THOMAS JEFFERSON UNIVERSITY
Kimmel Cancer Center

TELEPORT STUDY:

A Pilot Feasibility Trial Examining The Use of Telehealth in Post Radiation Therapy Visits

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Protocol Number:	*15D.580*

*Investigator allowed to perform Telehealth visits for New Jersey residents

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Version 6.0 (2017-10-16)

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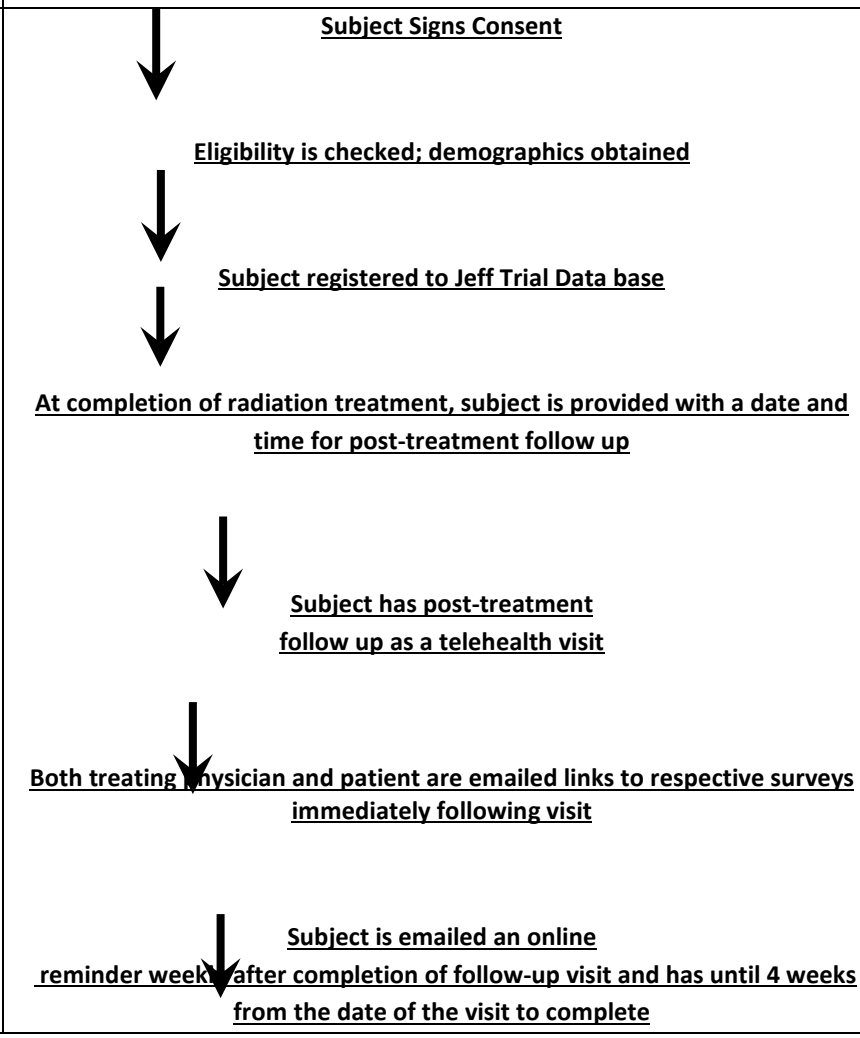
List of Abbreviations

TELEPORT- Telehealth in post radiation therapy visits
RT – radiation therapy
KPS - Karnofsky Performance Status
PSCC – patient satisfaction with cancer care scale
CAT – communication assessment tool

Study Summary

Title	*TELEPORT Study: A Pilot Feasibility Trial Examining The Use of Telehealth in Post Radiation Therapy Visits*
Short Title	*TELEPORT Study: Telehealth in Radiation Oncology*
Protocol Number	*15D.580*
Phase	*single arm pilot study*
Methodology/Study Design	*Any malignancy or benign condition treated with radiation single arm feasibility study*
Study Duration	*24 months for enrollment; 32 months for study duration*
Study Center(s)	*Single-center*
Objectives	*Primary objective:* - *to investigate the feasibility of conducting a future phase 2 randomized study comparing telehealth and in person visits for patients returning for a post-radiation treatment visit* *Secondary objectives:* - *To examine patient satisfaction with a telehealth visit* - *To examine patient assessment of physician communication during a telehealth* - *To examine patient distrust in the healthcare system following a telehealth visit* - *To examine physician ability to perform a patient assessment during a telehealth visit* - *To examine physician perceptions of telehealth visits* - *To examine monetary and time cost to patients for telehealth visits* - *To calculate clinic savings derived from telehealth visits*
Number of Subjects	65
Diagnosis and Main Inclusion Criteria	*Patients receiving RT for any indication*
Study Therapy,	*Telehealth visit for the first post treatment follow up*

