Protocol Title: SCH: Context-aware Freezing of Gait mitigation in real-world setting

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classification. Normally, the window length is set to cover several walking steps, which leads to delay of vibration mitigation. During this delay period, the patients have an increased risk of falls.

2. How to construct the FoG detection model using unbalanced data samples? As FoG typically happens intermittently, the collected positive class samples (i.e., FoG gaits) are fewer than the collected negative class (i.e., normal gaits) samples. However, to adequately train deep learning algorithm-based FoG detection models, several hours of FoG episode data are required for each patient and each ap- plication scenario. The shortage of FoG data may cause the detection results to be biased toward the negative class.
3. How to differentiate between FoG and an abrupt stop? We need the ability to detect FoG pattern versus normal cessation of walking, thereby providing a practical solution in a real-world setting.

In the following subsections, we present our solutions to answer each of the above research questions, and how we plan to validate our process.

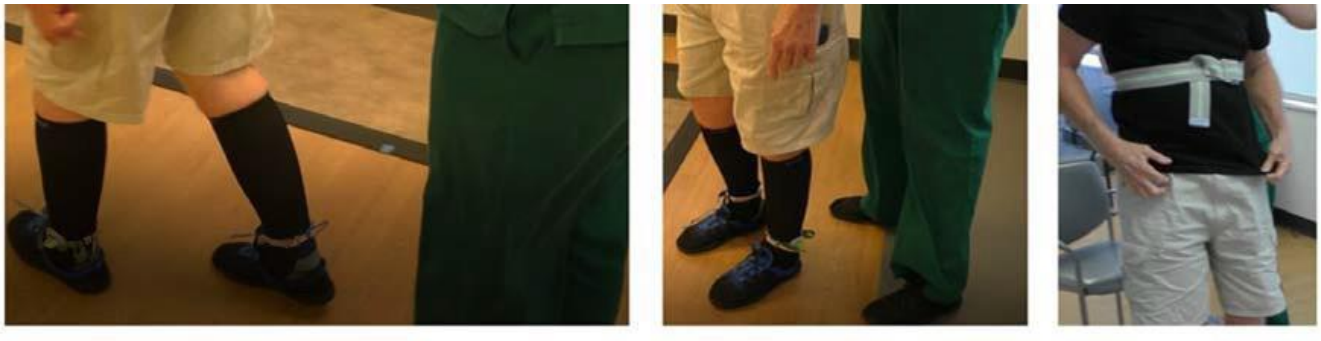
2.2.1 Convolutional Neural Network (CNN) model-based FoG detection

To minimize the time delay of vibration mitigation when FoG happens, we propose a method capable of detecting FoG in only one walking step. First, the continuous sensor data are segmented for each walking step, and the raw motion sensor data of one walking step is extracted as a sample. Then, a convolutional neural network (CNN) model is trained to identify one walking step as either FoG gait or normal gait.

During walking, when the leg sways forward, the corresponding angular velocity is relatively large. Accordingly, the gyroscope readings show an obvious peak. Alternatively, when the heel strikes the ground, the angular velocity decreases greatly, and the gyroscope readings show a valley [20]. Through localizing the leg sway and the subsequent heel strike, the continuous motion sensor data can be segmented for each walking step, and the non-walking segments can be filtered out.

The walking segments have the following characteristics: 1) the lengths may be different based on the time consumed for each step; 2) each walking segment is a multidimensional time series and consists of a series of three accelerometer axes and a series of three gyroscope axes, and 3) each walking segment represents one complete step. The sensor readings are in order and have temporal dependence. Based on the above characteristics, we propose to develop a FoG detection model using deep learning algorithm for sequential classification. Specifically, a Convolutional Neural Network (CNN), a special neural network, is used to process sensor readings sequentially and learn the local correlation and dependence between them. Instead of extracting explicit features, a CNN network takes the raw data of the walking segments as input and generates class labels as output.

We choose CNN models because they are able to capture local correlations of consecutive sensor readings, which enables them to demonstrate accurate classification results and high classification speed in literature [21] [22] [23]. For example, in our previous work of classifying 275 American Sign Language (ASL) signs, our proposed 9-layer CNN model [21] achieves 98% accuracy, which is 30% higher than the state-of-the-art K Nearest Neighbor (KNN) model [24] [25]. Also, the fast 0.62 millisecond classification time of our CNN model also enables the ASL recognition to be real-time.



(a) A PD patient walks in a clinical environment with a UG device on each foot (b) The PD patient turns around (c) A safety belt on the patient

Figure 4: Our pilot study with a PD patient walking in our clinical environment. The patient wore a UG device on each foot. A nurse is behind the patient to ensure the patient's safety. The patient is wearing a safety belt that was attached to the upper body.

