STUDY PROTOCOL

VIRTUAL VS PHONE EDUCATION IN RADIOTHERAPY – RANDOMIZED CLINICAL TRIAL

Michael Velec FCAMRT, PhD, MRT(T)
Anne Koch, MD, FRCPC, PhD

Department of Radiation Therapy
Princess Maragaret Cancer Center

Protocol Version 1
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Protocol Summary

Full Title: *Virtual vs Phone Education in Radiotherapy – Randomized Clinical Trial*

Short Title: *VIPER-RT*

Study Type: *Randomized Clinical Trial.*

Sample Size: *130 breast cancer patients. All radically treated breast cancer patients at the Radiation Therapy Department in Princess Margaret Cancer Center will be approached*

Study Population*: Breast cancer patients being treated with adjuvant breast radiotherapy at the Princess Margaret Cancer Centre (PMCC)*

Accrual Period: *7 months*

Study Design: *This study will employ a randomized clinical trial in which consented patients will be randomized into one of two groups for pre-treatment radiotherapeutic education. Patients will be placed into either the Control Group – Radiation Therapist led pre-treatment education using telephone calls as part of standard care, or the Intervention Group – Radiation Therapist led pre-treatment education using Microsoft Teams videoconferencing. Patients will be given a set of questionnaires prior to any education (T1), after their CT simulation appointment (T2) and at the end of their first radiation therapy treatment (T3) to assess effectiveness of education at reducing patients' procedural concerns, anxiety and overall satisfaction.*

Study Duration: *November 2025 to May 2026*

Study Intervention: *Pre-treatment radiotherapy education using video-conferencing software (i.e. Microsoft Teams)*

Primary Objective: *To compare whether the use of videoconferencing is more effective than telephone pre-treatment education at reducing breast cancer patients' procedural fears and concerns related to their radiation therapy treatment.*

Secondary Objective: *To compare whether the use of video-conferencing is more effective than telephone pre-treatment education at reducing patient reported anxiety levels.*

Endpoints of the study:

- *Patient reported procedural fears and concerns measured by the Cancer Treatment Survey procedural fears and concerns subscale (CaTS-PC)*
- *Patient reported anxiety levels measured by Hospital Anxiety and Depression Scale anxiety subscale (HADS-A)*
- *Patient reported satisfaction with virtual care measured by survey adapted from Berlin et Al*

1.0 GENERAL INFORMATION

1.1 Virtual vs Phone Education in Radiotherapy – Randomized Clinical Trial (Version 1)

Co-Principal Investigators:
Michael Velec[1 2], PhD, fCAMRT, MRT(T)
Radiation Medicine Program, Princess Margaret Cancer Centre
University Health Network
610 University Avenue, RM 2B-615
Toronto, ON, M5G 2M9 Phone: 416-946-4501 x 4885
Email: Michael.velec@uhn.ca

Anne Koch[1 2], MD, FRCPC, PhD
Radiation Medicine Program, Princess Margaret Cancer Centre
University Health Network
610 University Avenue, RM 4-902
Toronto, ON, M5G 2M9 Phone: 416946 4501 x 2125

Co-Investigator(s):

- Alvin Cuni[1 3], MRT(T), MSc(cand.)
- Yat Tsang[1 2], PhD
- Jennifer Croke[1 2], MD, FRCPC
- Anna Santiago, MSc

[1]Radiation Medicine Program, Princess Margaret Cancer Centre, University Health Network
[2]Department of Radiation Oncology, University of Toronto
[3]Institute of Medical Sciences, University of Toronto

2.0 BACKGROUND INFORMATION

2.1 Background

Breast cancer (BC) is a major health concern worldwide. In 2024, it was stated that breast cancer makes up almost 25% of all new cancer diagnoses in women. Breast cancer was also found to be the leading cause of cancer death in women[1]. The use of Radiation Therapy (RT) plays a major role in the treatment of breast cancer. Although RT has such a large role, the complexity of RT can be psychologically and physically demanding for patients. Many patients are provided with information by their oncologist at initial consultations; however, their information needs remain high before treatment planning and commencement[9]. These same patients will seek out a large amount of information to help facilitate understanding of RT[4,5]. In almost 50% of patients experience heightened anxiety and distress prior to radiotherapy, potentially resulting in longer daily treatments and worse treatment adherence[10].

