Remote Assessment of Physical Function

NCT04339959

Dr. Cindy K. Blair

University of New Mexico

K07CA215937

PROTOCOL TITLE:

Validity of Videoconferencing for Remote Assessment of Physical Performance in Cancer Survivors with Functional Impairment

PRINCIPAL INVESTIGATOR:

Name	*Cindy Blair*
Department	*Internal Medicine*
Telephone Number	*505-925-7907*
Email Address	*ciBlair@salud.unm.edu*

VERSION NUMBER:

11

VERSION DATE:

07 October 2021

Table of Contents:

NOTE: The study described in this protocol is one of two studies proposed in the NCI Cancer Prevention, Control, Behavioral Sciences, and Population Sciences Career Development Award (K07). The K07 is a five-year award. A separate protocol has been submitted for the second study, which is a distance-based light-intensity physical activity intervention for older cancer survivors.

1.0 Objectives

.1 Primary Objectives and Hypotheses

1.1.a The primary objective is to evaluate the validity and reliability of using videoconferencing to assess physical performance tests self-administered by older cancer survivors in their own homes. This remote assessment will be compared to the traditional face-to-face (i.e., in-person) assessment and to accelerometer (activPAL) data.

1.1.b We hypothesize that older cancer survivors, in the presence of a family member or friend, will be able to successfully complete the physical performance self-assessment in the home environment.

1.1.c We further hypothesize that the results (time to complete performance tests in seconds) between the videoconferencing method and the traditional face-to-face method will be within a clinically acceptable limit (intra-class correlation coefficient (ICC) $\geq .80$).

The ultimate goal of this research study is to develop a test protocol to allow older cancer survivors to self-administer physical performance tests in their own home, while an investigator remotely assesses the tests via videoconferencing. The test protocol includes written and video instructions and the test kit (tablet, tablet stand, measurement tools). To achieve this objective, we will proceed with a series of phases. We will apply a similar concept of "saturation" as is done in qualitative studies. In qualitative studies, the number of focus groups or interviews is based on the saturation point, i.e., the point at which no new information is learned. For the current study, we propose to include a range of participants at each study phase. At the point at which no new information is being learned, i.e., no further adjustments are needed to the test protocol, we will proceed to the next phase.**

Phase 1: First, we will test proof-of-concept that participants will be able to follow the testing protocol and use the tablet PC to communicate with the investigator (10-12 participants). The test protocol will be refined based on what is learned after a minimum of 10 participants. We anticipate no more than 12 participants needed for this phase.

Phase 2: Next, 10-20 new participants will be enrolled to evaluate the validity of videoconference vs. face-to-face assessment (i.e., direct observation) of physical performance. Communication will occur between the remote assessor and the participant. The direct observer will not communicate directly to the participant, unless there is a safety issue. After completing 10 participants without a major change in the test protocol, we will proceed to the next phase.

Phase 3: This phase involves participants repeating the test protocol, but without the face-to-face assessment (i.e., direct observation). This will test the ability of the participant to receive the box of test instructions and materials in the mail or delivered by a study team member, unpack the box, communicate with the remote assessor via videoconferencing, pack up the box, and return it to the study team (postage paid) or retrieved by a study team member. This step will involve 5-10 participants from Phases 1 and 2, who have provided

approval for future contact (see approved Future Contact form). Once 5 participants have successfully and safely completed the test protocol, we will proceed to Phase 4.

Phase 4: This phase is the same as Phase 3, except it includes newly enrolled participants, i.e., representing the first-time participants have enrolled/participated in this study. This will eliminate the practice effect that will occur in phase 3. This step will enroll 5-10 participants.

Therefore, the anticipated number of enrolled participants ranges from 30 to 52.

** NOTE: Phase 1 and 2 above are already included in the currently approved study protocol (dated 25Oct2019). Phases 3 and 4 are new to the protocol. The four study phases are now introduced to better clarify the distinction between the approved study phases and the new study phases.

2.0 Background

Physical functioning, an important patient-reported outcome (PRO), is a key measure of physical health and well-being in older cancer survivors. Self-reported physical function is typically collected by questionnaire (e.g., SF-36, PROMIS, etc.[1-4]). Objective measures of physical function (i.e., physical performance) are typically collected in a clinic setting (e.g., Short Physical Performance Battery, Rikli and Jones Senior Fitness Test, etc.[5-7]). Currently, low-cost, valid, reliable, and easy to use methods to remotely assess physical performance in older adults do not exist. Wearable sensors are very expensive,[8,9] proprietary,[10] and/or require technicians present for testing.[8,11,12]

Telerehabilitation studies have been conducted using videoconferencing to assess physical performance; however, to date, these studies have included a technician or study investigator in the same room as the study participant during the tests.[13-16] Nor have these studies been tested in rural areas. We propose to evaluate the validity and reliability of using videoconferencing to assess physical performance tests self-administered by older cancer survivors. In order to evaluate validity, a member of the research team will need to be at the participant's home, and in the same room as the participant (face-to-face assessment of performance tests). However, the idea is to test if the participant is able to use the technology (an android tablet with videoconferencing software) to communicate with an off-site research investigator. We will also be testing the feasibility, acceptability, and most importantly the safety of having the participants perform two standard gerontologic physical performance tests in their own home (see below).

A friend, neighbor or relative is requested to be present during the assessment. This person will be able to communicate via the videoconferencing session with the investigator and must have access to a telephone should medical attention be required. However, if this person is unable to be present during the assessment once it has been scheduled, then the research investigator conducting the face-to-face assessment will cover their responsibilities. Face-to-face assessment is the traditional method for assessing these physical performance tests. We will be testing whether the remote assessment via videoconferencing can produce similar results (time in seconds to complete the tests) as the traditional (face-to-face) method.

The two different assessment methods (remote vs. face-to-face) should be within a reasonable margin of error ($r \geq .80$) The two performance tests include the Timed Up & Go (TUG) Test and the 30-second chair stand test (30s-CST). The TUG test involves standing up from a standard

armchair, walking 10 feet, turning around (180° turn), and walking back to the chair and sitting down. This is a timed test, to be performed at the speed that is comfortable for the participant. The 30s-CST involves standing up from a chair and sitting down as quickly and safely as possible, preferably without the use of upper extremity support. It is measured by the number of times a person comes to a full standing position from a chair in 30 seconds. Both tests are timed with a stopwatch.