Accordingly, the CNN model detects FoG for each walking step separately and independently. To increase the accuracy and robustness of the detection model, we propose to fuse the probabilistic CNN outputs of several recent walking steps. We plan to redesign the classification output layer of the CNN network so that it outputs a

probability vector rather than a single class label. The probability vector indicates the likelihood of classifying one walking segment into the corresponding two classes (i.e. normal gait or FoG gait). With the assigned weights, the probability vectors of recent walking steps are fused together to generate the final detection result.

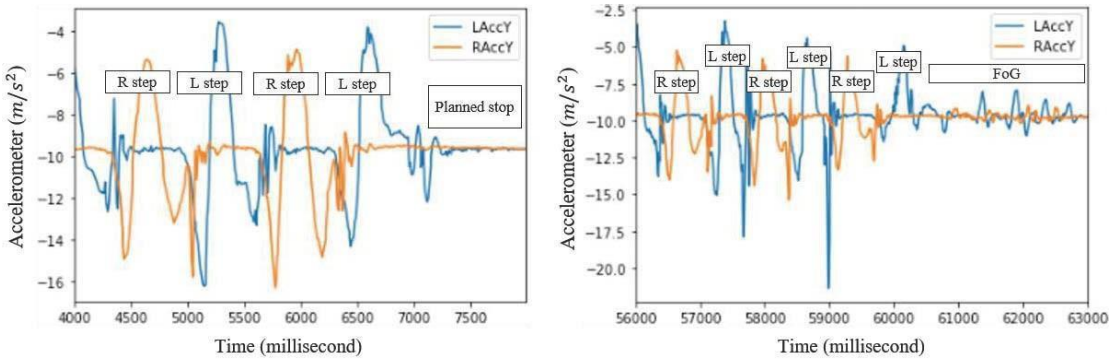
2.2.2 Rebalancing FoG detection model using data resampling and class weighting

To solve the unbalanced data problem, we propose to rebalance the classification model by combining two methods: data resampling and class weighting.

Data resampling aims to generate more FoG segments so that the sample numbers of these two classes are more balanced. These generated FoG segments originate from existing FoG segments. They are different from the existing ones but have similar patterns. We first cluster all existing FoG segments using a density- based spatial clustering algorithm [26]. This algorithm groups together points that are close with each other and leaves outlier points in low-density regions. The distance between any two segments is calculated by using dynamic time warping (DTW), an algorithm for measuring the similarity between two temporal sequences with different lengths [27]. After clustering, any cluster with its number of points less than a threshold NumThres is filtered out. For each remaining cluster, we calculate the average distance between any two segments, AvgDis. To generate a new FoG segment from this cluster, we randomly select one existing FoG segment. Then we add zero-mean white Gaussian noise to each sensor reading in this segment. The added noise may alleviate the overfitting problem and increase the robustness of the CNN detection model. If the DTW distance between one new generated FoG segment and any existing FoG segment is larger than an empirically determined threshold (a AvgDis) and smaller than another empirically determined threshold (b AvgDis), this generated FoG segment is accepted. Otherwise, it is dropped. The generated FoG segments are mixed with the existing ones to train the FoG detection model.

Although we are able to generate as many FoG segments as we want to, the above data resampling method may bring a new problem. The generated FoG segments are not the original FoG segments. When the generated FoG segments are much more than the original ones, the constructed FoG detection model may be contaminated by the noise introduced during data resampling. Then, the FoG detection accuracy may decrease. We will utilize the class weighting method to address this problem. If the FoG segments are not adequate even after the data resampling, we will further assign different class weights to the positive class and the negative class, respectively, in the classification output layer of the CNN model. The class weights are inversely proportional to the sample numbers of corresponding classes. That is, the more training samples one class has, the smaller its weight is and vice versa.

