STUDY PROTOCOL

Nurse-Led Telehealth Oncology Clinic on 'Home Management During Chemotherapy' for Gastrointestinal Cancer Patients: Study Protocol of a Mixed Method Study

Sarita Ahwal[1*], Kanika Rai[2], Ankur Jindal[3], Puja Sahai[4]

[1]Chitkara School of Health Sciences, Chitkara University, Punjab; Institute of Liver and Biliary Sciences, New Delhi, India
[2]Centre for Evidence Based Practice in Health Care, Chitkara School of Health Sciences, Chitkara University, Punjab, India
[3,4]Institute of Liver and Biliary Sciences (ILBS), New Delhi, India

DOI: 10.55489/njcm.150720243991

ABSTRACT

Introduction: Telehealth is increasingly being used for symptom management among cancer patients on chemotherapy. Objective of the study is to develop Nurse-led Tele-health Oncology Clinic for GI cancer patients regarding 'Home Management during Chemotherapy'.

Methods: The study will follow sequential explanatory mixed method design where during quantitative phase, using RCT (CTRI/2024/01/062028), GI cancer patients of age 18-65 years and undergoing 2nd or 3rd chemotherapy cycle will be randomised after obtaining consent to experimental (EG) & control (CG) groups. Ethical Clearance is already obtained. EG will be followed through Nurse-led Clinic which includes multiple virtual educational & counselling sessions, e-booklet on side effects management, PMRT, Support groups & telephonic follow ups. Effectiveness will be measured in terms of Quality of life, severity of side effects and Anxiety using FACT-G, CTCAE and DASS respectively. In qualitative phase, using extreme case sampling, in-depth interviews from consented participants will be conducted to explore experiences towards intervention.

Analysis: Analysis of quantitative data will use descriptive and inferential statistics. This follows thematic analysis and integration of data.

Conclusion: The study protocol will provide guidance to optimize utility of tele-medicine technology to improve healthcare outcomes especially for the GI cancer patients.

Key words: Nurse-led clinic, telehealth clinic, oncology clinic, Gastrointestinal cancer patients, chemotherapy, self-management, PMRT, Quality of life, severity of side effects

ARTICLE INFO

Financial Support: None declared
Conflict of Interest: None declared
Received: 29-03-2024, **Accepted**: 09-05-2024, **Published**: 01-07-2024
***Correspondence:** Ms. Sarita Ahwal (Email: saritanadiya222@gmail.com)

How to cite this article: Ahwal S, Rai K, Jindal A, Sahai P. Nurse-Led Telehealth Oncology Clinic on 'Home Management During Chemotherapy' for Gastrointestinal Cancer Patients: Study Protocol of A Mixed Method Study. Natl J Community Med 2024;15(7):572-580. DOI: 10.55489/njcm.150720243991

www.njcmindia.com | pISSN: 0976-3325 | eISSN: 2229-6816 | Published by Medsci Publications

INTRODUCTION

Gastrointestinal (GI) cancer cases are rising day by day representing over one-quarter (26%) of the global cancer incidence and over one-third (35%) of all cancer-related deaths.[1] As per the global burden of cancer report across India from 1990-2016, the number of new cases and deaths due to cancer doubled in India. Gastrointestinal cancers with high incidence in India included stomach, colorectal, oesophageal, liver, gallbladder, and biliary tract cancers.[2,3,4]

Chemotherapy is the treatment of choice for cancer patients but is associated with many side effects. The most common chemotherapy-induced side effects are nausea and vomiting, fatigue, decreased appetite, changes in taste, hair loss, dry mouth, and constipation. Other prominent ones include diarrhoea, numbness or tingling in hands and/or feet, skin changes (e.g. dry skin, redness, itch), fever, oral mucositis, flu-like symptoms, allergic reaction, memory problems, decreased kidney function, hearing loss and/or tinnitus.[5]

The severity of such side effects may vary among patients and in some they can even become life-threatening. Cancer patients have been reported to have the side effects when they are home.[6] In many cancer patients, the continuity of chemotherapy is negatively influenced by the side effects as they have been negatively associated with the quality of life among cancer patients.[7] Therefore, it is essential to identify the side effects in time and provide possible management at the earliest possible.[8]

Quality of life (QOL) is considered important determinant for making treatment related decisions.[9] Quality of life is documented to be more adversely affected in early chemotherapy cycles (cycle 2-5) as compared to the subsequent cycles (i.e., cycle 5 to 6).[10] Measures focusing on QoL of patient have been associated with better as well as patient outcomes and patient satisfaction.[11]