3.0 Inclusion and Exclusion Criteria

The proposed validation and reliability study will accrue between 30 and 52 adult cancer survivors from rural (~40%) and urban (~60%) areas who meet the following eligibility criteria:

The eligibility criteria will vary slightly depending on the recruitment method (New Mexico Tumor Registry [NMTR] vs. self-referrals). The NMTR criteria are based on increasing the likelihood of identifying and contacting cancer survivors who are still alive, healthy enough to participate in the study (vs. later stage disease), and for whom the contact information may still be accurate. Additionally, there is a 2 year lag in the completeness of data collected and managed by the registry. Several of these criteria are not necessary for recruiting through the general population, i.e., self-referrals who respond to study posted flyers. As this is a feasibility study, some of the eligibility criteria will be relaxed for self-referrals in order to assess our primary aims: the feasibility, acceptability, and safety of the study.

Screening for Recruitment via New Mexico Tumor Registry.

Initial screening will take place through the New Mexico Tumor Registry. *Only key research staff will be able to link the name of the cancer patient/survivor with the code number* (please refer to HRPO#: 85-001). Men and women who meet the following criteria will be identified:

- Diagnosed with one of the combinations of cancer-site and stage (SEER Summary Stage 2000) associated with a 60% or greater 5-year relative survival rate and common among older adults:

Cancer Site	Diagnosis Stage(s)	Percentage of cases by stage	5-year relative survival rate	Median age at diagnosis
Bladder	In situ, localized	51.0% 34.0%	95.8% 69.5%	73
Breast (female)	Localized Regional	62.0% 30.0%	98.8% 85.5%	61
Colon & rectum (excluding carcinoid tumors & cancers of the appendix)	Localized Regional	39.0% 35.0%	89.9% 71.3%	68
Corpus & uterus	Localized Regional	67.0% 21.0%	95.0% 69.0%	62
Kidney & renal pelvis	Localized Regional	65.0% 17.0%	92.5% 69.6%	64
Larynx	Localized	54.0%	77.4%	65

Melanoma of the skin	Localized Regional	84.0% 9.0%	98.7% 64.7%	63
Non-Hodgkin Lymphoma	Localized Regional	25.0% 31.0%	82.6% 73.2%	66
Oral cavity & pharynx	Localized Regional	29.0% 47.0%	84.4% 66.0%	62
Ovary	Localized Regional	15.0% 21.0%	92.4% 75.2%	63
Prostate	Localized Regional	77.0% 13.0%	100% 100%	66

- Diagnosed within the past 2 to 5 years. Note: This time frame was selected to increase the probability of obtaining accurate/current contact information for the patients. Additionally, the two-year minimum increases the probability that the patient has completed primary cancer therapy.
- Cases with multiple primary cancers are ineligible (less likely to have completed treatment).
- Current age 60 or older at the time of study enrollment
- Known to be alive at the last ascertainment of vital status
- Current address within the following counties: Bernalillo, Sandoval, Santa Fe, Valencia, Torrance, Socorro, Cibola, Guadalupe, Chaves.

NOTE 1: Cases treated solely at Veterans Affairs will not be included in the selection of cases identified by the NMTR for the current study, per standing agreement between Veterans Affairs and the NMTR.

Note 2: Given the short study timeline, it is not feasible to seek tribal approval for contacting American Indian/Native American cancer patients who are included in the NMTR. Therefore, per standard NMTR policies and procedures when tribal IRB approval has not been obtained, American Indian and Native American cancer survivors will not be contacted by the NMTR on behalf of the study.

Word of mouth

Word of mouth is often a successful method for recruiting study participants, especially rural individuals. Faculty and staff from the Division of Epidemiology, Biostatistics, and Preventive Medicine, the Prevention Research Center, and the UNM Comprehensive Cancer Center will be emailed a copy of the study flyer, provided approval from leadership (i.e., Division Chief, Director, Associate Directors or Program Leaders). The email will briefly explain the study, and indicate a $5 e-merchandise card for Amazon will be provided for anyone referring an individual to the study, regardless of final eligibility (referred individual must contact study staff).

The second screening for individuals identified by the NMTR or self-referrals includes the following eligibility criteria, which are assessed by the study team:

- Men and women 60 years and older residing in New Mexico
- Previous diagnosis of cancer, completed primary treatment (surgery, radiation, chemotherapy), and not currently being treated for a recurrence. Individuals on hormone

therapy are eligible, e.g., aromatase inhibitors for breast cancer and antiandrogen therapy for prostate cancer.

- Mild-to-moderate physical functional impairment (≥2 functions limited a lot or limited a little on the SF36 Physical Function Subscale); representing individuals most at risk for functional decline and most likely to benefit from a home-based lifestyle activity intervention based on our previous research.
- Able to speak, read, & understand English. (Within the NM Hispanic population, 83% are US born and 94% speak English very well. Additionally, this is just a small pilot study.)
- Participating in less than 120 minutes per week of MVPA (determined using Godin Leisure Time Exercise Questionnaire – low respondent burden).
- Living independently and capable of walking 3 blocks without stopping to rest.
- Availability of a family member or friend to be present (for safety) during remote assessment of performance tests (Note: This criterion is in preparation for an intervention trial that will potentially use this videoconferencing remote assessment method. Information regarding the interactions between the participant, family member, and investigator will be used to refine the protocol to be used in the future intervention trial.)
- No severe impairments or pre-existing medical limitations for engaging in daily LPA (e.g., severe orthopedic conditions, pending hip/knee replacement, chronic vertigo, dementia)
- No severe hearing or vision deficits that would inhibit communication with the research team via videoconferencing and tablet use.
- Willing to use a tablet computer and videoconferencing software to communicate with a study team member during the assessment.
- Enough space (12 to 15 feet by 4 feet) to safely conduct the physical function tests.
- Not at high risk for falls (score below 15 on the Fall Risk Assessment portion of the recruitment/eligibility screener). Individuals who score 15 or above will be asked if they would like more information on Fall Prevention, and if yes, will be mailed a brochure from the CDC STEADI Program (see section 13.0).

