Research Protocol
Title: **Dance-Based Avenues to Advance Nonpharmacologic treatment of Chemotherapy Effects** (DAANCE)
Contact PI: Lise Worthen-Chaudhari
MPI: Dr Maryam Lustberg will serve as MPI and Medical Director of this trial as an agent of Yale University. Dr. Lustberg will access and review Adverse Events (AE), including any PHI required for consideration of AE management, via secure email correspondence or secure video call with Dr. Worthen-Chaudhari.

I. Objectives

The objective of this study is to assess the feasibility (Phase 1) and effect (i.e., Phase 2 clinical trial) of dance-based interventions among cancer survivors, focusing on survivors with balance deficits who are deconditioned or nerve damaged (e.g. due to Chemotherapy Induced Peripheral Neuropathy).

Phase 1: evaluate the feasibility of dance-based interventions for balance and analyze any outcome data collected during the course of this intervention.

Phase 2: Evaluate the effect of Adapted Argentine Tango (Tango) relative to home exercise (HEX) among cancer survivors with Chemotherapy-Induced Neuropathy (CIN) and companions with regard to:

II. Background and Rationale

Group dance classes have been found to improve markers of quality of life and physical health (i.e., balance) among some populations engaged in rehabilitation, such as the elderly[2,3] and individuals with Parkinson Disease[4–9]. However, such interventions have yet to be studied among cancer survivors despite the relevance of quality of life and physical health within cancer survivorship[10–13]. Group dance classes are a promising avenue in that they deliver activity-based medicine in a social context, thus potentially improving physical as well as psychosocial aspects of health. To further this avenue of inquiry, we propose to study the feasibility (Phase 1) and effect (Phase 2) of dance-based interventions for cancer survivors.

III. Feasibility (Phase I) Procedures

A. Research Design

We will assess the feasibility of participation in dance-based, physical medicine intervention for cancer survivors and their caregivers. To accomplish this goal, a series of classes will be offered to cancer survivors and their caregivers through James Care for Life. Enrollment/attendance in the class will be documented as well as identification as a survivor or caregiver and client satisfaction at the end of the class. In addition, participants will be given an opportunity to consent to participate in clinical outcomes data collection throughout the course of the intervention. The number and reasons for refusal will be documented.

Intervention: Twenty sessions of Adapted Argentine Tango (Tango). The Tango dance genre has been shown to improve balance function in other populations requiring rehabilitation, such as individuals with Parkinson Disease[5,7–9] and the elderly [2]. To establish feasibility of this intervention for cancer survivors data will be over the course of the intervention as well as approximately 4 weeks after the end of the intervention in order to assess retention of any gains.

B. Sample

Up to 50 cancer survivors over the age of 18, with or without neuropathy, and up to 50 of companions chosen by enrolled survivors are eligible for this study.

Because the number of participants to enroll in this intervention is an outcome measure, we will place no hard cap on sample size. In the unlikely event that recruitment numbers approach the maximum number of individuals we seek to test, we will submit an amendment to increase our approved participant count. Furthermore, in the event that enrollment in the class exceeds capacity during a single James Care for Life session, additional sections of the class will be created until the need is met.

In the event that the intervention is found feasible, these data will represent the first data regarding the effect of a dance-based intervention among cancer survivors. In order to plan for this eventuality, and support any resulting future grant proposals, we aim to collect outcome data from no fewer than 12 cancer survivors per dance-based intervention. While there is no existing preliminary data in this population with which to establish a sample size estimation, this study is modeled on a similar study conducted in Parkinson Disease[9] which reported a treatment effect of .92 in the Berg Balance Scale measure. Average treatment effect values in rehabilitation research has been reported to be .69, thus the reported effect size is high but not unusual within the field.

C. Measurement / Instrumentation

Aim 1: to determine the feasibility of conducting dance-based balance interventions among cancer survivors given concerns regarding retention and compliance among participants who are receiving concurrent care in oncology and rehabilitation.

