Prospective Research Study Protocol Template

Study Protocol Title:
"Can A Prescribed Walking Program with or without Monitoring Impact Dizziness in the Older Adults?"

Study Sponsor:
Florida Hospital

Principal Investigator:
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List of Abbreviations:

ABC	- Activities-Specific Balance Confidence
DHI	– Dizziness Handicap Inventory
DGI	– Dynamic Gait Index
ICF	- International Classification of Functioning, Disability and Health
IPAQ	– International Physical Activity Questionnaire
mCTSIB	- Modified Clinical Test of Sensory Interaction for Balance
MET	– Metabolic Equivalent of Task
PI	- Principal Investigator
RR	- Relative Risk
TUG	– Timed Up and Go
VEDGE	- Vestibular Evidence Database to Guide Effectiveness
VOR	- Vestibuloocular Reflex
VR	– Vestibular Rehabilitation
VRW	- Vestibular Rehabilitation plus Walking instruction only
VRWP	- Vestibular Rehabilitation plus Walking plus Pedometer

Introduction

This document is a protocol for a human research study. This study is to be conducted in accordance with applicable Federal regulations and institutional research policies and procedures.

Background Information and Scientific Rationale

Dizziness is a common complaint reported by 30% of people above 65 years of age and by more than 50% of those 90 years of age and older.[1] The incidence increases with age because of the deterioration of the vestibular system. Age-related changes in the vestibular system are characterized by degeneration of vestibular receptors, decrease nerve conduction of vestibular nerve, [2] aging otolithic membrane, alterations in calcium metabolism and microvascular ischemia. [3] Disorders of the vestibular system are responsible for 40 to 50% of dizziness, and peripheral vestibular disorders in older adults are common. [4] Aside from vestibular sources, dizziness can be from nonvestibular sources that include, but not limited to, sensory loss, psychiatric and cardiovascular disorders, and adverse drug effects.[5] The majority of older adults with dizziness who live in the community have more than one underlying causes of dizziness.[6]

Rotational sensation or vertigo is one of the four types of dizziness. The other types are impending faint, disequilibrium, and vague lightheadedness. Vertigo results from a disorder of the vestibular system.[7] It is often accompanied by nausea, vomiting, staggering gait, and oscillopsia.[5] It can be from a peripheral or central origin, or mixed. Peripheral vestibular conditions that could affect the older adults include acute or recurrent vestibulopathy, Meniere's disease, unilateral or bilateral vestibular dysfunction, benign paroxysmal positional vertigo (BPPV), and postsurgical conditions affecting the vestibule or vestibular nerve. Patients with central causes of vertigo are harder to treat [4] because of concomitant signs and symptoms aside from the complaints of dizziness. Parkinson's disease (PD), Multiple Sclerosis (MS), head injuries and cerebrovascular disorders can be central causes of vertigo or dizziness.[4]

Age-related decline in vestibular, musculoskeletal, and neurologic performances compounded by a vestibular pathology can result to debilitating physical and psychological consequences. Dizziness is associated with an increased risk of falls.[8] Medical conditions such as unilateral and bilateral vestibular deficits produce unsteadiness of gait associated with head turns, walking in the dark, or walking on uneven surfaces.[5]

According to Menant and colleague, community dwelling older adults with dizziness have higher rate of falls.[9] Dizzy older adults were 1.6 times more likely to experience multiple falls (RR1.55, 95% confidence interval 1.08-2.23).[9] Liston and colleagues found that community dwelling older adults experiencing multiple falls have peripheral vestibular dysfunction.[8]

Research indicates dizziness to be independently associated with disability in the aged. The components of disability in the study conducted by Mueller and colleagues were limitations in social participation and activities of daily living. Patients with dizziness have restrictions in functional independence indoors and outdoors. Walking in and outside the home is a mobility

issue due to actual and perceived balance problems. This disabling condition is often accompanied by depression and anxiety.[10]

Dizziness can cause physical inactivity. Aside from being a risk factor for falls, the fear of falling or anticipation of a dizziness episode limits mobility.[11] Physical inactivity leads to a further reduction in vestibular function. Regular physical activity stimulates or maintains gaze control and posture stabilization in the older adults. [12] Therefore, the lack of mobility may lead to a decrease in responsiveness in the neurosensory systems. Vestibular disorders can also significantly decrease balance confidence. [13] The cycle of activity restriction can bring about sedentary lifestyle, which further hastens deconditioning, frailty, and disablement in the older adults.[11] People with dizziness may have low quality of life from the consequent loss of function and independence, however; there is currently no research on interventions to increase physical activity in older adults with dizziness.

Dondzila et al. found that older adults who considered themselves physically active actually walk more than those who do not rate themselves as physically active.[14] The Physical Activity Guidelines for Americans recommend 150 minutes each week of moderate intensity aerobic activity or 75 minutes each week of vigorous intensity aerobic activity.[15] The Centers for Disease Control and Prevention (CDC) reported that "1 out of 5 adults (21%) meet the 2008 Physical Activity Guidelines".[16] For the older adults, the threshold amount of physical activity associated with better physical health is >8000 steps/day and/or >20min/day at an intensity of >3 Metabolic Equivalent (METS) and for better mental health, >4000 steps/day and/or >5min/day at >3METS.[17] Men aged 65-69 years performed the highest steps per day (>9,126 steps/day) and women aged 85+years were in the lowest category of steps per day (<276 steps/day).[18]

