

https://dspace.org/

Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross Sectional Study

Pillay, Shaylin

2025

University of the Witwatersrand, Johannesburg

https://hdl.handle.net/10539/49705

Pillay, Shaylin . (2025). Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross Sectional Study [Master's dissertation, University of the Witwatersrand, Johannesburg]. WIReDSpace. https://hdl.handle.net/10539/49705

Downloaded from a DSpace repository. https://dspace.org/

Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross Sectional Study

Author: Shaylin Pillay

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine (MMED)

07/07/2025

Declaration:

I, Shaylin Pillay, declare that this research report is of my own, unaided work. The contents of the paper of my original work. It is being submitted for the degree of Master of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for a degree or examination at any other University.



Signed on this 7th day of July 2025

Dedication:

This project is dedicated to all the women who participated in this study. Their strength and perseverance through the journey of breast cancer is remarkable.

Presentations from this study:

This study has not been presented or published in any form.

Abstract:

Background: Breast-conserving surgery (BCS) combined with intraoperative radiotherapy (IORT) is an emerging treatment option for early-stage breast cancer. While its oncological outcomes have been well-studied, there is limited research on patient-reported satisfaction and quality of life (QoL) following IORT, particularly in South Africa. This study aims to assess patient satisfaction and QoL after IORT using the BREAST-Q Breast-Conserving Therapy (BCT) module.

Methods: A cross-sectional study was conducted at Milpark Hospital, Johannesburg. Patients who underwent BCS with IORT from 2017 - June 2024 were invited to participate. The BREAST-Q BCT questionnaire was used to assess key QoL domains, including breast satisfaction, psychosocial well-being, sexual well-being, cancer worry, and radiation-related side effects. Statistical analyses, including descriptive statistics, and non-parametric comparisons, were performed in JASP.

Results: There was a 42% response rate. Breast satisfaction scores were generally high, with most patients reporting favourable outcomes. Psychosocial well-being and sexual well-being showed moderate to low satisfaction levels, and cancer worry remained a prevalent concern. No significant differences were observed between patients receiving IORT alone versus those who received additional external beam radiation therapy ($p > 0.05$).

Conclusion: The study is limited by its small sample size (n=55) and single-centre design, which may affect generalisability. Future multi-centre studies with larger cohorts are needed. These findings support the use of patient-reported outcome measures in evaluating breast cancer treatments and highlight the need for psychosocial interventions to improve long-term well-being.

Acknowledgements:

I would like to thank all participants for their invaluable contributions to this research. Their willingness to share their experiences has been essential in understanding patient-reported outcomes in breast cancer treatment. I would also like to thank Milpark hospital and the staff of the Breast Care Centre of Excellence, for all their assistance.

Without my supervisors, this study would not have been possible. Thank you to Prof Carol Benn, Dr van den Bergh and Prof Sofianos for their amazing support, assistance and insight.

Declaration of interests:

I have nothing to declare

Funding:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Table of Contents

Declaration: 2
Dedication: 3
Abstract: 4
Acknowledgements: 5
Introduction: 9
Methods: 11
Study Population and Data Collection: 11
Data Collection 11
Data Analysis 12
Results: 12
Discussion: 15
Limitations 17
Conclusion: 17
Appendix List: 22

Figure 1: BREAST-Q BCT Module [14] 10
Figure 2: Patient Recruitment to Study 13
Figure 4: Scatter plot comparing psychosocial well-being and cancer worry response scores 15
Figure 3: Scatter plot comparing sexual well being and psychosocial well-being scores 15

Table 1: Descriptive Statistics of the Breast -Q BCT responses 14

Abbreviations/Nomenclature:

1. APBI: Accelerated Partial Breast Irradiation
2. BCS: Breast Conserving Surgery
3. BREAST-Q: Breast Questionnaire 2.0
4. BREAST-QBCT: A patient-reported outcome measure designed to assess satisfaction with breast cancer treatments.
5. DCIS: Ductal Carcinoma In Situ
6. EBRT: External beam radiation therapy, a method of delivering a beam of high-energy x-rays to the location of the tumour.
7. ER: Oestrogen Receptor
8. HER2: Human Epidermal Growth Factor Receptor 2
9. HRQoL: Health Related Quality of Life
10. IDC: Invasive Ductal Carcinoma
11. IQR: Interquartile Range
12. IORT: Intra-operative radiation therapy, a form of radiation treatment delivered during surgery.
13. KI-67: A marker of cell proliferation
14. PR: Progesterone Receptor
15. PROs: Patient Reported Outcomes
16. PROM: Patient Reported Outcome Measures
17. QoL: Quality of Life

Introduction:

Breast cancer remains a significant global health challenge, representing the most frequently diagnosed cancer among women and accounting for a substantial proportion of all female cancer diagnoses [1–3]. The rising incidence of breast cancer [4], coupled with advancements in early detection [3], underscores the critical need for effective and patient-centred treatment strategies. Breast-conserving surgery (BCS) followed by radiotherapy has become a standard approach for early stage breast cancer [5].

Radiation for early-stage breast cancer can be done in several ways, depending on the clinical picture [6]. These radiation options include whole-breast external beam radiation therapy (EBRT) or accelerated partial breast irradiation (APBI). The choice of radiation modality is often guided by the patient's individual risk of recurrence [7].

EBRT is done over multiple visits post operatively. It is administered through an external beam and has been associated with increased irradiation of normal tissue, leading to long term complications [6]. EBRT is currently the most commonly used form of radiation in South Africa. In November 2017 Milpark Hospital in Gauteng, was the first hospital, in South Africa, to offer single dose intraoperative radiation therapy (IORT), a type of APBI, for early-stage breast cancer [8].

IORT provides a targeted, single-dose radiation directly to the tumour location during BCS [7]. This approach minimizes radiation exposure to surrounding tissues and eliminates the need for multiple postoperative visits, potentially offering significant advantages for patients [6].

IORT holds promise as a valuable adjunct to BCS, potentially leading to improved patient satisfaction [9]. Integrating patient-reported outcome measures (PROs) is essential for comprehensively evaluating the impact of radiation therapy on quality of life (QoL) [10]. By incorporating the patient's perspective on their treatment experience and its effect on their QoL, clinicians and researchers can gain deeper insights into the effectiveness and broader impact of different treatment modalities [10].

The BREAST-Q is a validated instrument specifically designed to capture PROs related to breast surgery, including health-related quality of life (HRQoL) and patient satisfaction [11]. Developed at Memorial Sloan Kettering Cancer Centre (in 2009), this tool has been widely adopted by both clinicians and researchers due to its demonstrated reliability and validity in measuring these outcomes [12]. A 2018 systematic review highlighted the BREAST-Q's ability to provide meaningful data that can inform clinical decision-making [13].

The questionnaire is modular in nature and offers different versions tailored to specific

breast cancer treatments [7]. The BREAST-Q BCT module is designed specifically for patients undergoing BCS and has been widely used in research and translated into numerous languages, demonstrating its cross-cultural validity [11,14]. The BREAST-Q BCT comprises several stand-alone domains, including quality of life and satisfaction scales, which can be used individually or in combination (Figure 1) [14].

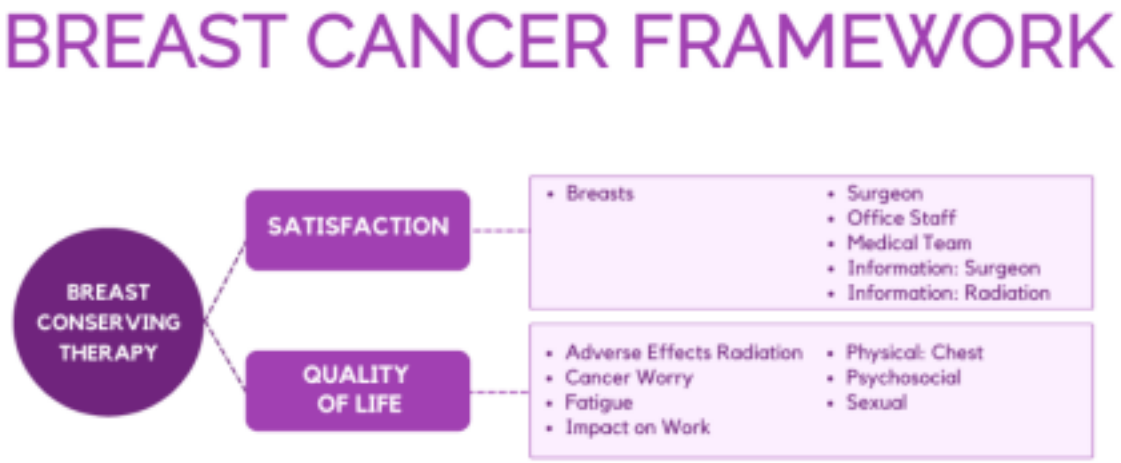


Figure 1: BREAST-Q BCT Module [14]

Each question uses a scale measure, and the self-administered questionnaire can be used cross-sectionally or longitudinally, pre- and post-operatively [14]. The BREAST-Q BCT is a valuable tool for assessing patient satisfaction and QoL after IORT, providing insights into the patient experience and informing potential areas for improvement [12,13].

IORT has experienced a surge in global adoption, with over 260 facilities across 35 nations currently offering this treatment [15]. Patients are increasingly choosing IORT over EBRT due to its convenience and reduced travel burden [15]. However, despite this growing adoption, research examining patient-reported outcomes following IORT remains limited. This study aims to address this gap by investigating patient satisfaction and quality of life among South African breast cancer patients who have undergone IORT in conjunction with breast-conserving surgery, within the private healthcare sector.

Methods:

This cross-sectional study utilised data from files and patient reported outcomes to evaluate patient satisfaction and quality of life among South African breast cancer patients following breast-conserving surgery (BCS) and intraoperative radiation therapy (IORT). The study was conducted at the Breast Care Centre of Excellence, located in Milpark Hospital, Johannesburg, South Africa.