Outcome measures collected each session:

- attendance
- participant satisfaction with the intervention

Additional information collected:

- cancer diagnosis
- attendance with/without partner
- concurrent rehabilitation and oncology care
- rehabilitation and oncology care in the two months prior to enrollment. These data will be collected because treatment experience immediately prior to enrollment may impact attendance and baseline performance data.
- falls or partial falls experienced in 3 months prior to class enrollment OR since last class.
- reasons why eligible volunteers refuse (e.g., challenges with regard to transportation or scheduling).

Aim 2*:* to establish pilot data regarding impact of participation in this intervention on quality of life and health.

Outcome Measures:

- SF-36[12,13]
- EORTC QLQ-C30[15]
- EORTC CIPN20[16]
- mTNS[17]
- Ankle JPS[18]
- Berg Balance Scale[19]
- Quantified measures via portable force plate: medial-lateral sway range, mean and variability during bilateral static standing with eyes open and eyes closed[20]; duration of uninterrupted single leg stance in seconds[21]
- Quantitative gait stability measures via portable motion capture system: average and variability measures of spatiotemporal gait parameters (e.g., stride length, stride time, step width)[22]
- Laban Movement Analysis qualitative effort measures[23]

Timing and analysis of outcome testing:
Participants will be tested at enrollment, intermittently during the study, at exit from the study, and, finally, approximately 4 weeks after exit from the study to evaluate retention. An intention to treat analysis will be performed with resulting data.

Aim 3: to determine the feasibility of conducting a 6 week, dance-based balance intervention in which postural control and symptoms data are collected before and after each session.
Outcome measures collected each session:

- attendance
- participant satisfaction with the intervention including data collections
- EORTC QLQ-C30[15]
- Rating of Perceived Exertion (RPE; 6-20 scale)[24]
- Quantified measures via portable force plate: medial-lateral sway range, mean and variability during bilateral static standing with eyes open and eyes closed[20]; duration of uninterrupted single leg stance in seconds[21]

D. Detailed study procedures

Interventions: These classes will be open to all adult cancer survivors (with or without CIPN) and their family members, even those not directly involved in this study, to encourage community outreach and increase patient participation.

The Tango intervention will be facilitated by investigator Wor Breast Center (SSCBC then-Chaudhari and/or their representative. Class will be held in the Stefanie Spielman Comprehensive).

Data collection timeline: Information about attendance, satisfaction with the intervention and concurrent therapeutic activity, symptoms, rating of perceived exertion, and/or basic biomechanical data (balance as measured by a force platform and kinematic data recorded during class) will be collected at each session and will require no more than 10 minutes duration per participant/session. Clinical outcome measures (i.e., SF-36, EORTC QLQ C30, EORTC CIPN20, mTNS, ankle JPS, Berg Balance, force platform measures, gait analysis) will be collected at 5 and 10 weeks and once approximately 4 weeks after intervention finish. The ankle JPS test consists of measuring the error in ankle flexion angle as patients attempt to reproduce a specified angle without the aid of vision. Gait analysis will consist of patients walking on a treadmill for no more than 6 minutes. Patients will be asked to walk at a comfortable speed while wearing removable bands that have reflective markers attached. These markers will be used to record body segment movements as the patients walk, which will be used to calculate the spatiotemporal gait parameters.

Every session will be observed by staff and/or recorded with a portable motion capture system, such as a digital camera or Microsoft Kinect™, to enable Laban Movement Analysis. This analysis is done by observing a participant's movement performance, often from video, and will require no additional assessment time on the part of the participant.

Completed documents associated with this study, such as informed consent, will be stored securely in a locked cabinet and/or office within the Stefanie Spielman Comprehensive Breast Center and/or Dodd Hall.

Recruitment: Dance-based interventions for cancer survivors and care givers is being offered and advertised through James Care for Life. The population we are recruiting includes adults, minimum age of 18 years, who have a cancer diagnosis or who are the caregiver of someone with a cancer diagnosis.

Such broad eligibility requirements are appropriate for an initial study of intervention feasibility. In addition to recruiting volunteers through James Care for Life, this study will recruit from the Oncology Rehabilitation center in The James' Stefanie Spielman Comprehensive Breast Centerand Outpatient Neurologic Rehabilitation in the Martha Morehouse Pavilion in Columbus, OH.

E. Internal Validity

All measures will be conducted by a researcher trained in the administration of the measure.

