

Original Article

Impact of Psychological Intervention on the Quality of Life of Primary Care Givers of Patients with Cancer : Preliminary Report in City based Cancer Hospital, India

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Background and Aim : Caring for an individual with cancer can lead to significant stress, anxiety and feelings of sadness among primary caregivers, ultimately impacting their overall psychological and physical well-being. The aim of this research was to assess if cancer primary caregivers who underwent Psychological Interventions (PI) observed enhancements in their Quality of Life by decreasing levels of depression and anxiety.

Materials and Methods : A single-centre randomized control trial was conducted among 53 adult primary caregivers aged ≥ 18 years of age to ≤ 65 years and those involved with their patients' actual care not less than 12 hours per day, between April, 2023 to August, 2023. All participants went through the assessment of QoL and Depression and Anxiety levels by using validated tools. Participants were randomly assigned into two groups : Group-A (N=31), participants receiving psychological support and Group-B (N=22), who did not receive any psychological support. The intervention comprised five sessions. Following department protocol participants were followed-up based on 21, 42, 63, 84 and 105 days. Participants completed primary outcomes (Anxiety, Depression and Quality of Life) before one of each session to see the impact of each session. To identify the impact of PI, descriptive statistics were calculated as the Mean \pm Standard deviation of the score of validated tools based on primary outcomes.

Results : A total of 53, female caregivers (61%) were more than male individuals (39%). About 60.57% of the caregivers reported severe hampering of their QoL. The data showed significant improvements in outcomes measured from pre to post and from post-to-follow-up as compared to Group-B counterparts ($p < 0.005$). Group-A had statistically significant improvements in QoL in 120 days' follow-up time, compared with Group-B, $p < 0.01$.

Conclusion : Under challenging circumstances during the period of cancer treatment, PI is a useful intervention for standing continuous psychological support as it is associated with better Quality of Life for primary caregivers. Further research examining factors influencing the outcomes of psychological intervention will be justified.

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Key words : Cancer, Primary Caregivers, Quality of Life, Depression and Anxiety.

Cancer is a life-threatening illness that is stressful not only to the patients but also to the caregivers in terms of how it might be experienced. During this lengthy treatment period, which frequently lasts for months or years, the patient and their Primary Caregivers spends more time at the cancer centre than at home. There are significant changes in the daily routines of both parties and they need to work very hard to adapt to the demands of this life-threatening disease. The family feels obligated to work together

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Editor's Comment :

■ Psychological counseling is an essential resource for primary non-medical caregivers of cancer patients. It addresses the emotional and practical challenges of care giving, promotes mental health and fosters a supportive community. By prioritizing the well being of caregivers, we can enhance the quality of care for cancer patients and ensure that caregivers are able to sustain their vital roles over the long term.

to support the patient after learning that a family member has cancer⁹.

As is clear, daily practice reflecting the rise in cancer cases in India over the past ten years, the emotional anguish that it causes the family members, and the difficulty in coping with the diagnosis of their loved ones. The patient's primary caregiver is responsible for making decisions, monitoring changes in the patient's condition, giving hands-on care, adjusting care as needed, gaining access to resources, negotiating with the healthcare system, providing emotional support, and frequently securing funding for

the treatment. The primary carer has a difficult responsibility to complete both physically and emotionally: juggling the care of the cancer patient with his or her own daily routine²⁰. Since ancient times, providing care has been valued as a worthwhile experience, but the effects on the carers themselves are frequently disregarded. According to the Quality of Life in Life-Threatening Illness-Family Carer Version (QoLLTI-F) assessment, half of the carers in a recent study on the Quality of Life (QoL) of carers had a bad quality of life. The statistical results showed that characteristics like gender, religion, location, financial burden, lung cancer stage and kind, disability and patient depression had a substantial impact on the carers' Quality of Life.

