

IMPACT OF A MULTI-COMPONENT NURSE-LED INTERVENTION ON PSYCHOSOCIAL OUTCOMES AMONG FAMILY CAREGIVERS OF CANCER PATIENTS UNDERGOING CHEMOTHERAPY: A QUASI-EXPERIMENTAL STUDY

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ABSTRACT

Background: Family caregivers of cancer patients undergoing chemotherapy experience significant psychosocial burden, heightened distress, and inadequate preparedness for caregiving. Nurse-led interventions targeting caregiver outcomes represent a promising yet underexplored strategy in the Indian oncology context.

Objectives: To assess baseline levels of preparedness for caregiving, burden, need fulfillment, perceived social support, depression, anxiety, and stress; to evaluate the effectiveness of a structured Nurse-Led Intervention Programme (NLIP) on these outcomes; and to determine the association of outcome measures with selected caregiver profile variables.

Methods: A quasi-experimental pre-test post-test control group design with repeated measures was conducted at Shaleen Cancer Hospital, Ahmedabad, India. Fifty-four family caregivers were enrolled (experimental group n=26; control group n=28). The NLIP comprised four components: caregiver preparedness education, support group meetings, deep-breathing relaxation, and supportive telephonic follow-up, delivered over six weeks. Validated tools, including the Preparedness for Caregiving Scale, Caregiver Reaction Assessment, Need Fulfillment Scale, Multidimensional Scale of Perceived Social Support, and Depression Anxiety Stress Scale (DASS-21), were employed. Independent t-tests and paired t-tests were used for analysis at a 0.05 significance level.

Results: At six-week follow-up, the experimental group demonstrated significantly higher preparedness for caregiving (30.85 vs. 23.75, $p<0.001$), improved need fulfillment (60.04 vs. 39.93, $p<0.001$), and greater perceived social support (45.08 vs. 27.57, $p<0.001$). Caregiver burden, depression, anxiety, and stress were all significantly reduced in the experimental group compared to controls ($p<0.001$). Duration of caregiving and daily caregiving hours showed statistically significant associations with most outcome measures.

Conclusion: The NLIP was effective in improving caregiver preparedness, need fulfillment, and perceived social support, while reducing burden and psychological distress among family caregivers of chemotherapy patients. Integration of structured nurse-led caregiver programmes into oncology nursing practice is strongly recommended.

KEYWORDS: Caregiver burden; Nurse-led intervention; Cancer caregivers; Chemotherapy; Preparedness for caregiving; Depression, Anxiety and Stress; Perceived social support; Quasi-experimental study

1. INTRODUCTION

Cancer remains a leading cause of morbidity and mortality worldwide, with an estimated 20 million new cases diagnosed globally in 2022, a figure projected to rise significantly in the coming decade (Bray et al., 2024). In India, the burden of cancer has grown substantially, with over 1.46 million incident cases reported annually and a sharp rise in gastrointestinal and hematological malignancies (ICMR, 2023). Chemotherapy, while a cornerstone of cancer treatment, imposes profound physiological, psychological, and social sequelae not only on patients but also on the family members who assume primary caregiving responsibilities.

Family caregivers are broadly defined as unpaid individuals—spouses, children, siblings, or other relatives—who provide physical, emotional, and logistical support to cancer patients across the treatment trajectory (Given et al., 2021). In the Indian sociocultural milieu, family-based caregiving is deeply entrenched, often placing enormous and unrelenting demands on caregivers who lack formal training, structured support, or professional guidance (Mehrotra & Bhatt, 2020). These caregivers frequently face an erosion of personal health, financial strain, social isolation, and a heightened burden of psychological morbidity, including clinically significant depression, anxiety, and stress (Northouse et al., 2020; Ugalde et al., 2019).

Research has consistently demonstrated that the preparedness of family caregivers for their role is a powerful determinant of both caregiver and patient outcomes. Caregivers who feel underprepared report greater burden, lower quality of life, and poorer self-rated health (Schumacher et al., 2018). Conversely, targeted educational and psychosocial interventions

that enhance caregiver preparedness have been associated with reduced distress, improved coping, and higher care quality (Dionne-Odom et al., 2020). Despite this compelling evidence, structured caregiver support programmes remain largely absent from routine oncology care in India.

Nurses, by virtue of their continuous patient contact, holistic orientation, and therapeutic relationship with families, are uniquely positioned to deliver evidence-based caregiver interventions (Nissen et al., 2021). Nurse-led intervention programmes (NLIPs), which integrate caregiver education, peer support, and psychosocial skill-building, have demonstrated efficacy in Western oncology settings (Northouse et al., 2020; McMillan et al., 2019). However, robust evidence from the Indian subcontinent remains sparse, particularly with respect to culturally contextualized, multi-component programmes tested through rigorous experimental designs.

This study was therefore designed to evaluate the effectiveness of a structured Nurse-Led Intervention Programme (NLIP) targeting seven key outcome domains—preparedness for caregiving, caregiver burden, need fulfillment, perceived social support, depression, anxiety, and stress—among family caregivers of cancer patients undergoing chemotherapy at a tertiary oncology Centre in Ahmedabad, India. The study further sought to determine baseline associations between these outcomes and selected socio-demographic and caregiving characteristics, providing a contextual foundation for future programme scaling.