F. Data Analysis

An intent to treat analysis will be performed for variables of interest.

Variables of interest (Quantitative and Clinical Outcome Measures):

- Attendance with/without invited guest
- SF-36v2 [25]
- EORTC CIPN20 - sensory interference score[16]
- mTNS[17]
- ankle JPS[18]
- Berg Balance Scale[19]
- range of medial-lateral sway in bilateral stance with eyes opened[20]
- range of medial-lateral sway in bilateral stance with eyes closed[20]
- maximum duration of single leg stance with eyes opened[21]
- stride-to-stride variability in stride length during gait[22]

Variables of interest (Qualitative)*:*

Individuals trained in Laban Movement Analysis within the OSU Department of Dance will analyze additional data regarding quality of movement from live field observations and/or videos. Incidence of specific movement dynamics in time (i.e. quick vs. sustained) and space (i.e. use of functional workspace) will be quantified per session and compared.

IV. Effect (Phase II) Procedures

A. Research Design

Prospective 1:1 block randomized study, with random block sizes. Two arms: experimental and active control (Fig 1).

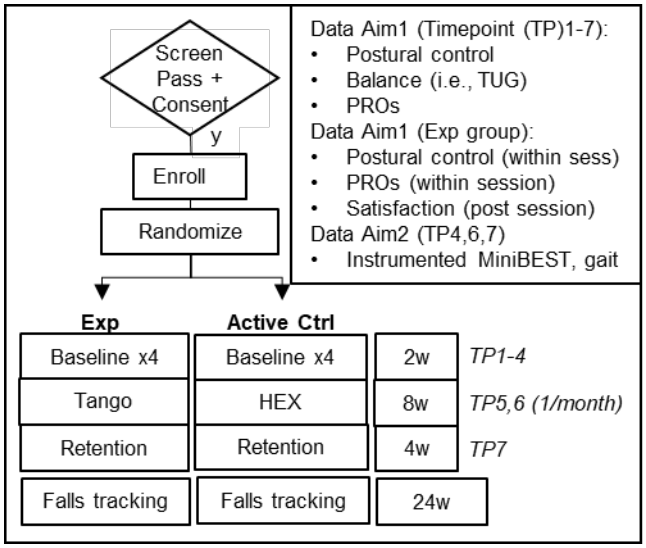

Fig1: Study design flowchart. TP = Testing timepoint.

B. Sample

Individuals with breast cancer-related neuropathy will be recruited for this study using the following inclusion and exclusion criteria.

Inclusion criteria:

- Breast cancer survivors ≥ 40 years old
- Symptomatic for neuropathy (CIPN20 sensorimotor score < 95 on transformed scale (100 maximum));
- postural control outside 70% CI for adults who are middle-aged without neurotrauma [20]);
- having completed taxane-based chemotherapy treatment at least 3 months ago;
- able to understand and comply with directions associated with testing and study treatments.

Exclusion criteria:

- Pre-existing vestibular deficit;

- poorly controlled diabetes (hgA1C $\geq$ 8);
- non-ambulatory or lower extremity amputation (assistive devices allowed);
- use of cytotoxic therapy during study (immune- and endocrine therapy allowed);
- participation in physical therapy during the study;
- contraindication to participate in Tango due to orthopedic issue (e.g., herniated vertebral disc);

In addition, survivors who are screened and found eligible to participate in this RCT will be asked to invite a companion to enroll with them in the study arm that the survivor is randomized into. (n=up to 100 companions)

Finally, up to 100 survivors screened who do not meet the criteria above will be offered enrollment without compensation in the intervention of their choice, along with their companion (up to n=100), as we have capacity to include them and using the "companion" consent form. Capacity will be defined based on space and staffing availability.

Therefore, in total, up to 200 survivors and up to 200 companions will be enrolled in Phase 2 of this protocol.

