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Effect of Nurse-led education on parent's anxiety, depression and stress on managing side effects of chemotherapy



# **A RESEARCH THESIS**

Submitted to the Board of Advanced Studies and Research Dow University of Health Sciences In partial fulfillment of the Requirement For the Degree, of Master of Science in Nursing (MSN)

By

# NOMI WAQAS GUL



Institute of Nursing (ION) Ojha Campus Dow University of Health Sciences Karachi, Pakistan June 30, 2019

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# DECLARATION

I Nomi Waqas Gul S/o Gul Hassan Afridi hereby state that my master's project titled "Effect of Nurse-led education on parent's anxiety, depression and stress on managing side effects of chemotherapy" is my own work and has not been submitted previously by me for taking any degree from Dow University of Health Sciences or anywhere else in the country/world.

At any time if my statement is found to be incorrect even after my Graduate the university has the right to withdraw my *MSN degree*.

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Student Master of Science in Nursing (MSN) Institute of Nursing (ION) Ojha Campus, Dow University of Health Sciences, Karachi, Pakistan

Signature

Enrolment No. <u>12/2015/912</u>

Date:

This is to certify that the project entitled "*Effect of Nurse-led education on parent's anxiety, depression and stress on managing side effects of chemotherapy*" submitted by *Mr. Nomi Waqas Gul* to *Institute of Nursing (ION) Ojha Campus, Dow University of Health Sciences, Karachi, Pakistan* for the award of the degree of Master of Science in Nursing (MSN), is a bona fide record of the research work carried out by him under my supervision and guidance. The content of the project, in full or parts have not been submitted to any other Institute or University for the award of any other degree or diploma.

RESEARCH SUPERVISOR Mr. Hakim Shah Associate Professor Institute of Nursing Dow University of Health Sciences Karachi

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RESEARCH CO-SUPERVISOR: Dr. Mehwish Hussain PhD (Statistics), Assistant Professor of Biostatistics, Department of Research Dow University of Health Sciences Karachi Date: \_\_\_\_\_

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CLINICAL SUPERVISOR Dr. Shamvil Ashraf Senior Consultant and Professor Pead's Oncologist Department of Pediatric Oncology at Indus hospital, Karachi

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**Prof. Shehla Naeem Zafar,** Associate Professor Institute of Nursing Dow University of Health Sciences Karachi

Date:

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# **LIST OF ABBREVIATIONS**

BASR	Board of Advanced Studies and Research
C.I	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DUHS	Dow University of Health Sciences
DASS	Depression, Anxiety and Stress Scale
ECT	Electroconvulsive Therapy
IRB	Institutional Review Board
IRD	Interactive Research and Development
MBT	Multimedia Booklet and Telephone
MRI	Magnetic Resonance Imaging
n	Number of samples /Participants selected
NCCN	National Comprehensive Cancer Network (NCCN)
NCSS	National Council for the Social Studies
PASS	Primary Avionics Software System
NIH	National Institutes of Health
O.R	Odd Ratio
P-Value	Probability Value
QOL	Quality of Life
RCT	Randomized control Trial
RM ANOVA	Repeated Measure Analyses of Variance
SPSS	Statistical Package for the Social Sciences
STAI	State-Trait Anxiety Inventory
USA	United State of America

#### ABSTRACT

#### **Background:**

A wide range of pediatric cancers are treated by chemotherapy. The adverse effects are usually managed by their parents at home. Ineffective coping and lack of knowledge about chemotherapy side effect management leads parent's psychology disorders. Contemporary research evidence that Nurse-led education, booklet providence and follow up about chemotherapy and side effect management, help to decrease parent's anxiety and depression.

#### **Objectives:**

To measure the effect of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's anxiety, depression and stress of children receiving chemotherapy for the first time.

#### Methodology:

A randomized control trial was conducted in the department of chemotherapy at Department of Pediatric Oncology at Indus hospital, Karachi from September-December 2018 on parents of children below 18 years of age undergoing chemotherapy for the first time. Total 100 parents were randomly divided into Intervention group (n=50) and Control Group (n=50). After excluding lost to follow up, the data was analyzed from 77 sample of parents (41 in intervention group and 36 in control group). The intervention group received multimedia education, booklet and weekly tele-nursing follow-up about chemotherapy and side effects management. The control group received routine care. Parent's anxiety, depression and stress were identified by using DASS-21 and repeated measures ANOVA was used to observe changes in outcomes over study period.

#### Result

Total 63.4% (n=48) children were under 12 years of age and 64.9% (n=50) children were male. Majority of the parents were non-residence of Karachi, labor and low education and income. 66.2% (n=51) children diagnosed with leukemia, 63.6% (n=49) children had no pain. At the baseline, depression was found in 84.4% (n=56) parents while 67.5% (n=52) parents were anxious and 55.8%(n=43) parents had stress, After the MBT intervention, significant reductions were observed in depression and stress (P-Value <0.05) of the parents in MBT group. A sharp decline was observed just after one week while at final stage intervention group showed higher decrease in depression and stress while anxiety was observed insignificantly different in both groups,

#### **Conclusion:**

There is a positive effect of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's depression and stress of children receiving chemotherapy showing in this study for the first time in Pakistan. For anxiety reduction, other strategies should also be incorporated.

#### **Keywords:**

Nurse-led, Multimedia education, Booklet, telephonic follow-up, chemotherapy, side effects, parents, anxiety, depression, children, cancer

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**CHAPTER 1: INTRODUCTION** 

### 1.1 Background

#### Children Cancer in Pakistan:

Millions of people are affected by cancer worldwide. Cancer is one of the major health problems in Pakistan [1, 2]. According to W.H.O in male, 61,624 incidence cases, 42,624 cancer deaths and in female 75,095 incidence cases and 43,188 deaths reported annually worldwide. About 8,000 children below 18 years are diagnosed with cancer annually. Most children diagnosed in advanced stage [2]. In Pakistan, 31% children have leukemia, 20% have Lymphoma, 08 % have sarcoma, 8 % have bone tumor, 7% have brain tumor, 6 % have retinoblastoma, 5 % have Wilms tumor, 4% have germ cell tumor, 4 % have neuroblastoma and the rest 7 % have other types of cancer [2, 3].Cancer affects families emotionally and physically. [4, 5]

# Chemotherapy and side effect:

Large number of cancer patient face difficulties due to chemotherapy worldwide. If the patient was not prepared properly for chemotherapy treatment,, he/she could face problem in coping with and managing the side effects of chemotherapy.[6]. Chemotherapy is the common method of treatment for cancer management [7]. The common side effects of chemotherapy as reported in literature include diarrhea, nausea and vomiting, hair loss, neuropathy, weight loss, dysphagia, oral ulcer, fatigue, dyspnea, constipation, insomnia and cognitive impairment [8-13]. It also affects quality of life, economic conditions, emotions and social wellbeing [7, 12-14]. As reported in literature, before starting chemotherapy treatment, the patient should receive written information about diagnosis, treatment goal, chemotherapy duration and side effects of drugs, and the material should be design at the level of patient knowledge.[15]