1.1 Objectives

- To assess the baseline levels of outcome measures (preparedness for caregiving, burden, need fulfillment, perceived social support, depression, anxiety, and stress) among family caregivers of cancer patients undergoing chemotherapy before the implementation of the NLIP.
- To evaluate the outcome of the NLIP in terms of preparedness for caregiving, burden, need fulfillment, perceived social support, depression, anxiety, and stress among family caregivers of cancer patients undergoing chemotherapy.
- To determine the association of outcome measures with selected variables of the family caregiver profile at baseline.

1.3 Hypotheses

H1: There will be statistically significant improvement in preparedness for caregiving, need fulfillment, and perceived social support scores in the experimental group compared to the control group at the 0.05 level of significance.

H2: There will be a statistically significant reduction in caregiver burden, depression, anxiety, and stress scores in the experimental group compared to the control group at the 0.05 level of significance.

H3: There will be a statistically significant association of outcome measures with selected variables of the family caregiver profile at the 0.05 level of significance.

2. REVIEW OF LITERATURE

2.1 Caregiver Burden and Psychological Distress

A systematic review and meta-analysis by Northouse et al. (2020) encompassing 29 randomized controlled trials confirmed that family caregivers of cancer patients report substantially elevated levels of anxiety, depression, and burden compared to population norms. The review noted that the intensity of chemotherapy regimens significantly moderated caregiver distress, with caregivers of patients receiving intensive intravenous protocols reporting the highest burden levels. Dionne-Odom et al. (2020) further established that caregiver burden in hematological and solid-tumor oncology is multidimensional, encompassing financial strain, schedule disruption, and health compromise, aligning with the domains captured in the Caregiver Reaction Assessment instrument.

In the Indian context, Mehrotra and Bhatt (2020) conducted a cross-sectional study among 180 caregivers at a tertiary cancer hospital in Mumbai, reporting that 62% exhibited moderate-to-high caregiver burden on the Zarit Burden Interview, with female caregivers and those with lower educational attainment at greatest risk. A subsequent study by Kaur et al. (2021) at the Post Graduate Institute of Medical Education and Research, Chandigarh, found that caregiver burden was significantly positively correlated with patient symptom severity, functional decline, and duration of caregiving—findings consonant with the present study's design.

2.2 Nurse-Led Interventions for Caregivers

A Cochrane systematic review by Candy et al. (2020) identified 14 randomized controlled trials evaluating nurse-led caregiver support interventions and concluded that structured programmes combining education, skills training, and peer support produced significant improvements in caregiver preparedness (SMD 0.58, 95% CI 0.31–0.85) and reductions in burden (SMD -0.44, 95% CI -0.71 to -0.17) compared to usual care. The review emphasized that multi-component interventions delivered over four to eight weeks were consistently superior to single-session approaches.

Dionne-Odom et al. (2020) evaluated the ENABLE (Educate, Nurture, Advise, Before Life Ends) Caregiver intervention, a nurse-led telephone-based programme, in a randomized trial of 322 caregiver-patient dyads. The intervention arm demonstrated significant reductions in burden, depression, and stress at 12-week follow-up, with the authors noting that early intervention initiation—at the time of chemotherapy commencement—yielded the greatest effect sizes.

Within India, a randomized controlled trial by Rao et al. (2022) at the National Cancer Centre Singapore (an institution with a large South Asian patient cohort) found that a nurse-led family caregiver education programme resulted in significant improvements in caregiver self-efficacy and perceived competence at six-week follow-up. The study

highlighted the importance of incorporating culturally specific content, peer support, and telephonic follow-up—design features mirrored in the NLIP developed for the present study.

Despite this growing body of evidence, nurse-led caregiver interventions remain poorly integrated into the Indian public health cancer care system, and high-quality quasi-experimental studies from tertiary Indian oncology settings are limited. The present study therefore addresses a significant evidence gap and contributes to the development of a locally valid, scalable caregiver support model.

3. METHODOLOGY

3.1 Research Design

A quantitative, quasi-experimental pre-test post-test control group design with repeated measures was employed. The research design is diagrammed in Table 1, illustrating the allocation of pre-test, intervention, and post-test assessments across experimental and control groups over a six-week period.

3.2 Study Setting

The study was conducted at Shaleen Cancer Hospital, Ahmedabad, Gujarat, India—a dedicated tertiary oncology facility offering comprehensive chemotherapy services to a diverse patient population from urban and semi-urban backgrounds. Ethical approval was obtained from the Parth Hospital Institutional Ethics Committee, Ahmedabad, prior to the commencement of data collection.

3.3 Study Period

The pilot study was conducted from 27th July 2023 to 14th September 2023, spanning six weeks of intervention and follow-up per participant cohort.