Dose, Route, Regimen	
Duration of administration and follow-up	*Follow up visit 3-8 weeks after completion of radiation treatment*
Reference therapy	*Standard in person office visit for first post treatment follow up*
Statistical Methodology	
Schema	

1.0 INTRODUCTION

This document is a protocol for a human research study. This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

1.1 Specific Aims and Hypothesis

The aim of the study is to determine the feasibility of conducting a future randomized trial comparing virtual teleheath visits and in person office visits for post treatment radiation follow up visits. Due to the length of cancer treatment, many oncology patients have had a long interruption of their normal daily lives, including leave of absences from work and additional, non-treatment office visits, contribute to further disruption of patients' lives when they are just beginning to resume their normal activities. After radiation therapy is complete however, patients may have side effects that warrant evaluation and therefore a post-radiation office visit has become standard for all patients who have received radiation. Minimizing the direct impact of this visit on patients' lives may have a positive impact on their post-treatment quality of life. One method to do so may involve a virtual office visit, which can be performed in the comfort of a patient's home or even in the workplace. This would decrease their time traveling to the doctor's appointment and waiting time in the waiting room as well as potentially decreasing cost to the patient. At this time however, it is unknown if a virtual visit would be sufficient for both the patient and the doctor, in terms of satisfaction and effectiveness of the visit.

In this proposal, we intend to investigate the feasibility of conducting a future randomized clinical trial comparing a telehealth and an in person office post radiation treatment visit. In addition we intend to examine patient and physician attitudes towards telehealth visits as well as physician effectiveness and will assess temporal and monetary costs of the visit for the patients.

We hypothesize we will be able to enroll enough patients in this study to justify a future randomized clinical trial comparing virtual post-radiation evaluations and in person visits. We hypothesize virtual visits will be satisfactory in terms of patient satisfaction, perception of physician communication and healthcare distrust. We further hypothesize that monetary cost, and time expenditure for patients will be decreased for telehealth visits as compared to theoretically calculated costs of in person office visits.

Aim 1: To determine the feasibility of conducting a future randomized trial comparing telehealth and in person visits.

Aim 2: To determine the patient and physician satisfaction as well as clinical effectiveness of telehealth visit in radiation oncology clinics as determined by patient and physician assessment

Aim 3: to determine whether the monetary and time costs associated with telehealth visits are decreased compared to an in person visit

1.2 Background and Rationale

Telemedicine refers to the use of telecommunications technology to deliver health care services to individuals at some distance from the provider (Currell, 2000). Driven by rapid advancements in technology, interest has steadily grown in the use of telemedicine, which has the potential to lower health care costs and improve patient access to care (Currell, 2000; Mair and Whitten, 2000).

Routine follow up care after primary cancer treatment is a promising application of telemedicine. Objectives of follow-up include management of complications from treatment, detection of recurrence, and provision of psychological support and information to the patient (Ataman, 2004; van Hezewijk, 2011). With increasing demand on outpatient services and limited resources, effectiveness of traditional follow-up care at accomplishing these objectives has come under scrutiny (James, 1994; Brada, 1995; Teagle, 2014).

In a variety of different cancers, including breast, colorectal, and testicular, physical examination has not been shown to significantly contribute to the detection of recurrence (Jeffery, 2007; Montgomery, 2007; Cunniffe, 2012). Furthermore, a number of studies have shown that telephone follow-up can be as effective as face-to-face visits at addressing the psycho-social effects of disease and treatment (Gotay, 1998; Beaver, 2010; Marcus, 2010). Nurses who conducted telephone follow-up for early stage breast cancer patients expressed confidence in their ability to deliver care through telemedicine platforms (Beaver, 2010).

Feasibility and acceptability of remote follow-up after treatment has been shown in high grade glioma, breast, prostate, bladder, endometrial, and colorectal cancers (Sardell, 2000; Faithfull, 2001; Shaida, 2007; Beaver, 2009; Kimman, 2010; Smits, 2015). In a randomized trial, Beaver et al. found that breast cancer patients who received follow up through the telephone were no more anxious

despite foregoing physical examination. Patients reported higher levels of satisfaction with telephone follow-up compared to traditional outpatient services with no impairment in the detection of recurrence. Patients cite convenience, reduced travel and wait times, and lower cost as reasons for their preference for remote follow-up (Mair and Whitten, 2000; Beaver, 2010). In another study, Shaida et al. examined patient satisfaction with nurse-led telephone follow-up of patients with prostate cancer. They found no significant differences in general satisfaction or perception of professional care between telephone and outpatient consultations. However patients who received telephone consultations were less satisfied in terms of depth of relationship with provider and perceived time of visit, perhaps suggesting some limitations in the use of technology to connect with patients.