Currently, 10,000 steps per day is a widely promoted dosage-based walking program. In older adults, increased lower and upper body strength, endurance, lower body flexibility, and agility/balance were significantly and positively associated with walking 6500 or more steps per day.[19] Low-activity, non-depressed older adults were able to maintain and/or improve their mental health.[20] High volume of steps led to an increase in the Timed Up and Go (TUG) score, 30-second leg lifts and 2-minute walking distance.[21]

Because of the detrimental effects of sedentary lifestyle, interventions to increase physical activity are a public health priority.[22] There are many instruments available to track the amount of physical activity of an individual subjectively and objectively.[23] A self-report physical activity questionnaire is a cost-effective method to obtain physical activity data. The International Physical Activity Questionnaire (IPAQ) is the most commonly used physical activity questionnaire worldwide. It has two versions, a 31-item long form and the nine-item short form. The short form records the amount of time spent in sitting, walking, moderate- and vigorous-intensity activities in the last 7 days.[24]

Vestibular Rehabilitation (VR) is a program consisting of exercises designed to address the impairments, functional limitations, and disability from vestibular hypofunction. Walking for endurance is cited as one of the components of vestibular rehabilitation in the "Clinical Practice Guideline for Peripheral Vestibular Hypofunction" together with gaze stability, habituation, and

balance training.[25] Aside from the general conditioning value of walking as an exercise, walking develops or maintains the efficiency of the two vestibular reflexes, consisting of the vestibulospinal and vestibuloocular reflexes involved in postural control.[12] Walking involves sensory integration of inputs from visual, vestibular and somatosensory for controlled translation of the center of gravity. In addition, walking is a form of physical activity accessible to all persons regardless of socioeconomic status. Although walking can offset the avoidance of physical activity from symptom provocation, no direct evidence has been found to support the effect of walking on postural and dynamic stability, function, and participation in people with dizziness.[25]

To evaluate the effectiveness of vestibular rehabilitation, various outcome measures have been utilized in the literature. Guided by the International Classification of Functioning, Disability and Health (ICF) as the biopsychosocial model, The Academy for Neurologic Physical Therapy created The Vestibular Evidence Database to Guide Effectiveness (VEDGE) task force that evaluated the domains targeted in vestibular rehabilitation namely: body structures and functions (postural stability, dynamic stability, gaze stability, VOR function), activity and participation restrictions and symptom severity. Among the outcome measures recommended by the task force are the Dynamic Gait Index (DGI), Timed Up and Go (TUG) tests, and Modified Clinical Test of Sensory Integration of Balance (mCTSIB) for postural or dynamic stability, and the Dizziness Handicap Inventory (DHI) for activity or participation for the general vestibular population.[26]

The TUG test assesses balance, walking ability, and fall risk in older adults. The cut-off scores indicating risk for falls have been established for community-dwelling older adults (13.5 seconds),[27] frail elderly (32.6 seconds)[28] and vestibular disorder (11.1 seconds).[29] It was found to have adequate to good psychometric properties and clinical utilities for acute, chronic, central and peripheral vestibular disorder.[26] Two cross-sectional studies tested the reliability of TUG in older adults with dizziness. The first was by Marchetti and colleagues who found moderately strong significant correlation between TUG and Activities-Specific Balance Confidence (ABC) scale.[30] Another study found significant negative correlation between TUG and the Mini Mental State Examination in elderly patients with chronic peripheral vestibular disease.[31] No studies to date tested the test-retest reliability of the TUG in older adults with dizziness.

The DHI is a 25-item self-assessment questionnaire to evaluate perceived disability from the dizziness.[32] This outcome measure is at the level of participation on the ICF. The VEDGE document reports that the DHI has a good to excellent psychometric properties and clinical utilities.[26] It has an adequate correlation with the DGI, a tool that assesses balance while walking in the presence of external demands,[33] and TUG test in subjects with multiple sclerosis.[34] The DHI is also found to have excellent correlation with Sensory Organization Test (SOT) composite score in individuals with vestibular neuritis.[35] The SOT equipment is used to objectively measure postural control but clinically, it is costly,[36] time- and space-consuming. An alternative test that was developed for postural control is the mCTSIB,[36] which is more practical than the SOT. In a study conducted by Whitney and Wrisley on mCTSIB, an abnormal mCTSIB has shown scores indicating greater amount of impairment in the DHI.[37] The predictive validity of TUG, DGI, and mCTSIB on disability as shown by DHI has not been established in older adults with dizziness.

Study Objectives

There are four purposes to this study. The primary purpose of this study is to evaluate the impact of walking as an exercise component of VR on both primary and secondary vestibular-specific outcome measures. The primary outcomes are mCTSIB, TUG test, DGI, and DHI, while the secondary outcomes are the total number of visits and length of interventions (in weeks). The second purpose is to evaluate whether pedometers increase the adherence of older adults with vestibular issues to a walking program. This will be measured by change in physical activity, as represented by International Physical Activity Questionnaire (IPAQ) Walking Metabolic Equivalent of Task (MET)-minutes/week and IPAQ Total Physical Activity MET-minutes/week scores from the IPAQ short form during the episode of care (admission and discharge) and on four-weeks follow-up compared to those patients who only received instructions to walk without a pedometer. The third purpose of this study is to establish test-retest reliability of the TUG test on older adults with dizziness. Lastly, the fourth purpose of this study to investigate if the TUG, DGI, and mCTSIB are significant and strong predictors of the DHI in older adults with dizziness. Protocol #1365169 "Predictors of Disability in the Older Adults" is being performed to supplement the number of subjects for the fourth objective of this study.