3.4 Population and Sample

The target population comprised family caregivers of adult cancer patients scheduled to receive chemotherapy cycles at the study setting. A total of 54 family caregivers were enrolled—26 in the experimental group and 28 in the control group. Final post-test data were available for 26 experimental and 28 control group participants after accounting for attrition.

3.5 Sampling Technique

Purposive sampling was employed to recruit eligible participants who met the predefined inclusion criteria. Groups were formed based on the chemotherapy scheduling (alternate weeks), ensuring minimal contamination between groups.

3.6 Inclusion Criteria

- A family caregiver accompanying a cancer patient scheduled to receive at least one additional chemotherapy cycle under the current treatment plan
- Blood relative or next of kin living with the cancer patient in the same household
- Age 18 years or above
- Ability to read and write in Gujarati, Hindi, or English
- Willingness to participate and provide written informed consent

3.7 Exclusion Criteria

- Caregiver whose patient had completed the last cycle of chemotherapy under the current plan
- Caregiver whose other family member was concurrently enrolled in the study

3.8 Nurse-Led Intervention Programme (NLIP)

The NLIP was a structured, multi-component programme developed by the investigator under expert guidance, comprising four evidence-based components delivered across six weeks (Table 2). The theoretical underpinning drew from Lazarus and Folkman's Transactional Model of Stress and Coping and the Preparedness for Caregiving conceptual framework.

Component 1 — Caregiver Preparedness Education (45–60 minutes, Day 1): A structured educational session delivered individually to each caregiver covering (a) a brief introduction to cancer and chemotherapy mechanisms, (b) recognition and management of chemotherapy side effects, (c) self-care strategies for family caregivers, and (d) guidelines for seeking urgent medical advice. A comprehensive Family Caregiver Guideline booklet was distributed.

Component 2 — Support Group Meetings (30 minutes, Days 1, 14, and 28): Three facilitated group sessions enabling caregivers to share experiences, express emotions, and receive peer validation under professional guidance. Sessions were structured using a semi-directive format, emphasizing emotional support and problem-focused coping.

Component 3 — Relaxation Training (5–10 minutes, Days 1, 14, and 28): Instruction in diaphragmatic deep-breathing relaxation techniques, supported by distribution of a pictorial flyer and a daily practice checklist shared via WhatsApp.

Component 4 — Supportive Telephonic Follow-Up (6–8 minutes, Weeks 2, 4, and 6): Structured telephone calls by the investigator-nurse providing follow-up support, reinforcing adherence to relaxation practice, and addressing emerging caregiving concerns.

3.9 Instruments

Data were collected using six validated tools administered at pre-test (Day 1) and post-test (Week 6) for both groups:

Tool 1 — Family Caregiver Profile Sheet: A self-developed instrument comprising 15 items across two sections: (A) socio-demographic characteristics (10 items) and (B) caregiving characteristics (5 items), administered in 3–5 minutes.

Tool 2 — Preparedness for Caregiving Scale (PCS): An 8-item, 5-point Likert scale (0=not prepared to 4=very well prepared) with a score range of 0–32; higher scores indicate greater preparedness. Reliability: $r=0.90$, $\alpha=0.88$.

Tool 3 — Caregiver Reaction Assessment (CRA): An 18-item, 5-point Likert instrument assessing five burden domains: impact on schedule, finances, family support, health, and caregiver esteem. Score range: 0–72 (after reverse-scoring of positive items). Higher scores indicate greater burden. Reliability: $r=0.81$, $\alpha=0.87$.

Tool 4 — Need Fulfillment Scale (NFS): A 16-item scale rated 0 (need not important) to 4 (need completely met), with a score range of 0–64; higher scores indicate greater need fulfillment. Reliability: $r=0.89$, $\alpha=0.82$.

Tool 5 — Perceived Social Support Scale (PSSS): A 12-item, 5-point Likert scale (0=strongly disagree to 4=strongly agree), score range 0–48; higher scores indicate greater perceived support. Reliability: $r=0.89$, $\alpha=0.91$.

Tool 6 — Depression Anxiety Stress Scale-21 (DASS-21): A standardised 21-item self-report scale with three 7-item subscales (depression, anxiety, stress), each scored 0–21; higher scores indicate greater psychopathology. Reliability: Depression $r=0.75$, $\alpha=0.83$; Anxiety $r=0.80$, $\alpha=0.73$; Stress $r=0.80$, $\alpha=0.78$.

3.10 Validity and Reliability

Content validity of self-developed tools was established through expert panel review by 16 subject matter experts comprising PhD-qualified nurse educators in Community Health Nursing and Oncology Nursing, professors in Preventive and Social Medicine, Psychiatry, and Sociology. A content validity index (CVI) of ≥ 0.80 was achieved for all items. Reliability coefficients for all tools exceeded the accepted threshold of 0.70, confirming adequate internal consistency and test-retest stability (Table 5 in Results).

3.11 Ethical Considerations

Ethical clearance was obtained from the Parth Hospital Ethics Committee, (Reference: PHC/IEC/2023/21A) prior to data collection. The study was conducted in accordance with the Declaration of Helsinki (revised 2013). Written informed consent was obtained from all participants. Confidentiality was maintained through use of coded identifiers. Participants retained the right to withdraw without consequence. Control group participants received standard hospital care; at study completion, they were offered access to the NLIP materials.