3.1 Exclusion Criteria

- Adults not able to consent are excluded from participation
- Based on the age criterion (60 years and older), individuals who are not yet adults (infants, children, teenagers) may not participate in this study due to the same age criterion above
- Pregnant women may not participate in this study due to the same age criterion above
- Prisoners may not participate in this study as this is a study of free-living individuals

4.0 Study-Wide Number of Subjects

This study will enroll 30 to 52 cancer survivors. We will first enroll 10-12 cancer survivors to test proof-of-concept that participants will be able to follow the testing protocol and use the tablet to communicate with the investigator (Phase 1). After refining the testing protocol and materials based on this proof-of-concept test period, we will enroll 10-20 cancer survivors to evaluate the validity of videoconference vs. face-to-face assessment of physical performance (Phase 2). The reliability phase will enroll 5-10 participants who completed the home visit,

and have consented to repeat the study (no home visit with direct observer; only remote assessor; Phase 3). The remote assessment phase will enroll 5-10 new participants to complete the study (no home visit with direct observer; only remote assessor; Phase 4). In order to achieve this accrual target, we estimate that the NMTR may need to contact 350 or more cancer patients identified in the registry due to the number of eligibility criteria and a conservative estimate of 14% participation rate.

5.0 Study-Wide Recruitment Methods

NA - This is not a multi-site study; see recruitment methods in section 22.0.

6.0 Multi-Site Research

NA - This is a single-site study.

7.0 Study Timeline

The proposed validation study is part of a career development award. As such, the first six months will include training for the PI, e.g., shadowing physicians in the clinic and accompanying them on home visits to gain "hands-on" experience with the study population. The actual timeframe for the validation study is 1.5 years, from development to manuscript submission.

Table 3. Study Timeline: 2018 - 2020	**Y1**		**Y2**	
Training for the PI				
Development				
Validity / Reliability study (30 participants total)				
Pre-test with 10 participants				
Test with 20 other participants				
Analyze Data / Prepare & submit manuscripts				

8.0 Study Endpoints

8.1 Primary and secondary study endpoints

8.1.a. Proof-of-concept that participants will be able to follow the testing protocol and use the tablet to communicate with the investigator. We will track technology issues (use of tablet, cellular reception, audio and video quality) as well as non-technology issues (understanding of test instructions, safety issues).

8.1.b Evaluation of the validity and reliability of videoconference vs. face-to-face assessment of physical performance. Both performance tests are timed tests (time in seconds to complete the TUG test; number of stands in 30 seconds). The validity

of the videoconference assessment will be evaluated using the limits of agreement statistic,[17] which is the range within which 95% of differences between measurements obtained by 2 methods will lie. The videoconference assessment will be considered valid if the limits of agreement are within a clinically acceptable limit.[17] This limit will be determined *a priori* through discussions between the PI and her mentoring team after the proof-of-concept portion of the study (first 10 participants). This will provide a better idea of inter-rater differences in timing these tests, under ideal conditions (both investigators directly observing the tests at the same time). The clinically acceptable limit will need to take inter-rater difference into account, i.e., a limit that is at or above the inter-rater difference under ideal conditions. Intraclass Correlation Coefficients (ICC) will be used to examine intra-rater and inter-rater reliability of the videoconference assessment of physical performance. Interpretation of ICC values is as follows: 0.75-1.00 = excellent reliability; 0.60-0.74 = good reliability; 0.40-0.59 = fair reliability; and <0.40 = poor reliability.[18]

8.2 Primary and secondary safety endpoints

All adverse events associated with the performance tests (see section 9.0) will be tracked. The performance tests incorporate movements typically undertaken during normal daily activities (standing from a chair, walking a short distance, sitting on a chair), and thus represent tests that are more likely to be safely performed in the home. For both the proof-of-concept and validation studies, one or more members of the study team will be present in the home during the performance tests. Safety checks will be made prior to the performance tests (see section 13.0 Potential Risks to Subjects / Protection Against Risks).

9.0 Procedures Involved

Study Design

Interested and eligible participants will be scheduled for a home visit (Phases 1 and 2). An android tablet with Wi-Fi and cellular will be used to compare videoconferencing with face-to-face assessment of 2 timed, physical performance tests. The tablet will contain videos demonstrating the performance tests, safety measures, and instructions, with features adapted for older adults (e.g., large font).** Further instructions will be provided by the investigator via videoconferencing. First, we will test proof-of-concept that participants will be able to follow the testing protocol and use the tablet to communicate with the investigator (10-12 participants). While one investigator is in a different room of the house conducting the videoconference assessment, another will be in the same room to directly observe and evaluate the impediments and barriers related to the technology and test protocol. After refining the study protocol and materials, 10-20 participants will be enrolled to evaluate the validity and reliability of videoconference vs. face-to-face assessment of physical performance. The performance tests will be assessed simultaneously by two investigators to eliminate intra-participant variation that would occur with sequential assessments. A simultaneous assessment (face-to-face and remote) vs. sequential assessments avoids learning effects (among high performers) and fatigability (among low performers). One investigator will perform the assessment from a remote location using videoconferencing (provides

instructions, starts, stops, and times test using a standard stopwatch). The other investigator will be at the participant's home to observe and time the tests. The videoconferencing software records the assessments for later viewing and scoring (i.e., timing via stopwatch). One-month later, the investigator who performed the videoconferencing assessment will watch the video recording and re-score the tests to determine intra-rater reliability. At least 3 different investigators will watch the video recordings and score the tests (using a stopwatch) to determine inter-rater reliability. All investigators will receive specific training in how to time the performance tests.

For Phase 3, individuals who provided consent to re-contact will be invited to repeat the study, only this time, without a direct observer in their home. Since these participants will have already completed the study, we anticipate the test instructions should be sufficient for the participants to safely self-administer the two physical performance tests in their own home, while only communicating with the remote assessor (located at UNM). Otherwise, further improvements/clarifications to the test instructions will be made.