The Quality of Life of the patient's primary caregivers, a group that is frequently disregarded, is a very important concern that has been addressed by the widespread usage of this questionnaire and its translation into many languages. The Turkish translation of the English CQOLC yielded results that were comparable to those of our study, suggesting that there were some concerns that were shared by families of cancer patients. It was also administered alongside the World Health Organisation Quality of Life Short Version (WHO-QoL-BREF) to breast and Gynaecological cancer patients and validated to the German version⁶. It demonstrated good reliability for burden, disruptiveness, and financial concerns but low reliability for positive adaptation. Utilising the same CQOLC scale, similar studies were carried out in Korea and the United Arab Emirates, with comparable results on demographic comparisons^{6,15}.

Previously many researchers in India have already discussed about depression, death anxiety and stress in cancer caregiver^{3,17,10} along with the burden the caregivers have to go through¹⁶. Keeping these psychological issues in mind, researchers have discussed about psychosocial intervention for the cancer caregivers' better Quality of Life^{19,5,8}.

After interacting with cancer caregivers, the most common psychological issues seen were anxiety (about losing loved ones), overprotectiveness, feeling of failure to give best their loves ones who has cancer and depression. Therefore, keeping all this factors in mind we have developed a psychosocial intervention in West Bengal for cancer caregivers for the first time. As the concept of psychosocial intervention is still new in West Bengal, we were unable to refer to previous state-wise researches about effect of psychological intervention on caregivers' Quality of Life (QoL).

The objective of this study was to evaluate the

impact of Psychological Interventions (PIs) on the quality of life of cancer primary caregivers, specifically in terms of reducing their levels of depression and anxiety.

MATERIALS AND METHODS

Study Design :

This study was a randomized controlled trial conducted at a tertiary cancer hospital in Eastern India after receiving approval from the institutional review board. Out of 149 cancer patients' primary caregiver between April, 2023 to August, 2023, only 66 participants were enrolled in the study after fulfilling eligibility criteria. Participants were randomly assigned by using computer generated random number to either the Group-A (N=34), participants receiving Psychological Intervention (PI) and Group-B (N=32), did not receive any PI. Sample size was calculated based on power 80% and alpha 0.05 and few patients previously agreed to take part in study and refused later. Hence, we omitted those participants leading to sample size- Group-A=33 and Group-B=29. These participants were screened using the Mini International Neuro-psychiatric Interview (MINI) and those with the diagnosis of first episode depression and anxiety (mild or moderate severity) as per International Classification of Diseases – 10th edition (ICD 10) criteria, as confirmed by an experienced clinical psychologist were included in the study. Those participants who received a diagnosis other than depression and anxiety [Group=A (N = 2) and Group=B (N=7)] were excluded.

Eligibility Criteria :

Inclusion criteria :

- (1) Diagnosed cancer patients and undergoing active cancer treatment
- (2) No evidence of previous psychiatric illness
- (3) Currently not enrolled in another PI study or psychiatric support
- (4) Age more than 18 years
- (5) Able to understand, read and speak the Bengali language. (Response from patients with oral cancer who were unable to verbalize was recorded with help of caregiver/ proxy)

Exclusion Criteria :

- (1) Caregiver not staying with the patient for not less than 12 hours per day.
- (2) Those unable to complete the questionnaires

Experimental Group —

After initial screening, participants fulfilling eligibility criteria were enrolled and explained about the study protocol in face-to-face form. Informed written consent was obtained and recorded in an official document form.

Each participant was asked to complete the baseline questionnaire (Bengali translated version for each study tool was already validated and easily available): demographic characteristics, Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Caregiver Quality of Life Index (CQoL-C). All these questionnaires measured various dimensions of depression, anxiety, and Quality of Life respectively. The psychologist messaged all the patients as a reminder one day before of each session and no reply from the patients was translated to the number of drop-outs in the study. We also noted the cause of the refusal to participate in the study. This information helped to determine the acceptability of the psychological support as well as document the major barriers to participation.

Control Group —

In this group, they did not receive psychosocial support on a regular basis. At first, clinical psychologists assessed the psychological factors at baseline by using a standardised questionnaire. Then it was reassessed twice in a month with a 15-day' gap and continued up to 120 days.