Study Design

Research Design

1. Experimental Design. To answer the first and second study objectives, a pragmatic, randomized, prospective, clinical study on 54 older adults with dizziness will be utilized. This will be conducted at Florida Hospital Sports Medicine and Rehabilitation locations that offer vestibular therapy. These are in East Orlando and Winter Park.

2. Correlation Design. A correlation analysis will be performed on the data collected on 54 subjects in the experimental design to establish the test-retest reliability of the Timed Up and Go.

3. Cross-sectional Descriptive Design. A regression analysis will be performed on three predictors of the Dizziness Handicap Inventory, obtained from the data collected on 54 subjects in the experimental design and from Florida Hospital Sports Medicine and Rehabilitation Physical Therapy medical charts from June 2015 to June 2018 that met the inclusion and exclusion criteria that were outlined in the Protocol #1365169.

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Study Agent, Device, and/or Intervention Description

54 participants will receive vestibular rehabilitation as prescribed by the treating therapists. Vestibular Rehabilitation is composed of four different exercise components: gaze stability, habituation, balance training and general conditioning.[25] Two of the intervention groups will receive vestibular rehabilitation plus walking with and without pedometer while the third intervention group will be vestibular rehabilitation only.

Study Site(s)/Location(s) and Number of Subjects

Subjects will be recruited through consecutive admissions at participating Florida Hospital outpatient departments until the target total number of subjects who met the inclusion and exclusion criteria is achieved (n=54).

Florida Hospital site locations:

The research will be conducted at Florida Hospital Sports Medicine and Rehabilitation locations that offer vestibular therapy. These are in East Orlando and Winter Park. Estimated number of subjects in each location is 27 subjects who met the inclusion and exclusion criteria.

Name of external site(s) outside of Florida Hospital:

N/A

Total number of all sites:

Estimated number of subjects at all sites combined is 54.

Multi-Site Research Logistics/Communication Plan

To streamline communication among sites, the PI will communicate online or in person to all sites' research staff the following information once they are available and during the monthly meetings: most current version of the protocol and consent form, reportable new information, amendments, and study progress. All modifications must be communicated to sites, and approved before the modification is implemented. Electronic and paper research data will be submitted to the study coordinator. The study coordinator will keep all research data in a locked filing cabinet in Florida Hospital and all electronic data in a password protected Florida Hospital computer. The study coordinator will ensure that the study is conducted by the research staff appropriately and will report non-compliance with the study protocol or applicable requirements in accordance with local policy to the PI and IRB. Problem, interim results, and closure of the study will be communicated to the study coordinator and PI.

Research Conducted in a Foreign Country

N/A

Community-Based Participatory Research
N/A

Subject Selection

Vulnerable Populations (if applicable)
N/A

Inclusion Criteria

1. Age 65 years or older referred for physical therapy evaluation for symptoms of dizziness, postural instability, or both
2. Able to walk without the physical help of another person, with or with no assistive device
3. Able to follow commands and execute the examination and intervention instructions in the English language
4. Willing to participate in a phone interview four weeks after discharge
5. Able to provide informed consent

Exclusion Criteria

1. Unstable medical issues, such as unstable or uncontrolled cardiovascular conditions, elevated blood pressure (Systolic greater than or equal to 140mmHg and diastolic greater than or equal to 90mmHg), orthostatic hypotension (a fall in systolic blood pressure of at least 20mmHg or diastolic blood pressure of at least 10mmHg when a person stands from a sitting or lying down position), uncontrolled metabolic disease, as determined by the evaluating physical therapist, documented in the Functional Comorbidity Index, vital signs and assessment portion of the initial evaluation.
2. History of falls from syncopal origin
3. Dizziness of central origin, such as stroke, head injuries, MS or PD;
4. Active BPPV (patients with positive dix hallpike and/or roll test)
5. Inability to walk without physical assistance.

Resources Available

Each site will have research staff (treating physical therapists). Prior to enrollment of subjects, training of the study coordinator and research staff will be conducted onsite or online by the principal investigator. This training will cover the following: multi-site communication, subject recruitment, informed consent, inclusion and exclusion criteria and data collection. Research staff will receive instructions on randomization, interventions, outcome measures, and the use of Fitbit Zip pedometer. To establish interrater reliability, participating therapists will rate the DGI, mCTSIB and TUG by watching a video of a volunteer patient, and the DHI and IPAQ short form sample

questionnaires. To ensure compliance with the outcome measure equipment, research staff will sign a Research Equipment Compliance Document. The principal investigator will conduct inspection of equipment in each site, co-sign the document and keep the paper record in a locked filing cabinet in Florida Hospital.

Principal Investigator: The PI will prepare, coordinate, conduct training onsite or online on each clinical site for protocol setting, and facilitate monthly meetings. The PI is one of the treating therapists. The PI will keep all electronic and paper based research data for seven years after data collection is completed.

Study coordinator: The study coordinator will keep all electronic and paper based research data until data collection is completed, and will conduct follow-up phone calls after four weeks of discharge to obtain the IPAQ scores. The study coordinator will perform review preparatory to research and will be mailing letter of invitation and informed consent form to potential participants prior to initial evaluation. Once a signed consent form is obtained, the study coordinator will conduct a retrospective chart review on the subject's initial evaluation and first follow-up visit if applicable, complete the Inclusion/Exclusion form, and determine the eligibility of the subject to participate in the study. The Study Coordinator is expected to attend the monthly meeting.