3.12 Data Analysis

Descriptive statistics (frequency, percentage, mean, standard deviation) described socio-demographic and caregiving characteristics. The chi-square test assessed group homogeneity at baseline for categorical variables. The independent samples t-test compared mean outcome scores between groups at baseline and post-intervention. Paired t-tests evaluated within-group pre-post changes. One-way ANOVA and independent t-tests determined associations of outcome measures with selected profile variables. All analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY). A two-tailed p-value <0.05 was considered statistically significant.

4. RESULTS

4.1 Socio-Demographic and Caregiving Characteristics

A total of 54 family caregivers participated in the study. Table 1 presents the distribution of socio-demographic characteristics. The majority of caregivers were aged >48 years (33.3%), predominantly male (79.6%), Hindu (90.7%), and married (90.7%). All participants were literate; 29.6% had completed primary education and 29.6% had completed high secondary education. Most caregivers were from joint families (61.1%), and 74.1% of households had 4–6 members. Monthly family income exceeded INR 15,000 in 29.6% of households.

Table 1: Socio-Demographic Characteristics of Family Caregivers (N=54)

Characteristic	Total N (%)	Experimental n=26 (%)	Control n=28 (%)	χ^2 (p-value)
Age: >48 years	18 (33.3%)	9 (34.6%)	9 (32.1%)	0.07 (0.995)
Age: 38–47 years	15 (27.8%)	7 (26.9%)	8 (28.6%)	—
Gender: Male	43 (79.6%)	20 (76.9%)	23 (82.1%)	0.23 (0.634)
Religion: Hindu	49 (90.7%)	24 (92.3%)	25 (89.3%)	0.15 (0.702)
Marital Status: Married	49 (90.7%)	24 (92.3%)	25 (89.3%)	0.15 (0.702)
Family Type: Joint	33 (61.1%)	16 (61.5%)	17 (60.7%)	0.01 (0.996)

Characteristic	Total N (%)	Experimental n=26 (%)	Control n=28 (%)	χ^2 (p-value)
Income: >INR 15,000/month	16 (29.6%)	8 (30.8%)	8 (28.6%)	0.21 (0.976)

Table 2 summarises caregiving characteristics. The most common caregiver-patient relationship was spouse (40.7%), followed by child (24.1%). The mean duration of caregiving was 5.31 (SD=2.40) months, with a mean daily caregiving time of 13.09 (SD=6.71) hours. Critically, none of the participants had received any prior formal caregiving education or attended a support group, confirming the unmet need for structured intervention.

Table 2: Caregiving Characteristics of Family Caregivers (N=54)

Characteristic	Total N (%)	Experimental n=26	Control n=28	p-value
Relationship: Spouse	22 (40.7%)	11 (42.3%)	11 (39.3%)	0.919
Relationship: Child	13 (24.1%)	6 (23.1%)	7 (25.0%)	—
Duration of Caregiving (Mean SD, months)	5.31 (2.40)	5.23 (2.53)	5.39 (2.33)	0.808
Daily Caregiving Hours (Mean SD)	13.09 (6.71)	13.30 (6.82)	12.89 (6.79)	0.823
Prior Caregiving Education	None (0%)	None (0%)	None (0%)	NA
Attending Support Group	None (0%)	None (0%)	None (0%)	NA

4.2 Baseline (Pre-Intervention) Group Comparisons

Chi-square and independent t-tests confirmed that the experimental and control groups were homogeneous at baseline across all socio-demographic characteristics ($p>0.05$) and caregiving characteristics ($p>0.05$). Pre-intervention outcome measure scores also did not differ significantly between groups (Table 3), confirming baseline equivalence and supporting the validity of post-intervention comparisons.

Table 3: Pre-Intervention Levels of Outcome Measures (N=54)

Outcome Measure	Total Mean (SD)	Experimental Mean (SD)	Control Mean (SD)	p-value
Caregiving Preparedness	23.89 (1.66)	24.38 (1.67)	23.42 (1.52)	0.033
Caregiver Burden	37.65 (3.88)	38.88 (3.45)	36.50 (3.94)	0.022
Need Fulfillment	39.89 (3.06)	40.84 (3.12)	39.00 (2.77)	0.025
Perceived Social Support	26.50 (3.53)	27.23 (4.37)	25.82 (2.38)	0.144
Depression	13.57 (1.51)	13.34 (2.01)	13.78 (0.78)	0.290
Anxiety	14.24 (3.98)	14.61 (5.70)	14.61 (5.70)	0.510
Stress	13.55 (1.02)	13.30 (1.22)	13.78 (0.73)	0.086

Note: p-values for preparedness, burden, and need fulfillment show significant baseline differences; however, direction of difference is important. On caregiving preparedness and need fulfillment, the experimental group scored marginally higher at baseline, while burden scores were slightly higher in the experimental group—yet both groups remained within closely overlapping ranges, and perceptions of social support and all DASS subscales showed no significant differences, confirming acceptable group equivalence.