C. Measurement/Instrumentation

Data collected at baseline x 4, mid-intervention and post intervention (*collected at baseline x1 only):

- Adverse events (i.e., PRO-CTCAE[26], falls or loss of balance, illness or hospitalization since last visit)
- SF-36[25]
- EORTC QLQ-C30[15]
- Neuropathy symptoms: measured using original or modified forms of the EORTC CIPN-20[16])
- Sports Concussion Assessment Test (SCAT) Symptom inventory (for comparison to CIPN-20)[27,28]
- Pain: measured using original or modified forms of the Brief Pain Inventory (BPI)[29]
- Fatigue: measured using original or modified forms of Cancer Related Fatigue (CRF) scales
- Rating of Perceived Exertion (RPE)
- Quantified measures via portable force plate: medial-lateral sway area, range, mean and variability during bilateral static standing with eyes closed[20]
- Timed-Up-and-Go (TUG)[30,31]
- Quantitative gait stability measures via portable motion capture system: average and variability measures of spatiotemporal gait parameters (e.g., stride length, stride time, step width)[22]*
- Mini-BEST[32]*
- Grip strength[33]*
- Goal Attainment Scale (GAS)[34]*
- Activities of Daily Living (ADL) [35] (e.g., Lawton-Brody iADL, Functional Status Questionnaire (FSQ) ADL, Katz ADL, QuickDASH[36])*
- Functional Fitness of Older Adults test [37]*
- Non-invasive Electroencephalography (EEG)*

Data collected within-session (before and after each session unless otherwise noted):

- Adverse events (before every session)
- Neuropathy: measured using original or modified forms of the EORTC CIPN-20[16]

- Sports Concussion Assessment Test (SCAT) Symptom inventory (for comparison to CIPN-20)[27,28]
- Pain: measured using original or modified forms of the Brief Pain Inventory (BPI)[29]
- Fatigue: measured using original or modified forms of Cancer Related Fatigue (CRF) scales
- Rating of Perceived Exertion (RPE)
- Quantified measures via portable force plate: medial-lateral sway area, range, mean and variability during bilateral static standing with eyes closed[20]
- satisfaction with intervention via 7-pt Likert Scale (after every session)[38]
- Goal Attainment Scale (GAS)[34] (before session, no more than once a week)
- Intrinsic Motivation Inventory (IMI)[39] (after session, no more than once a week)

Data collected by participant at home, daily, and reported to research staff on weekly basis:
We will ask participants to track the adverse event of falls or loss of balance using a daily journal that they take home with them or secure electronic data capture interface (e.g., REDCap, MyCap). We will collect these data weekly during the intervention, and for 6 months following the completion of intervention, through weekly check-ins with all participants

D. Detailed Study Procedures

Aim1: We will evaluate change in postural control over 16 sessions of Tango (exp) vs HEX (control) (n=26 per group; 1:1 randomization) as primary endpoint. As secondary measures, we will assess: balance function (i.e., TUG) and PROs (i.e., symptoms, pain, fatigue, mood, quality of life) *monthly* including 1 month post-intervention completion; postural control and symptoms *within-session*; and falls incidence *weekly for 6 months following intervention completion*. Hypothesis: At primary endpoint, members of the exp group will show more improvement than members of the control group in measures sensitive to neuropathy disease state (i.e., sway variability and area).

a. *Primary measure*: Posture (RMSml): has shown clinically relevant for future fall prediction[40–43] and neuropathy detection in cancer[44–46] and diabetes[47,48] in a host of studies. As our primary measure we will calculate this measure of medial-lateral sway variability (RMSml). Postural control (30 s duration) will be collected 2x/week during multiple baseline testing, monthly thereafter for HEX, and before and after each session for the Tango group. Center of pressure (COP) data will be recorded (1000 Hz) as participants stand quietly on a level, static balance platform (Bertec Corp, Columbus, OH) with eyes closed (QEC). As in past work[20,38,44–46], we will collect 30 second (s) of COP data and interpret these data with regard to healthy within-subject variability as defined in a middle-aged cohort [20]. RMSml will be calculated (as described by Prieto[49]) as the root-mean-squared value of COP excursion in the medial-lateral direction (mm), a formula which effectively returns the standard deviation from the mean. All data will be captured using custom software written in LabView (National Instruments, Austin, TX, US). Our team (LWC, MBL) has pioneered the biomechanical assessment of balance deficits associated with cancer treatment and neurorehabilitation [20,38,44–46]. Using center-of-pressure (COP) measures captured with portable force platform equipment, we have quantified the balance dysfunction that accumulates with cancer treatment sessions (Fig 1) [1,46,50] and identified a potential effect of Tango to remediate these effects[38]. Finally, in order to translate this quantified measurement paradigm to clinical care of individuals, we published normative measures of within-subject variability (WSV) [20] to enhance our interpretation of treatment effects.