Research Staff: Treating physical therapists are expected to undergo training during the protocol setting and to attend the monthly meeting. They are responsible in recruiting participants, obtaining informed consent, conducting follow-up phone call prior to next visit, collecting the outcome scores for DGI, TUG, DHI, mCTSIB, IPAQ-short form questionnaire, and implementing the interventions.

Research Assistant. The Research Assistant can conduct a follow-up phone call to a potential participant to give opportunity for questions. This responsibility will be given to the research assistant upon completion of an informed consent training conducted by the principal investigator and passing a compentency test on the informed consent.

Data Analysts: Electronic research data of the outcome measures will be forwarded to the data analysts from Adventist University for statistical analysis.

Equipment: The pedometers will be donated to the 54 participants who met the inclusion and exclusion criteria and randomized into one of the treatment groups, as a reward for participating in the research study and for them to perpetuate their physical activity.

Office and Filing Supplies: Under this category are office supplies for advertisement, recruitment, informed consent and outcome measure forms, training manuals, filing of research data.

Shipping and Mailing Fees: These cover mailing of letter of invitations, result of the study and shipping of pedometers to participants who did not belong to the VRPW group.

Study Procedures

Subject Recruitment and Screening

The advertisement will contain brief information about the research project, inclusion criteria and contact information of the study coordinator and principal investigator for inquiries. Advertisement on the study will be in the form of the following: electronic flyers, print out flyers, news article and emails. The electronic flyer and news article will be disseminated as email attachment and links respectively, sent to referring physicians and senior groups in the community and postings in social media such as Florida Hospital Facebook page. The news article will be submitted to the Florida Hospital Sports Medicine and Rehabilitation newsletter.

The print out flyers will be posted at the reception area of participating clinics, doctor offices and senior group locations. The study coordinator will perform review preparatory to research for Florida Hospital sites. He will be mailing letter of invitation and informed consent form to potential participants prior to initial evaluation. The study coordinator or treating physical therapist will be giving letter of invitation and informed consent form to potential participants before or after the initial evaluation.

Consent Process

Informed Consent of subjects will be obtained in writing following HRP-802 INVESTIGATOR GUIDANCE: Informed Consent. This will be documented following the INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803).

Documentation of Informed Consent Process

Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent. The research staff will complete the Documentation of Informed Consent Form (HRP-803) that contains the consent progress, date consent was obtained and that consent was obtained prior to initiating any research procedures. The research staff will explain the consent form to interested patients. A follow-up phone will be conducted by the principal investigator, research assistant or research staff to the potential participant prior to the beginning of the tenth visit. If the patient expressed willingness to take part in the research, the research staff will obtain a signature of subject during patient's visit/a face-to-face encounter with the patient. The study coordinator will perform a retrospective chart review on the subject's medical chart once a signed informed consent form is obtained.

Randomization

For the experimental design, block randomization will be performed to ensure

equal number of participants in each treatment group. The study coordinators will have a prerandomized masterlist of subjects generated using an online randomization program (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The signed informed consent must be returned prior to tenth visit. Once the study coordinator confirmed that the subject is eligible to participate in the study by completing the Inclusion/Exclusion Form based on the retrospective chart review of the patient's medical record, he will assign the subject with an ID number and randomize the subject into one of the three groups as determined by the prerandomized master list: first intervention group (n=18, VR plus walking with pedometer, VRWP), second intervention group (n=18, VR plus walking instruction only, VRW) and control group (n=18, usual care, VR). The study coordinator will keep paper and electronic records that contain the list of research numbers with names of all the subjects, date of birth and medical record number.

The VRWP group will have VR with an instruction to increase their number of steps daily to at least 3,000 steps using the pedometer (VR plus walking plus pedometer group). They will receive pedometers (Fitbit Zip), instructions on how to use the pedometer, step log forms, with home instruction handout to walk more at least more than ten minutes at a time. This group will be instructed to wear a pedometer on or below the waist such as belt, waistband, or in trousers' pocket, during waking hours, all day, except for bathing or swimming. A clip designed to keep the Fitbit Zip clipped to the clothing will be provided. There is no charging time. Fitbit Zip uses a replaceable watch battery that can last up to 6 months. The participants will record on their activity log the number of steps shown on the step display at the end of the day. The Fitbit Zip will be device inclusive. Subjects will not be given instruction to program their information or synchronize their Fitbit Zip with an application software on a smart phone, tablet, or any computer device. The daily step log form will be given to the research staff every visit for recording. The research staff will encourage their participants to increase their daily steps at least 10% until they achieve at least 3,000 steps daily. The older adults in the group will be trained on how to use the pedometers before they take them home, and will have the opportunity to review this instruction with the research staff on consecutive visits if needed. There may be cost associated with the study in case of lost or malfunction from using the pedometer due to the subject will be encouraged but not required to replace the pedometer. The subject will continue to be the VRWP group and this situation will be reported in the discussion of results.

The VRW group will receive VR and a time-based instruction to walk more daily at least 10 minutes at a time (VR plus walking no pedometer group). This group will be instructed on the benefits of walking (similar to the first group) but will not be given the pedometer. They will have home instruction handouts to walk more at least more than ten minutes at a time and a walking log sheet. The research staff will instruct their participants to increase their daily time at least 10% until they achieve at least 30 minutes of walking exercise daily. The walking log sheet form will be given to the research staff by the participant every visit for recording.

The VR (control) group will follow the conventional VR physical therapy without the encouragement of walking and without specification of walking in the home exercise program.