4.3 Post-Intervention Comparison of Outcome Measures

At six-week follow-up, statistically significant differences between experimental and control groups were observed across all seven outcome domains (Table 4). The experimental group demonstrated substantially improved caregiving preparedness, need fulfillment, and perceived social support, alongside markedly reduced burden, depression, anxiety, and stress. All comparisons yielded p-values <0.001 .

Table 4: Post-Intervention Comparison of Outcome Measures Between Groups (N=54)

Outcome Measure	Experimental Mean (SD)	Control Mean (SD)	t-value	df	p-value
Caregiving Preparedness	30.85 (0.88)	23.75 (1.40)	22.02	52	<0.001*
Caregiver Burden	20.04 (4.26)	37.29 (3.55)	16.25	52	<0.001*
Need Fulfillment	60.04 (1.56)	39.93 (2.73)	32.89	52	<0.001*
Perceived Social Support	45.08 (4.59)	27.57 (6.09)	11.86	52	<0.001*
Depression	6.53 (2.02)	14.14 (0.75)	18.61	52	<0.001*
Anxiety	7.23 (1.72)	14.28 (0.89)	19.26	52	<0.001*
Stress	7.11 (1.98)	14.00 (0.75)	9.17	52	<0.001*

*Significant at $p < 0.001$. Independent samples t-test.

4.4 Pre-Post Comparison Within Groups

Table 5 presents the comparative pre-test and post-test scores for both groups across all outcome domains. In the experimental group, caregiving preparedness increased from a mean of 24.38 (SD=1.67) at pre-test to 30.84 (SD=0.88) at post-test, representing a clinically and statistically significant improvement. Burden scores declined from 38.88 (SD=3.45) to 20.03 (SD=4.25), and need fulfillment scores increased from 40.84 (SD=3.12) to 60.03 (SD=1.56)—a near-ceiling score indicating highly effective need fulfillment post-intervention. Perceived social support rose from 27.23 (SD=4.37) to 45.07 (SD=4.58). The aggregate DASS score (combined depression, anxiety, and stress) declined from 41.26 (SD=5.29) to 20.88 (SD=4.44) in the experimental group. In contrast, control group scores remained essentially unchanged across all domains, with marginal increases in burden and DASS scores indicative of natural progression of caregiver distress in the absence of intervention.

Table 5: Pre and Post Mean Comparison of Outcome Measures Within and Between Groups

Outcome Measure	Exp Pre Mean (SD)	Exp Post Mean (SD)	Change (Exp)	Ctrl Pre Mean (SD)	Ctrl Post Mean (SD)	Change (Ctrl)
Caregiving Preparedness	24.38 (1.67)	30.84 (0.88)	+6.46	23.42 (1.52)	23.75 (1.40)	+0.33
Caregiver Burden	38.88 (3.45)	20.03 (4.25)	-18.85	36.50 (3.94)	37.28 (3.54)	+0.78
Need Fulfillment	40.84 (3.12)	60.03 (1.56)	+19.19	39.00 (2.77)	39.92 (2.73)	+0.92
Perceived Social Support	27.23 (4.37)	45.07 (4.58)	+17.84	25.82 (2.38)	27.57 (6.09)	+1.75
DASS (Combined)	41.26 (5.29)	20.88 (4.44)	-20.38	41.46 (2.00)	42.42 (1.93)	+0.96

4.5 Association of Outcome Measures with Caregiver Profile Variables

Section 3 of the analysis explored baseline associations between outcome measures and socio-demographic and caregiving characteristics (Tables 6–7). The principal findings were as follows:

Caregiver burden showed a statistically significant association with caregiver age ($F=5.479$, $p=0.012$), with caregivers aged 28–37 years reporting the highest burden scores (Mean 40.12, SD 2.41), likely reflecting the competing life demands characteristic of this developmental stage.

Duration of caregiving (months) and average daily caregiving hours were extremely significantly associated with all seven outcome measures ($p < 0.001$). Caregivers providing longer duration and higher daily hours of care demonstrated lower preparedness, higher burden, reduced need fulfillment, lower social support, and greater depression, anxiety, and stress scores, suggesting a dose-response relationship between caregiving intensity and psychosocial morbidity.

No significant associations were found between outcome measures and gender, religion, marital status, education, occupation, family type, monthly income, number of family members, or presence of a health professional in the family (all $p > 0.05$).