Cancer patients have also reported stress related to the diagnosis and treatment. Chemotherapy can cause physical and mental impairment among cancer patients. A high prevalence of anxiety and depression has been documented among cancer patients undergoing chemotherapy. Anxiety can increase the severity of physical and psychological side effects and can decrease quality of life among cancer patients.[12]

Progressive Muscle Relaxation Therapy (PMRT) has been documented to be effective in reducing anxiety among cancer patients. In addition to its effect on anxiety among cancer patients, PMRT may be beneficial to alleviate chemotherapy related side-effects as well. Studies have recommended PMRT therapy for cancer patients receiving chemotherapy to decrease chemotherapy related nausea/vomiting. However, more clinical trials need to be conducted on patients suffering with different types of cancer before PMRT is made as an integral part of the standard cancer treatment as a supportive therapy.[13,14]

Various factors related to patients' dissatisfaction have been identified such as lack of information, communication gaps, continuity of care, long waiting hours, duration of consultations, availability and accessibility of the healthcare professionals. Throughout treatment, symptom management is a crucial component of patient care.[15] Providing access to comprehensive and timely information is key to treatment adherence among patients receiving chemotherapy. Furthermore, adequate information is helpful in reducing anxiety and improving the QoL among patients.[16]

It has been demonstrated that nurse-led therapies greatly enhance cancer patients' physical and mental wellbeing. The impact of multifaceted health interventions on quality of life is strengthened. Henceforth, Nurse led clinics being multidimensional in nature may prove to be an effective way to provide holistic care to the cancer patients receiving chemotherapy. Nurse-led clinics when made an integral part of patient care may prove to be cost effective model of care for cancer patients. They might be helpful in reducing the severity of chemotherapy related side effects with their easy access and availability of nursing expert for managing the cancer patients.[15,16,17,20]

The utilization of telehealth has grown exponentially although more after COVID-19.[21] However, determining if telehealth is a successful treatment strategy for cancer patients which is considered to be one among the high risk health conditions is crucial.[22] Using telecommunication technology to deliver the care through nurse-led Tele-health oncology clinic further supports the idea to deploy digital health across the continuum of care as recommended in the national health policy 2017 of India.[23]

The aim of the present study is to evaluate the impact of Nurse-led Telehealth Oncology Clinic on 'Home Management during Chemotherapy' among GI Cancer patients.

METHODOLOGY

The protocol follows Recommendations for Interventional Trials (SPIRIT) 2013 for study protocol.[24] The protocol is registered under Clinical Trial Registry-India (CTRI) with registration number: CTRI/2024/01/062028.

Ethical consideration: Written informed Consent will be obtained before enrolment in the preferred language. The confidentiality will be maintained throughout the study. The study doesn't include any risk or harm to the participants. Both the groups will continue with their standard routine care. The control group participants will also be provided the intervention on completion of data collection. Ethical permissions from both the University (EC/NEW/

INST/2023/531/188) and the data collection site (IEC/2022/97/MA02) have been obtained.

Study design: The study will adopt a sequential explanatory mixed method design where the study is to be conducted in two phases, quantitative followed by qualitative phase. Randomised control group design for quantitative phase and narrative analysis design for qualitative phase will be used (Figure 1).