b. *Secondary measures*: Posture (other): will be calculated from the 30s duration of quiet standing data including COP ellipse area, velocity, and sample entropy[38]. In particular, the non-linear measure of sample entropy[38,51–54] may provide additional information regarding complexity of postural control regulation among cancer survivors with neuropathy. **Balance:** is a critical measure of clinical impact. The Timed Up-and-Go test, or **TUG**, (<2 min to administer) is a timed test of a person's ability to stand from a chair, walk 10 feet, turn around, and return to sitting with shorter times indicating better functional

balance. While our data indicate some clinical tests are not sensitive to chemotherapy-induced neuropathy state (e.g., Berg), Wampler et al (2007); Marshall et al. (2017); and Evans et al. (2019) reported that TUG time distinguished cancer survivors with neuropathy (n=20, 8, & 20 survivors respectively) from age-matched controls. **Patient-reported outcomes (PROs):** are critical secondary measures that will help us to understand participant perception of change with intervention. These will be collected 2x/week during multiple baseline testing then monthly thereafter with a subset captured per session to evaluate within-session effects. We will administer PROs during multiple baseline and monthly testing through retention. CIPN-20 and BPI instruments will be administered to complement one another: the CIPN 20 focuses on the effect of neuropathy symptoms on functional capacity while the BPI assesses pain symptoms. We will also collect the symptom inventory from the Sports Concussion Assessment Tool (SCAT). Additionally, we will document cancer-related fatigue (CRF), quality of life (SF-36), satisfaction with intervention, likelihood of recommending the intervention to a friend with neuropathy (thi will be included as a question on the satisfaction with intervention survey), perceived benefit, intrinsic motivation, depression/apathy/ anxiety (PRO-CTCAE), and adverse events including falls. **Falls:** each participant will use a diary format to report daily changes in falls, symptoms, use of assistive devices, and amount of concurrent medication use during the study period. These factors will also be recorded by research staff within adverse event reporting 2x per week before Tango lessons. For 6 months after intervention completion, we will collect falls incidence weekly from participant daily dairy records. **European Organization for Research and Treatment of Cancer's Quality of Life Questionnaire, Chemotherapy-Induced Peripheral Neuropathy (CIPN 20):** is a validated instrument for longitudinal evaluation of neuropathy symptoms induced by chemotherapy. This is a 20-item patient reported questionnaire that includes three subscales evaluating sensory, motor and autonomic symptoms. It is easy to use and filled out by patients themselves. This instrument was specifically designed and validated to evaluate patients' symptoms of neuropathy[55]. The **Sports Concussion Assessment Tool (SCAT)**: is a 22-item assessment on which patients grade symptoms (e.g., body pain, "mental fog", nausea, balance, and lability) in severity from 1(mild) to 6(severe). The SCAT self-report measure has not been validated in the cancer population explicitly, however, many of the symptoms inventoried are associated with mild cognitive impairment ("chemofog") and/or neuropathy experienced by many cancer survivors. Importantly, this measure is validated for ecological momentary assessment of individuals with mild cognitive impairment and is a primary outcome measure in our studies of Tango for concussion. Inclusion of the SCAT provides a measure of mild cognitive impairment that is validated for repeat use over short or long periods of time (although not specifically in the caner population); will enable us to compare the SCAT and CIPN-20 results; and will enable us to compare effect size among cancer survivors directly with results from our ongoing studies of dance-based interventions for concussion. **The Brief Pain Inventory (BPI)**: is a validated instrument that has been used to evaluate pain symptoms and functional capacity in our target population[56]. **Cancer Related Fatigue Scale (CRF):** is a 6 item PRO measuring fatigue in physical and psychological dimensions. **The Short Form Health Survey (SF-36):** has been validated as a quality of life (QOL) measure in cancer survivorship. In addition, one report found this measure also predicted fall risk among cancer survivors. **Satisfaction:** with intervention is measured after each class using a 7pt Likert scale and prompt for feedback about what did/did not work per class. Feedback is used to improve future sessions. Monthly, we prompt participants to rate the likelihood of future engagement. **The Intrinsic Motivation Inventory (IMI)** was developed from the perspective of Self Determination Theory to assess 7 dimensions of experience: Interest/Enjoyment, Perceived Competence, Effort/Importance, Pressure/Tension, and Choice[39,57–61]. We administer the 9 item short form of the IMI weekly to optimize instruction around high Perceived Competence and low Pressure/Tension[58,59] as well as explore relationships between adherence, motor effects, and IMI dimensions (including perceived benefit (Effort/Importance)). The Patient-Reported Outcome version of the **Common Terminology Criteria for Adverse Events v5 (PRO-CTCAE):** developed by NCI, is standard protocol in oncology to screen for signs of depression, anxiety, and apathy associated with cancer treatment or progression[62]. While not an outcome measure, we collect this staff-administered assessment per visit for adverse event screening, using the data to monitor and compare descriptive