For Phase 4, newly enrolled participants will complete the study as in Phase 3. Phase 4 eliminates the practice effect among the participants repeating the study in Phase 3.

**A copy of the video instructions for the study participant has been uploaded as a supporting document. The video is also available on YouTube via this private link: https://youtu.be/k5bHRnjNcuo.

Participants will wear an activity monitor during their physical performance test. The ActivPAL3 activity monitor is a small device (2.4 x 4.3 x 0.5 cm; 10g) that will be attached to the anterior midline of the thigh using a PALStickie™ (a double-sided hypoallergenic sticky pad) or Tegaderm Dressing (a transparent dressing/tape). The ActivPAL3 provides time-stamped data (sitting, standing, and stepping) that will be used to further assess the validity and reliability of the videoconferencing method to assess physical performance.

This is not a device study, i.e., this study does not evaluate the efficacy or safety of a device. There is no information on the FDA website regarding the activPAL3 monitor (NOTE: these monitors are from a company in Scotland, UK). However, these monitors are similar to the ActiGraph monitors except for the attachment method. The activPAL3 monitors are not investigational devices as they are commercially available (http://www.paltechnologies.com/); the shipment of activPAL3 monitors was cleared by the FDA and delivered to the Study PI. These monitors are the gold standard for objectively measuring sedentary behavior and ambulation in research study participants and have been used in many trials in the U.S. As with ActiGraph monitors, activPAL3 monitors are more expensive than consumer wearable monitors (e.g., FitBit, Jawbone) and require special software to analyze the data, thus these monitors are used in research rather than being purchased by consumers. In this study, the monitors are used to measure outcomes (frequency, duration, and intensity of free-living sedentary behavior and light physical activity), and are not used to diagnosis or treat disease, or to support/sustain life.

These monitors do not present a potential for serious risk to the health, safety, or welfare of the subject. There is a potential for a small risk of skin irritation due to the adhesive

used to attach the activPAL3 to the thigh. However, if irritation occurs, it usually occurs after several hours or days of use. The participant will only be wearing the monitor for approximately one hour.

Physical Performance Test

The physical performance tests include the 30-second chair stand test (30s-CST) and the Timed Up & Go (TUG) test. The TUG test is measured as the time to stand from a standard arm chair, walk 10 feet, turn around, return to start and sit down. The TUG test is a measure of mobility and balance, has good validity [$0.6<r<0.85$] and excellent reliability. The 30s-CST is measured as the number of times a person comes to a full standing position from a chair in 30 seconds, as quickly as possible, without using ones' hands. The 30s-CST is a measure of lower extremity strength and dynamic balance, has excellent reliability [ICC=0.84-0.92]. These two performance tests incorporate movements typically undertaken during normal daily activities, and thus represent tests that are more likely to be safely performed in a clinically unsupervised setting. Both of these tests are included in the CDC Stopping Elderly Accidents, Deaths, & Injuries (STEADI) toolkit for assessment of falls. Note that a friend or family member will be present during the test, with the requirement of being physically capable of providing support if needed (i.e., doesn't need a walker, wheel chair, etc.).

Modifications to procedures due to the COVID-19 pandemic

We were in Phase II of this study when the NM stay-at-home order was issued and UNM entered limited operations. The home visits that had been scheduled, were cancelled. Each participant who was already enrolled, but who hadn't completed the study, provided permission to be contacted once the study resumed.

The following are steps we will take to restart this study:

- Individuals enrolled in Phase 2 will be sent a letter indicating that we are restarting the study. They will be asked if they are interested in completing the study or are no longer interested in participating (no further contact by study team). A form is available for participants to select one of these options, and return to the study team (postage paid). Since home visits are not allowed at this time, interested participants will be moved to Phase 4.
- A sample of individuals who complete Phases 1 and 2 will be invited to repeat the study in the Phase III reliability study. There are two minor modifications to this phase: a) a handout will be provided indicating our plan for minimizing risk of exposure to the novel coronavirus; and b) the toolkit (cardboard box containing tablet, stand, portable wi-fi, etc.) will be dropped off and picked up from the participant's home by a study investigator since there are only 3 toolkits and using regular mail will add further delays (4 month delay so far due to COVID-19).
- Phase 4 will proceed as planned with the following minor modifications: a) a handout will be provided indicating our plan for minimizing risk of exposure to the novel coronavirus; and b) additional recruitment method to help enroll rural participants.

Please see handout listing the safety precautions taken during the study to reduce the risk of infection from the novel coronavirus causing COVID-19 for details. Briefly, this handout

lists steps for disinfecting the toolkit contents, and ways to minimize or eliminate direct contact with a study team member.

10.0 Data and Specimen Management

Data Management

Data will be stored and managed using REDCap, which is a web-based electronic data capture program. It is secure and HIPAA compliant. It is available for all HSC faculty, staff, and sponsored students. Participants will also have the option of completing the surveys online through REDCap.

A REDCap database has been created to store information during the recruitment process (eligibility criteria, reasons for refusal, etc.). This is the only location where both PHI (participant name, address, phone number, email address) and the unique study ID number will be found. Only key study personnel will have access to this database.

Each participant will be assigned a unique number to identify their data. This unique number will be placed on each document (data collection form) and included in each electronic file name (saved videoconferencing file for later reviewing and scoring to assess reliability) to identify the participant.

Participants will be mailed a packet with surveys to complete before the home visit. The study investigator will collect the completed surveys at the home visit for study phases 1 & 2. For study phases 3 & 4, the participant will return the completed surveys along with the test tool kit to the study team or via mail (postage paid). Note that the surveys will only include a unique participant ID, and no identifying information. Alternatively, participants will be offered the option to complete the surveys using a secure online link to the REDCap survey database.

A data collection form will be used by the study personnel conducting the remote assessment of physical performance. This form will be identified using the unique study ID number. Data from this form will be entered into a REDCap database. Only essential study personnel will have access to this database.

All electronic files will be stored on a secure UNM Comprehensive Cancer Center server.