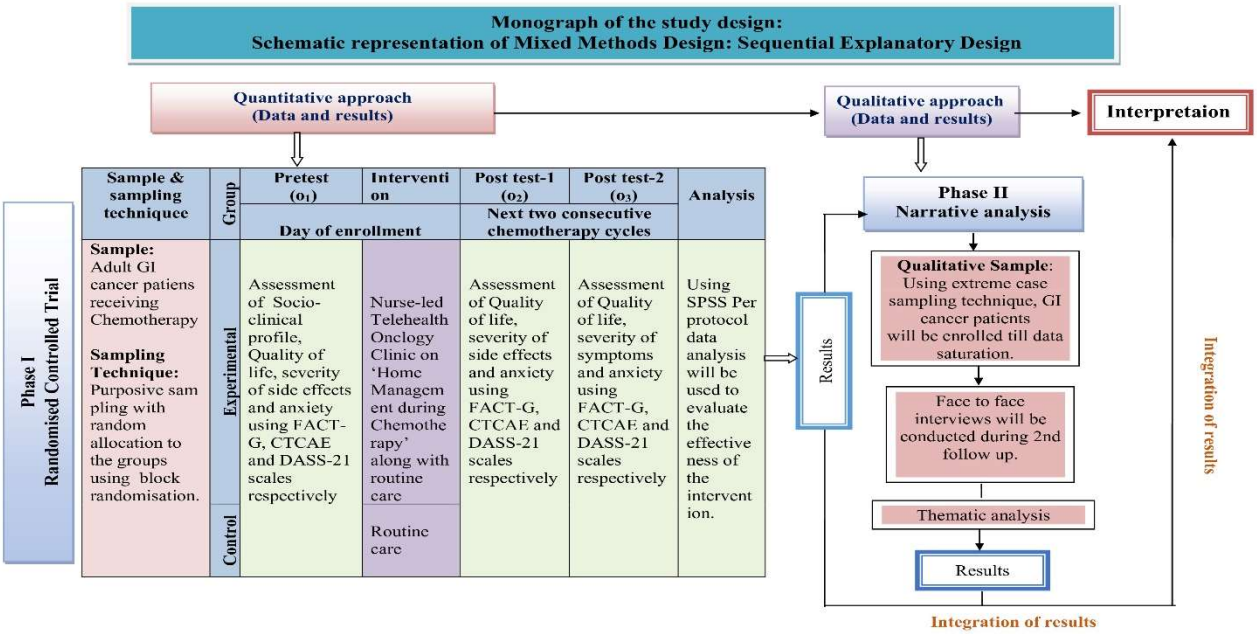

Figure 1: Monogram of the study design

Figure 2: The components of Nurse-Led Telehealth Oncology Clinic

Study arms: Experimental group will attend Nurse-led telehealth Oncology Clinic on 'Home Management during Chemotherapy through virtual psychoeducational sessions and follow-ups. Patient in the control group will receive routine care as per the hospital protocol.

Description of the intervention: Intervention is designed in the form of Nurse led tele-health Oncology Clinic and has been validated by Nine experts in the field of Medical Surgical Nursing, Oncology, Psychiatry and Psychology. This comprises of a virtual clinic managed independently by the Nurse researcher using telemedicine technology to provide evidence based psychoeducational nursing intervention (Figure 2) to the GI Cancer patients receiving chemotherapy.

Routine care: This will include education provided by the treating physician and the Oncology Nurse re-

garding the home management of chemotherapy related side effects in the form of verbal instructions and discharge sheet provided at the time of discharge. This doesn't include any telephonic contacts with the patients for follow up after they get discharged. The control group will receive only the routine care whereas the experimental group will receive Oncology tele-health Clinic as intervention in addition to the routine care.

Intervention nurses: Principal Investigator (PI) is a Ph.D. (Nursing) Scholar and has undertaken one month training from a clinical psychologist to be a certified PMRT trainer. The PI is responsible to implement the intervention and to collect the data.

Study sites: The enrolment of the study participants will be done through Oncology Day care centre at a superspecialty hospital in New Delhi. The data collection for both the experimental and control groups will be done during their visit to Oncology Day care for chemotherapy cycles. The setting is not currently running any nurse-led clinic for cancer patients receiving chemotherapy.

Eligibility criteria: All gastrointestinal cancer patients receiving chemotherapy at Onco day care and fulfilling the inclusion and exclusion criteria (Table 1) are eligible to take part in the study.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Quantitative phase:	
Patients diagnosed with GI cancer:	**GI cancer patients with:**
• between 18-60 years of age	• visual or auditory impairments.
• are receiving 2nd or 3rd chemotherapy cycles	• high care needs with Karnofsky Score <40.
• will be scheduled to receive at least two consecutive chemotherapy cycles.	• diagnosed psychiatric disease
	• on palliative chemotherapy and radiation therapy.
• can read and write Hindi or English.	• unwilling to participate in the study
• can be contacted through smart phones.	• are lost to follow up for any reason including death, becomes critically ill, require immediate hospitalization.
	• who fail to attend the Nurse-led tele-health Oncology Clinic regularly
Qualitative phase:	
• GI cancer patients who participated in the quantitative phase of the study.	• Gastrointestinal cancer patients who are unwilling to participate

Sample size

Quantitative phase: The sample size is statistically calculated using power analysis formula. Hence, assuming α=5% and power=80% and 2 follow ups, we need to enroll 100 cases i.e. 50 in each experimental al and control groups. Further, considering 10% drop outs, 55 is the final sample to be taken in each group.

Qualitative phase: The number of participants to be interviewed is based on data saturation. Once data saturation is observed, 2-3 more participants will be interviewed to confirm data saturation.

Screening and recruitment of participants: During the quantitative phase, using convenience sampling technique GI cancer patients will be first contacted during their visit to Oncology Day care for chemotherapy and screened for their eligibility to participate in the study based on inclusion and exclusion criteria. Participant information sheet will be discussed and written informed consents will be obtained from the study participants for their recruitment in the study and then they will be randomised to either the experimental or control groups. The consort diagram is shown in figure 3.

For qualitative phase, out of the participants of quantitative phase, using convenience sampling technique, the participants from the experimental group will be enrolled for the qualitative phase of the study during their 2nd follow up for chemotherapy based on their consent to participate.