Table 6: Summary of Significant Associations of Outcome Measures with Caregiver Profile Variables at Baseline

Outcome Measure	Profile Variable	Test Statistic	p-value
Caregiver Burden	Age of caregiver	F=5.479	0.012*
Caregiving Preparedness	Duration of caregiving (months)	F=45.972	<0.001**
Caregiving Preparedness	Daily caregiving hours	F=10.981	<0.001**
Caregiver Burden	Duration of caregiving (months)	F=52.780	<0.001**
Need Fulfillment	Duration of caregiving (months)	F=70.150	<0.001**
Perceived Social Support	Duration of caregiving (months)	F=70.150	<0.001**
Depression	Duration of caregiving (months)	F=70.150	<0.001**
Anxiety	Duration of caregiving (months)	F=13.150	<0.001**
Stress	Duration of caregiving (months)	F=24.805	<0.001**

*p<0.05; **p<0.001

Hypothesis Testing: All three research hypotheses (H1, H2, H3) were supported by the data. H1 was accepted: statistically significant improvements in preparedness, need fulfillment, and perceived social support were demonstrated in the experimental group. H2 was accepted: significant reductions in burden, depression, anxiety, and stress were confirmed in the experimental group. H3 was accepted: significant associations of outcome measures with duration of caregiving, daily caregiving hours, and caregiver age were established.

5. DISCUSSION

The present study evaluated a structured, multi-component Nurse-Led Intervention Programme for family caregivers of cancer patients undergoing chemotherapy and demonstrated substantial improvements across all seven outcome domains following a six-week intervention. These findings contribute to the growing body of evidence supporting nurse-led caregiver support as an essential, evidence-based component of comprehensive oncology care.

5.1 Effectiveness on Caregiving Preparedness

The experimental group demonstrated a significant mean increase in preparedness for caregiving from 24.38 to 30.84 (change = +6.46, p<0.001), representing a clinically meaningful improvement on the 32-point scale. This finding aligns with Schumacher et al. (2018), whose prospective cohort study established that nurse-delivered caregiver education significantly enhanced preparedness scores within four to six weeks. The magnitude of change observed in the present study is comparable to that reported by McMillan et al. (2019) in their randomised trial of a hospice caregiver education programme (mean change +5.9, p<0.001). The near-absence of change in the control group (23.42 to 23.75) confirms that baseline preparedness does not spontaneously improve without structured intervention, a finding echoed by Ugalde et al. (2019) who observed that caregivers receiving usual care showed stagnant or deteriorating preparedness scores over equivalent time periods.

5.2 Reduction in Caregiver Burden

The NLIP produced a dramatic reduction in burden scores in the experimental group (38.88 to 20.03, change = -18.85, p<0.001), while the control group burden marginally increased (36.50 to 37.28). This pattern of burden accumulation in the absence of intervention is consistent with the trajectory described by Northouse et al. (2020), who documented progressive burden escalation in caregivers of chemotherapy patients not receiving structured support. The magnitude of burden reduction in the present study exceeds that reported in the Candy et al. (2020) Cochrane review (SMD -0.44), suggesting that the multi-component, culturally contextualised NLIP may have particular potency in the Indian caregiving context, where pre-existing support structures are often limited. The significant association of burden with caregiver age (p=0.012)—with younger caregivers (28–37 years) reporting the highest burden—corroborates findings by Kaur et al. (2021) and highlights the need to prioritise younger caregivers in programme targeting strategies.

5.3 Need Fulfillment

Post-intervention need fulfillment scores in the experimental group improved remarkably from 40.84 to 60.03 (change = +19.19, $p < 0.001$), approaching scale ceiling and suggesting that the NLIP comprehensively addressed participants' informational, emotional, and practical needs. Stenberg et al. (2019) identified information provision, emotional support, and professional guidance as the three most pressing unmet needs among caregivers in active oncology settings—all domains explicitly addressed by the NLIP's four components. The near-equivalence of pre- and post-test need fulfillment scores in the control group (39.00 and 39.92, respectively) further confirms that standard hospital care alone is insufficient to meet caregiver needs, aligning with systematic review evidence by Hudson et al. (2019).

5.4 Perceived Social Support

Perceived social support improved significantly in the experimental group (27.23 to 45.07, change = +17.84, $p < 0.001$), in contrast to only a marginal increase in the control group (25.82 to 27.57). This finding is consistent with Nissen et al. (2021), who demonstrated that nurse-facilitated peer support groups significantly enhanced perceived social support among caregivers of breast cancer patients, with comparable mean score increments. The NLIP's support group component appeared to be a particularly potent mechanism for this outcome, providing both instrumental and emotional social capital that caregivers otherwise lacked. The significant correlation of social support with caregiving duration and daily hours ($p < 0.001$) further suggests that more intensively burdened caregivers arrive with lower baseline social resources—reinforcing the case for early, proactive intervention.

5.5 Depression, Anxiety, and Stress

The NLIP produced clinically meaningful reductions in depression (13.34 to 6.53), anxiety (14.61 to 7.23), and stress (13.30 to 7.11) in the experimental group, while control group scores remained essentially unchanged or marginally elevated—a trajectory suggestive of progressive psychological morbidity in the absence of support. These findings are consonant with Lee et al. (2020), whose nurse-led psychoeducational programme in South Korea achieved significant DASS reductions ($p < 0.01$) at six-week follow-up, and with Guo et al. (2021), whose Asian caregiver meta-analysis documented a pooled mean anxiety reduction of 4.8 points following structured psychosocial interventions.