While evidence is promising, the majority of studies examining telemedicine in follow-up care are not randomized, have small patient numbers and do not use validated tools to assess patient satisfaction. Also, no studies have examined the role of telemedicine in a radiation oncology setting (Dickinson, 2014). Our study aims to confirm patient and physician satisfaction with remote follow-up care using validated tools. We aim to show the acceptability of telemedicine follow-up for patients who have undergone radiotherapy, particularly focusing on the first visit following completion of treatment.

1.3 Study Therapy

Telemedicine refers to the use of telecommunications technology to deliver health care services to individuals at some distance from the provider. It has become an increasingly popular option across various medical specialties, with several studies demonstrating its potential clinical effectiveness. Earlier this year, Thomas Jefferson University Hospital launched an institution-wide TH program to use Telehealth to better connect with patients and their families. Applications have included, but are not limited to, virtual rounds, remote consults, and emergent visits. Training programs for providers, including a program for a Telehealth Coordinator, are being developed by the NACT education working group.

Through the new Telehealth service provided by TJUH, patients are able to connect with TJUH doctors through a smartphone, tablet or computer to receive real-time care, such as on demand visits, scheduled online visits and remote second opinions, from any location convenient to them.

In this trial, patients will receive their first post radiation treatment follow up as a virtual visit using Telehealth. During the visit, the patients will use the application from their own home or any other off-campus location that is convenient for them.

1.4 Clinical Data to Date

Several studies have examined patient perceptions of remote health care delivery. In a 2009 multicenter study from the UK, women with breast cancer with low to moderate risk of recurrence were randomized to telephone or hospital follow up after completion of treatment. Patients randomized to the telephone follow up receive phone calls from breast care nurses at regular intervals as per hospital policy. Patients in the hospital follow up group went for in person hospital follow up visits as per hospital policy. The study measured patient psychological morbidity, information needs, patients' satisfaction and time to recurrence. Participants' satisfaction with information received and with dealing with patient concerns was improved in the telephone group as compared to the hospital group (table 1 and 2). Patient anxiety was comparable in the two groups (figure 1).

Level of satisfaction	Hospital	Telephone	Between groups comparison P value	
			All categories*	First 4 categories
Start of trial				
Very satisfied	79 (46)	78 (45)	0.671	X^2_{trend}=0.31, 0.576
Satisfied	67 (39)	71 (41)		
Not very satisfied	4 (2)	8 (5)		
Very unsatisfied	1 (1)	0 (0.0)		
Did not receive information	10 (6)	6 (4)		—
Did not need information	10 (6)	10 (6)		—
Overall	171 (100)	173 (100)		—
Middle of trial				
Very satisfied	57 (49)	110 (80)	<0.001	X^2_{trend}=19.07, <0.001
Satisfied	41 (35)	22 (16)		
Not very satisfied	7 (8)	3 (2)		
Very unsatisfied	3 (3)	1 (1)		
Did not receive information	4 (3)	0 (0)		—
Did not need information	4 (3)	1 (1)		—
Overall	116 (100)	137 (100)		—
End of trial				
Very satisfied	78 (55)	121 (80)	<0.001	X^2_{trend}=14.33, <0.001
Satisfied	47 (33)	25 (16)		
Not very satisfied	8 (6)	3 (2)		
Very unsatisfied	1 (1)	1 (1)		
Did not receive information	7 (5)	0 (0)		—
Did not need information	1 (1)	2 (1)		—
Overall	142 (100)	152 (100)		—

Table 1: Satisfaction with information received by randomized group. Numbers are percent of women

Level of satisfaction	Hospital	Telephone	X^2_{trend}, P value
Start of trial			
Very helpful	44 (48)	44 (52)	0.69, 0.405
Helpful	36 (39)	31 (37)	
Not very helpful	10 (11)	9 (11)	
Very unhelpful	2 (2)	0 (0)	
Overall	92 (100)	84 (100)	—
Middle of trial			
Very helpful	28 (44)	80 (88)	28.27, <0.001
Helpful	26 (41)	9 (10)	
Not very helpful	9 (14)	1 (1)	
Very unhelpful	1 (2)	1 (1)	
Overall	64 (100)	91 (100)	—
End of trial			
Very helpful	42 (63)	84 (84)	10.35, 0.001
Helpful	15 (22)	13 (13)	
Not very helpful	10 (15)	2 (2)	
Very unhelpful	0 (0)	1 (1)	
Overall	67 (100)	100 (100)	—

Table 2: helpfulness in dealing with concerns at appointment by randomized group. Numbers are percent of women