Psychological Intervention :

This type of psychological support based on over-the-phone communication consisted of five sessions, each lasting 30-35 minutes. Before starting the psychological sessions, the first clinical psychologist assessed the psychological issues at baseline by using the standardised questionnaires. Again, psychologists used it before one day of each session to see the impact of each session. The department protocol for medical assessment was based on 21, 42, 63, 84, and 105 days. So, we followed the same pattern to make it easier.

Covered Areas of Psychological Intervention —

The intervention programme, held at a board room in the Oncology Unit of the Hospital, was coordinated by the coordinator. It comprised five face-to-face sessions (once a week for a month) delivered by experienced Psychologist. Each session was 40-45 minutes in length; a presentation of interactive content followed by questions and discussion. Each session had a specific theme: 1. Knowledge 2. Anxiety management 3. Activities of daily life 4. Bonding with patient 5. Develop social interaction (Table 1)

Data Collection :

Socio-demographic data were collected from both groups followed by structured interviews.

Instruments—

Structured Proforma : A structured proforma was developed to assess the Socio-demographic and

No of Session	Content
Session 1 (21 days)	In this first session, the content of the intervention was explained, an evaluation was made of essential information about respective cancer, from which the patient is suffering.
Session 2 (42 days)	Discuss the role of caregiver during critical management of the patient
Session 3 (63 days)	Advice on communication between caregiver and patient (interactive daily activities) and Dealing with the emotional aspect of caring his or her patients (not to show overloaded sympathy which makes a feeling of burden to patients)
Session 4 (84 days)	Self-care: its importance and strategies to promote self-care (develop social interaction)
Session 5 (105 days)	Discuss and explain the common symptoms of the patients during the whole course of planned treatment and dealing with the patients' emotional changes.

clinical details of the study subjects.

Mini International Neuropsychiatry Inventory (MINI):

MINI is a short structured diagnostic interview, developed jointly by Psychiatrists and Clinicians in the United States and Europe, for DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, American Psychiatric Association - IVth Edition) and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, it is easy to administer¹⁸.

Caregiver Quality of Life Index : The CQoL-C is a self-administered rating scale designed to assess QoL issues in family caregivers of patients with cancer. It had 35 QoL-specific items, each of which was graded from 0 to 4 on the Likert scale, where "0" denoted "Not at all," "1" denoted "A little bit," "2" denoted "Somewhat," "3" denoted "Quite a bit," and "4" denoted "Very much." The maximum total score for the instrument is 140. All 35 things were added together for a final score, which was taken into consideration for analysis²⁰. Three separate translators (2 with medical background and one with a master's degree in Bengali) translated the scale into Bengali and the final, approved version was utilised to gather the data. The caregivers were personally interviewed for the data collection. Test-retest reliability was 0.95 and internal consistency was 0.90. The instrument has good divergent validity. The instrument is also responsive to changes in the health state of the patient, as measured by the ECOG-PSR ($r=0.45$).

Beck Depression Inventory (BDI) :

The original English version of BDI II consists of 21

items to measure the severity of depression. Each item is a list of four statements arranged in ascending order of severity about a particular symptom of depression which could be rated from 0 (symptom not present) to 3 (symptom strongly present), with resulting summary scores ranging from 0 to 63. The time reference for the response set has 2 weeks. The severity rating guidelines and cut-off scores suggested by the authors for total scores of patients diagnosed with major depression are 0-13 minimal; 14-19 mild; 20-28 moderate; and 29-63 severe. In the translation and validation process, a validated Bengali version of BDI II was produced to measure depression and its severity among the Bengali population¹².

Beck Anxiety Inventory (BAI) :

This scale is a self-report measure of anxiety. It consists of 21 items. Internal consistency for the BAI = (Cronbach's $\alpha=0.92$) Test-retest reliability (1 week) for the BAI = 0.75. The severity rating guidelines and cut-off score suggested by the authors for total scores of patients diagnosed with anxiety are 0–21 low; 22–35 moderate, and 36 and above potentially concerning levels of anxiety⁷.

Consent form :

Informed verbal consent was obtained from all participants and recorded in audio format.