Study Population and Data Collection:

The study population comprised women aged 18 years and older who underwent BCS and IORT at Milpark Hospital between 2017 and June 2024 for early-stage breast cancer. Patients were eligible for inclusion if they had received IORT at least six months prior to data collection. To ensure a representative sample and minimise bias, no other exclusion criteria were implemented.

Permission to conduct the research was granted by Prof. Carol Benn, who leads the Breast Care Centre of Excellence at Netcare Milpark Hospital and the CEO of Milpark Hospital. Following ethical approval from the University of the Witwatersrand Human Research Ethics Committee (Medical) (HREC(Medical)), protocol number M241169, potential participants were identified and contacted by the Breast Care Centre of Excellence secretary.

Participants were provided with information about the study telephonically, and those who agreed were given a link to the self-administered BREAST-Q BCT questionnaire via RedCap. The questionnaire was anonymous.

Data Collection

The BREAST-Q license was obtained for research purposes, and copyright information was included on all questionnaires.

The BREAST-Q BCT questionnaire, integrated into RedCap, was pre-tested using a focus group. Six of the 15 scales of the BREAST-Q BCT were selected for this study, focusing on satisfaction with breasts, psychosocial well-being, sexual well-being, cancer worry, physical well-being, and adverse effects of radiation.

Data collected from the files only occurred after the BREAST-Q BCT questionnaire was completed. The data collected included patient demographics (age at surgery and current age, comorbidities, smoking history, and race), and clinical data (tumour characteristics: biology, location, size; and post-operative complications).

Data Analysis

The BREAST-Q BCT questionnaire uses Likert scales for individual questions. Domain scores were calculated by summing the responses for each domain and converting them to a standardized score out of 100 using conversion tables provided by the Q-portfolio.

Data were exported from RedCap to Microsoft Excel, and subsequent statistical analyses were performed using JASP software. Descriptive statistics were generated for all variables. Given that the majority of the data were non-parametrically distributed, the median and interquartile range were used as measures of central tendency and dispersion, respectively. For normally distributed data, the mean and standard deviation were reported.

Skewness and kurtosis were used to assess normality. Psychosocial well-being and satisfaction with breasts demonstrated relatively low skewness and kurtosis values, indicating approximate normality. However, sexual well-being, cancer worry, and physical well-being displayed moderate skewness, suggesting non-normal distributions. Given these findings, non-parametric tests were preferred for analysis. Kendall's Tau-b correlation coefficient (Ƭb), and Spearman's co-efficient was calculated and the Kruskal-Wallis test was done. A p-value of less than 0.05 was considered statistically significant.

Results:

Of the 197 eligible patients identified, 29 were deceased and 31 could not be reached. Questionnaires were sent to the remaining 137 patients, resulting in a 42% response rate with 58 completed questionnaires returned (Figure 2). Of these, 55 were included in the final analysis after excluding 3 incompletely filled questionnaires.

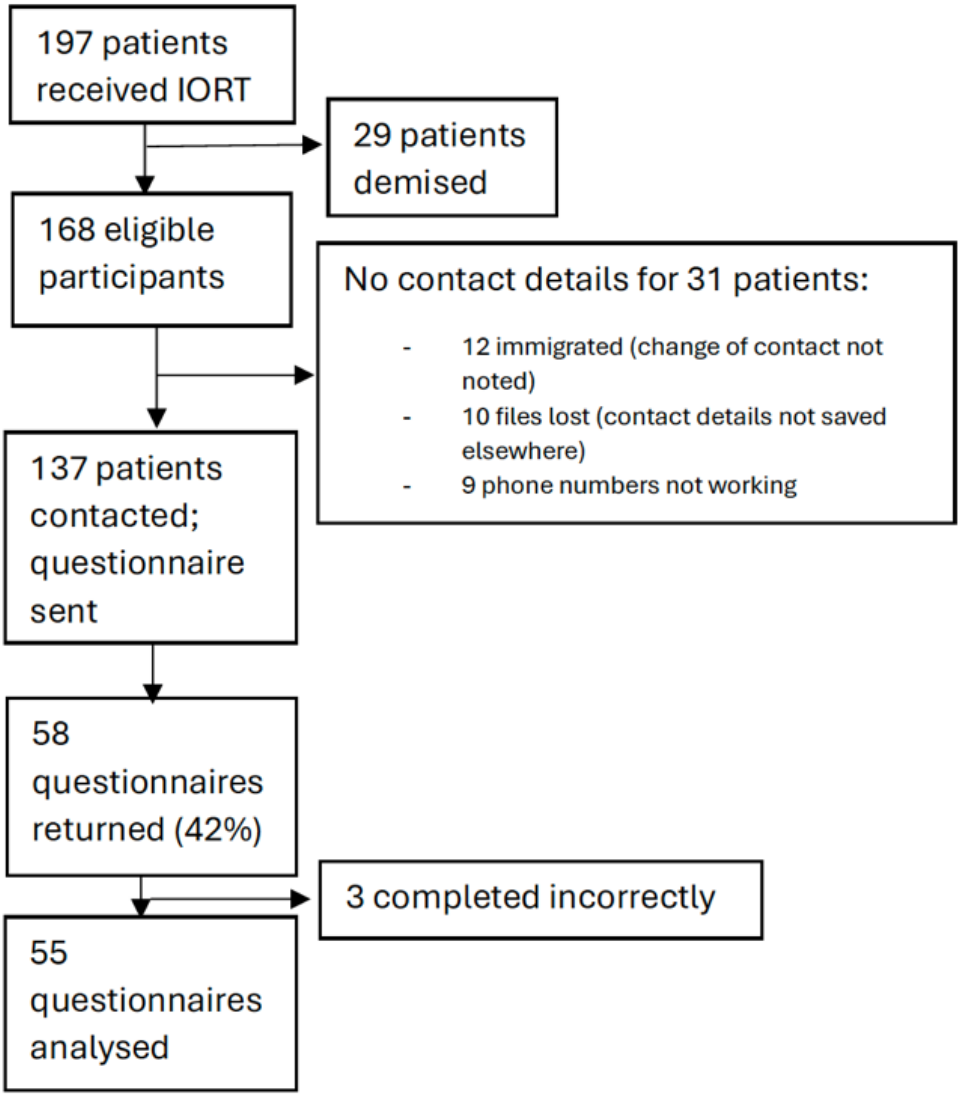


Figure 2: Patient Recruitment to Study

The average age at the time of IORT was 54 years (range: 27-82). The majority of participants (n=37, 67.3%) identified as Caucasian, followed by African (n=5, 9.1%) and South-East Asian (n=4, 7.2%). Ethnicity was not recorded for nine participants. All patients received IORT for primary breast cancer, with invasive ductal carcinoma (IDC) unspecified being the most common histological type. Ductal carcinoma in situ (DCIS) was also present in 49% of patients. Eleven percent of patients were smokers, and 75% had at least one comorbidity, such as anxiety or hypertension.

The mean tumour diameter was 25.8mm (range: 4.3mm-53mm). Six patients experienced complications, including two major complications (cancer recurrence). 31% (n=17) of participants received IORT only, 69% (n=38) received IORT and then EBRT booster.

Descriptive statistics for the BREAST-Q BCT domains are presented in Table 1. Satisfaction

with breasts (mean = 62.15, SD = 21.79) and physical well-being (mean = 66.58, SD = 17.94) showed the highest mean scores. Psychosocial well-being had a mean of 58.7 (SD=21.1). Cancer worry (mean = 53.89, SD = 21.90) and sexual well-being (mean = 42.94, SD = 20.34) had considerably lower mean scores. Cancer worry also exhibited the greatest variability in responses.

Table 1: Descriptive Statistics of the Breast -Q BCT responses

Question	Number of responses (n)	Mean (SD)	Median (Q1,Q3)
Sexual Wellbeing	51	42.94 (20.34)	43 (31, 57.5)
Psychosocial Wellbeing	55	58.7 (21.1)	58 (48, 67.5)
Physical Wellbeing	55	66.58 (17.94)	66 (52, 76)
Satisfaction with Breasts	53 (2 required mastectomy)	62.15 (21.79)	65 (51, 72)
Cancer Worry	55	53.89 (21.9)	51(42.5, 65)

Spearman's rank correlation coefficient was used to assess relationships between continuous ordinal variables. A statistically significant negative correlation was found between cancer worry and psychosocial well-being ($\rho = -0.47$, $p < 0.001$). Sexual well-being and psychosocial well-being were strongly and positively correlated ($\rho = 0.70$, $p < 0.001$) as seen in figure 3 and 4. Satisfaction with breasts and physical well-being demonstrated a moderate positive correlation ($\rho = 0.56$, $p = 0.002$). The correlation between age at the procedure and cancer worry was weak and not statistically significant ($\tau b = -0.089$, $p = 0.348$).

