Problem Statement (Intellectual Merit)

This SBIR Phase I project will produce a prototype for an automated physical-therapy (PT) treatment for patients suffering from Parkinson's Disease (PD). This automated prototype will act as a virtual coach encouraging patients to perform daily mobility exercises in the comfort and privacy of their own homes. This unique, automated technology will help rewire the brain of the PD patient by engaging both the mind and body which will slow the neurodegeneration inherent to PD. The system will automatically adjust the treatment protocol in terms of duration and difficulty based on the patient's unique situation including current medication levels. Objective, technology-based outcome measures will be summarized for caregivers working with the PD patient (primary care provider, physical therapists, neurologists, and so on). Physical therapists can oversee the treatment plan without needing specialized training in the PD domain.

Commercial Feasibility (Broader Impacts)

Over 1 million Americans currently suffer from Parkinson's Disease (PD) with an estimated 60,000 new diagnoses each year. This neurodegenerative disorder is a disease without a cure–once the first Parkinsonian tremor is detected that leads to diagnosis, over 80% of the brain cells associated with creating dopamine through natural processes have already died. Dopamine is a chemical released by neurons to communicate with other nerve cells and is essential to enable the basal ganglia network to control the body's movements. By engaging the PD patient with novel, highly-cognitive mobility exercises within our electronic system, automaticity is reprogrammed to utilize different regions of the brain to control movement. Ultimately, this rewiring will slow or possibly reverse the degenerative process which could reduce the U.S. economic burden assocated with this disease by $9B each year. Although this original prototype focuses on this one disease (PD), the technology could be applied to other sister diseases (e.g., Alzheimer's and Dementia), other conditions (traumatic brain injury, stroke, concussions, and so on), and/or for basic wellness.

Title: Engaging the Mind and Body: Technology to Automate Physical Therapy Treatments for Patients with Parkinson's Disease (PD).

Overview: Automation of exercise-based therapy for patients suffering from Parkinson's Disease (PD).

Keywords: Parkinson's Disease (PD), neurological degeneration disorder, physical therapy treatment, exercise program, automated system

Electronic Hardware, Robotics and Wireless Technologies (EW): EP1. Electronic Devices, Boards and Interfaces; RH1. Learning, Intelligence, and Motion; RH6. Human Assistive Technologies and Bio-related Robotics

ACTIVE THERAPY SYSTEMS

Empowering the Person with Parkinson's Disease

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1 Introduction

Celebrities with Parkinson's [5] [video]

Parkinson's Disease (PD) effects over one million Americans. Each year, another 60,000 are diagnosed with this devastating neurodegenerative disorder. Whether dodging punches or delivering punch lines, even celebrities like Muhammad Ali and Michael J. Fox (MJF) are not immune to this incurable disease–a disease that starts innocuous as a mild tremor and ends pernicious as an inability to stand, walk or get out of bed. By the time MJF had his first pinkie tremor working on *Doc Hollywood* in 1991 [10], over 80% of his brain cells responsible for producing dopamine to control body movement were dead. Like many others, MJF avoided the reality of his situation, turning to alcohol and not publically disclosing his condition until 1998. Some never disclose their condition; for example, Robin Williams, who, suffering from depression associated with PD, took his own life [29].

Along with the movement quirks with PD onset, a new PD sufferer faces the internal struggles with depression, coping, and mortality. Today, after years of therapy and hiding the reality from his fans and himself, MJF can now say that PD is a "gift" that has taught him how to be compassionate [11]. Although an optimist, MJF will admit that his daily realities of the disease are downright brutal: pain, discomfort, social anxiety, loss of independence, and an overall loss of former self. Although PD does not have a cure, there are treatment programs that can make this new reality manageable.

In the early 2000s, extensive research challenged the accepted view that exercise programs were 'a waste of time' to treat PD. Exercise became an important intervention to manage PD: staying limber, improving balance, and motor coordination [18]. Today, exercise programs have been demonstrated to reduce motor-skill degeneration and retrain the brain to compensate for motor impairment [8, 19, 25, 24]. Some evidence suggests that certain types of physical activity (PA) are most beneficial to maintain mobility (e.g., karate [21], cycling [31], dance [34, 12, 14, 16]). In general, physical therapists (PTs) suggest therapies that may compensate for a movement disorder (e.g., prevent falling) or help rewire the brain using attention strategies or external cues [19, 30]. The research emphasizes that continuous treatment is necessary to maintain any gains offered by an exercise regime. If your treatment is not ongoing, retrogression will ensue.

Our innovation is an ***automated PT treatment system*** that can be performed by the PD patient regularly in the privacy and comfort of their own home. Our innovation will assess the PD patient's current mobility state in realtime and tailor a custom protocol specific to the realities of the patient's current condition. This system will serve as a virtual PT coach to encourage, guide, and direct the PD patient to engage in exercises that will improve functional mobility, aid in the management of pharmacological cycles and interactions, and offer hope that the brain (via neuroplasticity) can heal itself finding new ways to control body movements and generate dopamine. Our technology will overcome a patient's pre-PD automaticity by training the patient how to ***learn new things*** and/or how to ***learn new methods related to old things*** and adapt over time to meet the changing needs of the PD patient.