Statistical analysis :

Descriptive statistics were used to summarize participants' demographic and clinical characteristics of all the participants. Socio-demographic and BAI, BDI, CQoL-C scores were categorized according to two participated groups. Chi-square was applied to observe comparability according to two cancer groups. The overall mean values of each scale at baseline/day on 21, 42, 63, 84, 105 and 120 days of psychological support course were calculated for both groups. Repeated measure was used to define significance of telephone based psychological support among metastatic cancer patients through psychological assessment score before, during and after participation. Independent "t" test was used to define the association between impact of telephone based psychological support and emergency visit.

RESULTS

Demographic Information :

Table 2 depicts the baseline demographic and clinical characteristics of the study participants. The majority of them belonged to middle-class socio-economic status (1000 to 2000 Indian rupees per capita per month). Both the study groups were comparable

Demographic details	Group A (N=81)	Group B (N=72)	p-value
Age	52.23±2.05	51.07±2.19	1.13
Gender :			
Male	49%	53%	1.12
Female	51%	47%	
Residence :			
Rural	54%	51%	1.11
Urban	46%	49%	
Relationship status :			
Living with spouse	74%	65%	1.14
Living without spouse	26%	35%	
Education :			
Illiterate	9%	6.5%	
Primary Education	17%	20.1%	
Secondary Education	41%	36.1%	
More than secondary education	33%	37.3%	0.098
Occupation :			
Engaged with work	49%	50.4%	
Unemployed	35%	39%	1.13
Home maker	16%	10.6%	
Family Income :			
≥500	13%	11%	
1000-2000	49%	56%	0.07
>2000	38%	33%	
Clinico Pathological (Diagnosis) :			
Head and Neck Cancer	20%	16.5%	
Gynaecological Cancer	22%	17.6%	1.01
GI and Thoracic cancer	3.5%	10.2%	
Ortho-oncology	15.5%	17.1%	
Treatment History :			1.42
Standard care Only	53%	54%	
Standard care with Palliative care			
Palliative care	31%	30.2%	
Palliative care Only	16%	15.8%	
Psychological Variable :			
Depression	43±1.13	44.2±1.07	1.32
Anxiety	18±1.02	19±1.22	
QoL	55.7±1.11	56±1.14	

at baseline.

In the Group-A, the mean age of participants was 52.23±2.05 years. 51% were female primary caregivers, 54% were residing in a rural area, 74% were living with their spouse and 41% received up to secondary education, 49% were working. Distribution of participants according to the cancer site: from head and neck (20%), from gyn-oncology (22%), from gastrointestinal tract (3.5%) and from ortho-oncology (15.5%). Their mean baseline levels were: for depression- 43±1.13; for anxiety- 18±1.02 and for QoL- 55.7±1.11.

In the control group, the mean age of participants was 51.07±2.19 years. 53% were female caregivers, 51% were residing in a rural area, 65% were living with their spouse and 36.1% received secondary education, 39% were unemployed. Distribution of

participants according to the cancer site: from head and neck (16.5%), from gyn-oncology (17.6%), from gastrointestinal tract (10.2%) and from ortho-oncology (17.1%). Their mean baseline levels were: for depression - 44.2 ± 1.07 ; for anxiety- 19 ± 1.22 , and for psychological well-being- 56 ± 1.14 .

All groups were comparable in terms of socio-demographic, clinico-pathological and psychological variables.

Mixed model results demonstrated that overall symptom severity for each individual psychological factors- depression, anxiety and QoL ($P < 0.001$) and progressively improved over the course of treatment. Statistically significant change in mean score has been observed over different study time points. We observed slight increase in mean scores- depression [44.2 versus 43 versus 39 versus 45 versus 31 versus 29]; anxiety [18 versus 20 versus 14 versus 23 vs 22 versus 19] and QoL [55.7 versus 55.3 versus 49.4 versus 50.2 versus 43.6] among Group-A. (Table 3)