Randomisation: During the quantitative phase, using 1:1 permuted block computerised randomisation technique of block size six, GI cancer patients will be randomly allocated to the experimental and control groups. The experimental group will receive treatment in the form of Nurse-led Tele-health Oncology Clinic in adjunct to the routine care whereas the control group will receive standard routine care as per the hospital protocol. The patients will be followed up telephonically for two consecutive chemotherapy cycles (Figure 4). Further, blinding is not possible in this study.

Study piloting: The intervention and the tools were pilot tested from June-July, 2023 with 26 GI cancer patients. The study was found to be feasible to conduct.

Data collection tools and technique: The tools have been selected after extensive review of literatures and expert's guidance. Tools for quantitative phase comprised of a structured questionnaire, Functional Assessment of Cancer Therapy - General (FACT-G).[25] Common Terminology Criteria for Adverse Events (CTCAE) Version-5[26] and Depression anxiety stress scale (DASS).[27] to assess socio-clinical profile of the patient, Quality of Life, severity of

chemotherapy related side effects and Anxiety respectively. All tools used in the study are available on public domain except the Hindi version of FACT-G for which required approval and licensing has been obtained. Structured face to face individual interview technique using Google form will be used to collect and record the data.

Karnofsky Performance Status (KPS)[28] scale developed by David A. Karnofsky in 1949 will be used to screen the patients at the time of enrolment. The KPS is an 11-point rating scale which ranges from normal functioning (100) to dead (0) in ten-point increments. A higher score means the patient is better able to carry out daily activities. In the present study, cancer patients with KPS score <30 will be excluded where a patient is Disabled, requires special care and hospitalization.

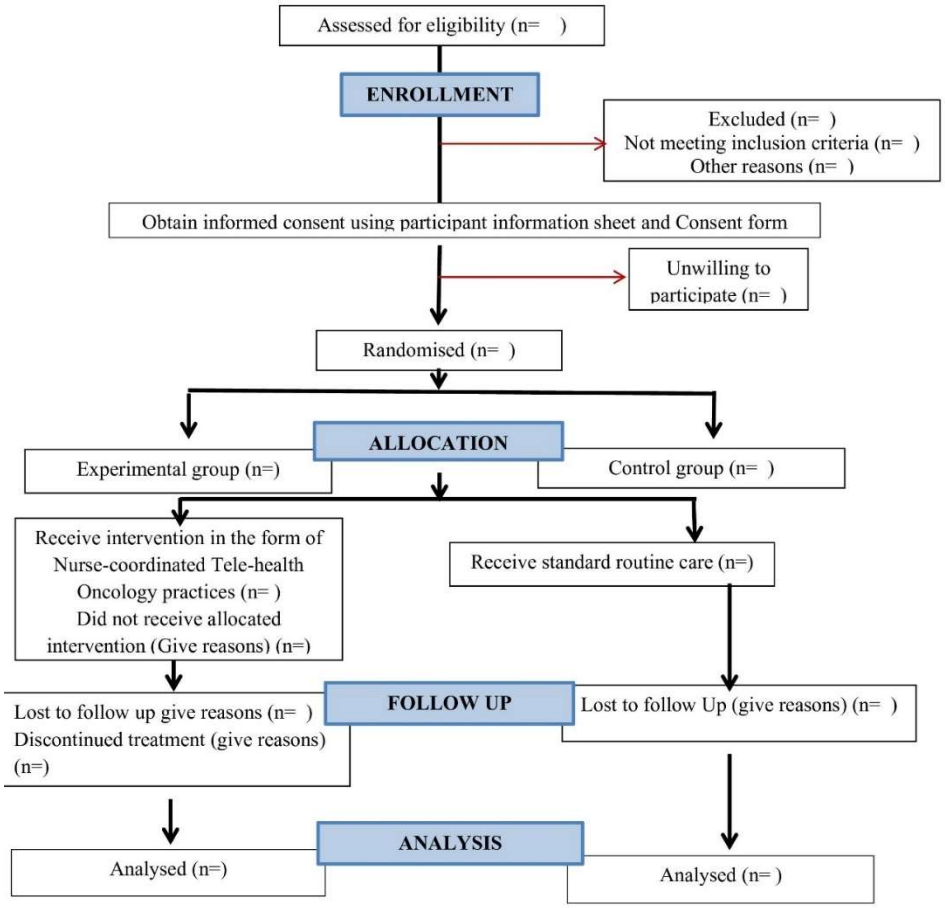

Figure 3: CONSORT flow chart

R: 1:1 Permuted Block randomisation
E: Experimental group: GI cancer patients receiving 2nd or 3rd chemotherapy cycle
C: Control group: GI cancer patients receiving 2nd or 3rd chemotherapy cycle
O1: Pretest on the day of enrolment in the study: Assessment of Socio-clinical profile, quality of life, Severity of side effects and Anxiety
X: Nurse-led telehealth Oncology Clinic on 'Home Management during Chemotherapy'
O2: Post-test on the day of first follow up chemotherapy cycle after enrolment: Assessment of quality of life, Severity of the chemotherapy related side effects and Anxiety
O3: Post-test before on the day of second follow up chemotherapy cycle after enrolment: Assessment of quality of life, Severity of the chemotherapy related side effects and Anxiety

