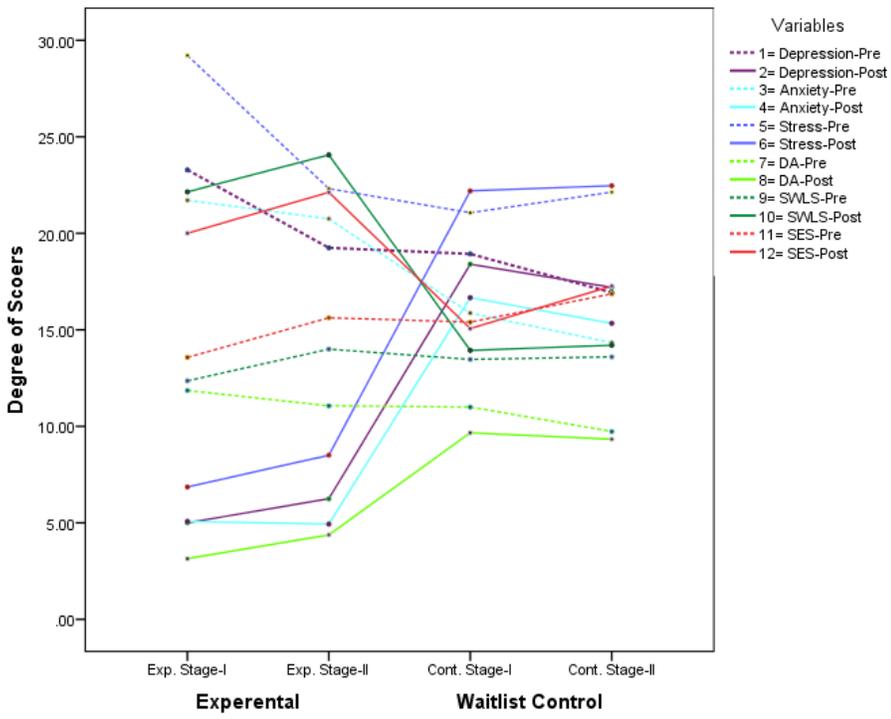Flow Diagram of Cancer Patients during Chemotherapy (CPdC)

Figure 2

Pre- and post-assessment analysis on the clinical variables between experimental and control groups