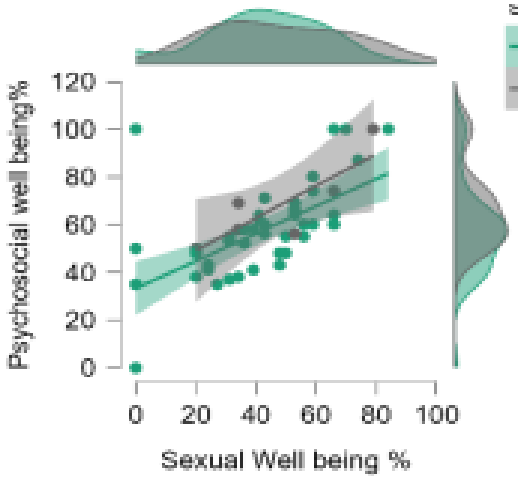


Figure 4: Scatter plot comparing sexual well being and psychosocial well-being scores

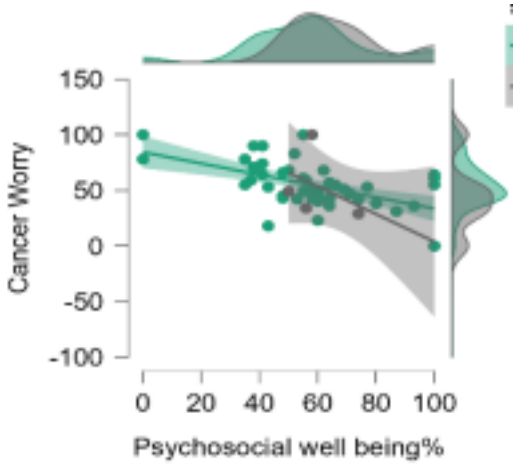


Figure 3: Scatter plot comparing psychosocial well-being and cancer worry response scores

Scatter plot key:
Green Dots: Individual patient responses
Black Line: Trend line showing the relationship between x-axis and y-axis
Shaded Grey Area: 95% Confidence interval around the trend line
Top/Right Density Plots: Distribution of each variable (histograms turned into

The Mann-Whitney U test and Kruskal-Wallis test were used to compare categorical variables with non-normally distributed continuous variables. No statistically significant differences were observed in cancer worry ($p = 0.116$), sexual well-being ($p = 0.091$), psychosocial well-being ($p = 0.939$), satisfaction with breasts ($p = 0.532$), or physical well-being ($p = 0.187$) between participants who received IORT alone and those who received IORT plus EBRT. Similarly, Kruskal-Wallis tests revealed no significant impact of neoadjuvant therapy, race, or cancer stage on participant satisfaction or well-being

Discussion:

This study investigated patient-reported outcomes following breast-conserving surgery (BCS) and intraoperative radiation therapy (IORT) in a South African cohort. The findings provide valuable insights into patient satisfaction and quality of life (QoL) following this treatment modality.

The BREAST-Q BCT results revealed varying levels of satisfaction and well-being across different domains. While participants reported relatively high scores for satisfaction with breasts (mean 62.15) and physical well-being (mean 66.58), scores for sexual well-being (mean 42.94) and cancer worry (mean 53.89) were considerably lower.

These findings align with previous research demonstrating that sexual well-being is often negatively impacted following breast cancer treatment [16]. The lower scores in sexual well-being may be attributed to a combination of physical factors (e.g., hormonal changes, menopausal symptoms, body image concerns) and psychological factors (e.g., anxiety, fear of recurrence, changes in self-esteem) [17]. Sexual well-being also had the lowest response rate as three participants noted that they were no longer sexually active and one participant

did not respond at all. The moderate level of cancer worry observed suggests that while participants may have concerns about recurrence, they are potentially coping effectively [13]. However, the wide range of responses for cancer worry (SD 21.9) indicates that individual experiences and coping mechanisms vary considerably.

The relatively high scores for satisfaction with breasts and physical well-being suggest that IORT, in conjunction with BCS, may effectively preserve physical function and aesthetic outcomes. These findings are consistent with studies reporting favourable cosmetic results and functional outcomes after IORT [16]. The positive impact on physical well-being could be attributed to the targeted nature of IORT, minimizing radiation exposure to healthy tissues and reducing the risk of long term complications associated with external beam radiation [9].

Comparing our findings with other studies is challenging due to variations in study populations, treatment protocols, assessment and statistic tools. Several studies did not look at cancer worry but instead focused on patient satisfaction with medical staff [18], while certain studies used a different survey tool [19].

Despite these challenges, some studies using the BREAST-Q BCT have also reported similar trends, with lower scores in sexual well-being and higher scores in physical well-being and satisfaction with breasts [16].

A study by Dahlback et al, in 2017 found that the median score for breast satisfaction (post BCS) was 66 (IQR 57-80)[20]. Another study, conducted in the Netherlands in 2018, by Lagendijk et al, showed a higher quality of life across all the variables. Lagendijk et al's study found a mean of 71.2 for physical well-being, 70.1 for psychosocial well-being, 65.7 for satisfaction with breasts and 57.5 for sexual well-being. The participants average age was 54 years old [21]. These variations highlight the importance of considering contextual factors when interpreting patient-reported outcomes.

Correlation analysis revealed a significant negative correlation between cancer worry and psychosocial well-being, indicating that higher levels of worry are associated with lower psychosocial well-being. This finding underscores the interconnectedness of psychological factors and the impact of cancer-related anxieties on overall well-being. The strong positive correlation between sexual well-being and psychosocial well-being suggests that improvements in sexual function and satisfaction may positively influence overall psychological and social well-being. The moderate positive correlation between satisfaction with breasts and physical well-being further supports the importance of aesthetic and functional outcomes in contributing to patient satisfaction.

Our study found no significant differences in any of the BREAST-Q domains between patients who received IORT alone and those who received IORT plus EBRT. This suggests that both treatment approaches may yield comparable patient-reported outcomes. Despite previous research linking EBRT to increased skin-related side effects [22] (which could negatively impact quality of life and satisfaction), our sample did not reflect these findings. This may be due to sample size limitations, variability in patient-reported perception, or the timing of questionnaire completion. Nevertheless, this observation warrants further investigation through studies with larger sample sizes and long-term follow-up to better assess the differential impact of radiation modalities on patient experience.

Limitations

This study has several limitations. The relatively small sample size (n=55) may limit the generalisability of the findings and reduce the power to detect statistically significant differences. The low response rate (42%) raises the possibility of response bias, as participants who chose to participate may differ systematically from those who did not. Furthermore, the cross-sectional design of the study provides a snapshot of patient-reported outcomes at a single point in time and does not capture changes over time.

The lack of pre-treatment baseline data also limits our ability to assess changes in QoL and satisfaction directly related to the treatment. Finally, the study was conducted at a single centre, which may further limit generalisability.

Future research should address the limitations of this study by including larger, more diverse samples, utilising longitudinal study designs, and incorporating pre-treatment baseline assessments. This study also did not evaluate the time elapsed since IORT as a variable. Future studies could explore how time since treatment affects patient-reported quality of life

Further investigation is also needed to explore the specific factors contributing to lower sexual well-being and to develop targeted interventions to address these issues. Qualitative studies exploring participants' experiences and perceptions of IORT could provide valuable insights to complement quantitative findings. Additionally, research comparing IORT with other radiation modalities, such as EBRT, using PROs is warranted.

Conclusion:

This study provides valuable data on patient-reported outcomes following BCS and IORT in a South African population. The findings highlight the importance of assessing multiple domains of QoL and satisfaction, including sexual well-being and cancer worry. While IORT appears to be associated with favourable physical and aesthetic outcomes, further research is needed to optimise patient-centred care and address the unmet needs of patients undergoing breast cancer treatment. As IORT becomes more accessible in the private sector,

tools like the BREAST-Q can be integrated into clinical pathways to support patient-centred decision-making and improve care delivery. This study lays the foundation for future local research focused on the lived experiences of South African breast cancer patients.

References

[1] Giaquinto AN, Sung H, Miller KD, Kramer JL, Newman LA, Minihan A, et al. Breast Cancer Statistics, 2022. CA Cancer J Clin [Internet]. 2022 Nov [cited 2024 Feb 2];72(6):524–41. Available from: https://pubmed.ncbi.nlm.nih.gov/36190501/

[2] WHO. WHO. 2024 [cited 2024 Jun 9]. Breast cancer. Available from: https://www.who.int/news-room/fact-sheets/detail/breast-cancer

[3] Dlamini Z, Molefi T, Khanyile R, Mkhabele M, Damane B, Kokoua A, Bida M, Saini KS, Chauke-Malinga N, Luvhengo TE, Hull R. From Incidence to Intervention: A Comprehensive Look at Breast Cancer in South Africa. Oncol Ther. 2024 Mar;12(1):1-11. doi: 10.1007/s40487-023-00248-1. Epub 2023 Nov 1. PMID: 37910378; PMCID: PMC10881925.

[4] Statistics South Africa. CANCER IN SOUTH AFRICA [Internet]. 2023 Mar [cited 2023 Nov 30]. Available from: www.statssa.gov.za

[5] Gilmour A, Cutress R, Gandhi A, Harcourt D, Little K, Mansell J, Murphy J, Pennery E, Tillett R, Vidya R, Martin L. Oncoplastic breast surgery: A guide to good practice. Eur J Surg Oncol. 2021 Sep;47(9):2272-2285. doi: 10.1016/j.ejso.2021.05.006. Epub 2021 May 11. PMID: 34001384.

[6] Wang Y, Shen J, Gu P, Wang Z. Recent advances progress in radiotherapy for breast cancer after breast-conserving surgery: a review. Front Oncol. 2023 Aug 21;13:1195266. doi: 10.3389/fonc.2023.1195266. PMID: 37671064; PMCID: PMC10475720.

[7] Brown A, Buss EJ, Chin C, Liu G, Lee S, Rao R, Taback B, Wiechmann L, Horowitz D, Choi JC, Katz LM, Connolly EP. Targeted Intraoperative Radiotherapy (TARGIT-IORT) for Early-Stage Invasive Breast Cancer: A Single Institution Experience. Front Oncol. 2022 Jun 29;12:788213. doi: 10.3389/fonc.2022.788213. PMID: 35847872; PMCID: PMC9277011.

[8] Ramdas Y, Benn CA, van Heerden M. First Intraoperative Radiation Therapy Center in Africa: First 2 Years in Operation, Including COVID-19 Experiences. JCO Glob Oncol. 2020 Nov;6:1696-1703. doi: 10.1200/GO.20.00258. PMID: 33156717; PMCID: PMC7713533.

[9] Vaidya JS, Vaidya UJ, Baum M, Bulsara MK, Joseph D, Tobias JS. Global adoption of single-shot targeted intraoperative radiotherapy (TARGIT-IORT) for breast cancer-better for patients, better for healthcare systems. Front Oncol. 2022 Aug 11;12:786515. doi: 10.3389/fonc.2022.786515. PMID: 36033486; PMCID: PMC9406153.