The NMTR will provide the following data in an Excel spreadsheet, which will be downloaded from the study team from a the NMTR secure FTP site and stored on a secure server. Of note, each NMTR case is assigned a NMTR patient ID. If a NMTR case meets the eligibility of a study, he/she is assigned a separate study ID (different than the NMTR patient ID, and it differs if he/she is eligible for more than one study). Only designated NMTR staff have access to the NMTR patient ID.

Data elements to be provided to the study team include the following: current age, age at diagnosis, year of diagnosis, cancer site, stage at diagnosis, summary treatment (yes/no): surgery, chemotherapy, radiation, hormone therapy, immunotherapy, and other therapy; and year of treatment.

**NOTE: Additional data will be provided by the NMTR to characterize the non-responders. NMTR will provide the aggregate status (total count) based on their attempt to contact the patient, prior to releasing names to study staff. The status values include:

- Released, Patient actively or passively agreed to participant in this study
- Refused, Patient actively refused to participate in this study
- Do Not Contact, patient is eligible to participate but does not want to be contacted for any studies
- Bad Address, unable to contact the patient because the letter was undeliverable
- Ineligible, the patient was ineligible to participate in this study because of age, date of diagnosis, site, etc. This could happen if the patient notifies us of a discrepancy in our data. I.e. Date of birth is wrong or different diagnosis.
- Deceased, patient died prior to our attempt to contact them or prior to releasing the data to the study.

Analyses

The validity of the videoconference assessment will be evaluated using the limits of agreement statistic,[17] which is the range within which 95% of differences between measurements obtained by 2 methods will lie. The videoconference assessment will be considered valid if the limits of agreement are within a clinically acceptable limit.[17] This limit will be determined *a priori* through discussions between the PI and her mentoring team. Intraclass Correlation Coefficients (ICC) will be used to examine intra-rater and inter-rater reliability of the videoconference assessment of physical performance. Interpretation of ICC values is as follows: 0.75-1.00 = excellent reliability; 0.60-0.74 = good reliability; 0.40-0.59 = fair reliability; and <0.40 = poor reliability.[18]

Maintaining Confidentiality

The following steps will be taken to secure the data and to maintain confidentiality:

- Study participants will be assigned a unique study ID.
- All data collected will be identified with the unique study ID.
- Identifying information (e.g., name, address, etc.) will be kept separate from the participant's study data.
- The PI and her Project Manager will have access to the electronic "link" between identifying information and the study ID (REDCap secure database). REDCap is secure, HIPAA compliant, and available for all HSC faculty, staff, and sponsored students
- Only trained study staff will have access to the data.
- Data obtained from the NMTR with name, address, etc. of cancer survivors who have not refused contact by study staff will be encrypted, password protected, and stored on a secure server. Access will be limited to key study personnel.
- Other data collected during the study will be stored on a password and firewall protected server and accessed via secured computers in the Cancer Research Facility.
- Any paper forms, including informed consent forms will be kept in a locked file cabinet in locked offices of the study staff for up to three years.

- Videoconferencing files will be downloaded from the tablet and stored on a secure computer server. The files will be password protected and the file name will not include any identifying information (e.g., study ID number rather than participant's name). These video files will be saved in a limited-access (only key personnel) folder on the secure server for up to 3 years upon completion of the validation study. This time will allow for publication of the study results and to allow the PI to retrieve any additional information to inform the remote assessment for the future intervention trial, if needed.
- After downloading the videoconferencing files, each android tablet will be restored to factory settings to remove all data and settings prior to being used by the next study participant.
- Study staff are required to have completed training for the responsible conduct of research.

11.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

The safety of subjects will be monitored in real-time, i.e., during the performance of the brief, timed tests. The study team will not allow the test to start or will stop it early if they believe there is a risk of injury to the participant, .e.g., if participant is feeling dizzy, is not feeling well, or has recently suffered an injury that could affect the participant's ability to safely perform the tests. Additionally, if the walking course for the Timed Up & Go test is not sufficiently long enough, wide enough, clear of clutter, and easy for the participant to navigate, this test will not be performed.

12.0 Withdrawal of Subjects

At any time during the study, participants may ask to withdraw from the study. If the investigator feels that it is no longer safe for the participant to participate in the study, i.e., no longer meets the study eligibility criteria, the participant will be withdrawn from the study without their consent.

13.0 Potential Risks to Subjects / Protection Against Risks

This validation study poses minimal risk, since a member of the research team will be present during home visits to remotely assess physical performance (Phases 1 and 2). This research team member will be timing the participant as part of the face-to-face assessment to be compared with remote (videoconferencing) assessment. Being in the same room as the participant, this research team member will also be able to supervise the performance tests. For Phases 3 and 4, a friend, neighbor, or family member of the participant must be present during the tests. The two tests were chosen since they incorporate movements typically undertaken during normal daily activities (standing from a chair, walking a short distance, sitting on a chair), and thus represent tests that are more likely to be safely performed in a (future) unsupervised setting. Nevertheless, there are some potential risks associated with these performance tests being conducted outside of the clinic setting.

Protection against risks during the physical performance tests will include the following:

- The participant will be asked to identify a friend, neighbor or relative to be present during the assessment. (Note: This criterion is in preparation for an intervention trial that will potentially use this videoconferencing remote assessment method. Information regarding the interactions between the participant, family member, and investigator will be used to refine the protocol to be used in the future intervention trial.) However, since this is a feasibility study, if the identified person is not able to be present for the performance tests, the study will commence as the face-to-face assessor will be present.
- A fall assessment will be administered as part of the eligibility screener. Individuals who are deemed to be at high risk of falls (score >15 on the nine questions) will be ineligible for the study. The study team will offer to mail one or more Fall Prevention brochures from the CDC Stopping Elderly Accidents, Deaths & Injuries (STEADI) program (brochures uploaded as supporting documents).
- The chair used for the 30 second Chair Stand Test must include a straight back, not contain wheels, and be placed against a wall and unable to slide backwards or to the side.
- The area for the Timed Up & Go Test must include a flat area, an appropriate surface (e.g., not shag/deep carpet, not a slippery floor), free of fall hazards (e.g., no cords, throw rugs, pets, papers or magazines on the floor in the walking path, etc.). The chair should be positioned such that it is unable to slide. The chair for this test may contain arms. The marker on the floor to designate the 3 m distance at which to turn around will be clearly visible, but not a tripping hazard.
- Proper apparel and safety gear such as athletic shoes or orthopedic shoes, eye glasses (if needed), no jewelry or loose clothing that can catch on the chair or anything along the walking path.
- No dogs/animals or small children that could interfere with the test and thus jeopardize the safety of the participant will be allowed within the space used to conduct the test (e.g., will need to be in a different room during testing).