The use of an assistive device can be recommended for any subject in any group by the research staff to maximize safety. The patient may need to purchase the assistive device.

Participants who do not belong to the intervention group with pedometer will receive a pedometer after they completed the study. They will receive instructions on how to use the pedometer prior or on the day of their last visit.

Study Visits

For the experimental design that will be conducted at Florida Hospital locations, the following data will be collected as standard of care by the physical therapist during initial evaluation, and if more time is needed, during the first follow-up physical therapy appointment: mCTSIB, TUG, DGI, DHI, age, gender, body mass index, home situation, Functional Comorbidity Index (FCI) total, ability to drive, medications and insurance type. After the subject signs the informed consent, the study coordinator will be notified by the research staff to conduct a retrospective chart review on the physical therapy initial evaluation and first follow-up visit, if applicable, of the subject. The study coordinator will extract the following baseline measurements from the subject's medical record: DGI, mCTSIB, DHI, TUG and socio-demographic data that include age, gender, body mass index, home situation (lives alone or with social support), Functional Comorbidity Index (FCI) total, ability to drive (able or unable), medications for vertigo and insurance type (Medicare/Non-medicare). Based on the retrospective chart review, the study coordinator will determine if the subject is eligible to participate in the study.

Visit 1: Once the study coordinator determined that the subject is eligible to participate in the study, the subject will be assigned a research number and will be randomized into one of the three intervention groups. The research staff can initiate or continue the VR program. For the test-retest reliability of the TUG test, there will be one practice trial followed by two final performances that will be included in the data analysis. The subject will also be asked to complete the IPAQ-short form questionnaire. The test-retest reliability of TUG and the IPAQ-short form questionnaire are for research purposes only.

Visit 2: The research staff can initiate the research intervention according to the intervention group.

Visit 3 to visit prior to discharge: The research staff can continue the VR and intervention according to the intervention group.

Discharge or last visit: All outcome measures (DGI, TUG, mCTSIB, DHI and IPAQ) will be reassessed. Discharge scores for DGI, TUG, mCTSIB and DHI are standard of care, while IPAQ is for research purposes only. The total number of visits and length of

interventions (in weeks) for every participant will be recorded as secondary outcome measures. These research data will be forwarded to the study coordinator, and will be stored in a locked cabinet and password protected Florida Hospital computer.

Four-weeks after discharge: The study coordinator will conduct a follow up phone call to all subjects four weeks after discharge summary is completed to obtain the level of physical activity using the IPAQ short form questionnaire. This is for research purposes only. A follow-up on a subject will be discontinued if a subject is not reached after three attempts of follow-up phone call made on three different days between 30 and 45 days. Data analysis will commence once all the data from 54 subjects are collected.

Table 1. Summary of Interventions for VRWP, VRW and VR Groups.

VRWP (n=18)	**VRW (n=18)**	**VR (n=18)**
• Visit 1: Test-retest of TUG. Subject will complete the IPAQ-short form. Randomization. Initiate or continue with VR. • Visit 2: initiate HEP on walking with pedometer. Patients will be given a pedometer and instruction on how to use it. Participants will be encouraged to increase their daily steps at least 10% until they achieve at least 3,000 steps daily. • Visit 3 to visit prior to discharge: Continue with VR. Continue with instruction on how to use the Fitbit Zip pedometer as needed. Treating therapist will monitor and keep a record of the	• Visit 1: Test-retest of TUG. Subject will complete the IPAQ-short form. Randomization. Initiate or continue with VR. • Visit 2: Initiate HEP on time-based walking. Patients will be instructed to walk at least 10 minutes at a time. Participants will be encouraged to increase their daily steps at least 10% until they achieve at least 30 minutes of walking exercise daily. • Visit 3 to visit prior to discharge: Continue with VR. Treating therapist will monitor and keep a record of the patient's daily step log form every visit. • Discharge day: mCTSIB, DGI,	• Visit 1: Test-retest of TUG. Subject will complete the IPAQ-short form. Randomization. Initiate or Continue with VR. • Visit 2 to Visit prior to discharge: Continue with VR, without the encouragement of walking and without specification of walking in the home exercise program. • Discharge day: mCTSIB, DGI, DHI, TUG and IPAQ short form, total number of visits and length of intervention (in weeks). • Four-week follow-up: phone call for IPAQ short form • Pedometers will be mailed to participants as a reward for

patient's daily step log form every visit. • Discharge day: mCTSIB, DGI, DHI, TUG and IPAQ short form, total number of visits and length of intervention (in weeks) • Four-week follow-up: phone call for IPAQ short form	DHI, TUG and IPAQ short form, total number of visits and length of intervention (in weeks). • Four-week follow-up: phone call for IPAQ short form • Pedometers will be mailed to participants as a reward for participation.	participation.