Figure 4: RCT with two follow ups

A structured 10-item questionnaire is developed by the researcher for assessment of socio-demographic variables which include Age, Gender, marital status, type of family, Cohabitating with, History of any substance abuse, educational status, occupation status, monthly income, socio-economic status (SES). SES will be measured using Modified Kuppuswamy Socioeconomic Status Scale[29] which is one of the widely used scales for measuring socioeconomic status originally developed in 1976.[30] It takes education status and occupation of the head of the family and total monthly family income into account. It is available on public domain.

An eight-item structured questionnaire developed by the researcher was used to elicit information on clinical variables including diagnosis, stage/grading of cancer, duration of illness, current chemotherapy cycle, last chemotherapy cycle received, treatment regimen, previous treatment of cancer, presence of comorbidity, any medications used, family history of chemotherapy received, vital signs, and biochemical profile.

Quality of life of GI cancer patients will be assessed using Functional Assessment of Cancer Therapy - General (FACT-G).[25] FACT-G is a patient reported outcome measure five-point rating scale (0 = Not at all; 1 = A little bit; 2 = Somewhat; 3 = Quite a bit; and 4 = Very much). It is comprised of four subscales: physical well-being (PWB; 7-items, score range 0-28), social/family well-being (SWB; 7-items, score range 0-28), emotional well-being (EWB; 6-items, score range 0-24), and functional well-being (FWB; 7-items, score range 0-28). Scores are calculated for each domain and in total as well where higher subscale and total scores indicate better QoL. The tool is available in both English and Hindi languages.

The chemotherapy related side effects including fatigue, anorexia, nausea, vomiting, diarrhea, mocositis, fever, abdominal pain, Palmar-Plantar erythrodysesthesia (hand-foot syndrome) and Biochemical parameters (Bilirubin, AST, ALT, ALP, GGT, INR, albumin and Creatinine) among GI cancer patients will be assessed by using Common Terminology Criteria for Adverse Events (CTCAE) Version-5.[26] This tool will be filled by the principal investigator in this study. Grades are used to categorise the severity of adverse events as Grades 1 through 5 with specific clinical explanations of severity for each AE.

A set of three self-report scales known as the Depression, Anxiety and Stress Scale - 21 Items (DASS-21)[27] is used to measure the emotional states of depression, anxiety, and stress. The three DASS-21 scales each have seven items that are broken down into subscales with related material. In the present study, the subscale related to assessment of anxiety will be used which contains seven items. The anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. Scores on the DASS-21 will need to be multiplied by 2 to calculate the final score. The anxiety scores are then categorised into four severity levels as normal (0-7), mild (8-9), moderate (10-14), Severe (15-19) and Extremely Severe (20 and above). Translated versions of the tool are available in English and Hindi as well.

Interview guide: A semi structured interview guide is developed by the researcher to collect data for qualitative phase of the study as shown in table 2.

I. What problems did you face in performing activities of daily living after being diagnosed with Cancer?

II. What are the physical symptoms you experience?

III. How do you feel about caring yourself after being diagnosed with cancer?

IV. How is your relationship between you and your family members, relatives and with other people in your community?

V. What are the problems you have faced in establishing or maintaining the relationships with others after being diagnosed with cancer?

VI. How do you feel after the participating in the Nurse led tele-health Oncology clinic?

Information Sheets: The researcher developed an Investigator Log Book and Patient Diary to document data by the researcher and the patients regarding practicing of Progressive muscle relaxation therapy till the patient come for the follow up.

Validity and Reliability of the tools: The content validity of the tools was established by nine experts in the fields of medical surgical Nursing, Gastroenterology and Oncology. The reliability testing was performed using Cronbach's alpha for internal consistency reliability for FACT-G, CTCAE version-5 and DASS whereas Inter-rater reliability was employed to assess the reliability of Checklist on skill of performing PMRT. All the tools were found to have adequate validity (CVI > 0.9) and reliablity (r>0.8).

Language validity: All the tools have been validated by the experts in English and Hindi languages where in the tools were translated from English to Hindi language and vice-versa.