[10] Weldring T, Smith SM. Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs). Health Serv Insights. 2013 Aug 4;6:61-8. doi: 10.4137/HSI.S11093. PMID: 25114561; PMCID: PMC4089835.

[11] Stolpner I, Heil J, Feißt M, Karsten MM, Weber WP, Blohmer JU, Forster T, Golatta M,

Schütz F, Sohn C, Hennigs A. Clinical Validation of the BREAST-Q Breast-Conserving Therapy Module. Ann Surg Oncol. 2019 Sep;26(9):2759-2767. doi: 10.1245/s10434-019-07456-y. Epub 2019 May 21. PMID: 31115853.

[12] Panayi AC, Knoedler S, Knoedler L, Tapking C, Hundeshagen G, Diehm YF, Fischer S, Thamm OC, Kneser U, Haug V. Patient-reported Outcomes Utilizing the BREAST-Q Questionnaire After Breast-Conserving Surgery With and Without Oncoplastic Breast Surgery: A Systematic Review and Meta-analysis. Aesthet Surg J. 2024 Oct 15;44(11):NP778-NP789. doi: 10.1093/asj/sjae002. PMID: 38195101.

[13] Liu LQ, Branford OA, Mehigan S. BREAST-Q Measurement of the Patient Perspective in Oncoplastic Breast Surgery: A Systematic Review. Plast Reconstr Surg Glob Open. 2018 Aug 7;6(8):e1904. doi: 10.1097/GOX.0000000000001904. PMID: 30254830; PMCID: PMC6143323.

[14]BREAST-Q | Breast Cancer - Q-Portfolio MEASURING WHAT MATTERS TO PATIENTS [Internet]. [cited 2024 Jun 20]. Available from: https://qportfolio.org/breast-q/breast-cancer/

[15] Corica T, Nowak AK, Saunders CM, Bulsara M, Taylor M, Vaidya JS, Baum M, Joseph DJ. Cosmesis and Breast-Related Quality of Life Outcomes After Intraoperative Radiation Therapy for Early Breast Cancer: A Substudy of the TARGIT-A Trial. Int J Radiat Oncol Biol Phys. 2016 Sep 1;96(1):55-64. doi: 10.1016/j.ijrobp.2016.04.024. Epub 2016 Apr 23. PMID: 27511847.

[16] Caldana M, Lombardi D, Urbani S, Pellini F, Mirandola S, Granuzzo E, Pollini GP. Quality of Life Assessment After Conserving Breast Surgery and Intraoperative Radiotherapy (IORT) in Breast Cancer Patients Using the BREAST-Q Questionnaire. Arch Breast Cancer [Internet]. 2020 Nov. 16 [cited 2025 Jul. 9];:183-8. Available from: https://www.archbreastcancer.com/index.php/abc/article/view/318

[17] Ussher JM, Perz J, Gilbert E. Changes to sexual well-being and intimacy after breast cancer. Cancer Nurs. 2012 Nov-Dec;35(6):456-65. doi: 10.1097/NCC.0b013e3182395401. PMID: 22222680.

[18] Cha R, Barnes E, Locke MB. Patient-reported outcomes following breast reconstruction surgery in a public hospital: use of the Breast-Q questionnaire. N Z Med J. 2013 Nov 22;126(1386):43-55. PMID: 24316992.

[19] Jacobs DHM, Horeweg N, Straver M, Roeloffzen EMA, Speijer G, Merkus J, van der Sijp J, Mast ME, Fisscher U, Petoukhova AL, Zwanenburg AG, Marijnen CAM, Koper PCM. Health-related quality of life of breast cancer patients after accelerated partial breast irradiation using intraoperative or external beam radiotherapy technique. Breast. 2019

Aug;46:32-39. doi: 10.1016/j.breast.2019.04.006. Epub 2019 Apr 28. PMID: 31075670.

[20] Dahlbäck C, Ullmark JH, Rehn M, Ringberg A, Manjer J. Aesthetic result after breast-conserving therapy is associated with quality of life several years after treatment. Swedish women evaluated with BCCT.core and BREAST-Q™. Breast Cancer Res Treat. 2017 Aug;164(3):679-687. doi: 10.1007/s10549-017-4306-5. Epub 2017 May 23. PMID: 28536951; PMCID: PMC5495840.

[21] Lagendijk M, van Egdom LSE, van Veen FEE, Vos EL, Mureau MAM, van Leeuwen N, Hazelzet JA, Lingsma HF, Koppert LB. Patient-Reported Outcome Measures May Add Value in Breast Cancer Surgery. Ann Surg Oncol. 2018 Nov;25(12):3563-3571. doi: 10.1245/s10434-018-6729-6. Epub 2018 Sep 3. PMID: 30178391.

[22] Zhang L, Zhou Z, Mei X, Yang Z, Ma J, Chen X, Wang J, Liu G, Yu X, Guo X. Intraoperative Radiotherapy Versus Whole-Breast External Beam Radiotherapy in Early-Stage Breast Cancer: A Systematic Review and Meta-Analysis. Medicine (Baltimore). 2015 Jul;94(27):e1143. doi: 10.1097/MD.0000000000001143. PMID: 26166124; PMCID: PMC4504561.

Appendix List:

Appendix A: Approved Study Protocol

Appendix B: Milpark Hospital CEO Approval

Appendix C: Human Research ethics committee clearance certificate

Appendix D: Turnitin report cover page

Appendix E: Journal guidelines to authors

Appendix A: Approved Study Proposal

Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross-Sectional Study

Shaylin Pillay

Student Number: 300854

Supervisors:

1) Professor Carol Benn, FCS (SA)
   Head of Breast Care Centre of Excellence, Milpark Hospital
   Supervising Capacity: 33,3 %
2) Dr Barend van den Bergh, FC Plast Surg (SA), MMed (Wits)
   Oncological Breast Reconstructive Plastic Surgeon at Breast Care Centre of Excellence, Milpark Hospital
   Supervising Capacity: 33,3%
3) Professor Chrysis Sofianos, MBBCh (Wits), MSc (Ed), FC Plast Surg (SA), MMed (Wits), FRCS Plast (Eng), FACS, FEBOPRAS
   Head of Division of Plastic Surgery and Adjunct Professor, University of the Witwatersrand
   Supervising Capacity: 33,3%

A research proposal submitted to the Faculty of Health Sciences, University of the Witwatersrand. In fulfilment of the requirements for the degree of Master of Medicine (MMed),2024

Table of contents

List of Figures..... ii

Nomenclature iii

1.1 Introduction / Background 4 1.2

Literature Review..... 4 1.3

Study aim and objectives 7

Methodology 8 2.1

Research Question:..... 8 2.2

Research Design 8 2.3

Study Population..... 9

Inclusion Criteria:..... 9

Exclusion Criteria 9

2.4 Sample Size: 9

2.5 Study Site: 10

2.6Data Collection:..... 10

2.7Data Storage 11

2.8Data analysis 11

2.9Ethics 12

3.1Timing..... 13

3.2Funding 13

3.3Limitations..... 13

4.References 15

Appendices..... 19

Appendix A: BREAST-Q BCT 20

Appendix B: Data Collection Form..... 29

Appendix C: Participant Information Sheet 34

List of Figures

Figure 1.1: BREAST-Q BCT Module(23)..... 7
Figure 2: Data Collection Flowchart.....11
Figure 3.1 GANTT Chart 13

Nomenclature

18. APBI – Accelerated Partial Breast Irradiation 19. BCS Breast Conserving Surgery 20. BREAST-Q Breast Questionnaire 2.0 21. BREAST-Q BCT BREAST-Q Breast Conserving Therapy 22. EBRT External Beam Radiation Therapy 23. HRQoL Health Related Quality of Life 24. IORT Intraoperative Radiation Therapy 25. IQR Interquartile Range

26. PROs Patient Reported Outcomes 27. PROM Patient Reported Outcome Measures 28. QoL Quality of Life

1.1Introduction / Background

Breast cancer remains a prevalent health concern worldwide (1), and substantial research has focused on optimising treatment outcomes (2). It is the most commonly diagnosed cancer among women (3), necessitating effective and patient-centred treatment strategies. Breast-conserving surgery (BCS) combined with radiotherapy is a standard treatment modality aimed at removing cancer while preserving breast appearance and function in early stage cancer (4). Intraoperative radiation therapy (IORT) is a promising adjunct to BCS, offering targeted radiation during surgery and potentially improving patient outcomes (5). Assessing patient satisfaction and post treatment quality of life (QoL) is critical for understanding the holistic impact of these interventions (6). The BREAST-Q is a validated tool specifically designed for this purpose, providing insights into patient-reported outcomes of breast cancer treatment (7).

1.2Literature Review

In 2018, 23.2% of all cancers diagnosed in females were attributed to breast cancer (8). The incidence is increasing (8). Through health promotion, breast cancer is being diagnosed at earlier stages (3). South Africa's current guidelines, for early-stage breast cancer, advise breast-conserving surgery with/without radiation or a mastectomy only (9).

Radiation for early-stage breast cancer can be done in several ways, depending on the clinical picture (10). These radiation options include whole-breast external beam radiation therapy (EBRT) or accelerated partial breast irradiation (APBI). The choice of radiation depends on the patients' risk for recurrence (11).

EBRT is done over multiple visits post operatively. It is administered through an external bean and has been associated with increased irradiation of normal tissue, leading to long term complications (10). EBRT is currently the most commonly used form of radiation in South Africa, however in November 2017 Milpark Hospital in Gauteng was the first hospital to offer single dose intraoperative radiation therapy (IORT), a type of APBI, for early-stage breast cancer (12).

IORT provides irradiation directly targeted to the tumour location, in theatre, during breast conserving surgery (11). It is a single dose, thereby not requiring patients to make multiple visits to the hospital for radiation therapy and it is targeted, reducing

the risk of irradiating normal, surrounding tissue (10).