A study comparing the use of two in-person radiation therapist led education sessions, one prior to CT-Simulation and the other prior to the first day of treatment found significantly lower levels of anxiety, depression and radiotherapy concerns post day 1 of radiation[10]. Likewise, a study comparing the use of two medical physicist led education with radiotherapy patients prior to CT-Simulation and treatment to the standard radiation therapist led education session found statistically significant decreased anxiety levels, and increased patient technical satisfaction at the first treatment time point. Evidence from these studies suggests the use of pre-treatment education session led by a Radiation Therapist(s) can be beneficial to reduce patients' procedural fears, concerns and overall anxiety levels[7,10].

Due to the COVID-19 pandemic a significant transition to virtual appointments was done at Princess Margaret Cancer Centre[12]. In the radiation therapy department specifically, the major shift was in pre-treatment education. The change resulted in all pre-treatment education appointments moving to telephone calls from in-person education., with the use of telephone calls has remaining as the standard since. Recently, evidence has come out to show the use of videoconferencing-based education having high levels of patient's satisfaction than that of telephone calls, as well as a larger patient preference for telephone calls. Recently a study by Magliozzi et al found the use of videoconferencing-based education demonstrated high levels of patient satisfaction and preference over telephone consultations[11.]

2.2 Rationale for the study

At our institution since the COVID 19 pandemic, restrictions to in-person activities are no longer in place. However practices for pre-treatment radiotherapy education with telephone calls have remained, largely as a convenience for staff and patients. Currently, evidence directly comparing these two modalities against each other is lacking.

2.2 Participant Risks and Benefits

2.2.1 Potential Risks and Risk Management

There are no associated risks to patients in this study.

2.2.2 Potential Benefits

The main benefits include reduced radiation therapy related fears and concerns, and anxiety. Since use of videoconferencing allows for a face-to-face educational approach with patients with images and graphics to help facilitate patient understanding, that the use of telephone calls does not have. Patient informational needs and questions are more likely to be answered, resulting in less concerns and fears due to treatment and lower anxiety levels.

2.3 Study Population

Study population is limited to patients receiving radical breast cancer radiotherapy at the Princess Margaret Cancer Center. These patients must be 18 years of age or older, have access to an internet connected device with Microsoft Teams platform, and be able to communicate in English with or without the help of a hospital issued translator or caregiver.

3.0 STUDY OBJECTIVES AND HYPOTHESIS

3.1.1 Primary Objectives

To determine whether the use of videoconferencing for pre-treatment education is more effective at reducing patient procedural fears and concerns.

3.1.2 Secondary Objectives

3.1.2a Anxiety Levels

To determine whether the use of videoconferencing for pre-treatment education is more effective at reducing patient anxiety levels in relation to radiotherapeutic treatment.

3.1.2b Satisfaction

To determine whether the use of videoconferencing for pre-treatment education has higher satisfaction levels than telephone calls.