Rigor of the qualitative data: The rigor of the qualitative data will be established using various strategies as described in table 2.

Data analysis: Both descriptive and inferential statistical analysis will be carried out using the SPSS, version 29 and STATA (version 18). The data will be checked for normality and appropriate tests parametric or nonparametric will be used. The statistical significance will be fixed as conventional value of 0.05 (two-tailed). The continuous data will be presented as mean and standard deviation whereas categorical data will be presented as frequencies with percentages.

Table 2: Key strategies to be adapted to establish rigor of the qualitative data

Rigor Criteria	Original Strategies	Planned Strategies to be applied to achieve rigor
Credibility	• Prolonged and varied engagement with each setting	• Interviewers will spend an average of 2–4 weeks to engage with participants.
	• Interviewing process and techniques	• Interview protocol will be tested using 1–2 pilot interviews.
	• Establishing investigators' authority	• The investigators have the required knowledge and research skills to perform her roles.
	• Collection of referential adequacy materials	• Interviewer will keep all the field notes safe for analysis and storage.
	• Peer debriefing	• The investigator will have regular debriefing sessions with key members.
Dependability	• Rich description of the study methods	• The investigator will prepare detailed drafts of the study protocol throughout the study.
	• Establishing an audit trail	• A detailed track record of the data collection process will be developed.
Confirmability	• Reflexivity	• We will examine own beliefs, judgments and practices that may influence the results and keep them aside. Also, a monthly investigator meeting will be kept to discuss the same.
	• Triangulation	• We will apply triangulation techniques using both quantitaive and qualitative approaches.
Transferability	• Purposeful sampling to form a nominated sample	• Extreme case sampling will be employed.
	• Data saturation	• We will quantify operational and theoretical data saturation.

Data analysis: Both descriptive and inferential statistical analysis will be carried out using the SPSS, version 29 and STATA (version 18). The data will be checked for normality and appropriate tests parametric or nonparametric will be used. The statistical significance will be fixed as conventional value of 0.05 (two-tailed). The continuous data will be presented as mean and standard deviation whereas categorical data will be presented as frequencies with percentages.

Both the groups will be compared in terms of variables related to socio-demographic & clinical profile, quality of life, anxiety and severity of side effects to establish homogeneity among the groups at baseline. Wherever applicable Fisher's exact or Chi square will be used to compare the categorical data whereas independent t test will be computed for continuous data. Any differences found will then be statistically adjusted.

To evaluate the effectiveness of the intervention, pretest total as well as subscale scores of Quality of life and anxiety will be compared with the respective post-test 1 and 2 scores using Repeated Measure ANOVA. To compare the severity of chemotherapy related side effects, chi square will be computed to compare frequency distribution at pretest and post-tests.

Logistic regression will be performed to describe the relationship between severity of side effect, anxiety and quality of life. Correlation between physical, social, emotional and functional wellbeing will be analyzed using Karl Pearson correlation coefficient method. Association between total quality of life gain scores, gain scores of each QoL subscales and anxiety reduction score with socio-demographic and clinical variables will be analyzed using one way analysis of variance F-test and student independent t-test.

Simple bar diagram, Multiple bar diagram, simple bar with 2 standard Error bar, Box-plot and Scatter diagram with regression estimate will be used to represent the data.

Qualitative data analysis works with text-based unstructured data which will be available in the form of transcripts of audio-recorded interviews, field notes. Narrative analysis will be utilised to analyse the qualitative data which include five steps: organization and preparation of the data, obtaining a general sense of the information, coding process, categories or themes, and interpretation of the data.

The findings of the quantitative and qualitative phases will be integrated to find any commonalities.

Strengths and Limitations

The study utilises a mixed method approach which will help in establishing the generalizability of the study findings. The intervention developed by the researcher is validated by experts in the field. All the tools used are standardised tools.

One of the major limitations of the study is that the intervention developed is only for those GI cancer patients who are techno friendly.

Dissemination and Expected Outcomes of Study

The findings of the study will be presented at national and international conferences and published in

peer-reviewed journals. The study will help in the development of an Evidence Based Comprehensive Home-based Nursing intervention for GI cancer patients in the form of Nurse-led Tele-health Oncology Clinic which may be helpful in relieving severity of side effects of chemotherapy and anxiety and, hence improving the quality of life among GI cancer patients.

Additionally, a Nurse-led telehealth oncology clinic for GI cancer patients could have several significant implications as it leads to an increased access to care and convenience as telehealth eliminates geographical barriers, allowing patients in remote or underserved areas to access specialized oncology care and consultations bypassing the need of travel and associated expenses. It enhances the continuity of care, facilitates early intervention and empowers patients by providing them with greater control over their healthcare.