Study Duration

TIMELINE

Month Task	2017 Dec	2018 Jan	Feb	Mar	Apr	May	June
IRB Submission	**X**						
Protocol Set	**X**						
Completion of Training Requirements by Research Personnel	**X**						
Subject Enrollment		**X**	**X**	**X**	**X**	**X**	**X**
Data Collection		**X**	**X**	**X**	**X**	**X**	**X**
Data Analysis							
Interpretation							
Dissemination							

Month Task	2018 July	Aug	Sept	Oct	Nov	Dec	2019 Jan
IRB							

Submission							
Protocol Set							
Completion of Training Requirements by Research Personnel							
Subject Enrollment	**X**	**X**					
Data Collection	**X**	**X**					
Data Analysis			**X**	**X**			
Interpretation			**X**	**X**			
Dissemination					**X**	**X**	**X**

Materials of Human Origin: Collection, Preparation, Handling and Shipping
N/A

Study Outcome Measures (Endpoints)

The DHI is a 25-item self-report questionnaire that quantifies the functional, emotional and physical impact of dizziness. Answers are graded 0 for no, 2 for sometimes and 4 for yes, with a maximum total score of 100. Interpretations are mild dizziness for scores between 0-30, moderate for 31-60 and severe for 61-100.[32] DHI has been found to have excellent negative correlation (r=-0.64) with the Activity Specific Balance Confidence Scale (ABC) in the elderly.[39] For the population with vestibular dysfunction, it has excellent correlation with ABC (r=-0.64) [39] and SF-36 (r=0.53-0.72),[40] and moderate statistically significant negative correlation with Sensory Organization Test conditions 2 (r=-0.39), 4 (r=-0.36), 5 (r=-0.42) and 6 (r=-0.35).[41] The Minimal Detectable Change (MDC) for peripheral and central vestibular pathology is 17.18 points and the Minimally Clinically Important Difference (MCID) for vestibular dysfunction is at least 18 points between the pretreatment and post-treatment scores.[32] The MDC and MCID scores for older adults with dizziness are not established.

The TUG is a test of balance and risk for falls.[27] This test measures the time it takes to walk 3 meters starting from a sitting position and it ends when the patient is seated again. Among the population studied for the TUG are the frail elderly and vestibular disorders.[42] The cut-off scores that indicate risk for falls are greater than 13.5 seconds for community dwelling older adults [27] and greater than 11.1 seconds for vestibular disorders.[29] It has an excellent inter-rater reliability for elderly adults.[43] Podsiadlo and Richardson found that in the elderly adults, the TUG has excellent correlation with Berg Balance (r=-0.81), gait speed (r=-0.61), and Barthel Index of ADL (r=-0.78).[42] It has 80% sensitivity and 56% specificity in falls prediction for vestibulopathic elderly.[29] MDCs have been established for Alzheimer's Disease (4.09 seconds) [44] and

Parkinson's Disease (3.5 to 11 seconds).[45-47] There is no established MDC for older adults with dizziness.

The DGI assesses the ability to maintain balance while walking in the presence of external demands. It is scored based on a 4-point ordinal scale (3=no gait dysfunction, 2=minimal impairment, 1=moderate impairment and 0=severe impairment) with the highest possible score of 24.[33] A cut-off score of less than 19 is indicative of increased fall risks in community-dwelling elderlies.[48] It has an excellent intrarater (ICC=0.89) and interrater (ICC=0.82) reliability for community dwelling older adults with baseline impairment [49] and adequate inter-rater reliability (k=0.64) for the vestibular population.[33] It has excellent correlation with Balance Self-Perceptions test (r=0.76) and Berg Balance Test (r=0.67) and adequate correlation with assistive devices history (r=-0.44) and history of imbalance (r=-0.46) in community dwelling older adults;[48] and excellent concurrent validity with the Berg Balance Scale (r=0.71) in the vestibular population.[50]

The mCTSIB quantifies the ability of the patient to use information from somatosensory, visual and vestibular system effectively for postural stability. This test eliminated conditions 3 and 6 of the original CTSIB, which use an altered visual input (visual conflict dome). It is performed with the feet together, a modification from the original test, which is with feet apart.[51] The four conditions of mCTSIB are standing on firm surface eyes open, standing on firm surface eyes closed, standing on compliant surface eyes open, and standing on compliant surface eyes closed. The patient is timed for 30 seconds and the average score of three trials is obtained. It only requires a timer and balance foam to administer the test. It has been found to have good agreement (kappa values 0.53-0.81) between two testers and is considered as a less costly alternative to computerized analysis of balance.[36] There is no established MDC and MCID on mCTSIB for older adults with dizziness.

The IPAQ short form is an instrument evaluation tool of physical activity among the adults. It has three categories: low, moderate and high. The specific type of activities assessed are walking, moderate intensity activities and vigorous intensity activities. All continuous scores are expressed in MET-minutes/week with walking =3.3 METs, Moderate PA=4.0 METs and Vigorous PA = 8.0 METs. An overall total physical activity score can be computed as the sum of the total MET-minutes/week scores.[23] This outcome measure will be used to compare the pre- and post-intervention physical activity level of the participants. The total time walked per week item of the IPAQ short form has a test-retest reliability of 0.72 using Spearman Correlation. [52]

Data Management and Quality Plan

Data De-identification

Each subject will be assigned a research number for data de-identification. The research number is based on the randomization list generated by the online randomization program (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The list of names with corresponding research numbers will be kept in a locked cabinet in Florida Hospital and password protected Florida Hospital computer by the study coordinator