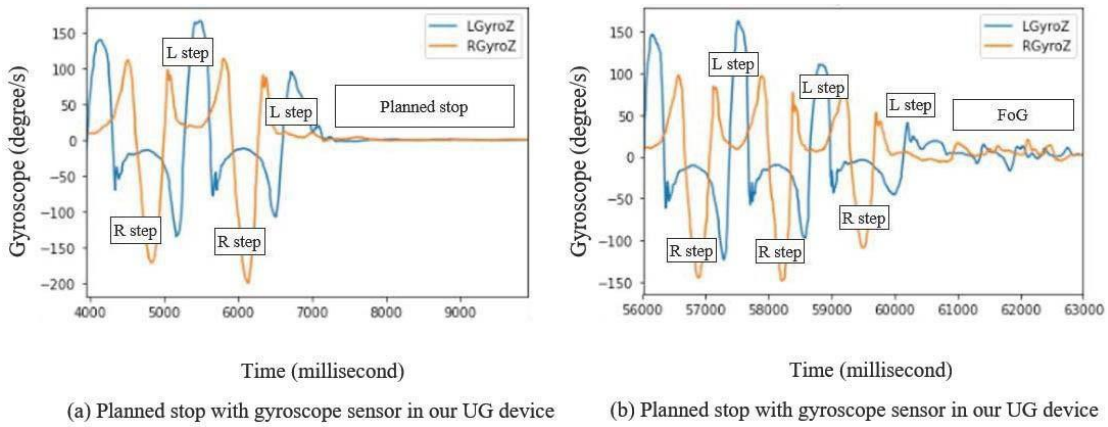
It is important to validate the accuracy of the UG device in assessing FoG parameters, beyond our Pilot study described below. Therefore, we will calculate number and duration of FoG episodes using a combination of ZenoMat walkway output (ProtoKinetics, 2019), 10-Meter-Walk-Test [28], and video confirmation while collecting data with the UG device. Using this method, we will be able to establish the reliability and validity of the UG motion sensor to detect these metrics in a person with Parkinson's disease. These parameters will become the outcome measures used to calculate the optimal vibration in Task 2. In case our proposed CNN model fails to detect FoG in one walking step, our alternative plan is to develop a smart-phone app, with which a healthcare professional can "demand" the wireless-connected PDVibe3 device to immediately deliver pre-programmed vibration dose once (s)he identifies FoG with her/his own eyes.



(a) Planned stop with accelerometer sensor in our UG device

(b) FoG with accelerometer sensor in our UG device

Figure 5: Accelerometer sensor readings with a planned stop vs. FoG



(a) Planned stop with gyroscope sensor in our UG device (b) Planned stop with gyroscope sensor in our UG device

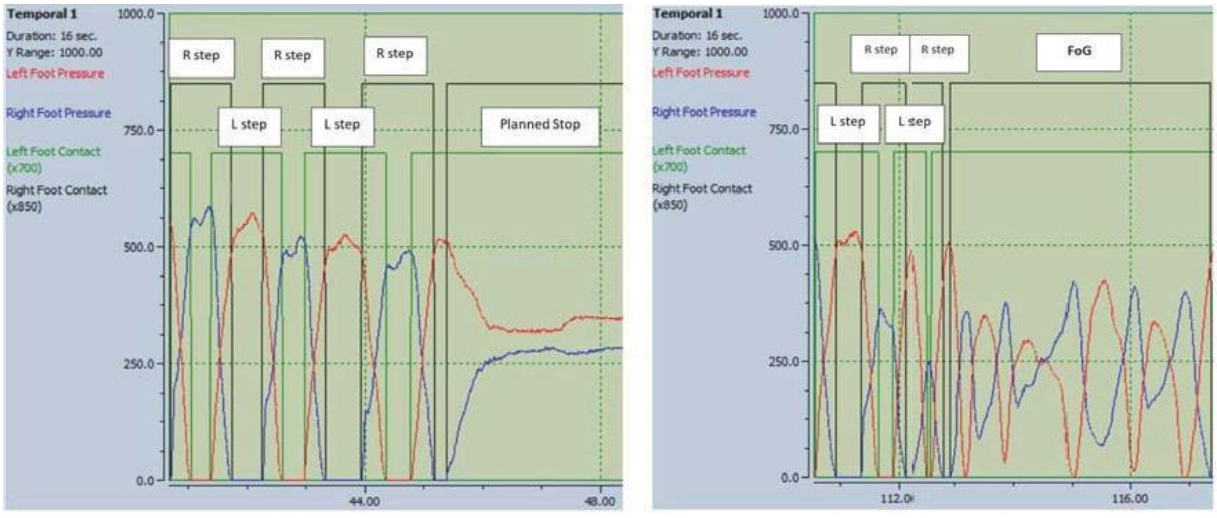
Figure 6: Gyroscope sensor readings with a planned stop vs. FoG

2.2.3 A pilot study in VCU clinic and our results

We conducted a pilot study with a PD patient wearing our UG devices. The patient wore one UG sensor on each foot and walked back and forth on a 15-meter path around the perimeter of the VCU clinic while being videotaped. As show in Figure 4, a nurse is behind the PD patient with a safety belt tied to patient's upper body, in case the patient loses balance.

Our UG devices collected the accelerometer sensor data as well as gyroscope sensor data. In Figure 5(a), we present the accelerometer sensor data related to FoG and its proceeding walk. The data we presented is representative in our finding. In Figure 5(b), we present the accelerometer sensor data related to a planned stop and its proceeding walk. We obtain the following two observations.