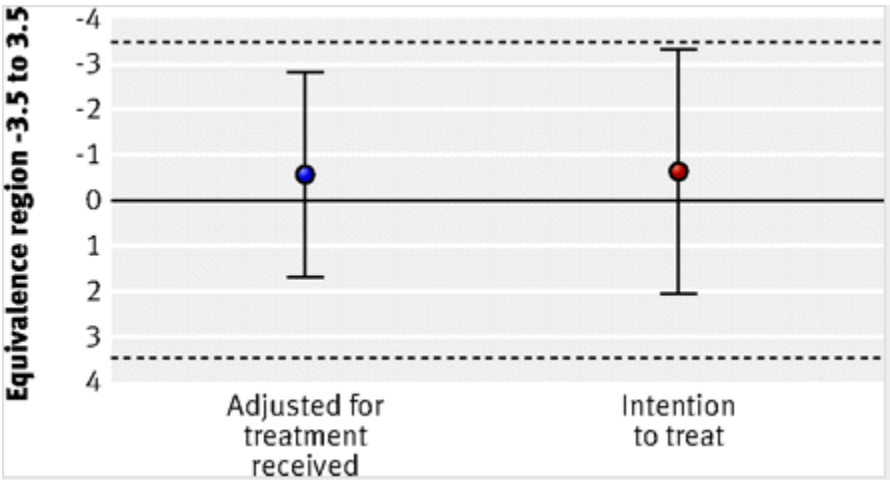


Figure 1: mean differences with 95% confidence intervals for telephone group minus hospital group for state-trait anxiety inventory

In a 2015 prospective study from the UK, approximately 250 patients with dermatological conditions seen in a general practice setting who would have been subsequently referred to a dermatologist had a teledermatology visit instead. Over the course of 2 years this strategy resulted in an estimated saving of $18,600. 97% of patients rated themselves as satisfied or very satisfied with the process and 93% felt comfortable with the process.

1.5 Dose Rationale and Risk/Benefits

If during the telehealth visit the treating physician feels he or she is unable to fully assess the patient, or has any concerns, he or she will ask the patient to come in for an in person visit.

2.0 STUDY OBJECTIVES

2.1 Primary Objective:

The primary objective is to examine feasibility of conducting a trial comparing a telehealth visit and an in person office visit

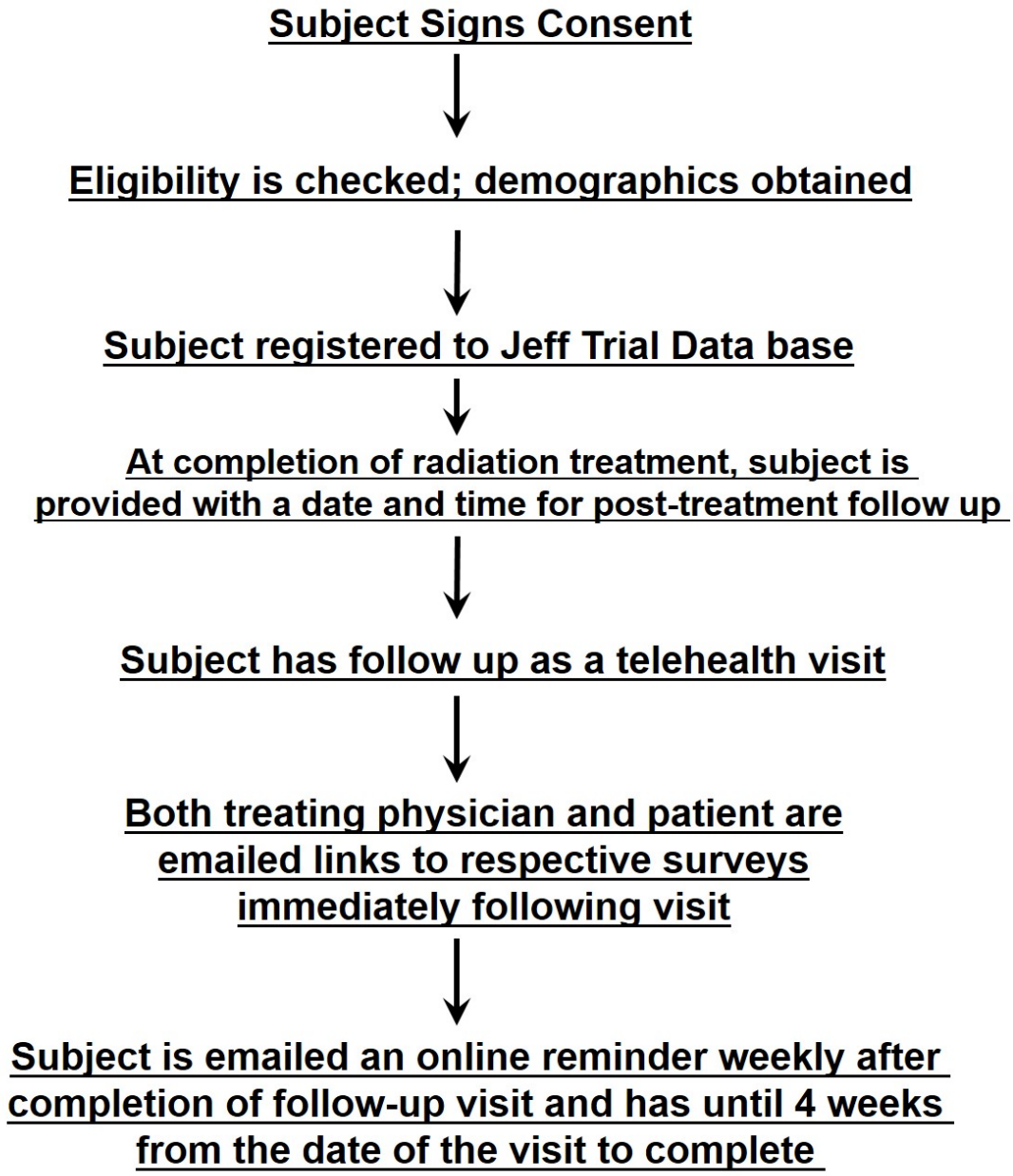
2.2 Secondary Objective:

The secondary objectives of this study include to examine patient satisfaction, patient assessment of physician communication during a telehealth visit; to examine patient distrust in the healthcare system following a telehealth visit; to examine physician ability to perform a patient assessment during a telehealth visit; to examine physician perceptions of telehealth visits; to examine monetary and time cost to patients for telehealth visit; to calculate clinic savings derived from telehealth visits.

3.0 STUDY DESIGN

3.1 General Design

This is a single arm pilot feasibility study examining a telehealth visit for the first post radiation treatment visit. Patients will be asked to fill out a questionnaire within a week of the visit. There will be no subsequent follow up per trial.
The expected enrollment duration of the study is 24 months. The overall study duration is expected to be 32 months.



3.2 Primary Study Endpoints

The primary endpoint of the study is feasibility (i.e., rate of accrual) of conducting a future randomized clinical trial comparing telehealth and in person visits

3.3 Secondary Study Endpoints

Secondary endpoints include:

- patient satisfaction with telehealth visits as measured by the PSCC (see appendix II). In the PSCC each item is scored on a 1-5 scale, corresponding to statements ranging from strongly agree to strongly disagree.
- patient assessment of physician communication during a post-treatment visit as measured by the CAT (see appendix II). In the CAT each item is scored on a 1-5 rating scale, with higher scores indicating higher satisfaction with physician communication.
- patient distrust in the healthcare system as measured by the health care system distrust scale (see appendix II). Items are scored strongly disagree to strongly agree.
- physician ability to evaluate a patient during a telehealth visit as measured by the physician questionnaire (see appendix II). Individual items are scored yes, no or N/A
- physician satisfaction with post-treatment telehealth visit as measured by the modified physician satisfaction scale (see appendix II). Individual items are scored strongly disagree to strongly agree.
- patient and clinic costs for a telehealth visit

4.0 SUBJECT SELECTION AND WITHDRAWAL

4.1 Inclusion Criteria

1. Patients who underwent, currently undergoing or planned to start radiation treatment with curative, adjuvant or palliative intent, who have not yet had their first post-treatment visit
2. Age ≥ 18
3. KPS score ≥ 60
4. Patients must be capable to read and speak English and provide study specific informed consent prior to study entry
5. Patients must have access to a computer or smartphone, email and internet connection at home or at a location convenient to them on which they would be willing to do a telehealth study
6. Pennsylvania or New Jersey residents*

*Telehealth visits for New Jersey residents will only be performed by physicians with a current medical license issued by the state of New Jersey.

4.2 Exclusion Criteria

1. Patients under the age of 18

2. KPS <60%
3. No access to a computer, smartphone or internet
4. Unable to read and/or speak English
5. Decisionally impaired patients
6. Patients not residing in Pennsylvania or New Jersey

4.3 Gender/Minority/Pediatric Inclusion for Research
This protocol will enroll women and men with any malignancy or benign condition treated with radiation therapy and will include minorities in the research protocol. Pediatric patients will be excluded.

4.4 Subject Recruitment and Screening
Patients who are 18 years of age or older with a cancer or benign diagnosis are eligible for the study. Patient can be recruited from the Principal investigator, co-investigator or referring physicians' clinical practices. Potential study subject should be referred to Principal investigator, co-investigator or study designated research nurse/associate. Principal investigator, co-investigator, or designated research nurse/associate will screen and determine the final eligibility of the subject for enrollment.