#### Anxiety, Depression & Stress:

The prevalence of anxiety is high among cancer patient due to unawareness about chemotherapy's side effect. 47% of cancer patient undergoing chemotherapy have anxiety due to chemotherapy [16]. The power to control disease can be lost because of anxiety [17]. Side effect of chemotherapy management required self-care and this capability of patient can be effected due to depression.[18]. Anxiety and depression had an association with cancer, chemotherapy related fatigue, lack of education about chemotherapy side effect management and long term exposure of children in hospital [4, 11, 19-21]. Cancer treatment requires nursing intervention to reduce anxiety and depression [4, 22]. Anxiety leads to delay chemotherapy treatment and prognoses [11, 23].

## Evidences of Multimedia education to reduce Anxiety and depression:

This is the main responsibility of oncology nurse to educate patient about the management of side effect of chemotherapy but most patient received only written material instead of proper education regarding management of chemotherapy side effects [11, 18, 24-26]. The recommended practice to reduce anxiety of patient is to educate the patient about the side effects of chemotherapy. The patients should be educated both for short term management and long-term management. Education about side effects of chemotherapy helps the patient in decreasing their anxiety[27, 28]. The effect of multimedia education to reduce anxiety is evident in mammography, MRI, ECT, cardiac surgeries, gynecological laparotomy, laparoscopic cystectomy, hemodialysis, teeth removal and peptic ulcer disease.[23, 29-45]. Nursing intervention through education helps to reduce anxiety and stress [8, 9, 19, 20], after chemotherapy, promote side effect management, decrease complications and increase psychological wellbeing. [11, 15, 16, 46]. Many resource materials are available on internet for

patient education on cancer about chemotherapy and its side effects, and to enhance the psychosocial health of cancer patients. These resources can be utilized as a part of continuous nursing education [11, 16].

#### Anxiety and depression in Pakistan:

Anxiety and depression are common psychological disorders in Pakistan due to lack of resources and proper infrastructure for mental health services [4].

#### Aim of the study:

The aim of this study is to determine the effects of nurse led chemotherapy education on parent's anxiety and depression, as parents have the key role in caring their children cancer. This study helped to examine the effects of psycho-education about chemotherapy and its side effect management on parent's anxiety, depression and stress at Department of Pediatric Oncology at Indus hospital, Karachi Pakistan.

#### 1.2 Statement of Problem

The prevalence of cancer among children has been projected drastically since last decades in Pakistan [1, 2]. Children cannot look after themselves. Parents are the primary caregiver of children [5, 21, 47]. If they initially feel anxiety and depression, it is difficult for them to manage chemotherapy and side effects [5, 11, 15, 47-49]. Education about chemotherapy has been neglected due to heavy workload and other responsibilities of duty nurses [11, 15, 50]. More than 50% of individual newly diagnosed with cancer have unknown anxiety related to chemotherapy and their side effect [51]. As per literature, those who do not receive chemotherapy education prior to treatment face difficulties in later life [6]. The side effects of chemotherapy, like vomiting, nausea, loss of appetite and fatigue were managed through self-care [52]. After an intensive literature review it was found that no study has been conducted in Pakistan focusing on effect of nurse-led multimedia education and telephonic follow up on chemotherapy side effects management for parent's anxiety and depression.

#### **1.3 Rationale of Study**

Pediatric cancer is the leading cause of children mortality and morbidity in Pakistan. More than 8,000 children under 18 years of age are diagnosed with cancer in a year. Cancer treatment are managed by the parents, usually by the mothers of children [5, 21]. Evidences showed lack of knowledge about chemotherapy and dissatisfaction of the information about what they had received leads to uncertainty, apprehension and delay continuation with chemotherapy treatment [4, 11, 15, 52]. Many organizations have developed booklet for patient's education about chemotherapy and side effect management. They have also provided online resources. The patient read the information using their own efforts [11, 16, 29-37]. Multimedia education and Tele-nursing follow up are reported as cost effective method to reduce family anxiety in many countries [11, 23, 25, 26, 29-46, 51, 53, 54]. Parent's anxiety and depression lead to poor management of cancer treatment for their child. Literature reveals that Nurse led psycho-education through multimedia education and telephonic follow up was found cost effective method to reduce anxiety and depression related to treatment process. According to a senior oncologist in Pakistan, parents are anxious not only about chemotherapy side-effect but also about the disease itself [2]. Most parents have the same knowledge of side effects of chemotherapy as they experienced with friend's relatives who had undergone to course treatment. Secondly, side effect was mentioned at first counseling session by primarily oncologist.

#### 1.4 Objectives

To measure the effect of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's anxiety, depression and stress of children receiving chemotherapy for the first time

# **1.5 Research Question:**

Are there effects of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's anxiety, depression and stress of children receiving chemotherapy for the first time?

# **1.6 Operational Definitions**

**Depression**: The score greater than 9 under DASS-21 scale Criteria **Anxiety**: The Score Greater than 7 under DASS-21 scale Criteria **Stress**: The Score Greater than 14 under DASS-21 scale Criteria

#### **CHAPTER 2: LITERATURE REVIEW**

#### 2.1 International Findings:

European literature reported that 20 minutes of video education was more effective than verbal and written education [55]. A randomized control trial was done by Williams and Schreier (2005), the experimental group (n=38) received audiotaped 20 minutes of education on management of fatigue, sleep disturbance and anxiety along with standard care and the control group (n=33) received verbal instruction and written material. The anxiety level was measured at 1 month and 2 months. More number of patient (n=16) in control group reported anxiety as compared to experimental group (n=10) significantly (p=0.001) [26] Similar results were found from the study of Malone (2007) that education helps to reduce anxiety.<sup>[25]</sup> Another study mentioned that familiarity with environment of chemotherapy was necessary as it has also an impact on anxiety [11, 56]. Almost 50% cases diagnosed with cancer reported the symptoms of anxiety [51]. According to NCCN guideline, the anxiety management related to chemotherapy and side effect management was the primary responsibility of oncology team including oncology nurse [16]. Study from USA mentioned that the caregiver of children diagnosed with cancer had 44% greater stress as compared to 24% parents of healthy children [47]. Another study mentioned that 98% participant were satisfied with chemotherapy educational experience, all study participants found educational environment as supportive and 81% felt that quality of life could be improved through education [46]. Another study mentioned 87.6% participant were satisfied with chemotherapy education, 87.5% agree that it helps to reduce anxiety, 93.3% participant felt that it was effective if given first time before chemotherapy, 86.6% participant was satisfied for 30 minutes of education timing before chemotherapy treatment. 85.7% participant report that quite room environment was effective for chemotherapy education [11]. In another study 84% patient reported that educational class was a help to reduce anxiety and 64.7% participant disagree for education in group [25]. A randomized control trial was

conducted in Greenville and concluded that 23% participant in control group reported anxiety after 1 month of treatment as compared to 14% in interventional group [26]. Written information before chemotherapy should be provided to patient, the information should include chemotherapy and side effect, future plan, and follow-up [15]. Many studies had mentioned that that psycho-education was effective to reduce anxiety during chemotherapy management [28, 51, 56, 57].