Note that both the 30s-CST and TUG tests have been routinely conducted in adult populations with mild to severe functional impairment such as cerebral palsy, COPD, knee osteo-arthritis, low back pain, multiple sclerosis, Parkinson's disease, renal transplant, rheumatoid arthritis, stroke, vestibular disorders, and frail elderly.[19,20] Any serious adverse events that occur will be immediately communicated to Dr. Blair, who will confer with members of her mentoring team (Dr. Herman (MD), Dr. Davis (PhD)). All data will be used for research purposes and will be protected and kept strictly confidential. Although steps will be taken to ensure confidentiality of collected data, there is a very slight risk that data will inadvertently be released.

There is a potential risk of skin irritation from the adhesive on the ActivePAL3 monitor that is worn on the thigh during the performance assessment. Skin irritation is more likely with prolonged wear (i.e., days without changing the adhesive). Wear time will be limited to 1 to 1.5 hours. If irritation should occur, the monitor will be removed and the participant instructed to wash the area with soap and water. If irritation should occur, the assessment will be conducted without the monitor.

14.0 Potential Benefits to Subjects

There are no direct benefits to the study participants in the proof-of-concept or validation studies. The validation study will provide important information on the validity, reliability, acceptability and safety of using videoconferencing to remotely assess physical performance in older adults in the home setting. The advantage to having a low-resource, valid, reliable and safe method to remotely assess physical performance is the ability to assess an important measure of physical health in older adults. The TUG and 30s-CST tests are standard gerontologic tests that are responsive to change, and thus represent useful tests for interventions aiming to improve physical performance. Remote assessment will allow interventions to reach rural older adults, an underserved population. Furthermore, this method eliminates travel burden for the participant and is cost-effective.

15.0 Vulnerable Populations

NA - This study is not enrolling individuals from vulnerable populations.

16.0 Community-Based Participatory Research

NA - this study does not involve CBPR

17.0 Setting

As mentioned earlier, this is primarily a home-based study. The videoconferencing software records the assessments for later viewing and scoring (i.e., timing via stopwatch). One-month later, the investigator who performed the videoconferencing assessment will watch the video recording and re-score the tests to determine intra-rater reliability.

18.0 Resources Available

Study Personnel

Cindy K. Blair, PhD, MPH, Principal Investigator: Dr. Blair is an Assistant Professor in the Division of Epidemiology, Biostatistics, and Preventive Health, in the School of Medicine as well as a member of the UNM Comprehensive Cancer Center (UNMCCC). Dr. Blair is a Cancer Epidemiologist with 16 years of training, research experience, and collaborations in cancer epidemiology in general, and cancer survivorship and intervention development and implementation in particular. She has knowledge and experience with clinical trial design, recruitment and retention of study participants, data collection (subjective, objective, and biologic data), project management (observational studies, randomized controlled trials), supervising data collection staff and study coordinators, intervention tracking and delivery, and statistical analyses. Her background in epidemiology and biostatistics, and research experiences have well prepared her to lead the proposed trial, coordinate all aspects of data collection and management, deliver the intervention, and conduct the statistical analyses.

Carla Herman, MD, MPH, Co-Investigator. Dr. Herman is a Professor in the Division of Geriatrics in the UNM Department of Internal Medicine. Dr. Herman is a geriatrician,

researcher, and educator, with more than 20 years of experience in NM. She provides clinical care at the Senior Health Center 1.5 days per week. Her research interests include successful aging, health promotion/exercise in older adults, and frailty and falls prevention. She will provide expertise on how to safely and effectively conduct home assessments of physical performance among older cancer survivors with existing comorbidities and functional limitations.

Elizabeth Harding, PhD, M.S., Project Manager/Co-Investigator: Dr. Harding has a Doctoral Degree in Human Physiology and is working as a Research Postdoctorate Fellow with Dr. Blair. Dr. Harding was the project manager on Dr. Blair's previous studies, and thus has excellent research skills and abilities to be the Project Manager on the current study. Dr. Harding will assist Dr. Blair with recruitment and screening, the home visits to assess physical functioning, and other key aspects of the study, including study design and implementation, data collection, management, and analyses, and manuscript preparation. Dr. Harding left the study in November 2020.

V. Shane Pankratz, PhD., Co-Investigator. Dr. Pankratz is Professor of Biostatistics, Department of Internal Medicine, and Director of the Biostatistics Shared Resource in the UNM Comprehensive Cancer Center. He has considerable expertise in a broad variety of statistical methods related to observational and interventional studies. As a statistician, he will contribute to study design, statistical analyses, interpretation of the results, and manuscript preparation.

Sally M Davis, PhD, Co-Investigator. Dr. Davis is Director of the UNM Prevention Research Center, and Professor and Chief, Division of Prevention & Population Sciences in the School of Medicine. Dr. Davis has more than 40 years of experience conducting prevention research in partnership with underrepresented populations in the Southwest, especially in rural communities. Her research focuses on the prevention of obesity, cardiovascular disease and cancer by promoting good nutrition, physical activity, and decreased tobacco use. Dr. Davis will provide expertise on recruitment and retention strategies, interpretation of the results, and manuscript preparation.

Tawny Boyce, MS, MPH, Database Management. Ms. Boyce is an Associate Scientist working with both the Behavioral Measurement and Population Sciences and Biostatistics Shared Resources. She earned a dual Master's degree from Tufts University in 2010 focusing on epidemiology, biostatistics and nutrition. Ms. Boyce will provide database development services. She will develop a recruitment/participant tracking database in REDCap as well as a REDCap database for capturing quantitative data collected from participants. She will also assist Dr. Blair in assessing the reliability of the remote assessment of physical performance via videoconferencing.