We are able to differentiate between FoG and normal cessation of walking. Our sensors readings in Figure 5 show a clear distinction between a planned stop and FoG. As shown in Figure 5(a), during a planned stop, the accelerometer sensors on the left foot (LAccY) and right foot (RAccY) show similar readings. Also, both readings are close to the earth gravity value 9.8. However, during FoG as shown in Figure 5(b), the sensors on both feet show non-zero readings with severe asymmetry. This is reasonable because during FoG the patient tried to move (even though failed to actually move the steps forward) each foot alternatively, generating acceleration in the Y direction (i.e. the gravity direction) of the accelerometers.



(a) A planned stop measured by ZenoMat. (b) FoG measured by ZenoMat

Figure 7: The left figure (a) illustrates a synchronous gait pattern with a PLANNED stop at the end. Data collected via ZenoMat. In the right figure (b), the ZenoMat clearly shows the asynchronous stepping pattern that occurs just prior to the FoG stop.

Such distinct asymmetry difference between the planned stop and FoG is also clearly observed in our gyroscope sensor readings. As shown in Figure 6(a), during a planned stop, both sensor readings are close to zero; however, during FoG as shown in Figure 6(b), as the patient tried to move both feet forward in an alternating way (even though failed to actually move the steps forward), the corresponding angular acceleration

towards the moving direction (the Z direction here) are captured by our gyroscope sensors.

One thing worthy to emphasize is that the local correlations, such as "largely decreasing but non-zero readings," "reading asymmetry between the left and right feet," were also well observed by a gold-standard Gait Analysis System (ZenoTM Walkway, ProtoKinetics) used in clinical research. It is a mat installed on the ground that incorporates pressure sensors. This further strengthens the fidelity of our UG device in capturing such FoG related features. Figure 7 shows pressure patterns of both feet during FoG and a planned stop.

(2) CNN model is promising for FoG detection. According to Figure 5(b) and 6(b), detecting FoG is highly feasible. This is because when FoG occurs both the accelerometer reading (in the Y direction) and gyroscope reading (in the Z direction) largely reduce. The reduction is also statistically significant, much beyond 3 standard deviations. Plus, this reduction is also different from that of a planned stop because the readings are not close to zero. Instead, the reading on the left and right feet alternately dominates, demonstrating strong asymmetry. Plus, the readings keep reducing with time until the patient finally gives up the efforts of moving steps, at which moment closer-to-zero sensor readings will be obtained.

According to [21] [22] [23], CNN is well positioned for capturing local correlation and dependency in streaming sensor data. The demonstrated "largely shrinking readings" local correlation and the "non- zero by alternatively dominating sensor readings on both feet" local correlation could be well captured by a CNN model in a timely way. Plus, before FoG, the preceding walking steps also demonstrated to be quicker and shorter as observed in Figure 5 and 7. Such "quicker steps" and "shorter steps" that lead to FoG can also be well captured by a CNN model.

Factor	Validated Scale
Cognition	Montreal Cognitive Assessment [29]
Fatigue	Parkinson's Disease Fatigue Scale [30]
Balance Confidence	Activities-specific Balance Confidence (ABC) scale [31]
Fear of Falling	Falls Efficacy Scale-International [32]
Quality of Life	Parkinson's Disease Questionnaire-8 [33]
Freezing of Gait	Freezing of Gait questionnaire [34]
Nonmotor Symptoms	MDS-UPDRS part 1 [35]
Walking Speed and Step Length	10 Meter Walk Test [28]

Table 1: Scales used in Tasks 1, 2, and 3 to capture relevant physical and neuropsychological covariates.

In summarizing the findings from Task 1, we will fully describe the five participants in terms of demographics (age, gender, race), disease descriptors (disease duration and stage, presence or absence of various motor and nonmotor disease symptoms, medications used, and timing of last dose of antiparkinsonian medication), average time they spend in a FoG episode (during data collection), and the total number of FoG episodes. Additionally, physical and neuropsychological factors that can influence or be influenced by FoG such as fatigue, cognition, balance and falls self-efficacy, as well as quality of life will be captured by validated scales (Table 1).

3 Task 2: Determination of Optimal Vibration Metrics for Different Triggers FoG

Empirical evidence suggests that PD-related FoG responds better to slower rather than to typical faster stimulation frequencies used for treating such features as bradykinesia and tremor [36]. These observations suggest that contrasting vibration parameters could similarly produce variable effects on different aspects of FoG. Current work, Drs. Pretzer-Aboff and Cloud are investigating the optimal vibration parameters to improve the functional ambulation performance score (FAP) in a sample of PD patients as they walk a straight unobstructed path on a Protokinetics ZenoMat walkway before, during and after vibration therapy (Michael J. Fox Foundation, grant number #16496). FAP is a composite gait metric that has advantages, primarily that it takes more factors into account than simply gait velocity; however, the FAP has a number of limitations, including the fact that it does not quantify gait variability [37] making it a poor outcome measure for studying FoG. Thus, the MJFF study is not designed to look at FoG specifically, nor is it challenging patients with obstacle courses intended to provoke FoG or other gait abnormalities. It is also not seeking to customize vibration therapy to the needs of the individual, but rather to determine the best "one size fits all" vibration stimulation parameters to improve overall gait metrics such as reduced speed or shuffling. The outcome of the currently funded MJFF study will be the determination of optimal vibration parameters (frequency, amplitude, and duration of stimulation)

to improve a variety of gait parameters in most PD patients using the "one size fits all" approach. In contrast, the proposed work in this NSF application is to determine the optimal vibration frequency (*ff*) and amplitude (*va*) parameters to mitigate FoG triggered by five different commonly encountered scenarios, using a closed loop system that will detect FoG. Thus, the vibration will only be used when it is needed.