#### 2.2 Regional Finding

A study from Korea mentioned 38% (n=342) caregiver of children bearing cancer had anxiety, with 5 % of them had severe anxiety. 82% (n=737) caregiver had depression, and 16% abode severe depression of cancer patient. The predicted anxiety level of family caregiver was 9.22 times higher with poor Quality of life (QOL), for burdensomeness 3.44 times higher for degree of disturbance and 2.12 times higher for financial concerns. There are many evidences of nursing intervention effect on anxiety and depression other than chemotherapy side effect management. A study from Turkey mentioned the effect of multimedia nursing education for cardiac care on anxiety and depression score from  $6.1\pm0.7$  and  $5.4\pm0.6$  reduced to  $1.9\pm0.2$ and  $1.9 \pm 0.3$  [37]. In Iran effect of nurse led telephonic follow on anxiety and depression for hemodialysis patients was studied [42] Other studies provided evidences of family anxiety reduction in cardiac care [23, 29, 34, 38], during electroconvulsive therapy [33], elderly care [22] and for laparoscopic cholecystectomy [41].. Another study from Korea also mentioned the effect of nursing intervention on anxiety during laparoscopy hysterectomy [58]. A study from Azerbaijan mentioned positive effect of nursing intervention on anxiety during endoscopy [53] and from Egypt mentioned positive effect of nursing intervention on anxiety during MRI procedures [32]. Studies from China also mentioned the effect of nursing intervention on anxiety level for peptic ulcer [44], breast cancer [40], tooth extraction [43] and laparotomy [39].

#### 2.3 Local findings:

A study from Rawalpindi revealed that 10%-25% participant reported anxiety and depression during chemotherapy and 16% had anxiety and 27% had depression [4]. Myeloid leukemia was commonly diagnosed in younger age but mostly reported in chronic phase [59]. A study from Lahore mentioned that 56% parents had depression, higher in mothers specially those who were low educated and had poor socio-economic class [5]. A study from Karachi mentioned caregiver stress related to cancer patients, 17% mild, 34% moderate and 49% had severe stress. It was also concluded that caregiver stress for cancer patient had significant association with caregiver age, relationship with child, female gender and longer duration of care [49]. A study was conducted in Karachi to identify the psychological need of parents of children disposed with cancer and found that correct and adequate information through education is necessary for parents [60].

We fail to find study both regional and locally focusing this concept.

## **CHAPTER 3: METHODS AND MATERIALS**

#### 3.1 Study Design:

Randomized control trial (RCT)

#### 3.2 Study Setting:

Department of Pediatric Oncology at Indus hospital, Karachi

# 3.3 Study Duration:

September 2018 to December 2018

#### 3.4 Study Population:

The populations of interest were parents along with their children receiving chemotherapy treatment for the first time.

# 3.5 Inclusion criteria:

- 1. Parents along with their children younger than 18 years of age
- 2. Parents along with their children newly diagnosed with cancer in last three weeks
- 3. Parents along with their children schedule to receive first time chemotherapy in the outpatient department

# 3.6 Exclusion Criteria

- 1. Parents along with their children refused to participate
- 2. Parents along with their children already receiving interventions like multimedia education, booklet providence and telephonic follow up for chemotherapy and side effect management
- Parents taking medicine for their anxiety and depression. (e.g. Anxiolytics/ Antidepressant)
- 4. Parents showing uneasiness and discomfort during educational session.

#### 3.7 Sample Size:

By using NCSS PASS v.11 repeated measure analyses of variance (RMANOVA), at 80% power, and 95% confidence interval., RMANOVA of STAI Anxiety score for interventional group at Pre-Intervention means 42.01 (SD=12.96), Post intervention means 37.27 (SD=13.47) and 2 weeks post intervention means 38.40 (SD=10.55) [11], The sample size calculated was 30 samples per group. After adjusting error in non-response of data collection 50 samples were drawn from each group. Total 100 caregivers along with their children was recruit in this study.

#### 3.8 Sampling Technique:

Samples were randomly drawn by using block randomization list. This allocation was based on computer generated random allocation with randomly selected size of block i.e. number of patients on a given day. The participation of each parent in each session was based on the given generated numbers. For example, if on a given day block of parents was recommended by the consultant to the researcher then based on generated block random number; parents were allocated to either intervention arm or control arm. The same procedure was repeated on other day until the sample size in each group was completed. This sampling technique was referred as stratified random sampling.

#### 3.9 Data Collection Procedure:

- Approval: Being a part of academic research, approvals were taken from scientific committee, institutional review board (IRB) and Board of Advanced Studies and Research (BASR) of Dow University of Health sciences, Karachi. Then ethical review committee of Research Department, Indus hospital Karachi was obtained where the study participants were approached.
- 2. **Multimedia Room arrangement**: A room was arranged for multimedia chemotherapy education.
- 3. **Approach to target population**: The target population was approached through Pediatrics oncology registration counter. A help was also taken from the primary adviser to acknowledge each newly advised chemotherapy children along with their parents to Multimedia education room.
- 4. **Parent selection:** In the multimedia room, consent was taken from the parents and they were selected according to the above-mentioned inclusion and exclusion criteria.
- 5. **Randomization:** The parents were allocated to Intervention group and Control group per the generated random number as mentioned in sampling technique defined in section 3.8.
- 6. Socio-demographic and others information: The socio-demographics and others information were collected as given in Annexure -1.
- Pre-Intervention Anxiety, Depression and stress: Parent's anxiety, depression and stress levels were assessed by using DASS-21 (Urdu version) as mentioned in Annexure –II.
- 8. **Post-intervention Anxiety, Depression and stress:** After two weeks the anxiety, depression and stress levels were again assessed by using DASS-21 after multimedia education of "Pre-intervention anxiety and depression" identification. The data were collected during next appointment/mail/Telephonic follow up. The main objective of post intervention was to measure the mean difference of DASS score against Pre-intervention.