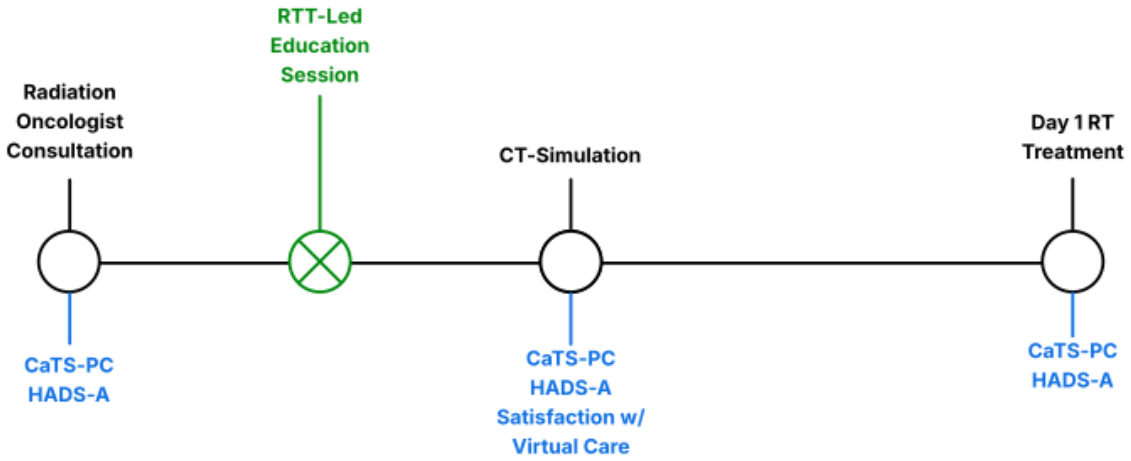
3.2 Study Hypothesis

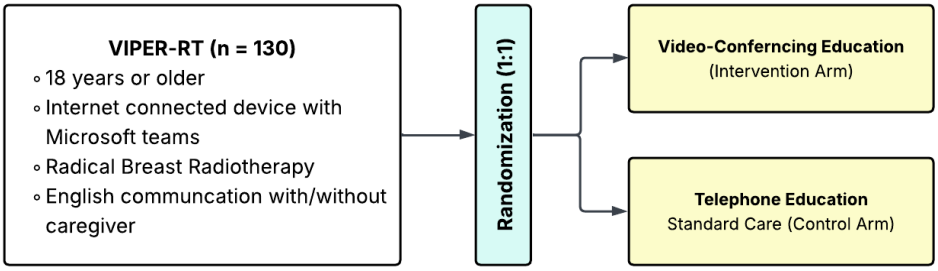
The use of videoconferencing for pre-treatment radiotherapy education will decrease breast cancer patients' procedural fears and concerns.

4.0 STUDY DESIGN

This study will employ a single centre randomized clinical trial in which patients will be randomized into one of two groups. The study will have prospective longitudinal data collection via a set of questionnaires given at three time points. Time one (T1) baseline, Time two (T2) post CT simulation, and Time three (T3) after radiation treatment one. Participation in the questionnaires is mandatory for patients in the study population; however, patients are free to withdraw from the study at any points. An online or paper version of the questionnaires will be given to patients at each of the time points and will be collected by

research team for data analysis. Patients will be reminded by their Radiation Therapists that they will have questionnaires to fill out before any of the appointments.





4.1 Endpoints

4.1.1 Primary Endpoints
This will be measured using the Cancer Treatment Survey (CaTS) procedural fears and concerns subscale (CaTS-PC) at 3 time points, T1 baseline, T2 post CT Simulation and T3: post RT day 1. These measurements will be compared between the control and intervention group at each time point.

4.1.2 Secondary Endpoint(s)

4.1.2a Anxiety Levels
Anxiety levels will be measured using the Hospital Anxiety and Depression Scale (HADS) anxiety subscale (HADS-A) at 3 time points, T1: baseline, T2: post CT-Simulation and T3: post RT day 1. Anxiety levels will be compared between the control and intervention groups at each time point.

4.1.2a Satisfaction
Measured using a survey adapted from Berlin et Al looking at patients' satisfaction with virtual care[12]. This will be measured at time T2. Satisfaction will be compared between control and intervention group.

4.2 Specific Design
As this study employs a prospective randomized clinical trial design all consent patients will be randomized 1:1 into either the control group (telephone) or intervention group (videoconferencing) for their pre-treatment RTT-led education session

5.0 SELECTION OF PARTICIPANTS

5.1 Inclusion Criteria

- 18 years or older
- Access to internet connected device with a working microphone and webcam.
- Radical radiotherapy treatment for breast cancer
- Able to communicate in English with/without caregiver.

5.2 Exclusion Criteria

- Previous radiotherapy treatment

5.3 Withdrawal of Participation

Study participants may withdraw their participation at any time.