statistics between groups. Changes in depression, anxiety, or apathy identified within check-ins, will be addressed.
c. *Within-Session Effects* **Posture:** will be captured before and after each Tango session in order to assess within-session change over time. A subset of **PROs:** (i.e., CIPN-20, BPI, and CRF) will be collected routinely before and after Tango training to allow analysis of within-session change. Finally, satisfaction with intervention will be collected after each session

Aim2: We will evaluate change in gait variability after 16 sessions of Tango (exp) vs HEX (control) (n=26 per group; 1:1 randomization). As secondary measures, we will analyze local and orbital dynamic stability (pre, post, and 1mo post-intervention), PROs (monthly), and falls incidence (weekly) following intervention completion. Hypothesis: At primary endpoint, members of the exp group will improve more relative to control group members in gait variability (i.e., stride-to-stride variability in speed).

a. *Instrumented measures:* Using a commercially available inertial measurement unit (IMU) and electromyographic (EMG) system (Delsys Trigno, Boston MA), we will record kinematics & muscle activity during performance of the MiniBEST and 3 minutes of steady-state walking. The **Mini Balance Evaluation System Test (MiniBEST):** evaluates sensory organization, anticipatory and reactive postural control, and dynamic gait indices[63]; was recently recommended for use in studies of neuropathy[13]; and discriminated BC survivors from controls in at least 1 prior study[32]. Instrumentation of MiniBEST will enable calculation of spatiotemporal, kinematic, and co-contraction measures. **Gait variability:** is indicative of mild cognitive impairment [64], age [65], fall risk in the elderly [22,66,67], and neuropathy [68] regardless of age or type of cancer[69] including specifically in BC[70,71]. These data add to findings from MPI Lustberg that orbital stability during gait worsens with even mild neuropathy when compared to age-matched controls[72]. Therefore, gait variability is a relevant behavioral mechanism to study[22,66,67]. Our preliminary data suggests gait variability is trainable among cancer survivors through Tango practice [73]; if feasible to study, gait variability/stability may provide critical insight into neuromotor mechanisms relevant for treatment of persons with neurotrauma. Participants will walk overground at their own speed for a minimum of 3 minutes after a 30 second acclimatization period. gait characteristics will be calculated per stride (e.g., speed). From multiple strides collected over 3 minutes, the coefficient of variation (CV) will be calculated for step length, gait speed and other measures of variability previously found sensitive to health status [22,66,73]. **Local dynamic stability**[74,75] **and orbital stability**[72,76]: will also be analyzed, measures shown sensitive to neuropathy that have yet to be employed in prospective interventional studies. **Co-contraction index (CCI):** calculated from electromyographic (EMG) signals of the tibialis anterior and medial gastrocnemius muscles, provides unique insight into neuropathy effects[68,77]. CCI will be calculated during steady-state gait[68] and quiet standing tasks[77] within the MiniBEST. If proven feasible, the ability to assess CCI in concert with biomechanical measures of balance (i.e., postural control) and locomotion (i.e., gait variability, orbital stability, and local stability) will represent a powerful methodological combination through which to investigate mechanisms of neurorecovery in future trials. MPI Worthen-Chaudhari has extensive experience distilling biomechanical variables of interest into clinically-relevant performance measures of neurologic health [1,44,78–80,80–87] for her own research as well as for other leading investigators. **PROs, AEs, and future falls incidence:** as above.