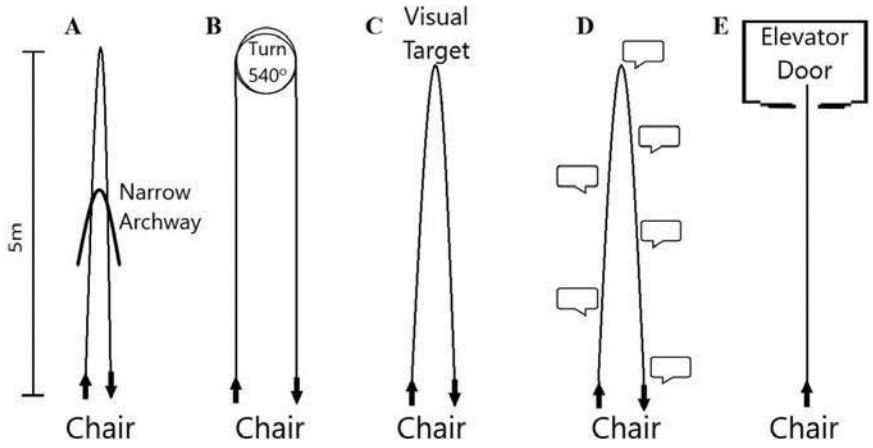


Figure 8: Triggering scenarios shall include a 5 meter walking path with one of 5 triggers inserted into the path: (A) walking through a narrow passage, (B) turning 540 degrees, (C) approaching a destination (e.g., chair), (D) walking while dual tasking (e.g., performing a verbal fluency challenge while walking), and (E) a time-sensitive task such as walking through an elevator door before it closes.

To accomplish this goal, walking courses will be developed in the VCU physical therapy gym to mimic the five most common triggers of FoG [5]. Using response surface methodology employing a central composite design [38], we will determine the best dose of vibration (frequency and amplitude) for each of five common triggers for FoG (see Figure 8) using a small sample of human participants. To determine the optimal vibration frequency (*ff*) and amplitude (*va*) parameters for preventing or mitigating FoG in each of these scenarios, 13 participants with PD who experience FoG in at least two of the scenarios, confirmed by a neurologist will be recruited. Participants who participate in Task 1 are not eligible to participate in Task 2 or 3. Participants in Task 2 will be evaluated ON their medications. Participants will be asked to walk through each of five, 5-meter walking courses that will each include one of the triggering scenarios illustrated above. Measurements will be taken once at baseline and again in triplicate as they walk the path wearing the FoG detection/vibration device.

Each of the 13 PD participants with FoG will be assigned to one of 9 different *ff* and *va* settings as prescribed by the central composite design (CCD). The CCD, described below, is an elegant and efficient experimental design used in response surface methodology to estimate an optimal response. In the current case, the goal is to estimate the *ff* and *va* settings that will maximize the difference between the baseline and post-treatment time spent in a FoG state for each of the 5 triggering scenarios individually and in total.