Data Confidentiality, Storage, and Retention

The Research Staff will keep the paper records of the following: Informed Consent, Documentation of Informed Consent Form, Visits Chart, Completed Research Subject Profile and Data Collection Flowsheet Form on each subject who met the inclusion/exclusion criteria and were randomized into one of the treatment groups in a locked filing cabinet in Florida Hospital. The study coordinator will keep all paper records of Review Preparatory for Research Masterlist, Inclusion/Exclusion Form, Research Subject Database and Florida Hospital Study Coordinator Data Collection Flowsheet in a locked filing cabinet in Florida Hospital and store the electronic records of Review Preparatory for Research Masterlist and Research Subject Database in a password protected Florida Hospital computer until data collection is completed. Once data collection in a research site is complete, the study coordinator will collect all paper forms personally from the Research Staff. The study coordinator will forward all paper and electronic records to the principal investigator, and delete all electronic records from his secured computer. The principal investigator will complete the following electronic excel templates for data analysis: Clinical and Sociodemographic Characteristics at baseline_FL Hospital; Clinical and Sociodemographic Characteristics at baseline_Outside Fl Hospital; Timed Up and Go Test-Retest; IPAQ Admission, Discharge and 4-weeks; TUG, DGI, mCTSIB and DHI on Admission and Discharge; and Total Number of Visits, Length of Intervention, Step Log and Step Goal. The principal investigators will forward completed excel templates to the data analysts for statistical analysis by email. The principal investigator will keep all electronic regards in a secured Florida Hospital computer and all paper records in a locked filing cabinet in Florida Hospital for seven years after the research study has been closed. After that period of time, all paper records will be shredded and electronic records will be deleted in the computer.

Data Quality

N/A

Data Sharing (outside of Florida Hospital)

The principal investigator may share the research data with accreditation organizations and regulatory agencies, dissertation committee, and publications, medical meetings, or scientific journals for the purposes of completing the research study, and analyzing and evaluating the results. Individual patients (subjects) will not be identified during data sharing, and a research number will be used instead during the data sharing process, unless necessary to carry out the research study or required by law.

Sample Size Determination

A priori power analysis predicting a large effect size (F=.25) determined that a total of 54 subjects (18 in each group), who met the inclusion and exclusion criteria will be needed, with alpha at the conventional value of .05 to achieve a .80 power, that includes an assumption of a dropout rate of 10% .

Statistical Analysis Plan

The results will be presented through the following tables with supporting explanations:

- Clinical and sociodemographic characteristics of participants by group at baseline.
- Comparisons of TUG, DGI, mCTSIB and DHI between the three intervention groups on admission and discharge.
- Comparisons of self-reported walking activity (walking MET-min/week) and total self-reported energy expenditure (total physical activity MET-min/week) as determined from the IPAQ short form on admission, discharge and four-week follow-up between the three intervention groups
- Comparisons of averages of compliance to step log recording and compliance rate for meeting step goal between the VRWP and VRW groups. Compliance is defined as low (<33%), moderate (33%-75%) and high (>75%) based on the step log or walking log. This grading of compliance was used by Hall and colleagues in their research on efficacy of gaze stability exercises in older adults with dizziness.[53]
- Comparisons of total number of visits and length of interventions in weeks between the three intervention group.
- Intraclass Correlation Coefficients for the Timed Up and Go test-retest reliability
- Result of stepwise linear regression analysis for TUG, DGI, mCTSIB and DHI

All interval and ratio data will be tested for normality prior to undertaking the data analysis. Descriptive statistics will be used to describe the characteristics of the sample and compare the three groups at baseline. This will include Analysis of Variance (ANOVA) for parametric and Chi Square for nonparametric sociodemographic and clinical data.

Analyses will employ five repeated measures Analysis of Covariance (ANCOVA), adjusting for age, with two independent variables (group and time) and five outcome measures (TUG, DGI, DHI, mCTSIB and IPAQ short form). The adjustment of age is based on age-related decline. Intraclass Correlation Coefficient will be calculated to establish the test-retest reliability of the TUG and a stepwise linear regression with age as covariant will be conducted for all 54 subjects at baseline to determine if TUG, mCTSIB and DGI are predictors of DHI. Two-tailed test will be utilized to compare the compliance with step log recording and meeting step goals between the two walking groups (VRWP and VRW), and ANOVA to compare of total number of visits and total length of intervention in weeks between the three groups. Alpha for all analyses will be set at 0.05 to test for significant difference.

Potential Risks and Benefits

Potential Benefits

Possible benefits include improved physical function.

Potential Risks

The addition of a prescribed walking program in the treatment of dizziness will challenge the subject's balance, and in rare cases may result in falls or more dizziness.

Performance-based outcomes such as mCTSIB, DGI, and TUG check for the subject's reaction whenever in a condition of unsteadiness. The risks associated with these tests are the potential for falls and for dizziness. Self-report questionnaires such as the DHI and IPAQ will need the subject to read the questions and recall past experiences. Looking down and reading the questions may provoke dizziness and eye strain. Other possible risks for subjects are: 1) finding the questions to be sensitive 2) emotional discomfort (uncomfortable/embarrassed/sad/tired) and 3) distress as subject thinks of experiences.

Mitigation of Risks

The research staff (treating physical therapist) will supervise the treatment at all times to minimize any such risks.

Provisions to Protect the Privacy Interest of Subjects

Subjects will be assigned research numbers for study-related records and data sharing. The patient's confidentiality will be protected by observing the HIPAA policies and procedures.

Early Withdrawal of Subjects

Investigator Withdrawal of Subjects

The PI may terminate the participation of the subject in the study if the subject may be in any danger or no longer meets the inclusion criteria of the study.

Subject Request for Withdrawal from Study

Subjects may withdraw or take away the permission to use and disclose their health information for any reasons at any time. This can be done by sending a written notice to the PI. Information that has already been gathered may still be used or given to others, however no new health information that might identify the subject will be gathered after the subject withdraw from the study.

Data Collection and Follow-up for Withdrawn Subjects

Patients who request withdrawal or who are withdrawn by the PI from the study will have their information that has already been gathered and shared in the research database. These data will be included in the data analysis. The percentage of patients withdrawing will be calculated.