New Mexico Tumor Registry Personnel: Charles Wiggins, PhD**,** as Director of the New Mexico Tumor Registry will oversee the identification of potential participants using the NMTR records. He will ensure that proper scientific and ethical standards are followed in accordance with NMTR and UNM guidelines. Barbara Evans is the IT Manager and will be responsible for patient selection and tracking. Angela Meisner is an Associate Scientist and will be responsible for project coordination of the NMTR activities for the study.

Time Devoted to Conduct the Research

The proposed validation study is part of a career development award. As such, the first six months will include training for the PI, e.g., shadowing physicians in the clinic and accompanying them on home visits to gain "hands-on" experience with the study population. The actual timeframe for the validation study is 1.5 years, from development to manuscript submission.

Study Timeline: 2018 - 2020	**Y1**		**Y2**	
Training for the PI				
Development				
Validity / Reliability study (30 participants total)				
Pre-test with 10 participants				
Test with 20 other participants				
Analyze Data / Prepare & submit manuscripts				

19.0 Recruitment Methods

We plan to use passive recruitment methods for this validation study, given the small sample size. We will distribute flyers in areas frequented by older adults in the urban communities, such as libraries, senior centers, cancer support groups, clinics, etc. For rural communities, we will expand the location of flyers to include gyms, grocery stores and any location where older rural dwellers frequent. We may also utilize the New Mexico Minority/Underserved NCI Community Oncology Research Program and the UNM Clinical & Translational Science Center Community Health Network (CHN) via their approved protocol. The CHN includes Community Health Workers (CHWs) who help underserved rural populations of New Mexico to overcome cultural barriers in order to help improve health outcomes.

Word of mouth

Word of mouth is often a successful method for recruiting study participants, especially rural individuals. Faculty and staff from the Division of Epidemiology, Biostatistics, and Preventive Medicine, the Prevention Research Center, and the UNM Comprehensive Cancer Center will be emailed a copy of the study flyer, provided approval from leadership (i.e., Division Chief, Director, Associate Directors or Program Leaders). The email will briefly explain the study, and indicate a $5 e-merchandise card for Amazon will be provided for anyone referring an individual to the study, regardless of final eligibility (referred individual must contact study staff).

Note: For the passive recruitment strategies, we will not be reviewing PHI to identify eligible subjects, and therefore, will not be requesting a waiver of HIPAA authorization for screening/recruitment purposes.

Another method of recruitment will be the identification of potentially eligible study participants through the New Mexico Tumor Registry (NMTR). Per current NMTR policy, a letter will be mailed to the cancer patient/survivor that explains the purpose of the NMTR and why the patient's cancer diagnosis is collected/maintained by the registry. The letter also very briefly describes the proposed study and provides different options for contacting the NMTR if the patient does not want to be contacted by the study investigator. A study flyer with additional information about the study is included with this letter. Passive consent is assumed if there is no response from the subject within three weeks of receiving the letter. Contact information for patients not refusing contact is then forwarded to the study investigator.

Upon active or passive consent to contact, subjects will be mailed a letter explaining the study and inviting them to participate, a consent form, a response post-card, and a self-addressed, stamped envelope to return the response post-card and/or consent form. Individuals who do not refuse contact (via post-card, e-mail or telephone) will be telephoned by staff to summarize the goals of the study, answer questions, verify eligibility, and begin the consent process for those interested in participating in the study. Written informed consent for those interested and study eligible will be obtained via mail or through REDCap eConsent.

Subjects for whom the study has permission to contact (after initial contacts via the New Mexico Tumor Registry) will receive the following recruitment materials (attached to this application):

- A one-page letter introducing them to the study and inviting their participation.
- A copy of the consent/HIPAA form
- A response postcard (and self-addressed, stamped envelope) as one method to communicate with study staff regarding interest or disinterest in learning more about the study.

Individuals will be provided with a toll-free study number and an email address to contact the study team for more information. A member of the study team will schedule a telephone call to explain the study, answer questions, verify eligibility, and begin the consent process for those interested in participating in the study. The participant has the option to complete the informed consent form electronically via REDCap or on a paper form mailed to their residence. Prior to signing, another telephone call will be scheduled to review the form and answer questions. Written informed consent must be received by study staff prior to the participant's home visit.

To enhance recruitment, retention, and adherence rates, as well as to compensate study participants for their time, the following strategies will be utilized: 1) Appointments at participants' homes will be made at their convenience, and 2) A monetary incentive ($50 merchandise card) for the completed assessment.

20.0 Number of Subjects

The goal of this study is to accrue 30 senior (aged ≥ 60 years) cancer survivors.

21.0 Provisions to Protect the Privacy Interests of Subjects

Personal identifying information such as name and address will only be provided to the study from the NMTR for cancer survivors who did not object to contact by study staff. Subjects will then be contacted by mail with a letter introducing them to the intervention study and inviting them to participate. Subsequently, subjects will be contacted by telephone by research staff to summarize the goals of the study, answer questions, and assess final eligibility.

During recruitment and the consent process, we will communicate to the study participant that their privacy is important, and what steps will be taken to protect their privacy. Examples include:

- There is a very slight chance that someone else could get your personal information from us by accident. But to keep this from happening, we will keep all your personal information in a locked file cabinet or in password-protected computer files.
- Only key research personnel will be able to access your personal information.
- All data collected during the study will be identified with only a unique identifier.
- Videoconferencing files will be downloaded from the tablet and stored on a secure computer server. The files will be password protected and the file name will not include any identifying information (e.g., study ID number rather than participant's name). These video files will be saved in a limited-access (only key personnel) folder on the secure server for up to 3 years upon completion of the validation study. This time will allow for publication of the study results and to allow the PI to retrieve any additional information to inform the remote assessment for the future intervention trial, if needed.

The research team will not have access to medical records or other sensitive information not provided by the subject (self-reported medical conditions, cancer type, etc.) or the NMTR (cancer site and stage, age at diagnosis, year of diagnosis, first course of therapy [surgery, chemotherapy and/or radiotherapy]).