Through such clinics, Nurses can provide valuable emotional support and counselling to GI cancer patients and their families, helping them cope with the psychological and emotional challenges associated with cancer diagnosis and treatment.

Overall, a Nurse-led telehealth oncology clinic for GI cancer patients has the potential to revolutionize cancer care delivery by improving access, convenience, continuity, and patient outcomes while also reducing costs and enhancing patient satisfaction.

REFERENCES

1. Arnold M, Abnet CC, Neale RE, Vignat J, Giovannucci EL, McGlynn KA, et al. Global burden of 5 major types of gastrointestinal cancer [Internet]. U.S. National Library of Medicine; 2020 [cited 2024 Mar 6]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8630546/
2. Dhillon PK, Mathur P, Nandakumar A, Fitzmaurice C, Kumar GA, Mehrotra R, et al. The burden of cancers and their variations across the States of India: The global burden of disease study 1990–2016. The Lancet Oncology. 2018 Oct; 19(10): 1289–306. doi:10.1016/s1470-2045(18)30447-9
3. Rai, A. et al. (2023) 'Nano-based approaches for diagnosis and therapy of Gastric Cancer', International Journal of Surgery, Publish Ahead of Print. doi:10.1097/js9.0000000000000116.
4. Saini S, Chhabra J, Sharma A, Kumar M, Singh I, Pahwa R. Assessing the potential of gastroretentive technology for gastric cancer targeting. J Appl Pharm Sci, 2023; 13(05):033–040. https://doi.org/10.7324/JAPS.2023.130301
5. Jonsson BH, Winzer R, Gornitzki C. Letter to the editor: Are older studies lost in database searches for systematic reviews? Psychological Medicine. 2017 Nov 27; 48(7): 1218–9. doi: 10.1017/s0033291717003294
6. Wochna Loerzel V. Symptom experience in older adults undergoing treatment for cancer. Oncology Nursing Forum. 2015 May 1;42(3). doi:10.1188/15.onf.e269-e278
7. Enright K, Grunfeld E, Yun L, Moineddin R, Ghannam M, Dent S, et al. Population-based assessment of emergency room visits and hospitalizations among women receiving adjuvant chemotherapy for early breast cancer. Journal of Oncology Practice. 2015 Mar;11(2):126–32. doi:10.1200/jop.2014.001073
8. Theobald DE. Cancer pain, fatigue, distress, and insomnia in cancer patients. Clin Cornerstone. 2004;6 Suppl 1D:S15-21. doi:10.1016/s1098-3597(05)80003-1
9. Tabernero J, Elez E. Faculty opinions recommendation of primary MFOLFOX6 plus bevacizumab without resection of the primary tumor for patients presenting with surgically unresectable metastatic colon cancer and an intact asymptomatic colon cancer: Definitive analysis of NSABP trial C-10. Faculty Opinions – Post-Publication Peer Review of the Biomedical Literature. 2012 Oct 8; doi:10.3410/f.717954590.793462725
10. Tantoy IY, Cooper BA, Dhruva A, Cataldo J, Paul SM, Conley YP, et al. Quality of life of patients with gastrointestinal cancers undergoing chemotherapy. Quality of Life Research. 2018 Apr 21;27(7):1865–76. doi:10.1007/s11136-018-1860-1
11. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, et al. Patient-reported outcomes in routine cancer clinical practice: A scoping review of use, impact on health outcomes, and implementation factors. Annals of Oncology. 2015 Sept;26(9):1846–58. doi:10.1093/annonc/mdv181.
12. Cheng C, Chan N, Chio JH, Chan P, Chan AO, Hui W. Being active or flexible? role of control coping on quality of life among patients with gastrointestinal cancer. Psycho-Oncology. 2010 Dec 19;21(2):211–8. doi:10.1002/pon.1892
13. Pelekasis P, Matsouka I, Koumarianou A. Progressive muscle relaxation as a supportive intervention for cancer patients undergoing chemotherapy: A systematic review. Palliative and Supportive Care. 2016 Nov 28;15(4):465–73. doi:10.1017/s1478951516000870
14. Kapogiannis A, Tsoli S, Chrousos G. Investigating the effects of the progressive muscle relaxation-guided imagery combination on patients with cancer receiving chemotherapy treatment: A systematic review of randomized controlled trials. EXPLORE. 2018 Mar;14(2):137–43. doi:10.1016/j.explore.2017.10.008
15. Prip A, Møller KA, Nielsen DL, Jarden M, Olsen M-H, Danielsen AK. The patient–healthcare professional relationship and communication in the oncology outpatient setting. Cancer Nursing. 2018 Sept;41(5). doi:10.1097/ncc.0000000000000533
16. Chandra S, Ward P, Mohammadnezhad M. Factors associated with patient satisfaction in Outpatient Department of Suva Sub-divisional Health Center, Fiji, 2018: A mixed method study. Frontiers in Public Health. 2019 Jul 2;7. doi:10.3389/fpubh.2019.00183
17. Lai XB, Ching SS, Wong FK, Leung CW, Lee LH, Wong JS, et al. A nurse-led care program for breast cancer patients in a chemotherapy day center. Cancer Nursing. 2019 Jan;42(1):20–34. doi:10.1097/ncc.0000000000000539
18. Kwok C, Degen C, Moradi N, Stacey D. Nurse-led telehealth interventions for symptom management in patients with cancer receiving systemic or radiation therapy: A systematic review and meta-analysis. Supportive Care in Cancer. 2022 Apr 14;30(9):7119–32. doi:10.1007/s00520-022-07052-z
19. Ream EK, Richardson A, Wiseman T, Hughes AE, Forbes A. Telephone interventions for symptom management in adults with cancer. Cochrane Database of Systematic Reviews. 2009 Jan 21; doi:10.1002/14651858.cd007568
20. Vijay, V. and Kang, H.K. (2019a) 'Efficacy of nurse-led-interventions on dialysis related diet and fluid non-adherence and Morbidities: Protocol for a randomized controlled trial', Journal of Global Health Reports, 3. doi:10.29392/joghr.3.e2019083.
21. Weiss CR, Roberts M, Florell M, Wood R, Johnson-Koenke R, Amura CR, et al. Best practices for telehealth in nurse-led care settings—a qualitative study. Policy, Politics, & Nursing Practice. 2023 Sept 26; 25(1): 47–57. doi:10.1177/15271544231201417
22. Koonin LM, Hoots B, Tsang CA, Leroy Z, Farris K, Jolly B, et al. Trends in the use of telehealth during the emergence of the