6.0 STUDY INTERVENTION

Currently the standard of care at Princess Margaret Cancer Center is for all new breast radiotherapy patients is to receive a 30-minute Radiation Therapist (RTT) led telephone pre-treatment education session to explain all procedures and answer patients' questions about their upcoming radiotherapy treatment and associated appointments. Telephone appointments are scheduled for the day before the patients CT-Simulation procedure. Given the preliminary pilot experience for the use of videoconferencing for pre-treatment education the study intervention will employ a 45-minute RTT-led education session with the use of Microsoft Teams also scheduled the day before the patients CT-Simulation appointment. Information given for both sessions will remain consistent across both the control and intervention arm. Videoconferencing will use a standardized slide show with images and graphics to help facilitate patient education and explain procedures, however information shown on the slides will be consistent with that given to patients over the phone in the control arm. The slide show has been previously developed as part of standard care. Patients will be given time to ask questions and a contact to follow up should any questions arise.

7.0 STATISTICS

A total sample of 116 patients (58 Telephone, 58 Videoconference), measured at 3 time points, will achieve 80% power at a 0.05 significance level to detect a 0.44 mean difference in Cancer Treatment Survey (CaTS) Procedural Concerns subscale scores between groups using a repeated measures design. The assumed standard deviation is 1.35, with a compound symmetry covariance structure and autocorrelation of 0.08. Based on the study by Halkett et al. (2018) for the same subscale score, the mean difference was derived from the estimate at the Prior to Treatment Planning (F1) time point, the assumed standard deviation is 25% lower than the estimated value of 1.80 from all confidence intervals, and the autocorrelation value was estimated from the reported Cohen's d at the Treatment completion (F3) time point. Anticipating a 10% dropout rate, the target recruitment sample is 130 (65 Telephone, 65 Videoconference). Sample size was calculated using PASS 2025, version 25.0.2.

8.0 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

Access to the study data will be restricted to authorized study personnel only. This includes the Principal Investigators and co-investigators only. Data access will be managed through secure login credentials. Data collected from online questionnaires will be recorded electronically in REDCap and will be stored on secure servers at UHN for 10 years. Data collected from paper questionnaires will be transferred onto excel and kept on secure servers at UHN for 10 years. Paper questionnaires will be kept in a key-locked cabinet. Data integrity measures will be put in place, including audit trials to track data entry. Participant confidentiality will always be maintained. Any demographic information collected from patients will be

stored separately from the study questionnaire responses. Study results will be published in scientific journals and presented at conferences. However, only aggregated data will be reported, and no individual participant will be identifiable in any publications or presentations.

9.0 ETHICS

Informed consent will be obtained at the time of radiation oncology consult which will be either in-person or virtually. Patients will be presented information regarding the study from a member of the study team. Individuals who agree to the study will sign the consent form at this time. Participants will have the right to withdraw at any point. The participants responses will be kept confidential, and all demographic details will only be reported when aggregated. All information will be kept in a password protected drive, accessible only to the study team. Patients paper questionnaires (if applicable) will be kept in a key-locked cabinet.

9.1 Consent Process

Potential participants will be identified using patient electronic medical records (EPIC). A study team member will speak with all potential participants with a brief study introduction. Participants will fill out a paper consent form if seen in-person by the study team member or will fill complete an eConsent process if approached virtually. If the potential participant indicates they consent to participate, the co-investigator will then give them the paper questionnaire set.

9.2 Ethical Review

The study will be submitted for initial and ongoing annual UHN REB review. Study related procedures will not commence prior to receipt of REB approval. Any amendment to the study will be submitted for REB review before any changes are implemented, unless required to eliminate immediate hazard to the study participants

9.3 Protocol Deviations

A protocol deviation is defined as any noncompliance with this clinical trial protocol and/or the Good Clinical Practice guidelines. All deviations from the protocol will be noted in the study files. Any deviation will be reported to the study team, and corrective actions will be implemented promptly where possible. Any serious protocol deviations will be reported to the REB.

13.0 Data Handling and Record Keeping

Access to all data will be managed through secure login credentials. Data collected via questionnaires will be recorded electronically in REDCap and will be stored on secure severs at UHN for 10 years.

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