4.5 Early Withdrawal of Subjects
4.5.1 When and How to Withdraw Subjects
Patients will be informed that they have the right to withdraw from the study at any time for any reason, without prejudice to their medical care. The investigator also has the right to withdraw patients from the study for any of the following reasons:

1. Intercurrent illness
2. Patient request
3. Non-compliance
4. Administrative reasons
5. Patients may withdraw from the study voluntarily at any time;

At the time of withdrawal, all study procedures outlined for the End of Study visit should be completed. The primary reason for a patient's withdrawal from the study is to be recorded in the source documents.

4.5.2 Data Collection and Follow-up for Withdrawn Subjects
According to FDA regulations, when a subject withdraws from the study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.

A subject who is withdrawing needs to state whether he/she wishes to provide continued follow-up and further data collection subsequent to withdrawal from the interventional portion of the study.

If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the subject will continue follow up visit and evaluation per the protocol.

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, study data related to the subject collected prior to the subject's withdrawal from the study will included in the study analysis. However, the subject's clinical data will not be used for dose escalation determination.

5.0 STUDY DRUG/THERAPY

5.1 Description

Through the new Telehealth service provided by TJUH, patients are able to connect with TJUH doctors through a smartphone, tablet or computer to receive real-time care, such as on demand visits, scheduled online visits and remote second opinions, from any location convenient to them.

In this trial, patients will receive their first post radiation treatment follow up as a virtual visit using Telehealth.

5.2 Treatment Regimen

Following obtaining informed consent, patients will return for their first post-treatment visit as a virtual visit via Telehealth. During the visit the patients will use the application from their own home or any other off-campus location that is convenient for them. Patients will meet with a study representative to be introduced to the application.

Following the visit, patients will be emailed to ask to complete a survey regarding their perceptions of the visit.

5.3 Risks

Risks of the study include potential anxiety caused to the patients

5.4 Method for Assigning Subjects to Treatment Groups

This is a single arm study

5.5 Preparation and Administration of Study Therapy
Patients will be shown how to download the application to their electronic device and they will be instructed on the use of the application. A demonstration of the software will be done in the office to ensure patient understanding. A written hand out regarding application use will also be provided to the patients. Patients will receive follow up instructions including date and time of post-treatment visit.

5.6 Subject Compliance Monitoring
Compliance in the study is defined as subject return for post-treatment visit. Patients who fail to return for post-treatment visit will be deemed non-compliant.

6.0 STUDY PROCEDURES
6.1 Study Visit Schedule
Screening:
Potential candidates for the study will be identified by their treating radiation oncologist. Eligibility of patients will be verified based on eligibility criteria (section 4.1). Those eligible patients will receive detailed information about the study. Patients will be informed of possible risk and benefits. Informed consent will be obtained from patients. Demographics and patient KPS will be assessed at the time of the screening visit

Visit 1:
Patients will undergo their first post-treatment visit as a virtual telehealth visit. Following the visit the treating physician will fill out the physician questionnaires on paper or online, while patients will be emailed a patient-specific link to a survey. Physicians will have 2 weeks following the date of the visit to complete the survey. Patients will have up to 4 weeks after the visit to complete the survey. Patients will receive weekly reminder emails regarding the survey up to 3 times after the visit. Patients will also have the option to fill out a paper survey (provided at the time of treatment discharge with the discharge instructions) and mail it into the office.

Follow-up
There will be no subsequent follow up

6.1.1 Study Flowchart

	Screening visit	Post-treatment visit	Sent to patient following visit
Informed consent	X		
Background information	X		
KPS	X		
Patient Satisfaction with Cancer Care Scale[b]			X
Communication assessment tool[b]			X
Health care system distrust tool[b]			X
Physician questionnaire[a]		X	
Modified physician satisfaction scale[a]		X	

a. Physicians are to complete surveys and satisfaction scale within 2 weeks following the visit.
b. Patients are to complete surveys within 4 weeks following the visit. They will be emailed reminders weekly following the visit.

7.0 STATISTICAL PLAN

7.1 Sample Size Determination

Accrual rate. This pilot study is designed to assess whether the accrual rate at Jefferson will be sufficient for a future noninferiority trial. For that noninferiority trial, we project that we will need to enroll a total of about 180 patients in three years, i.e., a minimum accrual rate of 5 patients per month. The enrollment duration of this pilot study will be 24 months. If the true accrual rate is 6 patients per month (i.e., 72 patients per year), then the pilot study has 83% power to establish that the accrual rate exceeds 5 patients per month (using a 1-sided test for Poisson rate, with alpha 0.05).

Patient satisfaction. The expected sample size of 60patients will also have >90% power to establish that patient satisfaction will exceed 80%, assuming a true PSCC score of about 90% and a standard deviation of about 5% (using a one-sample t-test with alpha 0.05).