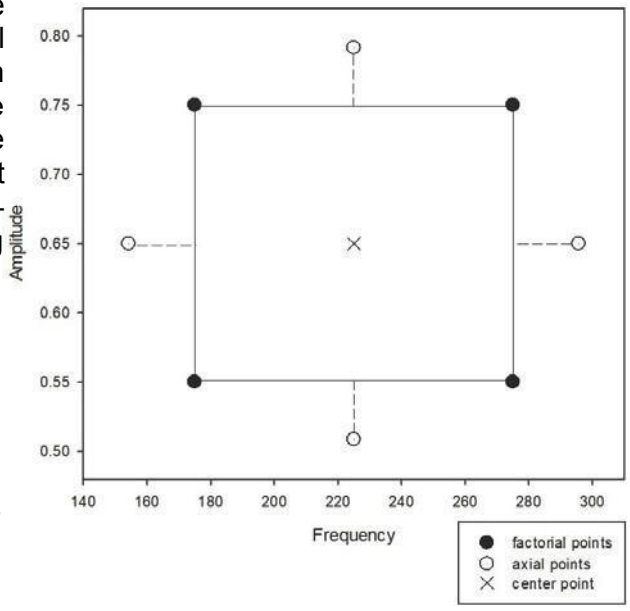


Figure 9: The Central Composite Design

The CCD is specified by first defining a 2x2 factorial with four (*ff*, *va*) design points: (175, 0.55), (175, 0.75), (275, 0.55) and (275, 0.75) denoted in the plot by the solid dots (Figure 9). The design points are based on *ff* and *va* parameter settings C2 tactors are capable of delivering (C2 tactor datasheet) used in previous vibration research conducted by Pretzer-Aboff (PI). The four factorial design points are sufficient to estimate a first-order response surface that is flat (no curvature). In order to estimate a second-order response surface (or curvature in the response surface), the 2x2 factorial is augmented with axial points and multiple center points. Assuming a frequency range of 175 to 275 from the factorial portion, the axial points are defined as (154.29, 0.65), (295.71, 0.65), (225, 0.509) and (225, 0.791) denoted by the open dots emanating from the face of the cube. These axial points are chosen such that the design is rotatable, i.e., the prediction

variance is constant on spheres around the center of the design. The number of center points (225, 0.65) denoted by "X") is chosen to be five to optimize estimate of the prediction variance and lack-of-fit. Thus, the full CCD with five center points will require 13 PD participants. To determine the optimal vibration frequency (*ff*) and amplitude (*va*) parameters for preventing or mitigating FoG, 13 participants will be randomly assigned to one of 9 different frequency (*ff*) and amplitude (*va*) settings as prescribed by the central composite design (CCD). Using response surface methodology, the response surface based on the baseline value minus the average of 3 post-vibration trials will be estimated yielding settings of frequency and vibration that will be the difference between the baseline and post-treatment time spent in a FoG state.

An overall optimum *ff* and *va* will be estimated using response surface methodology by fitting the following second order model:

$$y_i = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2i} + \beta_{11} x_{1i}^2 + \beta_{22} x^2_{2i} + \beta_{12} x_{1i} x_{2i} + \varepsilon_{ij}$$

where i = 1, 2,… ,13 denotes the participants. In this regression model, the linear effects ($\beta_1 x_{1i}$, $\beta_2 x_{2i}$) and quadratic effects ($\beta_{11} x^2_{1i}$, $\beta_{22} x^2_{2i}$) for frequency (x_1) and amplitude (x_2) and a frequency by amplitude interaction effect ($\beta_{12} x_{1i} x_{2i}$) are needed to estimate the second order response surface. This information will be used in Task 3 to program the device to deliver the optimal vibration *ff* and *va* to be tested in the real-world setting.

Vibration Dose Contingency Plan: Assuming that we determine that all scenarios have the same optimal vibration dose, then we will use the single dose for each of the five FoG triggering scenarios in Task 3. However, it is possible that we will not identify a unique optimal dose for each of the five FoG triggering scenarios. If no optimal vibration dose is identified for any of the scenarios, then we will use the highest tolerated dose in Task 2, for Task 3. If only some scenarios have an identified optimal dose and others do not, we will use the optimal doses for those scenarios it works for and use the highest tolerated dose for all other scenarios in Task 3.

In addition to reporting the estimated optimal frequency and amplitude setting for the six outcomes in Task 2, we will collect information on time spent in FoG state, number of FoG episodes, total time it takes to walk through the five courses, stride length, and speed of walking. Additionally, the sample characteristics will be reported. These characteristics include the demographics (age, gender, race), and disease descriptors (disease duration and stage, the presence or absence of various motor and nonmotor disease symptoms, medications used). Psychological factors such as fatigue, balance and falls self-efficacy, and quality of life will also be tracked using the scales in Table 1. This data will be described in tabular form.

4 Task 3: Dealing with Confounding Factors in Real-world Scenarios

To determine both the efficacy and generalizability of our wearable system in a real-world environment, we selected an outdoor setting where participants will all walk the same pre-determined path with a variety of real-world confounding variables (see Figure 10). Participants will walk through paths in an open-air setting with FoG triggers similar to those that were constructed in the lab setting. Participants will be asked to walk down a path approaching a chair; walk through a narrow doorway into a restroom, turn around 540 degrees, and come back out, and progress toward a time-sensitive electronic door and pass through before it closes. We anticipate other people walking around the space, intrusive noises, and various other unpredictable environmental challenges, thus presenting the participants with typical community distractions, and resulting in a more realistic evaluation of the device. There are two related research questions to answer prior to more rigorous real-world testing: 1) how to automatically and accurately detect the FoG triggering scenarios or contexts? and 2) how to adapt the vibration parameters based on the contexts? For the first question, we will use a hierarchical positioning method that combines Global Positioning System (GPS) and Bluetooth low energy (BLE) beacons. GPS determines the patient's coarse-grained location in the outdoor environment, and a series of BLE beacons that are capable of identifying the patient's fine-grained triggering scenarios in the outdoor environment. Both the GPS and BLE modules will be embedded in the

Figure 10: (A) Aerial view, of proposed real-world walking paths at an outdoor mall near the VCU clinic. (B) Example of walking path that includes approaching a visual target (chair). (C) Walking path that includes a narrow passageway (unisex restroom) where the participant can turn 540 degrees. (D) Walking path that includes a time sensitive trigger (getting through an automatic door before it closes).

participants' carried mobile device. For the second question, in each automatically detected scenario, the device will be programmed to deliver appropriate vibration doses when a FoG episode occurs.