- 9. 2-week Post-Intervention Anxiety, Depression and stress: The parent anxiety, depression and stress were again assessed after two weeks of 'post intervention anxiety depression" identification. The technique of data collection was same as mentioned under Pre and post intervention. The main objective of two-week post intervention was to measure the mean difference DASS score against Post-intervention
- 10. Anxiety, depression and stress mean difference: Finally, mean differences in the anxiety and depression level of parents in both Intervention Group and Control group were measured.
- 11. **Recruitment**: The parents were recruited in the study from September 2018 to November 2018 and follow up were continued from October 2018 to December 2018. After the completion of follow up to 5th December 2018 the trail was ended due to the completion of target sample sized (N=100) of parents and follow up schedule.

#### 3.10 Interventions:

After an intensive literature review [11, 18, 24-29, 37-39, 42, 44, 46, 52, 54, 55, 58, 61, 62] following intervention strategy was develop in consultation with expert Pediatric Oncologist detail as mentioned below.

#### 3.10.1 To Intervention group:

#### **Before chemotherapy:**

- Multimedia Education: The Intervention group received 60 minutes of PowerPoint multimedia education in Urdu language about chemotherapy, its side effect and nutritional guide. The copy of PowerPoint presentation is given in Annexure –III. It was ensured that well explained and comfortable friendly environment was provided to the parents.
- 2. Booklet providence: A booklet "Chemotherapy and you" in Urdu translation were provided to the parents focusing on the detailed information about chemotherapy and its side effects management. The copy of the booklet is enclosed in Annexure –VI.

# After chemotherapy:

Follow up were done, during follow up side effect appear in their child were determined and the parents were re-educated as per their appearance. There were 18 side effect of chemotherapy in booklet and it was not necessary that all would appear, e.g. example after chemotherapy the child may develop vomiting and diarrhea, but other 16 side effect may remain silent or appear later.

#### 3. Tele-Nursing follow-up:

- **3.1** The parents were provided opportunity to call from 9:00 a.m. to 5:00 p.m., in any week day to ask question related to chemotherapy and its side effect management according to booklet. The education was again provided according to the booklet. If any information asked by parents was not related to the booklet, they were referred to their primary consultant.
- 3.2 Each parent was called by the researcher on weekly basis according to following schedule, day of education (day 0) to 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 28<sup>th</sup> day. The content of telephonic conversation majorly focused on (i) list of problem related to chemotherapy side effect and (ii) Management techniques according to the booklet. The approximate duration of call was 15 minutes depending upon the problems identified by the parents.

## 3.10.2 To control Group:

## **Before chemotherapy:**

They were recruited in the study and were informed about the day of data collection for post-analysis.

# After Chemotherapy:

Control group followed routine care. During routine care parent verbally educated by the physician and nurses about Chemotherapy and Side effect Management.

#### 3.11Pilot Study:

#### Content Validity of Booklet "Chemotherapy and you"

The pilot study was conducted to ensure the 'content validity' of educational material "*Chemotherapy and You*', as it was adopted through international Guideline of NIH: National Cancer Institute, so that applicability of educational guideline at Department of Pediatric Oncology at Indus hospital, Karachi need to be ensured. Though, minor changes were determined in the education materials during pilot study which were later incorporated under the supervision of expert reviewers in educational material according to educational need of parents and study setting.

# Training of Principal Investigator for Multimedia education and telephonic Follow up:

During Pilot Study, researcher was also observed and guided by the most senior expert educationist already working in education department from 'Department of Pediatric Oncology Indus hospital Karachi", on how to educate the Parents on multimedia education and Telephonic Follow up. After ensured that, researcher is capable to educate Parents, preceded to final study. It was also ensure that no additional information other than booklet "Chemotherapy and you" will be given. If parents will asked any question other than booklet, will be refer to primary consultant.

#### **Reliability of DASS-21 Scale:**

Although DASS-21 Scale is a reliable tool and has an evidence of its usage in Pakistani context. But in order to ensure its local applicability, total 10 samples (10% of sample size of original study) were taken and it was found a 88.7% reliable. From control group, it shows 92.5% reliability and from intervention group it shows 67.4% reliability.

#### 3.12Ethical Consideration:

The research study got approvals from the scientific and ethical bodies as defined in section 3.9. Furthermore, signed consent was obtained from the selected participants after briefing the information about study. They were told that their relevant personal informed like names of child and parents, their phone number would only be used for telephonic follow up with parents and would be kept confidential within investigators of the study.

#### 3.13 Study Variables

# 3.13.1 Dependent Variable:

Depression (D) anxiety (A) and stress (S) were outcome variables. [63]. They were identified by using DASS-21 Scale. The use of DASS-21 scale was evident in different research studies from Pakistan [62, 64-67]. There were 21 questions in this scale equally divided into three parts having seven questions for Depression, Anxiety and stress respectively. Each question had four level of measurement 0, 1, 2 and 3, represent past week experiences. 0 means not applicable to person, 1 means applicable to some degree or sometime, 2 means applicable to considerable degree or good part of time, 3 means applicable to person very much or most of the time. Each question was separated for Stress(s), Anxiety (a) and Depression (d). The questions focusing the concept (1) (s) hard to wind down, (2)(a) dryness of mouth, (3)(d) experience of positive feeling, (4)(a) breathing difficulty, (5)(d) difficulty in initiation of work, (6)(s) overreaction according to situation, (7)(a) experience of trembling in hand, (8)(s) use of excessive nervous energy, (9)(a) worriedness about panic situation, (10)(d)noting to look forward, (11)(s) getting agitated, (12)(s) difficulty in relaxation, (13)(d)feeling of downhearted and blue, (14)(s) lack of tolerance, (15)(a) feeling of panic, (16)(d)lack of enthusiasm, (17)(d)lack of worthiness as a person, (18)(s) feeling of somewhat sensitive, (19)(a) palpitation and increase of heart beat, (20)(a) feeling of scary and (21)(d) feeling of meaningless life. The cut-off scoring for (1) Depression was Normal (0-9), Mild (10-13), Moderate (14-20), severe (21-27) and extreme Severe (28+), (2) Anxiety was Normal (0-7), Mild (8-9), Moderate (10-14), severe (15-19) and extreme Severe (20+)and (3) Stress was Normal (0-14), Mild (15-18), Moderate (19-25), severe (26-33) and extreme Severe (34+). For further categorical analysis, the depression, anxiety and stress were dichotomized into "No" and "Yes" where "Yes" category was generated while combining the statuses of "mild", "moderate", "severe" and "extremely severe". The Scores on DASS-21 scale was multiplied by 2 to get the final score.