Data collection: data may be collected using paper or electronic (e.g. MyCAP) versions of approved instruments.

Data storage: paper versions of source documentation will be kept in a locked cabinet within an OSU office that is accessible only to OSU clinical or research staff. Electronic data may be stored in a password protected spreadsheet or through RedCAP.

Interventions: training may be delivered in-person, via video conferencing, or via asynchronous instruction.

E. Internal Validity

All measures will be conducted by a researcher trained in the administration of the measure.

F. Data Analysis

Sample Size Justification: Preliminary data from our group was used to determine sample size requirements for this proposed randomized trial. Aim 1: Five cancer survivors with postural control deficits (RMSml>4.0mm) at baseline who participated in Tango practice improved RMSml from mean(SD) of 7.9(1.2) at baseline to 4.6(0.5) after 8 Tango sessions. Assuming more heterogeneity in our analysis sample, (SD=2.7 in control and intervention groups) we estimate Cohen's d=1.22. Thus we require an analysis sample of n=14 participants per group to provide 85% power at a 5% type1 error rate. To account for anticipated drop-out and Aim2 analysis we will **enroll n=26 participants per group**. Aim 2: Preliminary data shows an Coefficient of Variation gait speed (CVspeed) SD of approximately 1.2 among survivors with neuropathy and postural deficits prior to Tango practice. With a sample size of n=19 per group (per Aim1) and this SD, we have 80% power to detect a difference of 1.32 (d=1.1). A cohort of 7 survivors with heterogeneous treatment progress (during and after chemotherapy exposure), not screened for or limited to those with postural control deficits, demonstrated a decrease in CVspeed (p=0.003) from 3.0(1.15) to 2.2(1.10) after <=16 sessions of Tango practice (d=0.711). We will enroll **n=26 participants per group** to detect a reduction of this magnitude with 80% power.

Statistical Analysis Plan: Unless otherwise noted, all analyses will be performed on an intent-to-treat basis, and all hypothesis tests will be two-sided and at the 5% significance level. Enrolled participant characteristics will be summarized by assigned treatment groups.

For *Aim 1*, a linear mixed effects model will be used to model postural sway (RMSml). Fixed effects will be included for time, treatment, treatment-by-time interactions, and concurrent medication use. Random effects for subjects will be used to account for correlation between observations from the same subject. The primary estimand will be a difference-in-difference representing the difference in mean RMSml change from baseline to week 16 between treatment groups. While we expect balance between the two groups due to randomization, we will adjust for potential confounders including baseline RMSml, age, body mass index, concurrent medications (e.g., duloxetine) and other variables if imbalance between groups occurs by chance. Similar analyses will be performed for the PROs sensory symptoms (CIPN-20), pain (BPI-SF), fatigue (0–10 Likert), quality of life (SF-36), and falls incidence following intervention completion. Finally, Pearson's R will be calculated to correlate postural control and balance outcomes, PROs, and future falls incidence.

For *Aim 2*, a similar analysis strategy will be used to compare biomechanical mobility between the two groups (linear mixed models; one-sided hypothesis test) as well as the correlation between biomechanical mobility outcomes, PROs, and falls incidence following intervention completion (Pearson's R).

Not all enrolled subjects will complete the intervention and have follow-up data. The linear mixed model analyses can use available data from all participants with at least one observation, regardless of whether or not they complete follow-up. We will compare the baseline characteristics of subjects who complete the study to those who drop out to assess the potential for attrition bias. A sensitivity analysis will be performed using multiple imputation to assess the impact drop-out has on study conclusions.

V. Funding

This project was funded, initially in Phase 1, through a 2015-16 Pelotonia Undergraduate Fellowship. We secured Phase 2 funding in 1R21AG068831 through the NIH National Institute of Aging (Note: this includes visit reimbursement for cancer survivors only).

VI. References

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