COVID-19 pandemic — United States, January–March 2020. MMWR Morbidity and Mortality Weekly Report. 2020 Oct 30;69(43):1595–9. doi:10.15585/mmwr.mm6943a3

23. National Health Policy-2017 (2017c) Ministry of Health and family welfare, Government of India. Available at: https://main.mohfw.gov.in/sites/default/files/9147562941489753121.pdf (Accessed: 2024).
24. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. Spirit 2013 statement: Defining standard protocol items for clinical trials. Annals of Internal Medicine. 2013 Feb 5;158(3):200. doi:10.7326/0003-4819-158-3-201302050-00583
25. King MT, Stockler MR, Cella DF, Osoba D, Eton DT, Thompson J, Eisenstein AR. Meta-analysis provides evidence-based effect sizes for a cancer-specific quality-of-life questionnaire, the FACT-G. J Clin Epidemiol. 2010 Mar; 63(3):270-81. doi: 10.1016/j.jclinepi.2009.05.001. Epub 2009 Aug 27. PMID: 19716264.
26. Freites-Martinez A, Santana N, Arias-Santiago S, Viera A. Using the Common Terminology Criteria for Adverse Events (CTCAE - Version 5.0) to Evaluate the Severity of Adverse Events of Anticancer Therapies. Actas Dermosifiliogr (Engl Ed). 2021 Jan;112(1):90-92. English, Spanish. doi: 10.1016/j.ad.2019.05.009. Epub 2020 Sep 3. PMID: 32891586.
27. Kumar K, Kumar S, Mehrotra D, Tiwari SC, Kumar V, Dwivedi RC. Reliability and psychometric validity of Hindi version of Depression, Anxiety and Stress Scale-21 (DASS-21) for Hindi speaking Head Neck Cancer and Oral Potentially Malignant Disorders Patients. J Cancer Res Ther. 2019 Jul-Sep; 15(3): 653-658. doi: 10.4103/jcrt.JCRT_281_17. PMID: 31169235.
28. Karnofsky DA, Abelmann WH, Craver LF, Burchenal JH. Karnofsky palliative performance scale. PsycTESTS Dataset. 1948; doi:10.1037/t60198-000
29. Ananthan VA. Modified Kuppuswamy scale for socioeconomic status of the Indian family- Update based on New CPI (IW) series from September 2020. J Family Med Prim Care. 2021 May; 10(5): 2048-2049. doi: 10.4103/jfmpc.jfmpc_2242_20. Epub 2021 May 31. PMID: 34195150; PMCID: PMC8208178.
30. Ain SN, Khan ZA, Gilani MA. Revised kuppuswamy scale for 2021 based on new consumer price index and use of conversion factors. Indian J Public Health. 2021 Oct-Dec;65(4):418-421. doi: 10.4103/ijph.ijph_1108_21. PMID: 34975091.