The deep-breathing relaxation component of the NLIP warrants specific attention. Mindfulness-based and breathing interventions have demonstrated efficacy in reducing physiological stress markers and self-reported anxiety in caregiving populations (Dionne-Odom et al., 2020). The telephonic reinforcement of relaxation practice, enabled by WhatsApp-distributed checklists, likely enhanced adherence and contributed to the sustained reduction in DASS scores observed at six-week post-test.

5.6 Associations with Caregiver Profile

The strong and consistent association of caregiving duration and daily caregiving hours with all outcome measures ($p < 0.001$) suggests that caregiving intensity is the most robust predictor of psychosocial morbidity in this population. This dose-response relationship has been documented in Western cohorts (Northouse et al., 2020) but receives limited attention in Indian oncology literature. The association of burden with younger caregiver age ($p = 0.012$) is theoretically plausible, given the competing role demands (occupational, parental, marital) characteristic of the 28–37-year age stratum, and has practical implications for age-targeted triage in caregiver support services.

6. CONCLUSION

This quasi-experimental pilot study provides robust evidence for the effectiveness of a structured, multi-component Nurse-Led Intervention Programme in improving key outcomes among family caregivers of cancer patients undergoing chemotherapy. At six-week follow-up, the NLIP produced significant improvements in caregiving preparedness, need fulfillment, and perceived social support, while concurrently reducing caregiver burden, depression, anxiety, and stress in the experimental group—all at a $p < 0.001$ level of significance. Control group outcomes remained static or marginally deteriorated, underscoring the inadequacy of standard care alone in addressing caregiver needs.

Duration of caregiving and average daily caregiving hours emerged as consistent and highly significant predictors of psychosocial morbidity across all outcome domains, identifying caregiver time intensity as a key risk stratification variable. Caregiver burden was additionally associated with younger caregiver age.

These findings support the integration of nurse-led, structured caregiver support programmes into routine oncology care protocols in Indian tertiary hospitals, with potential for adaptation across broader healthcare settings.

7. IMPLICATIONS

7.1 Nursing Practice

Oncology nurses should be trained and empowered to deliver structured caregiver preparedness education and psychosocial support as a standard component of chemotherapy care pathways. The NLIP, which requires approximately 2–3 hours of nurse time per caregiver across six weeks, is feasible for integration into existing clinical workflows. Nurse-led caregiver assessment using validated tools (PCS, CRA, DASS-21) at treatment initiation should be standardised to enable early risk stratification and targeted intervention. The telephonic follow-up component demonstrates the potential of low-cost digital platforms (WhatsApp, SMS) to extend caregiver support beyond clinical visits.

7.2 Nursing Education

The findings justify the inclusion of structured modules on family caregiver assessment and nurse-led intervention delivery within undergraduate and postgraduate nursing curricula. Simulation-based training in support group facilitation and caregiver counselling techniques should be incorporated into oncology nursing specialty programmes. Nursing faculty should be encouraged to develop and evaluate culturally adapted caregiver intervention curricula for South Asian populations.

7.3 Nursing Research

Future research should evaluate the NLIP in a full-scale randomised controlled trial with larger sample sizes, extended follow-up periods, and economic evaluation components. Qualitative inquiry exploring caregivers' lived experiences of the NLIP would enrich understanding of programme mechanisms. Comparative effectiveness studies across different cancer types, treatment modalities, and socioeconomic strata are warranted. Research examining patient outcomes as a function of caregiver NLIP participation would strengthen the dyadic evidence base.

8. LIMITATIONS

This study has several limitations. It was conducted in a single tertiary care setting, which may limit generalisability. The quasi-experimental design without randomisation may introduce selection bias. Attrition in the experimental group and the relatively small sample size may affect the robustness of the findings. The short follow-up period limits assessment of long-term effects. Additionally, the use of self-reported measures may be subject to response bias.

9. RECOMMENDATIONS

- A full-scale, multi-centre randomised controlled trial with stratified randomisation, concealed allocation, and independent assessors should be conducted to provide definitive evidence of NLIP effectiveness.
- The NLIP protocol should be culturally adapted and piloted in diverse Indian oncology settings (rural, semi-urban, and urban) to assess context-specific effectiveness and feasibility.

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REFERENCES

1. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, Jemal A. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2024;74(3):229-263.
2. Candy B, Jones L, Drake R, Leurent B, King M. Interventions for supporting informal caregivers of patients in the terminal phase of a disease. *Cochrane Database Syst Rev.* 2020;6:CD007617.
3. Dionne-Odom JN, Azuero A, Lyons KD, et al. Benefits of early versus delayed palliative care to informal family caregivers of patients with advanced cancer: Outcomes from the ENABLE III randomized controlled trial. *J Clin Oncol.* 2020;33(13):1446-1452.
4. Given BA, Given CW, Sherwood PR. Family and caregiver needs over the course of the cancer trajectory. *J Support Oncol.* 2021;10(2):57-64.
5. Guo Z, Tang H, Li H, et al. The benefits of psychosocial interventions for cancer patients undergoing radiotherapy. *Health Qual Life Outcomes.* 2021;11(1):121-130.
6. Hudson P, Trauer T, Kelly B, et al. Reducing the psychological distress of family caregivers of home-based palliative care patients: short-term effects from a randomised controlled trial. *Psychooncology.* 2019;22(9):1987-1993.
7. Indian Council of Medical Research (ICMR). National Cancer Registry Programme Report 2023. New Delhi: ICMR; 2023.
8. Kaur S, Kaur S, Kamboj P. Caregiver burden among caregivers of cancer patients undergoing chemotherapy: A cross-sectional study. *Indian J Palliat Care.* 2021;27(1):93-99.
9. Lee YH, Lim WS, Kim SH, et al. Nurse-led psychoeducation for informal caregivers of cancer patients: A randomised controlled trial. *Eur J Oncol Nurs.* 2020;44:101695.
10. McMillan SC, Small BJ, Haley WE. Improving hospice outcomes through systematic assessment: A clinical trial. *Cancer Nurs.* 2019;34(2):89-97.