We will evaluate the device's ability to both detect patient location within predefined locations at the outdoor setting (Figure 10), and to administer the correct dose of vibration (i.e., *ff* and *va*) when the patients are exposed to these trigger scenarios.

Due to the innovative nature of studying this device in a real-world environment, no pilot data exists from which to run a traditional power analysis. However, Van Belle proposed that a minimum of 12 observations should be used to calculate confidence intervals based on the t-statistic with n – 1 degrees of freedom. This rule is based on the fact that the half-width confidence interval for the mean decreases rapidly up to n = 12, at which point the decrease is less dramatic and the half-width curve begins to asymptotically decrease. Thus, in order to ensure the good estimates of the means and variances (pre- and post-) [39] fifteen volunteers who have been diagnosed with PD by a neurologist and who exhibit FoG will be asked to participate in the testing of the device.

Participants will walk the paths once with and without vibration and while ON their medications. We will compare the differences in the duration and number of FoG episodes, time walking through the path, average stride length, and speed of walking. It is anticipated that "pre" versus "post" trials for each of these five variables will be compared using a paired t-test. All participants in Task 3 will be described in terms of demographics, disease and psychological characteristics as in Task 2. Detailed field notes will be made of observations from study staff and comments from subjects to record the extent and type of unpredictable challenges faced by each participant.

We must also consider that the confounding factors in the real-world scenarios may impact the FoG detection model developed in Task 1. We have proposed to train FoG detection model in Task 1. However, determining whether or not these models are context dependent or independent is essential. As such, we plan to first train a general FoG detection model for the five described triggering scenarios in Task 2. Then, we evaluate these models in real-world testing in Task 3, and if these models do not work well, we will build a FoG detection model for each triggering scenario in the real-world setting. After that, these FoG detection models will be adapted online based on the performance in real-world scenarios.

5 Evaluation Plan

Evaluation settings. Device testing using human participants for Task 1 and 2 will be conducted at the VCU Health Neuroscience, Orthopedic and Wellness (N.O.W.) center, where the VCU Parkinson's & Movement Disorders Center (PMDC) is located. The N.O.W. center, which opened its doors in June 2016, is a full-service outpatient building that houses specialty care clinics and therapeutic services. The VCU PMDC is housed on the 4th floor, and the research space is located on the 2nd floor. The five FoG triggering courses will be set up in a quiet room with minimal distractions within the space of the physical therapy treatment suite on the 2nd floor. Device testing in the real-world setting (Task 3) will occur in the shopping mall next door to the N.O.W. building or in another similar location. This is a relatively busy open-air, two-story mall with all the normal distractions of a public space. This mall has several outdoor elevators, electronic doors, hallways that are narrow, and public seating. This is the ideal setting for a real-world test of the device.

User study with PD participants. The VCU Parkinson's and Movement Disorders Center (PMDC) has developed strong ties with the Parkinson's community and has fostered a population that is willing and eager to participate in research projects. Based on our experience with prior PD projects, we believe the proposed plan will lead to successful recruitment for this project. Strategies include recruiting from our clinic patient population, from our VCU PMDC patient registry, a database with more than 2000 patients (approximately 1000 with PD) who have given permission to contact them to discuss research studies, from printed brochures distributed at community educational events and PD support groups, and via e-communications using the PMDC's email list and social media sites.

Inclusion criteria includes: individuals over the age of 21, have PD diagnosed by a movement disorder specialist using UK Brain Bank criteria, are able to walk independently or with a simple device (e.g., cane or walker), and are observed by the research team to have PD-related FoG in at least two of the previously described common trigger scenarios.

Exclusion criteria includes: individuals with known Parkinson plus syndrome, presence of dementia (Montreal Cognitive Assessment < 21), an additional disorder (not related to PD) impairing gait, history of implantable cardiac device or any other implanted electronic device except DBS, peripheral neuropathy, or any condition that, in the opinion of the PI, would compromise participant safety, data integrity, or data interpretation.