DISCUSSION

The obtained results suggest that the implementation of a psychological intervention in primary caregivers enhanced their QoL and reducing their psychological issues-anxiety and depression. A repeated measure analysis conducted revealed that psychological issues and overall QoL reported significant differences in scores over the time frames between the Group-A and Group-B. Supporting our results, similar studies that conducted intervention programmes and discussed positive significant impact of a psychoeducation intervention on the QOL of primary caregivers as well as and its dimensions across the time points^{4,1,14,2}. Following studies measured caregivers' QoL using CQOLC, but different psycho-educational intervention programmes were evaluated¹; administered the Caring for the Caregiver Programme (CCP) among family caregivers of patients with advanced cancer². Another study had worked among family caregivers of women with breast cancer

using COPE (creativity, optimism, planning, and expert information) and result was same there¹¹. The present study results had contradicted from those of using the COPE intervention programme, who reported a significant decline in caregiver QoL¹³ and who conducted FOCUS programme for 134 dyads (only breast cancer patients and their family caregivers). Following the results, there were no significant difference in the dyads' QoL across the three time points (from baseline to 6 months)¹³.

In respect to the psychological intervention in the first session, we provided the primary caregivers- patient psychological care-related information and answers to their concerns. After this session, we went to take the assessment on the caregiver's Quality of Life, following the test score report their Quality of Life had not statistically significantly improved, but according to their feedback they have understood the importance of psychology in

Table 3 — Distribution of psychological issues among participants during the time frame

Experimental Group	Control Group	p-Value
		<0.01*
		<0.01*
		<0.01*

oncology and they have become more aware of their own psychological issues. Regarding the psychological intervention during the second session, we provided caregivers with information on how to manage cancer patients during their critical condition. The motto of this session is to give psychological support to help caregivers respond effectively to critical challenges, thereby helping them manage their anxiety and depression. Upon reassessing the caregiver's Quality of Life, the obtained score report indicated that the QoL of the caregiver has improved moderately comparing with last session. In relation to the psychological intervention during the third session, we provided caregivers with advice on how to interact with the patient and keep them engaged in family decisions. The primary caregiver requires mental support as they tend to become over protective towards the patient due to the fear of losing them. For the wellbeing of the patient's mental health, the primary caregiver's mental wellbeing should be prioritised as well. Proper support from the caregiver can often keep the patient happy and give them hope which in turn can help the caregiver too. After reassessing the caregiver's Quality of Life, the report states that the QoL of the caregiver has improved significantly. With respect to the psychological intervention in the fourth session, we provided the caregiver with ways to develop social interaction skills and knowledge about the patient's diagnosis and treatment. We also advised them to join peer support groups if possible. After reassessing the caregiver's quality of life, the report states that the QoL of the caregiver does not significantly improve due to the unavailability of peer support group or cancer support group according to diagnosis in West Bengal. For the last psychological intervention session, the psychologist discusses about the patient's mental health journey from the beginning of the cancer diagnosis till the duration of standard care treatment. The psychologist also discusses about the various psychological issues that come up, such as, fear of death, feeling of financial burden, unable to accept present situation of the disease, believing that cancer is the result of their own "karma". After the final reassessment of psychological issues, the reports state that, unfortunately the Quality of Life does not significantly improve due to the caregivers becoming puzzled whether to take care of their physical health or mental health.

The most important session during the whole Psychosocial Intervention was the third session, as it showed a very positive impact on the primary caregiver's QoL. This is due to the psychologist's

advice given to the primary caregiver, through which they take care of the patient by including them in family decisions, having regular family meals and including them in small household chores. It reduces the patients feeling of being a 'family burden', which in turn reflects on their health and behaviour, while also decreasing the caregiver's psychological issues, anxiety and depression, manifesting through the caregiver's QoL.

The concept of Psychology in the field of Oncology is still new in West Bengal, therefore, there is not much research to refer to, but as per patients' family member's responses, along with the primary treatment they do take part in taking care of the patient's and their own psychological wellbeing.

CONCLUSION

In conclusion, our current randomized controlled trial supports the use of psychological interventions for primary caregivers of cancer patients, which might be highly acceptable and effective in improving their QoL and psychological outcomes in India. Future studies will expand the sample pool, apply to primary caregivers of patients with different cancer types and investigate the cost-effectiveness of such psychological interventions.

Disclosure Statement :

No potential conflicts of interest were reported by the authors.

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