Only de-identified data will be used in data analyses. Only aggregate data will be used in presentations, reports, and publications.

22.0 Compensation for Research-Related Injury

NA - this research study does not involve more than Minimal Risk to subjects.

23.0 Economic Burden to Subjects

Participants will have minimal to no economic burden to participate because they will receive a stipend of $50 in the form of a visa card. This is to compensate participants for their time and any inconvenience incurred as a result of investigators coming to their homes. This is a sufficient amount as there will be no travel burden to participants and appointments will be made at their convenience.

24.0 Consent Process

The subject will be introduced to the study through a study flyer or from a letter from the NMTR. The consent process will begin by a telephone conversation with a member of the study team regarding the purpose of the study, possible risks and benefits to participating, confidentiality, etc. If the subject expresses interest in the study, final eligibility will be assessed. The participant has the option to complete the informed consent form electronically via REDCap or on a paper form mailed to their residence. Prior to signing the form, another telephone call will be scheduled to review the consent form with the participant, answer questions, and assess understanding, The following questions will be asked to assess the subjects' understanding of the consent process. Do you have any questions about the study? We have covered a lot of information. Could you please describe for me what you think participating in this study requires? Do you have the toll free study telephone number?

If signed electronically, a copy of the consent form will be available for download. A paper version can also be mailed to the participant if preferred. Participants signing a paper consent form will have received an extra copy to keep for their records. If the participant chooses to sign a paper copy of the signed consent form, it must be received by the study team prior to actually conducting the home visit (phases 1 & 2) or the remote assessment (phases 3 & 4) to assess the physical function tests.

Each participant is allowed to choose when s/he begins the study, which allows for additional time to consider study participation, if needed. Research staff will be available via telephone to answer any questions that the subject may have. Additionally, staff will have received proper training in human subjects' protection. The subject may decline participation in the study or drop out of the study at any time. This will be stated both verbally (phone call, home visit) and in writing (consent form). Contact information for the researchers, the Human Research Review Committee, and the Human Research Protections Office will be made available to potential participants.

Given that this is a validation study, only English speaking subjects are eligible, and thus the consent process will be conducted in English.

25.0 Process to Document Consent in Writing

Either the PI, the Project Manager, or well-trained staff will obtain written informed consent from the study participants. Each participant will receive a copy of the signed consent form to keep for their records.

REFERENCES

1. Ware JE, Kosinski M. *SF-36® Physical & Mental Health Summary Scales: A manual for users of Version 2 (2nd ed).* Lincoln, RI: QualityMetric Inc.; 2007.
2. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical care.* Jun 1992;30(6):473-483.
3. NIH PROMIS - Dynamic Tools to Measure Health Outcomes from Patient Perspective - Measures. http://www.nihpromis.org/measures/measureshome.
4. PROMIS (Patient-Reported Outcomes Measurement Information System). PROMIS Adult Profile Instruments. http://www.assessmentcenter.net/documents/PROMIS%20Profile%20Scoring%20Manual.pdf.
5. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, Scherr PA, Wallace RB. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol.* Mar 1994;49(2):M85-94.
6. Rikli RE, Jones CJ. *Senior fitness test manual.* Champaign, IL: Human Kinetics; 2001.
7. Rikli RE, Jones CJ. *Senior Fitness Test Manual - 2nd Edition.* Champaign, IL: Human Kinetics; 2013.
8. BioSensice: Innovative Research Realized (LEGSys, BalenSens, PAMSys products)(http://www.biosensics.com/).
9. McRoberts DynaPort Move Monitor and the MoveTest (https://www.mcroberts.nl/old/products).
10. Geraedts HA, Zijlstra W, Zhang W, Bulstra S, Stevens M. Adherence to and effectiveness of an individually tailored home-based exercise program for frail older adults, driven by mobility monitoring: design of a prospective cohort study. *BMC public health.* Jun 07 2014;14:570.
11. Mohler MJ, Wendel CS, Taylor-Piliae RE, Toosizadeh N, Najafi B. Motor Performance and Physical Activity as Predictors of Prospective Falls in Community-Dwelling Older Adults by Frailty Level: Application of Wearable Technology. *Gerontology.* 2016;62(6):654-664.
12. Schwenk M, Mohler J, Wendel C, D'Huyvetter K, Fain M, Taylor-Piliae R, Najafi B. Wearable sensor-based in-home assessment of gait, balance, and physical activity for discrimination of frailty status: baseline results of the Arizona frailty cohort study. *Gerontology.* 2015;61(3):258-267.
13. Crotty M, Killington M, van den Berg M, Morris C, Taylor A, Carati C. Telerehabilitation for older people using off-the-shelf applications: acceptability and feasibility. *J Telemed Telecare.* Oct 2014;20(7):370-376.
14. Hoffmann T, Russell T, Thompson L, Vincent A, Nelson M. Using the Internet to assess activities of daily living and hand function in people with Parkinson's disease. *NeuroRehabilitation.* 2008;23(3):253-261.
15. Hwang R, Mandrusiak A, Morris NR, Peters R, Korczyk D, Russell T. Assessing functional exercise capacity using telehealth: Is it valid and reliable in patients with chronic heart failure? *J Telemed Telecare.* Feb 2017;23(2):225-232.
16. Russell TG, Hoffmann TC, Nelson M, Thompson L, Vincent A. Internet-based physical assessment of people with Parkinson disease is accurate and reliable: a pilot study. *J Rehabil Res Dev.* 2013;50(5):643-650.
17. Bland JM, Altman DG. Measuring agreement in method comparison studies. *Stat Methods Med Res.* Jun 1999;8(2):135-160.
18. Cicchetti DV, Sparrow SA. Developing criteria for establishing interrater reliability of specific items: applications to assessment of adaptive behavior. *Am J Ment Defic.* Sep 1981;86(2):127-137.
19. Rehabilitation Measures Database. Rehab Measures: Five Times Sit to Stand Test. http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=1015.
20. Rehabilitation Measures Database. Rehab Measures: Timed Up and Go. http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=903.