Multiple studies have been carried out, in multiple settings on multiple population groups comparing the efficacy of single dose IORT in comparison to post operative EBRT (5). The largest study was the TARGIT – A trial, which was a randomised controlled trial. The study was conducted across 10 countries in 32 centres and included 2298 women aged 45 and older with invasive ductal carcinoma (13). The study's primary outcome was to assess the local recurrence rate after five years between patients who received IORT and EBRT (13). The study also compared breast cancer mortality and morbidity from other causes between the two arms. The study found that IORT was as effective as EBRT in preventing local recurrence and IORT resulted in less deaths from other causes (13).

The study is generalisable due to its multicentre approach and large sample size from different countries; however, it has been criticised on the choice of non-inferiority margin (study decided on 2.5% for local recurrence) (14). The patients and clinicians also knew which treatment was received which may have led to bias in the reporting of outcomes and patient management. Nevertheless, IORT has been proven to be effective in subsequent trials carried out in China, Japan and the USA to name a few (11,15).

During the Coronavirus (COVID-19) pandemic, IORT was found to be an invaluable tool as it limited vulnerable patient's exposure to the virus, by decreasing their need for post operative radiation (12). This decrease in patient visits was not only beneficial to the patient but was also noted to reduce the resource strain to hospitals (12). A follow up to the TARGIT- A trial also noted the environmental benefits of IORT (due to reduced carbon emissions from travelling)(17).
No matter which radiation option a patient undergoes, there is a myriad of complications that may occur, these are both psychological and physical (18). Patient reported outcome measures are a vital tool in monitoring these complications and their effect to a patient's quality of life (19). By including the patient's perspective on their management and the effect to their quality of life (QoL), researchers and clinicians can gain further insight into the efficacy of their treatment modalities (19).

The BREAST-Q is a validated tool for collecting patient-reported outcomes (PROs) (20). It was developed in 2009 and has been used by both clinicians and researchers alike to collect health-related quality of life (HRQoL) and patient

satisfaction data related to breast surgery (21). It was developed by the Memorial Sloan Kettering Cancer centre. Multiple studies have found the questionnaire to be effective in measuring patients' satisfaction and HRQol. A systematic review carried out in 2018 noted that the information noted in the BREAST – Q was reliable and meaningful, with a potential to impact clinical decision making (18). Another systematic review conducted in 2021 by a different group of researchers also found the BREAST – Q to be effective and reliable and concluded that it was an important tool to assess surgical outcomes (22).

The BREAST – Q has different questionnaires depending on the management choice (7). There is a BREAST – Q designed specifically for BCS – the BREAST-Q BCT. The BREAST – Q BCT has been utilised in multiple studies and has been translated into many languages (23). A study conducted in Europe, translated the BREAST – Q BCT to German and found the validity of the questionnaire still held (20).

The BREAST – Q BCT is further separated into several domains. The modules are stand alone questionnaires and may be used all together or on their own (23). The domains consist of quality of life and satisfaction domains. The domains are shown in fig 1 (23).

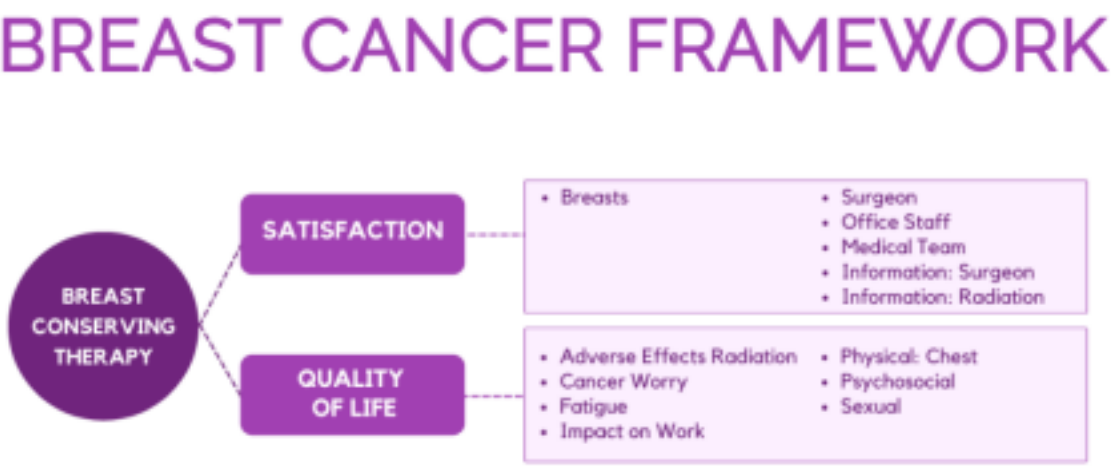


Figure 5.1: BREAST-Q BCT Module(23)

Each of the questions are a scale measure. The questionnaire is self-administered and can be administered as a cross-sectional survey or longitudinally pre-operatively and thereafter, postoperatively. Each component may be used and interpreted independently (23).

The BREAST-Q BCT can be utilised to assess patient satisfaction and quality of life post IORT and provide insight into the effectiveness of IORT from a patient perspective (18). The questionnaire can assist in ascertaining whether the IORT experience is satisfactory for patients and if not, highlight areas of improvement (21).

Intraoperative radiation therapy (IORT) has seen a surge in global adoption, with over 260 facilities across 35 nations currently providing this treatment option (17). Patients are increasingly favouring IORT over EBRT due to its convenience and reduced travel requirements (24). However, despite this growing utilisation, there remains a dearth of research examining patient-reported outcomes following IORT.

The present study aims to address this gap by investigating the level of patient satisfaction and quality of life among South African breast cancer patients who have undergone IORT in conjunction with breast-conserving surgery.

1.3Study aim and objectives

Aim:

To evaluate the level of patient satisfaction and quality of life following breast conserving surgery combined with intraoperative radiation therapy in a cohort of South African breast cancer patients, as measured by the BREAST-Q BCT Questionnaire.

Objectives:

1. To evaluate the impact of IORT on patients' quality of life, focusing on the psychosocial, sexual and physical well-being domains.

2. To identify factors influencing patient-reported outcomes, such as age, tumour biology, and surgical complications, and how they affect satisfaction and QoL post treatment.

3. To compare the post-operative experiences of patients who received IORT with findings from existing literature.

Methodology

2.1 Research Question:

What is the level of patient satisfaction and quality of life, as measured by the BREAST-Q BCT, among South African breast cancer patients who have undergone

intraoperative radiation therapy and breast-conserving surgery in a single-centre cross-sectional study?

2.2 Research Design

This is a cross-sectional study.Data will be collected from patient files. The Breast-Q BCT questionnaire will be distributed to patients who have met the inclusion criteria, are at least six months post radiation and have provided consent.

Six of the 15 scales were found to be relevant to this study and will be used independently (stated in table 1).

Table 2 Illustrating Datapoints

Data Category	Data Point

Demographics	Age (current and at surgery), comorbidities, smoking history, race
Clinical Data	Tumour Characteristics: Biology, Location, Size Post-operative complications
Patient-Reported Outcomes	Satisfaction with breasts, Psychosocial wellbeing, sexual wellbeing, cancer worry, physical wellbeing, adverse effects with radiation

The questionnaire is attached as appendix A

2.3 Study Population

All women from the age of 18 years who have had early-stage breast cancer and underwent breast-conserving surgery and IORT at Milpark Hospital between 2017 and 2024. Patients who suffered from distant metastases, required a modified radical mastectomy for local recurrence after breast-conserving therapy, or required EBRT post IORT will not be included. Patients suffering from serious co-morbidities

that could affect the quality-of-life assessment will also be excluded.

Inclusion Criteria:

1 Females >18 years of age, diagnosed with early-stage breast cancer 2 Patients who underwent breast conserving surgery and IORT at Milpark Hospital 3 Intervention provided from 2017 – June 2024
4 Patients that have undergone IORT at least six months prior to the interview 5 Informed consent signed

Exclusion Criteria: No exclusion criteria have been implemented in this study to minimise research bias and to ensure a more representative sample.

2.4 Sample Size:

The calculated sample size is 132 patients, with a total of 200 patients undergoing isolated IORT at Milpark hospital from 2017 – June 2024. This was calculated using a z score of 1.96 (95% confidence), a 5 % margin of error and 0.5 standard deviation.

Sample Size $= [z2 * p(1-p)] / e2 \,/\, 1 + [z^2 * p(1-p)] / e^2 * N]$

2.5 Study Site:

Milpark Hospital – A private hospital located in Johannesburg, South Africa, and the first hospital in Africa to offer IORT.

2.6 Data Collection:

The BREAST-Q patient-reported outcome measure licence was obtained under the condition that it would only be used for research purposes. Copyright will be included in all distributed questionnaires.

Once ethics has been approved, the secretary from the Breast Care Centre of Excellence will contact potential participants, explaining the nature of the study. Those who agree to participate will then be emailed a link to the self-administered questionnaire. If the patient does not understand English, a translator will explain the study in the language the patient understands. The questionnaire is self-administered, as such consent by the participant is implied by completing the questionnaire.

The questionnaire has been integrated into RedCap and will be pre-tested by a focus group. Participation is voluntary, and all information will remain confidential. For those uncomfortable with technology, the survey can be conducted telephonically or in person, with data manually entered into RedCap. Reminder emails and phone calls will be made to non-respondents.