Each of the three tasks will require working with PD volunteers. In Task 1 we will collect data using the UG

sensor on five participants. Data will be collected in one visit lasting 2 hours or less. The raw data will be used to identify pre-FoG gait patterns for FoG characterization. Task 2 will require 13 participants to volunteer for one 2-hour session to determine the optimal dose for each of the five FoG triggering scenarios. Lastly, in Task 3, we will ask 15 participants to test the device in the real-world setting. Task 3 will also require one 2-hour data collection session. A total of 33 participants with PD will be required to complete this project. Participants will be given a $25 store card in exchange for their participation.

Evaluation of FoG detection models. To evaluate the FoG detection models in Task 1, we will use the study data obtained from the PD participants described above. The evaluation metrics will be precision, recall, and F1 score (defined as 2*((precision*recall)/(precision+recall))) of the models. We will also measure the time delay, and system cost to the smartphone such as CPU and memory cost. This will help us evaluate whether or not the normal phone call function of smartphones will be impaired. If yes, we will limit the CPU cycles allocated to the learning models. We will also measure the power efficiency of the UG motion sensor and see how long it will last once the battery is fully charged. Validation of UG device to detect FoG will be established during Task 2 in the clinical setting.

Optimal dose evaluation. To determine the optimal dose for each of the five triggering scenarios (Task 2) we will use the dose response curve analysis described in Task 2, and 95% confidence intervals will be calculated around the estimated optimal dose for each of the six outcome measures. The relative width of the confidence interval will illustrate the usefulness of the estimated optimal dose. The outcomes expected with the optimal vibration dose will be a significant decreased time spent in FoG state and the number of FoG episodes, stride length, and increased speed while walking through triggering scenarios.

Real-world evaluation. Evaluation of Task 3 will be addressed in three parts. First, we will evaluate how well the context points in the real-world setting are detected by our GPS plus BLE method. Percentage of errors and confusion matrix will be used to evaluate the accuracy. Also, we will compare the precision, recall, F1 score, and delay of the context dependent and independent modelings for FoG detection. Second, we will administer user surveys to evaluate participant's view of the comfort, feasibility and effectiveness using the Clinical Global Impression Scale [40] of our proposed system. Third, to objectively evaluate the effectiveness of the adaptive device in the real-world setting, 15 participants will be asked to walk through the real-world path (illustrated above) wearing the FoG detection/vibration device. We will compare the baseline data (frequency of FoG events, time spent in FoG state, stride length and total time to complete the course) with vibration turned off, to the data collected as the participant walks through the same path with the vibration turned on.

6 Project Timeline

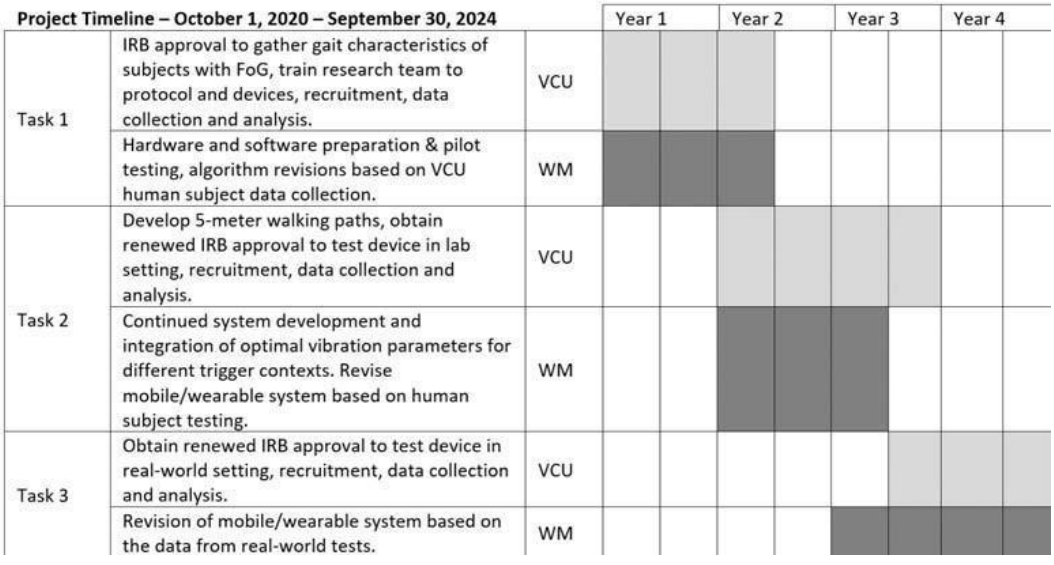


Figure 11. Project Timeline

This proposed project consists of 3 research tasks that will be collaboratively executed by VCU and WM. The proposed project timeline is presented in Figure 11.

Year 1. VCU will develop and test electronic data collection forms for the patient demographics, disease descriptors, medications, and validated scales. VCU Institutional Review Board approval for the recruitment of