#### 3.13.2 Independent Variable:

The independent variable was mentioned as socio-demographics and other information in **Annexure-I**. It included (1) Sectioned (A), Personal information focusing Child Age, Child gender, Primary Care taker area of residence, (2) Section (B), Socioeconomic and educational status of Childs caretaker focusing Occupation, Level of education, Employment status, Income per month and Treatment Expenses. (3) Section C, Cancer Information focusing Diagnoses, Type of cancer, Stage of cancer, treatment being sought, Duration of Chemotherapy, Date of diagnoses, Duration of diagnoses, Family History of cancer and Number of cancer patients in the family of the patient other than this case. (4) Section (D), Pain scale focusing Pain felt by the child at that moment and (5) Section (E), General information related to Anxiety and depression focusing, Caregivers awareness of whether he or she was anxious and depressed? Did caregivers taken any treatment sought for his anxiety and depression? Whether any health professional advices the Caregivers? and Do caregiver had smoking habits?

#### 3.14 Statistical analyses:

The data were analyzed by using SPSS version 21. The patient identification was omitted from analyses. The reliability measures were made using Cronbach's alpha. Descriptive analyses were performed for all the variables. Mean and standard deviation were computed for continuous variable such as DASS score, age etc. Frequency and percentages were computed for categorical variable such as DASS categories, gender and other socio-demographic variables. As the outcome variable were collected over three periods of time. One-way repeated measurement of ANOVA (RM ANOVA) was used for comparing the mean DASS scores over 28 periods of time. The post hoc test applied for each time of measurement and the differences were identified between pre-intervention (day 0), Post intervention (day 14) and 2 weeks after post intervention (day 28).

#### **CHAPTER 4: RESULT**

#### 4.1 Participant flow:

Consolidated Standards of Reporting Trials (COSORT) guidelines were used for organization of methods and results of the study [68]. Total 113 children were admitted in Department of Pediatric Oncology at Indus hospital, Karachi from September 2018 to November 2018. Out of 113, 13 parents along with their children were excluded for not meeting inclusion criteria i.e. non-confirmation of cancer diagnosis, no need for Chemotherapy and refused to participate in study. Thus, 100 parents were randomly allocated to intervention group and Control group with equal number of allocations in each group respectively.

Out of 50 parents in intervention group 4.5% (n=9) were lost during follow up, due to death (n=2) of the children and no response (n =7) from parents. In intervention group 4 children were lost in 1st week, 2 were lost in 2nd week, 2 were lost in 3rd week and 1 was lost in 4th week of follow up. On the other hand, 50 parents along with their children who were randomly allocated to control group as routine care, 3 children died, and 11 participants did not respond afterward. Total 6 were lost in 1st week, 4 were lost in 2nd week, 2 were lost in 3rd week and 2 were lost in 4th week of follow up in control group. It was further identified that lost to follow-up due to death and non-response was somewhat more in control groups as compared to intervention group. The detail is mentioned in *Figure 1* 



**Figure 1: Participants selection** 

#### 4.2 Baseline data:

#### **Personal information**:

Total 31.2% (n=24) children were under 2-4 year of age, 23.4% (n=18) were under 5-7 years, 31.2 % (n=24) were also under 8-12 year of age and 14.3% (n=11) children were under 13-18 years of age group. Female to male ratio was 1:1.85. Majority (88.3%) of primary caregiver of studied children were any one of the parents. Most of them belonged to non-local area, other than Karachi territory.

#### Socioeconomic and educational status of Childs care taker:

Total 54.4% (n=42) children's father were labors, 22.1% (n=17) were shopkeepers and 23.4%(n=18) had other occupations. Total 28.6 % (n=22) participate of them were found uneducated, 42.9% (n=33) were educated at School level, while 28.6% (n=22) were educated at higher level. Most of the father's worked on daily Wages, Total 37.7% (n=29) Primary care taker income had less than 10,000 incomes per month and 62.3% (n=48) had more than 10,000 incomes per month.

# **Cancer Information**:

Leukemia (blood cancer) was found to be the commonest cancer among the children (66.2%) and 33.8 % had other cancers. Nearly, 90.0 % caregiver had no history of cancer in their family. While 9.1% (n=7) had an active history of cancer in their family.

#### Pain scale (Visual analog scale):

When asked about the pain felt by the children, majority (n=49) children responded that they were not feeling any pain at that moment. Those who felt pain, was due to the invasive procedure of bone marrow biopsy. Minority complaints about pain were due to abdominal distention and nodules formations.

# Factor associated with Anxiety and depression:

Nearly, 42.9% parents had smoking habits, while 57.1 % did not have smoking habit. The baseline data of parents along with their child are shown in Table 1.

	Total	Intervention	Control	
Section A: Personal information	n=77 (100%)	n=41 (100%)	n=36 (100%)	Chi-Square
				P-Value
1. Child Age:	-	-	-	
2-4years	24(31.2)	13(31.7)	11(30.6)	0.98
5-7years	18(23.4)	10(24.4)	8(22.2)	
8-12 years	24(31.2)	12(29.3)	12(33.3)	
13-18 years	11(14.3)	6(14.6)	5(13.9)	
2. Child Gender:	50/54.0	<b>0</b> 4 ( <b>5</b> 0 <b>5</b> )		
Male	50(64.9)	24(58.5)	26(72.2)	0.20
Female	27(35.1)	17(41.5)	10(27.8)	
3. Primary Care Giver:	(0/00.2)	20(02.7)	20(02.2)	0.00
Mother/Father	68(88.3)	38(92.7)	30(83.3)	0.20
Other	9(11.7)	3 (7.3)	6 (16.7)	
4. Residency/Locality:	20(2( 4)	17(41.5)	11(20.6)	0.22
	28(36.4)	1/(41.5)	11(30.6)	0.32
Non-Local	49(63.6)	24(58.5)	25(69.4)	<b>A1</b> • A
Section B: Socioeconomic and	N=77 (100%)	Intervention	Control	Chi-Square
educational status of Childs care taker		n=41 (100%)	n=36 (100%)	P-Value
5. Occupation	12(54.4)	24(59.5)	19(50)	0.74
	42(54.4)	24(58.5)	18(50)	0.74
Shopkeeper	17(22.1)	8(19.5)	9(25)	
Other	18(23.4)	9(22)	9(25)	
6. Level of education		11(2(0))	11(20.0)	0.00
	22(28.6)	11(20.8)	11(30.6)	0.80
School Education	33(42.9)	1/(41.5) 12(21.7)	16(44.4)	
Higher Education	22(28.6)	13(31.7)	9(25)	
7. Employment status	40((2, ())	29((9.2)	21(59.2)	0.26
Daily wages	49(63.6)	28(08.3)	21(58.5)	0.30
Nonthly Salary	28(36.4)	13(31.7)	15(41.7)	
8. Income per month (Rupees)	20(27.7)	12(20.2)	17(47.2)	0.10
less than 10,000	29(37.7)	12(29.3)	1/(4/.2)	0.10
More than 10,000	48(62.3)	29(70.7)	19(52.8)	
Section C. Concer Information	N = / / (100%)	n=41 (1009/)	Control	D Voluo
0 Diagnosos		<u>II-41 (10070)</u>	II-30 (100 <i>%</i> )	<b>F-value</b>
J. Diagnoses	51(66.2)	28(68.2)	22(62.0)	0.59
Othora	31(00.2) 26(22.8)	20(00.3) 12(21.7)	23(03.9) 12(26.1)	0.58
10 Family History of cancor	20(33.8)	15(51.7)	15(50.1)	
No.	70(00.0)	34(82.0)	33(01.7)	0.25
	70(90.9)	7(17.1)	3(83)	
Section D: Pain scale (Visual analog	N=77 (100%)	Intervention	S(0.5)	Chi Sauara
scale)		n=41 (100%)	n=36(100%)	P_Voluo
11 Pain falt by the child			II-30 (100 /0)	I - Value
No	49(63.6)	23(56.1)	26(72.2)	0.14
Ves	28(36 /)	18(43.0)	10(27.8)	
Section F: Factor associated with	N=77(100%)	Intervention	Control	Chi-Square
Anxiety and depression		n=41 (100%)	n=36(100%)	P-Value
12. Do parent have smoking habits?			1 20(10070)	I - V aiut
No	44(57.1)	21(51.2)	23(63.9)	0.26
Yes	33(42.9)	20(48.8)	13(36.1)	
- •v			1 12(20.1)	1