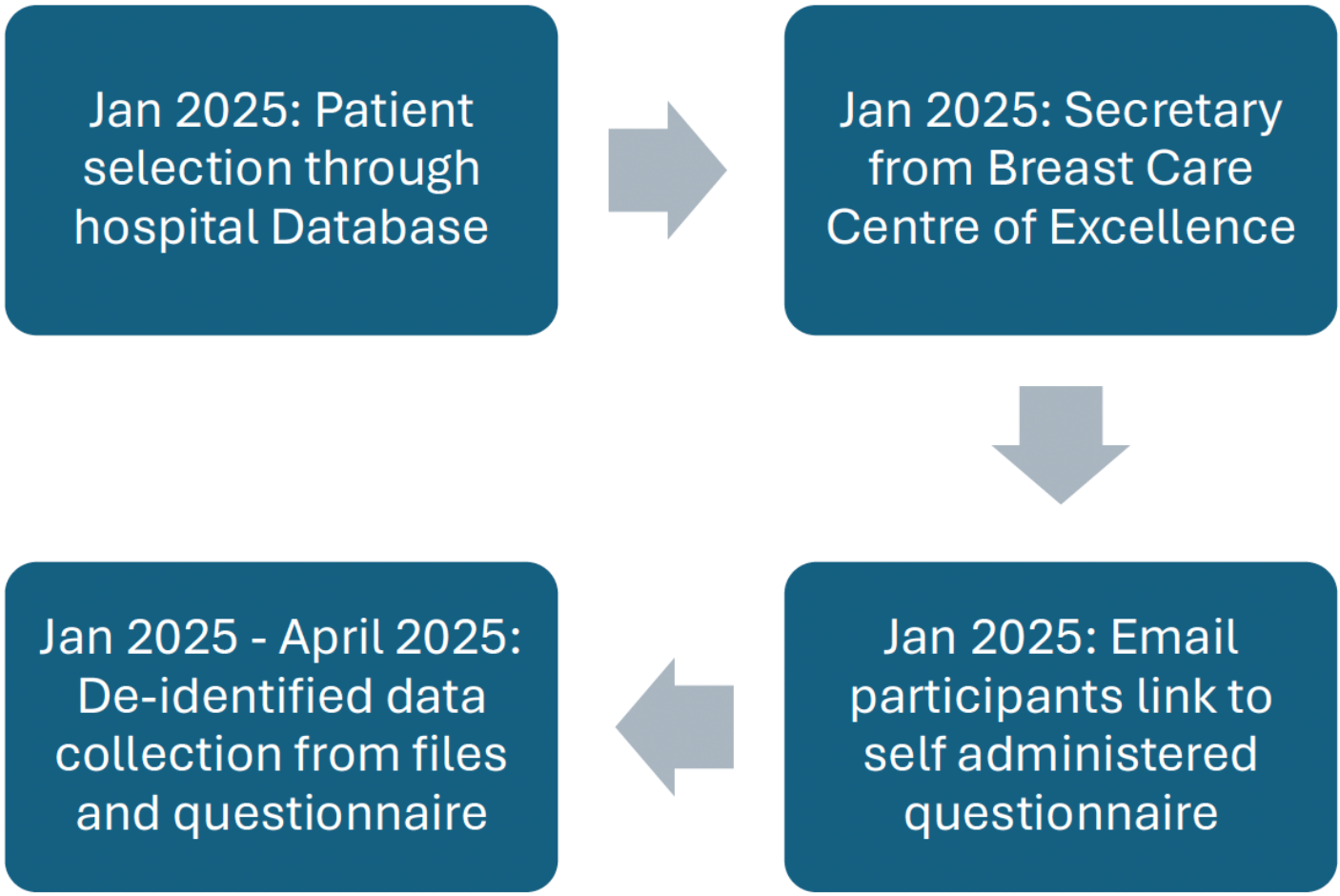


Figure 6: Data Collection Flowchart

2.7 Data Storage

All data captured will be kept anonymous using study IDs. All collected data will be stored securely within the RedCap system, which is compliant with data protection regulations and the POPIA act. Physical copies of consent forms will be stored in a locked cabinet within the principal investigator's office for at least 10 years. Digital data (including recordings) will be encrypted and backed up regularly, on a password protected laptop, to prevent data loss. Access to the data will be restricted to authorised personnel only, ensuring confidentiality and data integrity.

2.8 Data analysis

The data captured on RedCap will be exported into a pre-configured Microsoft Excel worksheet, and scores will be calculated according to the BREAST – Q conversion tables. The raw score is converted to a score of 0 – 100, with a higher score indicating a higher level of satisfaction or quality of life. The data collected will assess their current quality of life and satisfaction.

The score out of 100 for each category will then be interpreted and compared. Descriptive statistics will be used to summarise the characteristics of the data. Means and standard deviation will be utilised for the scores generated, while frequency distribution will be used to describe categorical variables e.g. tumour type and patient demographics. If the data is non-parametric then median and interquartile range will be used.

Comparative analyses will be conducted to assess differences in patient satisfaction and quality of life across various demographic and treatment-related factors. Inferential statistics, such as t-tests or ANOVA, will be used to determine the significance of observed differences, if variables demonstrate normal distribution. Kruskal Wallis analysis will be used if the variables are not normally distributed. A p-value of <0.05 will be considered statistically significant.

The strength of association between numerical variables will be assessed using the Pearson correlation coefficient for normally distributed variables, while the Spearman rank correlation coefficient will be used for variables that do not follow a normal distribution. A random -effect single arm meta-analysis of the mean scores will be run to compare the BREAST-Q means of this study with similar studies conducted.

2.9 Ethics

Ethics approval will be sought from the Human Research Ethics Committee (Medical) (HREC) at the University of the Witwatersrand (WITS). Data will be collected from the Breast Care Centre of Excellence at Netcare Milpark Hospital. The centre is run by Prof. Carol Benn (the supervisor of this research), who has explicitly provided permission to conduct this research.

All efforts will be undertaken to ensure patient confidentiality and anonymity, with the use of study identity numbers and the removal of any identifying features not relevant to the study. Informed consent and voluntary participation will be emphasised, with participants made aware that they may leave the study at any point and their information will only be used with their expressed permission. Data will be stored on encrypted devices and will only be accessible to the principal investigator and supervisors.

Further Considerations:

The participants will be constantly communicated with throughout the study and the findings will be reported back to them.

3.1 Timing

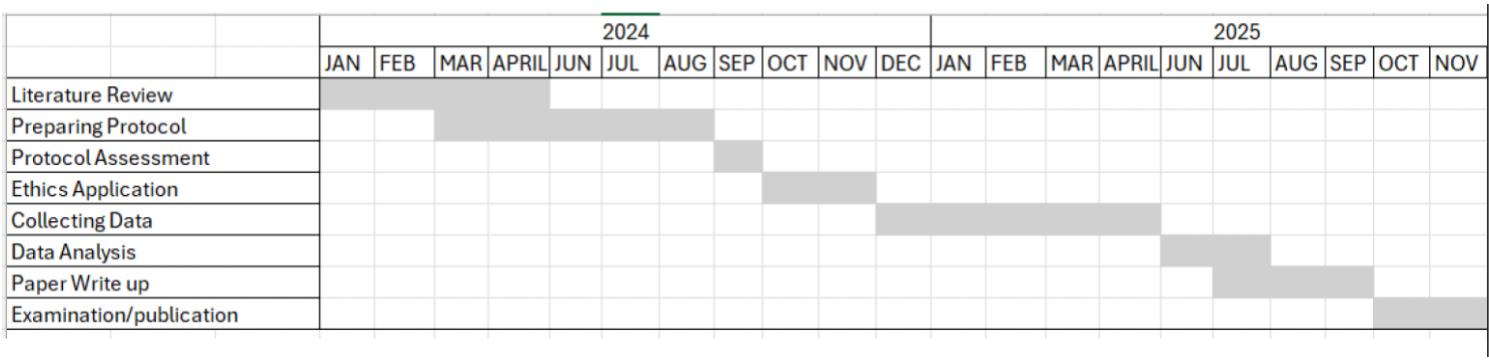


Figure 7.1 GANTT Chart

3.2 Funding

The anticipated cost of the study is R2000. The bulk of the cost will be telephone calls and will be self-funded by the author.

Table 3 Depicting Estimated Costs

Item	Price
Telephone Calls	R1300
Stationary	R100
Petrol	R600

3.3 Limitations

There may be an unwillingness to participate due inconvenience. Through emphasising that their information will be used to improve future patient's experiences and by trying

to accommodate any technological disadvantages through mail and telephonic questionnaires, the principal investigator hopes to mitigate this risk.

The other limitation is that patients may have recall bias when answering questions regarding their experience during the procedure. Nevertheless, the questionnaire mainly asks for their current quality of life and their level of satisfaction.

As a single-centre study, findings may not be generalisable to all South African breast cancer patients or those in different socioeconomic settings.

Cross-sectional design limits the ability to infer causality or track changes over time, it may be valuable to repeat the study, including a pre-operative and post-operative questionnaire.

4. Reference

1. Giaquinto AN, Sung H, Miller KD, Kramer JL, Newman LA, Minihan A, et al. Breast Cancer Statistics, 2022. CA Cancer J Clin [Internet]. 2022 Nov [cited 2024 Feb 2];72(6):524–41. Available from: https://pubmed.ncbi.nlm.nih.gov/36190501/

2. WHO. WHO. 2024 [cited 2024 Jun 9]. Breast cancer. Available from: https://www.who.int/news-room/fact-sheets/detail/breast-cancer

3. Dlamini Thulo Molefi Richard Khanyile Mahlori Mkhabele Botle Damane Alexandre Kokoua Meshack Bida Kamal Saini Nkhensani Chauke-Malinga Thifhelimbilu Emmanuel Luvhengo Rodney Hull ZS, Molefi Á Khanyile TR, Damane B, Kokoua A, Bida M, Saini KS, et al. From Incidence to Intervention: A Comprehensive Look at Breast Cancer in South Africa. [cited 2024 Jun 9]; Available from: https://doi.org/10.1007/s40487-023-00248-1

4. Gilmour A, Cutress R, Gandhi A, Harcourt D, Little K, Mansell J, et al. Oncoplastic breast surgery: A guide to good practice. European Journal of Surgical Oncology [Internet]. 2021 [cited 2023 Nov 28];47:2272–85. Available from: https://doi.org/10.1016/j.ejso.2021.05.006

5. Vaidya JS, Vaidya UJ, Baum M, Bulsara MK, Joseph D, Tobias JS. Global adoption of single-shot targeted intraoperative radiotherapy (TARGIT-IORT) for breast cancer—better for patients, better for healthcare systems. Front Oncol. 2022 Aug 11;12:786515.