7.2 Statistical Methods

The main analyses will focus on the monthly accrual rate (section 3.2). The number of patients accrued each month will be analyzed via Poisson regression. The mean (monthly rate) will be estimated and tested against the null value of 4 patients per month using a 1-sided test with alpha 0.05. In addition to accrual, we will also summarize the proportion of enrolled subjects who are lost to follow-up, since that could also impact the feasibility of the future randomized trial.

Additional analyses will focus on the secondary endpoints (section 3.3). For example, we will compute the average patient satisfaction score and test it against the null value of 75 using a one-sample t-test with alpha 0.05. We will also estimate the average patient rating of physician communication, patient distrust in the healthcare system, and physician satisfaction.

7.3 Subject Population(s) for Analysis

All enrolled subjects will be analyzed. Subjects who withdraw or are lost to follow-up during the study will be counted in the accrual rate (since they will be part of the future randomized trial as per the intent-to-treat principle).

8.0 DATA HANDLING AND RECORD KEEPING

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked

authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

8.2 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

8.3 Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

8.4 Records Retention

It is the investigator's responsibility to retain study essential documents for at least 2 years after the last approval of a marketing application in their country and until there are no pending or contemplated marketing applications in their country or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period if required by an agreement with the sponsor. In such an instance, it is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

9.0 STUDY MONITORING, AUDITING, AND INSPECTING

9.1 Study Monitoring Plan

The investigator will allocate adequate time for monitoring activities. The Investigator will also ensure that the medical monitor or other compliance or quality assurance reviewer is given access to all the above noted study-related documents and study related facilities (e.g. pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit.

9.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the IRB, the funding sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. pharmacy, diagnostic laboratory, etc.).

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

9.2.1 Independent External and Internal Audits

In addition to review by the DSMC, all studies initiated by SKCC investigators are audited by an independent auditor once they have achieved 10% of target accrual. However, a study can be audited at any time based on recommendations by the IRB, DSMC, PRC and/or the Director of Clinical Investigations, SKCC. Studies are re-audited once they have achieved 50% of target accrual. Special audits may be recommended by the IRB, DSMC or PRC based on prior findings, allegations of scientific misconduct and where significant irregularities are found through quality control procedures. Any irregularities identified as part of this process would result in a full audit of that study.

In addition to the audits at 10 and 50%, the CTO randomly audits at least 10 percent of all patients entered into therapeutic SKCC trials and other trials as necessary, on at least a bi-annual basis, to verify that there is a signed and dated patient consent form, the patient has met the eligibility criteria, and that SAEs are documented and reported to the TJU IRB.

All audit reports are submitted to the DSMC for review and action (when appropriate). A copy of this report and recommended DSMC action is sent to the PRC and TJU IRB. The committee regards the scientific review process as

dynamic and constructive rather than punitive. The review process is designed to assist Principal Investigators in ensuring the safety of study subjects and the adequacy and accuracy of any data generated. The TJU IRB may, based on the DSMC and auditor's recommendation, suspend or terminate the trial.

10.0 ETHICAL CONSIDERATIONS

This study is to be conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted independent Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator before commencement of this study.

All subjects for this study will be provided a consent form that is compliant with local and federal regulations, describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. See Attachment for a copy of the Subject Informed Consent Form. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. This consent form must be signed by the subject or legally acceptable surrogate, and the investigator-designated research professional obtaining the consent.

11.0 STUDY FINANCES

11.1 Funding Source

This study is unfunded.

11.2 Conflict of Interest

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All Jefferson University Investigators will follow the TJU Conflicts of Interest Policy for Employees (107.03).

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12.0 PUBLICATION PLAN

All investigators involved in the portion of the trial being published will review manuscripts prior to publication. The Principal Investigator will be ultimately responsible for the content of all manuscripts.

13.0 REFERENCES

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14.0 APPENDICES

Appendix I: Karnofsky Performance Scale

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

Appendix II. Case Report Forms

Version 6.0 (2017-10-16)

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TELEPORT Study Case Report Form (CRF)—Screening Visit

Date of Screening:_____

Patient Demographics

Age:_____ Race:_____

Current Email Address:

_____

_____

Marital Status:_____

Highest Education Level Completed:_____

Karnofsky Performance Status:

Please assess the patient's performance status based on the table provided. Circle the most appropriate functional capacity.

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

TELEPORT Inclusion/Exclusion Criteria Checklist
Inclusion Criteria:
Patients must meet all of the following criteria in order to be considered for entry into the TELEPORT trial.