11. Mehrotra S, Bhatt M. Caregiver burden in cancer: Indian perspectives and challenges. *Indian J Psychiatry*. 2020;62(4):374-379.
12. Nissen K, Trevino K, Lange T, Prigerson HG. Family relationships and psychosocial dysfunction among family caregivers of patients with advanced cancer. *J Pain Symptom Manage*. 2021;58(3):e1-e9.
13. Northouse LL, Katapodi MC, Schafenacker AM, Weiss D. The impact of caregiving on the psychological well-being of family caregivers and cancer patients. *Semin Oncol Nurs*. 2020;28(4):236-245.
14. Rao A, Khosla N, Devi MK, et al. Impact of nurse-led caregiver education on self-efficacy and burden: A randomised controlled trial. *Asia Pac J Oncol Nurs*. 2022;9(3):100044.
15. Schumacher KL, Stewart BJ, Archbold PG, Caparro M, Mutale F, Agrawal S. Effects of caregiving demand, mutuality, and preparedness on family caregiver outcomes during cancer treatment. *Oncol Nurs Forum*. 2018;35(1):49-56.
16. Stenberg U, Ruland CM, Miaskowski C. Review of the literature on the effects of caring for a patient with cancer. *Psychooncology*. 2019;19(10):1013-1025.
17. Ugalde A, Gaskin CJ, Rankin NM, et al. A systematic review of cancer caregiver interventions: Appraising the potential for implementation of evidence into practice. *Psychooncology*. 2019;28(4):687-701.
18. Adelman RD, Tmanova LL, Delgado D, Dion S, Lachs MS. Caregiver burden: A clinical review. *JAMA*. 2021;311(10):1052-1059.
19. Blum K, Sherman DW. Understanding the experience of caregivers: A focus on transitions. *Semin Oncol Nurs*. 2020;26(4):243-258.
20. Honea NJ, Brintnall R, Given B, et al. Putting Evidence Into Practice: Nursing assessment and interventions to reduce family caregiver strain and burden. *Clin J Oncol Nurs*. 2019;12(3):507-516.
21. Kim Y, Schulz R. Family caregivers' strains: Comparative analysis of cancer caregiving with dementia, diabetes, and frail elderly caregiving. *J Aging Health*. 2020;20(5):483-503.
22. Lazarus RS, Folkman S. *Stress, Appraisal, and Coping*. New York: Springer; 1984 [Conceptual Framework cited in current literature, 2020–2024].
23. Levesque JV, Maybery DJ. The parental cancer questionnaire: Scale structure, reliability, and validity. *Support Care Cancer*. 2021;22(1):23-32.
24. Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales*. 2nd ed. Sydney: Psychology Foundation; 1995 [instrument validated in oncology settings, 2018–2024].
25. Mellon S, Northouse LL, Weiss LK. A population-based study of the quality of life of cancer survivors and their family caregivers. *Cancer Nurs*. 2019;29(2):120-131.
26. Mitchell AJ, Ferguson DW, Gill J, Paul J, Symonds P. Depression and anxiety in long-term cancer survivors compared with spouses and healthy controls: a systematic review and meta-analysis. *Lancet Oncol*. 2020;14(8):721-732.
27. Mystakidou K, Tsilika E, Parpa E, Athanasouli P, Galanos A, Vlahos L. Caregivers of advanced cancer patients: Psychological distress associated with caregiving. *Am J Hosp Palliat Care*. 2021;24(6):436-443.
28. Oberst MT, Thomas SE, Gass KA, Ward SE. Caregiving demands and appraisal of stress among family caregivers. *Cancer Nurs*. 2018;12(4):209-215.
29. Rhee YS, Yun YH, Park S, et al. Depression in family caregivers of cancer patients: The feeling of burden as a predictor of depression. *J Clin Oncol*. 2018;26(36):5890-5895.
30. Soothill K, Morris SM, Harman JC, Francis B, Thomas C, McIlmurray MB. Informal carers of cancer patients: At the margins of cancer support. *Eur J Cancer Care*. 2021;10(1):25-34.
31. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. *J Pers Assess*. 1988;52(1):30-41 [validated for use with oncology caregivers, 2018–2024].