6. Javid SH, Lawrence SO, Lavallee DC. Prioritizing Patient-Reported Outcomes in Breast Cancer Surgery Quality Improvement. Breast J [Internet]. 2017 Mar 1 [cited 2024 Jun 5];23(2):127–37. Available from: https://pubmed.ncbi.nlm.nih.gov/27779352/

7. Cohen WA, Mundy LR, Ballard TN, Klassen A, Cano SJ, Browne J, et al. The BREAST-Q In Surgical Research: A Review Of The Literature 2009-2015. [cited 2024 Jun 8]; Available from: https://webcore.mskcc.org/breastq/

8. Statistics South Africa. CANCER IN SOUTH AFRICA [Internet]. 2023 Mar [cited 2023 Nov 30]. Available from: www.statssa.gov.za

9. CLINICAL GUIDELINES FOR BREAST CANCER CONTROL AND

MANAGEMENT.

10. Wang Y, Shen J, Gu P, Wang Z. Recent advances progress in radiotherapy for breast cancer after breast-conserving surgery: a review. Front Oncol [Internet]. 2023 [cited 2024 Jun 19];13. Available from: /pmc/articles/PMC10475720/

11. Brown A, Buss EJ, Chin C, Liu G, Lee S, Rao R, et al. Targeted Intraoperative Radiotherapy (TARGIT-IORT) for Early-Stage Invasive Breast Cancer: A Single Institution Experience. Front Oncol [Internet]. 2022 Jun 29 [cited 2024 Jun 19];12:1. Available from: /pmc/articles/PMC9277011/

12. Ramdas Y, Benn CA, van Heerden M. First Intraoperative Radiation Therapy Center in Africa: First 2 Years in Operation, Including COVID-19 Experiences. JCO Glob Oncol. 2020 Nov 6;(6):1696–703.

13. Vaidya JS, Bulsara M, Baum M, Wenz F, Massarut S, Pigorsch S, et al. Long term survival and local control outcomes from single dose targeted intraoperative radiotherapy during lumpectomy (TARGIT-IORT) for early breast cancer: TARGIT-A randomised clinical trial. The BMJ [Internet]. 2020 Aug 19 [cited 2024 Jun 5];370. Available from: /pmc/articles/PMC7500441/

14. Sasieni PD, Sawyer EJ. Intraoperative radiotherapy for early breast cancer - insufficient evidence to change practice. Nat Rev Clin Oncol. 2020 Dec;17(12):723-724. doi: 10.1038/s41571-020-00444-2. PMID: 33087894; PMCID: PMC7576112.

15. Mi Y, Lv P, Wang F, Li L, Zhu M, Wang Y, et al. Targeted Intraoperative Radiotherapy Is Non-inferior to Conventional External Beam Radiotherapy in Chinese Patients With Breast Cancer: A Propensity Score Matching Study. Front Oncol [Internet]. 2020 Oct 8 [cited 2022 Dec 26];10:550327. Available from: http://www.ncbi.nlm.nih.gov/pubmed/33134162

16. Sawaki M, Kondo N, Horio A, Ushio A, Gondo N, Adachi E, et al. Feasibility of intraoperative radiation therapy for early breast cancer in Japan: A single center pilot study and literature review. Breast Cancer. 2014;21(4):415–22.

17. Vaidya JS, Vaidya UJ, Baum M, Bulsara MK, Joseph D, Tobias JS. Global adoption of single-shot targeted intraoperative radiotherapy (TARGIT-IORT) for breast cancer—better for patients, better for healthcare systems. Front Oncol

[Internet]. 2022 Aug 11 [cited 2024 Jun 19];12. Available from: https://www.targit.org.uk

18. Liu LQ, Branford OA, Mehigan S. BREAST-Q Measurement of the Patient Perspective in Oncoplastic Breast Surgery: A Systematic Review. Plast Reconstr Surg Glob Open [Internet]. 2018 [cited 2024 Jun 19];6(8). Available from: /pmc/articles/PMC6143323/

19. Weldring T, Smith SMS. patient-Reported Outcomes (pROs) and patient Reported Outcome Measures (pROMs). Health Serv Insights [Internet]. 2013 [cited 2024 Jun 19];(6):61–8. Available from: http://www.la-press.com.

20. Stolpner I, Heil J, Feißt M, Karsten MM, Weber WP, Blohmer JU, et al. Clinical Validation of the BREAST-Q Breast-Conserving Therapy Module. Ann Surg Oncol [Internet]. 2019 Sep 15 [cited 2024 Jun 19];26(9):2759–67. Available from: https://pubmed.ncbi.nlm.nih.gov/31115853/

21. Panayi AC, Knoedler S, Knoedler L, Tapking C, Hundeshagen G, Diehm YF, et al. Patient-reported Outcomes Utilizing the Breast-Q Questionnaire After Breast Conserving Surgery With and Without Oncoplastic Breast Surgery: A Systematic Review and Meta-analysis. Aesthet Surg J [Internet]. 2024 Jan 9 [cited 2024 Jun 19]; Available from: https://dx.doi.org/10.1093/asj/sjae002

22. Seth I, Seth N, Bulloch G, Rozen WM, Hunter-Smith DJ. Systematic Review of Breast-Q: A Tool to Evaluate Post-Mastectomy Breast Reconstruction. Breast Cancer (Dove Med Press) [Internet]. 2021 [cited 2024 Jun 19];13:711–24. Available from: https://pubmed.ncbi.nlm.nih.gov/34938118/

23. BREAST-Q | Breast Cancer - Q-Portfolio MEASURING WHAT MATTERS TO PATIENTS [Internet]. [cited 2024 Jun 20]. Available from: https://qportfolio.org/breast-q/breast-cancer/

24. Corica T, Nowak AK, Saunders CM, Bulsara M, Taylor M, Vaidya JS, et al. Cosmesis and Breast-Related Quality of Life Outcomes After Intraoperative Radiation Therapy for Early Breast Cancer: A Substudy of the TARGIT-A Trial. Int J Radiat Oncol Biol Phys. 2016 Sep 1;96(1):55–64.

Appendices

Appendix A: BREAST-Q BCT

Questionnaire Appendix B: Data

Collection Tool Appendix C: Participant

Information Sheet

Appendix A: BREAST-Q BCT

BREAST-Q®

Version 2.0

Breast Conserving Therapy Module

Pre- and Postoperative Scales

English Version

The BREAST-Q, authored by Drs. Andrea Pusic, Anne Klassen and Stefan Cano, is the copyright of Memorial Sloan Kettering Cancer Center, The University of British Columbia, McMaster University, and Brigham and Women's Hospital (Copyright ©2017, Memorial Sloan Kettering Cancer Center). The BREAST-Q has been provided under license and must not be copied, distributed, or used in any way without the prior consent of Memorial Sloan Kettering Cancer Centre.

BREAST-Q™ – BREAST CANCER CORE SCALE (PRE- AND POSTOPERATIVE)

VERSION 2.0: PSYCHOSOCIAL WELL-BEING

With your breast area in mind, in the past week, how often have you felt:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Confident in a social setting?	**1**	**2**	**3**	**4**	**5**
b. Emotionally able to do the things that you want to do?	**1**	**2**	**3**	**4**	**5**
c. Emotionally healthy?	**1**	**2**	**3**	**4**	**5**
d. Of equal worth to other women?	**1**	**2**	**3**	**4**	**5**

e. Self-confident?	**1**	**2**	**3**	**4**	**5**
f. Feminine in your clothes?	**1**	**2**	**3**	**4**	**5**
g. Accepting of your body?	**1**	**2**	**3**	**4**	**5**
h. Normal?	**1**	**2**	**3**	**4**	**5**
i. Like other women?	**1**	**2**	**3**	**4**	**5**
j. Attractive?	**1**	**2**	**3**	**4**	**5**

BREAST-Q VERSION 2.0 © 2017 Memorial Sloan Kettering Cancer Center and The University of British Columbia. All rights reserved.

23

Thinking of your sexuality, how often do you generally feel:

	None of the time	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
a. Sexually attractive in your clothes?	**1**	**2**	**3**	**4**	**5**
b. Comfortable/at ease during sexual activity?	**1**	**2**	**3**	**4**	**5**
c. Confident sexually?	**1**	**2**	**3**	**4**	**5**

d. Satisfied with your sex-life?	**1**	**2**	**3**	**4**	**5**
e. Confident sexually about how your breast area looks when unclothed?	**1**	**2**	**3**	**4**	**5**
f. Sexually attractive when unclothed?	**1**	**2**	**3**	**4**	**5**

BREAST-Q VERSION 2.0 © 2017 Memorial Sloan Kettering Cancer Center and The University of British Columbia. All rights reserved.