7. Patients who underwent, currently undergoing or planned to start radiation treatment in the next month with curative, adjuvant or palliative intent who have not yet had their first post-treatment visit

- Age ≥ 18
- Karnofsky performance status at least 60%
- Able to read and speak English and provide study specific informed consent prior to study entry
- Have access to a computer or smartphone and internet connection at home on which they would be willing to do a telehealth study
- Pennsylvania or New Jersey residents*****

***Telehealth visits for New Jersey residents will only be performed by physicians with a current medical license issued by the state of New Jersey:**

Nicole Simone, MD*
Adam Dicker MD PhD*
Voichita Bar Ad MD*
Wenyin Shi MD*
Robert Den MD*
Mark Hurwitz MD*

Exclusion Criteria:
In addition to meeting inclusion criteria, patients are ineligible for enrollment if any of the following exclusion criteria are met.

- Patients under the age of 18
- KPS <60%
- No access to a computer, smartphone or internet
- Unable to read and/or speak English
- Decisionally impaired patients
- Patients not residing in Pennsylvania or New Jersey

Checklist for Screening Visit:

Informed Consent for Trial Obtained	
All Sections of CRF Completed	
Inclusion/Exclusion Criteria Evaluated	
Based on screening patient appears eligible	

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TELEPORT Study Case Report Form (CRF)—Follow up Visit

Patient Satisfaction with Cancer Care Scale (PSCC)

Below is a list of statements regarding your recent post-treatment visit. Please indicate your response

	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree (5)
I felt my concerns were understood					
I felt I was treated with courtesy and respect					
I felt included in decisions about my health					
I was told how to take care of myself					
I felt encourages to talk about my personal health concerns					
I felt I had enough time with my doctor					
My questions were answered to my satisfaction					
Making an appointment was easy					
I knew what the next step in my care would be					
I feel confident in how I deal with the health care system					
I was able to get the advice I needed about my health issues					
I knew who to contact when I had a question					
I received all the services I needed					
I am satisfied with the care I received					
The doctors seemed to communicate well about my care					
I received high quality care from my regular doctor					
I received high quality care from my specialists					
My regular doctor was informed about the results of the tests I got					

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Communication assessment tool (CAT)

Please use this scale to rate the way the doctor communicated with you.

	Poor (1)	Fair (2)	Good (3)	Very good (4)	Excellent (5)
Greeted me in a way that made me feel comfortable					
Treated me with respect					
Showed interest in my ideas about my health					
Understood my main health concerns					
Paid attention to me(looked at me, listened carefully)					
Let me talk without interruptions					
Gave me as much information as I wanted					
Talked in terms I could understand					
Checked to be sure I understood everything					
Encouraged me to ask questions					
Involved me in decisions as much as I wanted					
Discussed net steps, including any follow up plans					
Showed care and concern					
Spent the right amount of time with me					

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Health care system distrust scale

The next questions are about your opinion of the health care system in general. When we refer to the health care system, we mean hospitals, health insurance companies, and medical research. For each statement below, please indicate how strongly you agree or disagree

	Strongly agree (5)	Agree (4)	Not sure (3)	Disagree (2)	Strongly disagree (1)
Medical experiments can be done to me without my knowing about it					
My medical records are kept private					
People die every day because of mistakes by the health care system					
When they take my blood, they do tests they don't tell me about					
If a mistake were made in my health care, the health care system would try to hide it from me					
People can get access to my medical records without my approval					
The health care system cares more about holding costs down than it does about doing what is needed for my heath					
I receive high-quality medical care from the health care system					
The health care system puts my medical needs above all other considerations when treating my medical problems					
Some medicines have things in them that they don't tell you about					

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Physician questionnaire

	Yes	No	Not applicable
Were you able to assess the patient's symptoms?			
Were you comfortable assessing treatment related toxicity?			
Was a medication assessment done?			
Was KPS assessed and documented?			
If this was a telehealth visit, did you feel the need to bring the patient in to the office for further evaluation?			
Was patient provided with follow up instructions at the end of the visit?			
Was patient asked about follow up with other providers?			
Was patient provided with follow up labs and/or imaging instructions? Yes			
How long did today's visit take?	Today's visit took approximately _____ minutes		

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Modified physician satisfaction scale

	Strongly agree (5)	Agree (4)	Not sure (3)	Disagree (2)	Strongly disagree (1)
I was able adequately to review this patient's laboratory results					
I was able adequately to review this patient's imaging					
I was able to elicit an adequate history from this patient					
I was able to communicate facts adequately to this patient					
I think this patient was satisfied with this clinical encounter					
My ability to evaluate this patient was significantly hampered because s/he was seen via televideo rather than in person					
It was as easy to ask intimate questions today as it would have been in person					
In general, I found the televideo system frustrating to use					
Compared with an in-person clinical encounter, I felt less sure that I was getting all of the information I needed					
I would like to use the televideo system again					