# Table 1: Socio Demographical Features

#### 4.3 Depression, Anxiety and Stress over study period:

#### 4.3.1 Reliability analysis:

The Cronbach's alpha values of overall DASS measures were 75%, 85.1% and 85.3% at pre, post and 2-week post intervention period respectively. Among the control, their respective values were 79%, 84.9% and 83.5% while from intervention group, these were 69.4%, 81.1% and 78.2% at pre, post and 2-week post intervention respectively. From these values of Cronbach's alpha, it was perceived that consistency among the responses from the participants while responded to the questionnaire showed very good reliability.

# 4.3.2 DASS score and level over pre, post and 2 week post time:

The descriptive statistics of depression, anxiety and stress scores are given in table 2 while distribution of depression, anxiety and stress levels between intervention and control group over study periods are mentioned in table 3.

# **Depression:**

At the baseline depression score was  $15.82 \pm 6.6$ , while 15.6% had no depression and most of the parents 84.4% (n=65) had depression. One week after the depression score was reduced to  $7.97 \pm 5.15$ , in which 62.3% had no depression, while 37.7% (n=29) had depression. The average 'two-week post-depression' score was reduced to  $4.26 \pm 4.36$ , in which 85.7% had no Depression, while 14.3% (n=11) had depression. The percentage of depression in intervention group was reduced from baseline to 22% and 2.4% among intervention group at post and 2-week post intervention while it respectively retained to 55.6% and 27.8% in control group.

## Anxiety:

The average 'pre-anxiety' score was  $11.35 \pm 6.72$ , in which nearly one out of three (n=25) had no anxiety, while 67.5% (n=52) had Anxiety. The average 'post-anxiety' score was  $5.32 \pm 4.5$ , in which about three-quarter (n= 56) had no anxiety, while 27.3% (n=21) had anxiety. The average 'two-week post' anxiety score was  $4.26 \pm 4.36$ , in which 83.1% (n=64) had no anxiety and 16.9% (n=13) had anxiety. The anxiety level reduced to 14.6% to 4.9% in intervention group in post and 2 week post stages respectively though, 41.7% and 30.6% of parents in control group remained anxious in post and 2 week post stages.

#### Stress:

The average 'pre-stress score' was  $16.65 \pm 6.15$ , in which 44.2% (n=34) had no Stress, while 55.8% (n=43) had stress. The average 'post-stress score' was  $8.88 \pm 5.77$ , in which 87% (n= 67) had no stress, while 13% (n=10) had stress. The average 'two-week post stress' score was  $4.73 \pm 4.64$ , in which 96.1% (n=74) had no stress and 3.9% (n=3) had stress. There was steep declined in stress level in intervention group that no parent was in stressed at 2 week after intervention. However, 8.3% of parents in control group still had stress level at final stage of the study.

# Table 2: Average scores of Depression, Anxiety and Stress between intervention and control group

Dependent Variable		Total n=77 (Mean ± SD)	Intervention n=41 (Mean ± SD)	Control n=36 (Mean ± SD)
	Pre-Depression	$15.82 \pm 6.6$	$15.41 \pm 5.97$	$16.28 \pm 7.32$
DEPRESSION	Post-Depression	$7.97 \pm 5.15$	$6.44 \pm 3.94$	$9.72 \pm 5.82$
	Two- Week Post Depression	$4.26 \pm 4.36$	$2.63 \pm 2.98$	$6.11 \pm 4.94$
	Pre-Anxiety	$11.35\pm6.72$	$11.9 \pm 6.51$	$10.72 \pm 7$
ANXIETY	Post-Anxiety	$5.32 \pm 4.5$	$4.2 \pm 3.43$	$6.61 \pm 5.23$
	Two- Week Post Anxiety	$2.98 \pm 3.23$	$1.75 \pm 2.33$	$4.27 \pm 3.61$
	Pre-Stress	$16.65 \pm 6.15$	$16.63 \pm 5.96$	$16.67 \pm 6.45$
STRESS	Post-Stress	$8.88 \pm 5.77$	$7.02 \pm 4.59$	$11 \pm 6.3$
	Two- Week Post Stress	$4.73 \pm 4.64$	$2.88 \pm 3.1$	$6.83 \pm 5.22$

# Table 3:Distribution of depression, anxiety and stress levels between intervention and<br/>control group over study period