24

CANCER WORRY:

These statements ask about the WORRY you may be experiencing about breast cancer. With your BREAST CANCER in mind, how much do you agree or disagree with each statement:

	Definitely disagr	**Somewhat disagre**	**Somewhat agree**	**Definitely agree**

	ee	e		
a. I worry my breast cancer may spread to other parts of my body.	**1**	**2**	**3**	**4**
b. I worry I might get another type of cancer in the future.	**1**	**2**	**3**	**4**
c. Breast cancer is always in the back of my mind.	**1**	**2**	**3**	**4**
d. I worry about late effects that might happen to me. (Note: a late effect is a health problem caused by cancer or its treatment).	**1**	**2**	**3**	**4**
e. I worry about breast cancer treatment damaging my body.	**1**	**2**	**3**	**4**
f. I worry I may die from breast cancer.	**1**	**2**	**3**	**4**
g. I worry about my breast cancer treatment not working.	**1**	**2**	**3**	**4**
h. I worry about my breast cancer every day.	**1**	**2**	**3**	**4**
i. Worrying about my breast cancer interferes with my daily activities.	**1**	**2**	**3**	**4**
j. Worrying about breast cancer keeps me from enjoying my life.	**1**	**2**	**3**	**4**

Copyright ©2019, Memorial Sloan Kettering Cancer Center, Brigham and Women's Hospital, and McMaster University. All rights reserved

25

PHYSICAL WELL-BEING: CHEST

In the past week, how often have you experienced:

	None of the time	Some of the time	All of the time
a. Difficulty lifting or moving your arms?	**1**	**2**	**3**
b. Difficulty sleeping because of discomfort in your breast area?	**1**	**2**	**3**
c. Tightness in your breast area?	**1**	**2**	**3**
d. Pulling in your breast area?	**1**	**2**	**3**
e. Tenderness in your breast area?	**1**	**2**	**3**
f. Sharp pains in your breast area?	**1**	**2**	**3**
g. Aching feeling in your breast area?	**1**	**2**	**3**
h. Difficulty laying on the side of your lumpectomy breast?	**1**	**2**	**3**
i. Swelling of the arm (lymphedema) on the side(s) that you had your breast surgery?	**1**	**2**	**3**

BREAST-Q VERSION 2.0 © 2017 Memorial Sloan Kettering Cancer Center and The University of British Columbia. All rights reserved.

26

SATISFACTION WITH BREASTS

The following questions are about your breasts and your breast cancer treatment (by treatment, we mean lumpectomy with or without radiation). If you have had a lumpectomy and radiation of both breasts, answer these questions thinking of the breast you are least satisfied with. With your breasts in mind, in the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	**Somewhat Dissatisfied**	**Somewhat Satisfied**	**Very Satisfied**
a. How you look in the mirror clothed?	**1**	**2**	**3**	**4**
b. The shape of your lumpectomy breast when you are wearing a bra?	**1**	**2**	**3**	**4**
c. How normal you feel in your clothes?	**1**	**2**	**3**	**4**
d. Being able to wear clothing that is more fitted?	**1**	**2**	**3**	**4**
e. How your lumpectomy breast sits/hangs?	**1**	**2**	**3**	**4**
f. How smoothly shaped your lumpectomy breast looks?	**1**	**2**	**3**	**4**
g. The contour (outline) of your lumpectomy breast?	**1**	**2**	**3**	**4**
h. How equal in size your breasts are to each other?	**1**	**2**	**3**	**4**
i. How normal your lumpectomy breast looks?	**1**	**2**	**3**	**4**

j. How much your breasts look the same?	**1**	**2**	**3**	**4**
k. How you look in the mirror unclothed?	**1**	**2**	**3**	**4**

BREAST-Q VERSION 2.0 © 2017 Memorial Sloan Kettering Cancer Center and The University of British Columbia. All rights reserved.

27

ADVERSE EFFECTS OF RADIATION

If you have had radiation on both breasts, answer these questions thinking of the breast you are least satisfied with. With your radiated breast(s) in mind, in the past week, how much have you been bothered by:

	Not at all	**A little**	**A lot**
a. Your radiated breast skin looking different (e.g., too dark or too light)?	**1**	**2**	**3**
b. Marks on your breast skin caused by radiation (e.g., small visible blood vessels)?	**1**	**2**	**3**
c. Your radiated breast skin feeling dry?	**1**	**2**	**3**
d. Your radiated breast skin feeling sore (sensitive) when touched (e.g., changes in water temperature when you bathe/shower)?	**1**	**2**	**3**
e. Your radiated breast skin feeling unnaturally thick (rough, tough) when you touch it?	**1**	**2**	**3**
f. Your radiated breast skin feeling irritated by clothing that you wear?	**1**	**2**	**3**

BREAST-Q VERSION 2.0 © 2017 Memorial Sloan Kettering Cancer Center and The University of British Columbia. All rights reserved.

Appendix B: Data Collection Form

Data collected from files by investigator

1. Data to be collected from patient

Appendix C: Participant Information Sheet

Participant Information Sheet

Title of Study:

Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross Sectional Study

Principal Investigator:

Shaylin Pillay, 0837801511, shaylin.pillay@wits.ac.za

Study Association:

University of the Witwatersrand

Purpose of the Study:

My name is Shaylin Pillay, I am currently training to be a plastic surgeon. As part of my training I need to complete a Masters in Medicine, which requires research.. We are inviting you to participate in this research. The study aims to assess patient satisfaction following intraoperative radiation therapy and breast conserving surgery.and will not only assist me, but will also help us understand how patients feel about their treatment and overall quality of life after surgery. This will assist us in improving our services and management plans for future patients.

Procedures:

If you agree to participate in this study, you will be asked to:

- Complete the BREAST-Q BCT questionnaire, which includes questions about your satisfaction with your breast surgery and your overall quality of life.
- Provide demographic information such as age, and medical history related to your breast cancer treatment.

- This process will take approximately 20 minutes and is conducted online. If you are uncomfortable with computers, we may also conduct the survey in person or telephonically (depending on your preference)

Voluntary Participation:

Participation in this study is entirely voluntary. You may choose not to participate or to withdraw from the study at any time without affecting your medical care. Even if you have provided consent, you may still decide to not participate or for your data not to be used in our research.

Risks and Benefits:

- **Risks:** There are no physical risks associated with this study. Some questions may make you feel uncomfortable, but you are free to skip any question you do not wish to answer.
- **Benefits:** There are no direct benefits to you for participating. However, the information gathered may help improve future patient care and treatment strategies.

Confidentiality:

All information collected during this study will be kept **strictly confidential**. Any identifying information will be **removed** where possible and numbers will be allocated to protect your identity. No names will be recorded. This data will only be accessible to authorised researchers and stored securely according to the **Protection of Personal Information Act (POPIA)**.

Contact Information:

If you have any questions or concerns about the study, you can contact me on 0837801511 or shaylin.pillay@wits.ac.za. The findings of this study will be compiled

into a research report that can be accessed online via the university library website. If you have any questions, concerns, or complaints about the ethical procedures involved in this study, please feel free to reach out to the Wits University Human

Research Ethics Committee at +27(0)11 717 1408 or via email at hrec medical.researchoffice@wits.ac.za.

Thank you for considering participating in our study. Your input is invaluable in helping us improve the quality of care for future patients undergoing similar treatments. If you are happy to participate, please sign the attached consent form.

Yours sincerely,

Dr Shaylin Pillay

Appendix B: Milpark Hospital CEO Permission Letter

NETCARE hospitals

Netcare Hospitals (Pty) Ltd T/A
Netcare Milpark Hospital
9 Guild Road, Parktown West, Johannesburg, 2193
PO Box 91155, Auckland Park, 2006
Tel: +27 (0) 11 480 5600
Corporate Fax: +27 (0) 11 482 3317
www.netcare.co.za

17th December 2024

LETTER CONFIRMING KNOWLEDGE OF NON-TRIAL RESEARCH TO BE CONDUCTED IN THIS NETCARE FACILITY

Re: "Patient Satisfaction and Quality of Life After Breast-Conserving Surgery and Intraoperative Radiotherapy in South African Breast Cancer Patients: A Cross-Sectional Study.

Dear Dr Shaylin Pillay

We hereby confirm knowledge of the above named research application to be made to the Netcare Research Operational Committee and in principle agree to the research application for Netcare Milpark Hospital, subject to the following:

1. That the data collection may not commence prior to receipt of FINAL APPROVAL from the Sustainability Committee of Netcare (Research Operational Committee).
2. A copy of the research report will be provided to Netcare Research Operational Committee once it is finally approved by the tertiary institution, or once complete.
3. Netcare has the right to implement any Best Practice recommendations from the research.
4. That the Hospital/Site/Division Management reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects / Netcare or should the researcher not comply with the conditions of approval.

We wish you success in your research.

Yours faithfully

Signed by David Stanton
Hospital General Manager

17/12/2024
Date

Directors: R H Friedland (CEO), K N Gibson (CFO), E Bock (Managing Director: Hospital Division), C Grindell (Managing Director: 911) Company Secretary: C Vikisi Reg. No. 1996/006591/07

NETCARE

Appendix C: Human Research Ethics Committee (Medical) Ethics Clearance

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG	HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

Office of the Deputy Vice-Chancellor (Research and Innovation)

TO: Dr S Pillay
School of Clinical Medicine
Department of Surgery
Division of Plastic and Restorative Surgery
Faculty of Health Sciences

E-mail: say911p@gmail.com

CC: Supervisor: Professors C-A Benn and C Sofianos; Dr B van den Berg <drbenncarol@gmail.com>
and <HREC-Medical Research Office@wits.ac.za>

FROM: Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 2024/12/20

REF: R14/49

PROTOCOL NO: **M241169** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)

PROJECT TITLE: *Patient satisfaction and quality of life after breast-conserving surgery and intraoperative radiotherapy in South African breast cancer patients: a cross-sectional study*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.

MSWorks2000/Iain0007/Clearscan.wps

Appendix D: Turnitin Report

MMED Article Turnitin-1.docx

ORIGINALITY REPORT

19%	11%	13%	6%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	"2018 Annual Meeting Official Proceedings, Volume XIX", Annals of Surgical Oncology, 2018 Publication	3%
2	Submitted to University of Witwatersrand Student Paper	2%
3	www.ncbi.nlm.nih.gov Internet Source	2%
4	www.frontiersin.org Internet Source	1%
5	Steven J. Kronowitz, John R. Benson, Maurizio B. Nava. "Oncoplastic and Reconstructive Management of the Breast", CRC Press, 2020 Publication	1%
6	healthdocbox.com Internet Source	1%
7	Submitted to Oxford Brookes University Student Paper	1%
8	Submitted to Southern New Hampshire University - Continuing Education Student Paper	1%
9	Submitted to Touro College Student Paper	1%

Appendix E: Journal Guidelines