Adverse Event Reporting

At each therapy visit of the subject, the research staff/treating therapist will seek information if there is any adverse event caused by taking part in the study. In the event of a research-related injury, the subject should report this in person or by phone to the research staff/treating therapist and PI. All adverse events will be reported to Florida Hospital's IRB and Nova Southeastern University's IRB following their respective policies for reporting adverse events.

Safety Monitoring Plan

Safety Monitoring
N/A

Data and Safety Monitoring Board (DSMB) or Equivalent
N/A

Ethical Considerations

Subjects in the VRW and VR group will receive a pedometer after they completed the study.

Sharing of Results with Subjects

Results of the study that are part of standard physical therapy will be shared with subjects and referring physicians. Letters will be sent to all participants that contain the results of the research once the research is completed.

Funding Source
Application for funding will be done through the Adventist University in January 2018. The principal investigator is currently requesting managers to allow the allocation of her Continuing Education budget for 2018 for this study.

Subject Stipends or Payments

The pedometer will be donated to the 54 participants, who met the inclusion and exclusion criteria and randomized into one of the three treatment groups, as a reward for participating in the research study and for them to perpetuate their physical activity.

Publication Plan

It is anticipated that four research papers (one for each objective) can be published from the research study. The PI will the primary author. The dissertation committee composed of Dr. Mary Blackinton, Dr. Joann Gallichio and Dr. Ann Galgon, and Dr. Leana Araujo of Adventist University will be the co-authors. Non-author contributors will be acknowledged and their specific contributions will be specified. The PI will apply for poster presentations in the local state and national conferences. Internal dissemination will be done through presentations within Florida Hospital.

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Data Analysis

All statistical analyses were performed using SPSS version 26. Mean and standard deviation were used to describe interval and ratio data, and frequencies for nominal data. Statistical significance was set at alpha <0.05. Since the parameters of a normal distribution were not met, nonparametric statistical tests were chosen for statistical analysis.

Objective 1. To evaluate the impact of walking as an exercise component of VR on both primary and secondary vestibular-specific outcome measures.

Mean and standard deviations on the mean differences of pretest and posttest of TUG, DGI, DHI, and mCTSIB were calculated to compare walking (VRWP + VRW) and control groups (VR only). P-value was calculated using the Kruskal-Wallis test to check for between-group differences in the primary and secondary outcomes. For within-group differences, the Wilcoxon Signed Rank Test was used to examine significant differences between the pretest and posttest.

Objective 2. To evaluate whether pedometers increase the adherence of older adults with vestibular issues to a walking program.

To compare the VRWP, VRW and VR groups, IPAQ-Walk and IPAQ-Total scores were categorized as improve, same or decline in pretest and posttest, posttest and four-weeks follow-up, and pretest and four-weeks follow-up. P-value was calculated using the Kruskal-Wallis test to check for between-group differences of sociodemographic data, IPAQ-Walk, IPAQ-Total, compliance in meeting step goals and compliance in step log. Friedman's 2-way ANOVA by ranks test was used to examine significant differences within the group.

Objective 3. To establish test-retest reliability of the TUG test on older adults with dizziness.

Intraclass Correlation Coefficient (ICC) was calculated using the two-way mixed model, consistency type on a single measure model with a 95% CI for relative reliability. For absolute reliability, the Standard Error of Measurement (SEM), Minimal Detectable Change (MDC) 95% CI, and Bland-Altman 95% level of agreement were examined. The SEM provides the range of scores on retesting. A smaller value of SEM means the calculated score is close to the true score.[44] The MDC is used to reflect the true change in score that exceeded the errors of measurements. Both the SEM and MDC are the same units of the original measures, which allows easier interpretation of results when applied in the clinical practice.[74]

The Bland-Altman plots show the distribution of the difference scores of two measurements around zero. The 95% level of agreement means that 95% of the difference scores fall within two standard deviations above or below the mean of the difference scores. Values closer to zero means greater reproducibility between two repeated measures.

Objective 4. To investigate if the TUG, DGI, and mCTSIB are significant and strong predictors of the DHI in older adults with dizziness.

The subjects were then grouped based on the DHI test results, using the categories suggested by Whitney et al: 0-30 for mild, 31-60 for moderate, and 61-100 for severe.[104] This analysis is similar to the work of Vereeck et al[84] to obtain a better picture between the dependent variable DHI and the independent variables: mCTSIB, TUG, and DGI. Kruskal-Wallis analysis was calculated to compare group means for age, mCTSIB, TUG, and DGI. The significance values were adjusted by the Bonferroni correction for multiple tests.

Before the multiple linear regression analysis, assumptions were tested to establish the nature of the data. The obtained Durbin-Watson statistic for the analysis of the independence of

observations is 2.639. The Durbin-Watson statistic can range from 0 to 4, with a value of approximately 2 to indicate that there is no correlation between residuals. The obtained value is close to 2, therefore it can be accepted that there is the independence of observations. The assumptions of homoscedasticity, normality, and multicollinearity are upheld. There is no presence of outliers in the data.

The Spearman Rho correlation coefficients were calculated to establish the relationships between the DHI and mCTSIB, TUG and DGI. As a general guideline, the value 0.00 to .25 indicates little to no relationship, 0.25 to 0.50 suggests fair relationship, 0.50 to 0.75 denotes moderate to good relationship and above .75 is considered good to excellent relationship.[44] Then, a multiple linear regression analysis was conducted for a continuous dependent variable and three independent variables to identify the predictors of DHI.