Dependent Variable		Yes/No	Total (n=77) n(%)	Intervention (n=41) n(%)	Control (n=36) n(%)
	Pre-Depression	0= No	12(15.6)	6(14.6)	6(16.7)
		1=Yes	65(84.4)	35(85.4)	30(83.3)
DEPRESSION	Post Danrassian	0= No	48(62.3)	32(78)	16(44.4)
DEI RESSION	Post-Depression	1=Yes	29(37.7)	9(22)	20(55.6)
	Two Wook Post Donnession	0= No	66(85.7)	40(97.6)	26(72.2)
	1 wo- week i ost Depression	1=Yes	11(14.3)	1(2.4)	10(27.8)
	Pre-Anxiety	0= No	25(32.5)	11(26.8)	14(38.9)
		1=Yes	52(67.5)	30(73.2)	22(61.1)
ANVIETV	Post-Anxiety	0= No	56(72.7)	35(85.4)	21(58.3)
		1=Yes	21(27.3)	6(14.6)	15(41.7)
	Two- Week Post Anxiety	0= No	64(83.1)	39(95.1)	25(69.4)
		1=Yes	13(16.9)	2(4.9)	11(30.6)
	Pre-Stress	0= No	34(44.2)	19(46.3)	15(41.7)
		1=Yes	43(55.8)	22(53.7)	21(58.3)
STRESS	Post-Stress	0= No	67(87)	40(97.6)	27(75)
SIRESS		1=Yes	10(13)	1(2.4)	9(25)
	Two Wook Post Stress	0= No	74(96.1)	41(100)	33(91.7)
	I WU- WEEK FUST STLESS	1=Yes	3(3.9)	0(0)	3(8.3)

#### 4.3.3 Changes in depression, anxiety and stress scores over different periods:

Table 4 depicted significance values from RM-ANOVA and further post-hoc analyses. Profile plots mentioned as figure 2-4 displayed changes of mean scores of depression, anxiety and stress at baseline, post and 2-week post intervention.

**Depression**: The average depression between intervention and control group was significantly different (P=0.012) over study period (P<0.0001). Post-hoc analysis revealed that a reduction of 7.76 unit decrease in depression score from baseline to post intervention while it significantly reduced to 11.47 unit after 2 weeks of the study.

**Anxiety**: The anxiety level did not show any significant difference between intervention and control group (P=0.172) though both groups displayed concurrently significantly decline in anxiety level at pre, post and 2 week post study period (P<0.0001). Post-hoc analysis also discovered that a reduction of 5.90-unit reduction in Anxiety score from the reference line after intervention and significantly reduced to 8.29 unit after 2 weeks of the study.

**Stress**: The reduction in stress level depicted similar panorama as it was observed in depression score. Post-hoc analysis further exposed a decrease of 7.67-unit reduction in stress score from the baseline line after MBT intervention and significantly reduced to 11.79 units after 2 weeks of the study.

Denendent	Significance value between study groups	Significance value over time	Post Hoc Analysis P-Value with Mean differences		
Variables			Pre & Post	Pre & 2week Post	Post & 2week Post
Depression	0.012	<0.0001	<0.0001 Dif. (7.76)	<0.0001 Dif. (11.47)	<0.0001 Dif. (3.70)
Anxiety	0.172	<0.0001	<0.0001 Dif. (5.90)	<0.0001 Dif. (8.29)	<0.0001 Dif. (2.38)
Stress	0.012	<0.0001	<0.0001 Dif. (7.63)	<0.0001 Dif. (11.79)	<0.0001 Dif. (4.15)

Figure 3: Anxiety scores of intervention and control

Block

-Intervention -Control

 Table 4:
 Significant values of depression, anxiety and stress scores





Figure 4: Stress scores of intervention and control group during study period



	socio demographical features	Pre-Depression Chi-Square P-Value	Pre-Anxiety Chi-Square P-Value	Pre-Stress Chi-Square P-Value
1.	Child Age	0.58	*0.031	0.18
2.	Child Gender	0.42	0.15	0.35
3.	Primary Care Giver	0.69	0.41	0.46
4.	Residency/Locality	0.67	0.58	0.10
5.	Occupation	*0.017	0.25	0.20
6.	Level of education	0.13	0.25	0.15
7.	Employment status	0.28	0.96	0.76
8.	Income per month (Rupees)	0.32	0.07	0.92
9.	Diagnoses	0.97	0.77	0.81
10.	Family History of cancer	*0.02	0.20	0.77
11.	Pain felt by the child	0.12	0.11	0.51
12.	Do parent have smoking habits?	0.92	0.88	0.50
	Significant Association (P-V	/alue <0.05)		

 Table 5 : Association of Socio demographical features with pre-depression, pre-anxiety and pre-stress

The significant association has been identified between child age and pre-anxiety of parents, Occupation and pre-depression of parents and family history of cancer and pre-depression of parents. It is further identified that there is significantly 4 times more likely to have no Anxiety at the time of admission (pre-anxiety), if the child age is < 4 year as compared to the child age > 4 years [OR=4.1, 95%CI(1.0-16.2),P-Value=.042] Moreover, found that there is significantly 20% less likely to have no depression at the time of admission (pre-depression), if Family history has cancer as compared to no history of cancer patient in family [OR=0.20, 95%CI(.047-.880),P-Value=.033]. No association was found with other variable.

Since, almost all variables produced insignificant effect on the outcome variables at three stages of observations. Therefore, these variables were not proceeded for multivariable analysis.

#### **CHAPTER 5: DISCUSSION**

Parents are the primary care giver of the children. If parents will be in anxiety, so it will be difficult for them to manage side effect of chemotherapy. The main purpose of this study was to measure the impact of multimedia education, booklet providence and telephonic follow-up on parent's anxiety, depression and stress. As far as we know, the study is first of its kind that was conducted in Karachi Pakistan focusing this concept. We found significant reduction in depression and stress because of MBT intervention while anxiety was not significantly different between study groups.

#### **Epidemiology of Pediatric cancer:**

Large number of people are affected with cancer worldwide, leading major health problem of Pakistan [1, 2]. Approximately 8,000 children under 18 years of age are being diagnosed on yearly basis. In our study it was found that highest proprtion of patients were diagnosed with Leukemia (blood cancer) followed by Lymphoma (cancer of lymph gland), Similarly, one of the study from Pakistan also reported that Leukemia and Lymphoma were higher among children [2, 3]. The prevalence of leukemia is similarly higher in this study.

#### **Depression Anxiety and Stress among parents:**

In this study it was found that 84.4% parents had depression, 67.50% parents had anxiety and 55.50% parents had stress below normal range at baseline. The reason of mentioned in the literature that anxiety in parents was due to unawareness about chemotherapy side effect, lack of knowledge about disease, lack of knowledge above side effect management [4, 11, 16, 17, 19-21]. The findings are similar to this study, as mostly parents were unaware about the disease and management.

#### MBT as Nursing Intervention to reduce Anxiety Depression and stress:

In our study randomized control trial was done in which intervention group received multimedia education on chemotherapy and side effect management along with routine care and the control group received verbal instruction as routine care of hospital. The anxiety level was measure at 2-week differences up to 1 month and found that large no of parents reported anxiety in control group after 1 month as compared to experimental group. Similarly study was conducted by Williams and Schreier (2005) and reported larger number of patient in control group reported anxiety as compared to experimental group significantly. [26]. Another Malone (2007) and mentioned that education help in reduction of anxiety [25]. In our study it was found that parent who came at Department of Pediatric Oncology at Indus hospital, Karachi have the considerably highest pre-scores of anxiety, depression and stress.

Susan Swanson, 2008 mentioned that almost 50% cases diagnosed with cancer reported the symptoms of anxiety [51]. Similar in this study we have reported slightly higher Prevalence possibly due to study setting differences. Study from USA mentioned that, the caregiver of children diagnosed with cancer had 44% greater stress as compared to 24% parents of healthy children [47] According to National Comprehensive Cancer Network (NCCN) guideline, anxiety management related to chemotherapy and side effect management was the primary responsibility of oncology team including oncology nurse [16]. Similarly, the responsibility was assigned to physician, nurses and other paramedics. In our study it was found that almost 68% parents had anxiety and 84% caregiver had depression. Similarly, a study from Korea mentioned lower percentage that 38% caregiver had anxiety and 82% caregiver had depression [48]. In our study the effect of multimedia nursing education about chemotherapy and side effect management imparted significant reduction in anxiety (i.e. from  $11.35 \pm 6.72$  which reduced to 2.98 ± 3.23) in 1 month and in depression score (i.e. from  $15.82 \pm 6.6$  reduce to 4.26  $\pm 4.36$ ) in 1 month. This is similar to a study from Turkey that mentioned the significant

reduction of multimedia nursing education for cardiac care on anxiety and depression score from  $6.1\pm0.7$  and  $5.4\pm0.6$  reduce to  $1.9\pm0.2$  and  $1.9\pm0.3$  respectively [37]. In Iran significant effect of nurse led telephonic follow on anxiety and depression for hemodialysis patients were reported [42], evidences of family anxiety reduction in cardiac care [23, 29, 34, 38], during electroconvulsive therapy [33], elderly care [22], laparoscopic cholecystectomy [41], laparoscopy hysterectomy [58], endoscopy [53] MRI procedures [32], peptic ulcer [44], breast cancer [40], tooth extraction [43]and laparotomy [39] correspondingly supported the procedure for multimedia education and telephonic follow up. In this study we found that 30 minutes of education about chemotherapy and side effect management was enough for education to parents. In a European study they recommended 20 minutes of multimedia education [55].

We consider ourselves successful to report that our study focused on effect of nursing led education on chemotherapy and side effect management on parent's anxiety depression of children undergoing chemotherapy for the first time at local level in Pakistan. In literature we failed to find any study focusing this concept. Our study from Karachi reported 2 time higher parental anxiety and depression as compared to a study from Rawalpindi reported that 10-25% participant reported anxiety and depression during chemotherapy and 16% had anxiety and 27% had depression [4]. A study from Lahore mentioned that 56% parents had depression, higher in mothers specially those who were low educated and had poor socio-economical class. Another study mentioned that myeloid leukemia was commonly diagnosed in younger age but mostly reported in chronic phase [5, 59]. A study from Karachi mentioned caregiver stress related to cancer patients, 17% mild, 34% moderate and 49 % severe stress, mentioned that caregiver stress for cancer patient had significant association with caregiver age, relationship with child , female gender and longer duration of care [49]. The findings from our study showed that implementing MBT intervention would help to reduce depression, anxiety and stress in our setup.

This procedure adopted in this study was supported by the literatures that written material about chemotherapy side effect management is the responsibility of oncology nurses [11, 18, 24-26]. The main content of our education focused chemotherapy and side effect management. In literature it was further mentioned that education related to side effect management reduces anxiety of the patient [8, 9, 11, 15, 16, 19, 20, 27, 28, 46]. Using multimedia education for the reduction of anxiety was also found in mammography, MRI, ECT, cardiac surgeries, gynecological laparotomy, laparoscopic cystectomy, hemodialysis, teeth removal and peptic ulcer disease.[23, 29-45]. Anxiety and depression were more common due to lack of infrastructure in Pakistan [4]. Therefore, strategies like MBT intervention should be derived to reduce such psychological disorders in Pakistan especially among cancer patients and their caregivers.

# 5.2 Limitations

Few caveats should be taken while generalizing findings of the study. First, the study was conducted in a single center; therefore, results would be different if such psychological disorders persist in parents of cancer children in other clinical or community setups. Further effect of parents' age and gender could not be found out in our study.

The MBT intervention alone could not help in reducing anxiety significantly. The reason would be most of the participants were anxious about finding a suitable residence in the city during treatment period for which researcher could not help. Also, this element was not addressed in the study questionnaire so that the reason would be confounded to determine sole effect of MBT intervention on anxiety too.

#### 5.3 Strength of study:

There are certain strengths to report about this study. First, the study was of its first kind to report major psychological disorders among caregiver of cancer children in Pakistan. The novel internationally adapted MBT intervention showed noteworthy decline which added the strength that the intervention is replicable to reduce depression, anxiety and stress among target population. The higher reliability scores also strengthened the confidence in using the MBT intervention for the same.

Furthermore, despite having loss to follow-up, we retained more than desired sample size in both groups which yielded good power of the study.

# 5.5 Conclusion:

There is a positive effect of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's depression and stress of children receiving chemotherapy showing in this study for the first time in Pakistan. For anxiety reduction, other strategies should also be incorporated.

# 5.6 Recommendation:

Nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management can be recommended as supportive care to reduce parent's depression and stress of children receiving chemotherapy for the first time.

#### 5.7 Harms:

As no invasive procedure was done on parents along with their children and intervention is based on education guideline under NIH, hence did not cause any harm to the participant.

### 5.7 Generalizability:

As the sample was drown through randomized block design so it can be generalizable to caretakers of cancer children from similar setup.

#### 5.8 Registration

This Study is registered at ClinicalTrials.gov by Identifier NCT03753542,

#### 5.9 Funding:

It was a self-funded academic research project.

# 5.10 Recommendations for further studies:

Nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management can be recommended as supportive care to reduce parent's anxiety, depression and stress of children receiving chemotherapy for the first time. Though, further researches are needed to measure effect of MBT intervention based on parents' responses, their psychological aspects, age, gender, recovery of child and result association with public and private sector healthcare setting.

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# ANNEXURES

The following annexures were enclosed with this document.

- Appendix -I: Socio-demographic and others information
- Appendix -II: DASS-21
- Appendix -III: Multimedia Education
- Appendix -IV: Booklet
- Appendix -V: IRB Approval Letter
- Appendix -VI: IRD Approval Letter
- Appendix -VII Turnitin Digital Receipt
- Appendix -VIII Summary of the Similarity Index (Plagiarism)