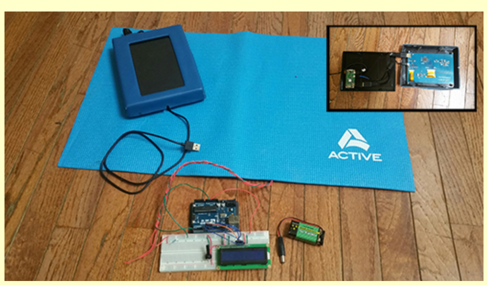
2 Innovation

We have developed a concept for a technology that will enable us to deliver PT treatments in an automated way to serve the PD community. Our system helps rewire the brain by coupling unique physical tasks with highly-engaging mental challenges. Our innovation has two key features: the underlying neuroplasticity regime of combining the mind and body and the electronics and accompanying software to make the system an automated virtual coach.

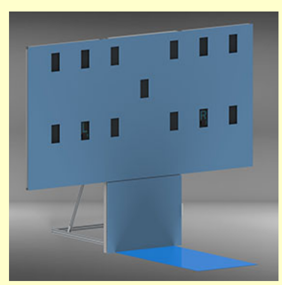
Imagine the benefits and implications of such an innovation. The PD patient's caregiver, many times the spouse, would not have the burden of getting to a medical facility [the treatment can be performed at home]. The initial treatment sessions could occur in the home by a PT emphasizing the importance of consistent exercise compliance. The home-based system could transmit data in an unobtrusive way [the PD patient will not have performance anxiety or feel like a lab rat behind the glass]. Events that are rarely observed (e.g., freeze of gait [FOG], a fall, dyskinesia, saccade) during an in-office clinical visit could be captured with relevant auxiliary data (time, location, pharmacology, motor activity, other physiology) and notify the healthcare providers. PD patients could opt-in to tying this data to general research or a specific intervention trial. The PD ecosystem would maximize the economics of the funds available for PD patients using PA solutions and allow for the integration of big-data analysis with pharmacological intake to compare and correlate function as it relates to dosage and medication states. In summary, in-home visits and/or telemedicine can supplement traditional office visits which could substantially change the quality of life for the PD patient and the landscape of how care is delivered.

The first key feature of our innovation is about neuroplasticity: why are certain types of physical activity (PA) most beneficial to maintain mobility: karate [21], cycling [31], dance [34, 12, 14, 16]? We posit that, for most PD sufferers, these are new activities; that is, they didn't cycle, dance, or know karate before they were diagnosed. Each of these activities are complex and they are learning them for the first time in their new normal (with the PD-disabled brain). We propose that these activities represent ***physical activity with cognitive engagement (PA$^+$)*** . The mind and body work together to rewire the brain. Abstracting PA$^+$, patients will not learn karate or a specific dance; rather, each protocol in the automated system will represent a unique set of cognitively-engaging movements that are easy-to-understand but require complex integrated motion.

Early Mockup Demo



First Early-stage Prototype



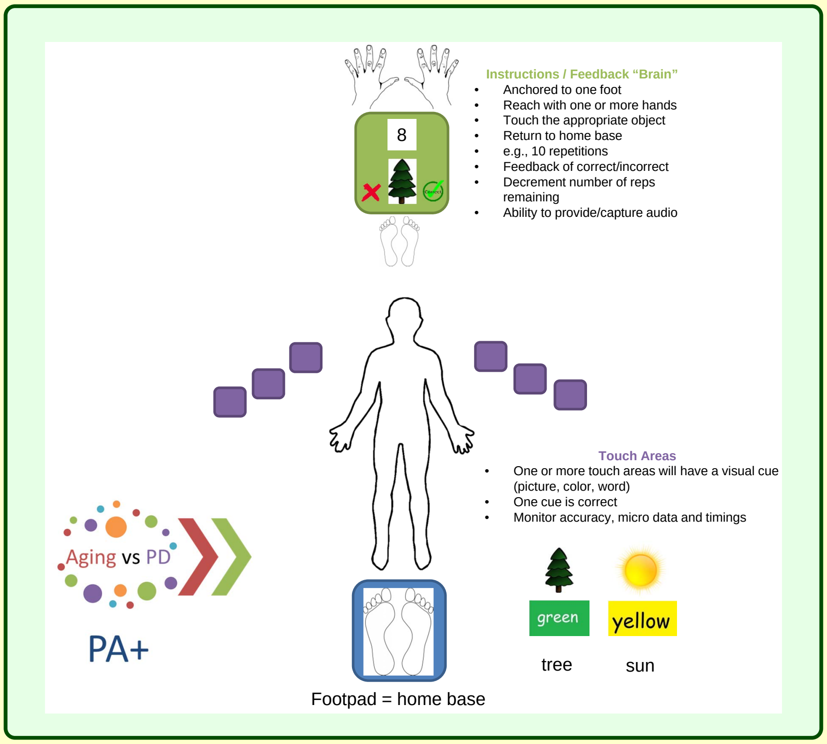
Concept for Phase I

For example, from the early mockup demo, "plant your right foot, step forward with your left foot and with your left hand reach directly to your left and with your right hand reach directly above you to touch the lighted sensors." This nontrivial task is new to the user and in their disabled condition, learning how to perform the task can enable the rewiring process (neuroplasticity).

The second key feature of this innovation is the hardware and software to automate the protocol process. Hereafter, we diagram the patent-pending system. Standing on a footpad sensor with arms at the side, a user faces a wall to receive instructions to perform a task. In front of the user is a tablet ("the brain") providing task instructions. For example, the brain may show a picture of a tree, and highlight the right arm, and the left foot. These instructions inform the user of the motor requisites to perform the task: anchored to the left foot (it does not move), reach with the right arm and touch the appropriate response touchscreen or tablet. Available responses are shown on one or more of the response areas to the left or the right of the user. To process the task instructions, cognitive engagement using executive function must first occur followed by performing the motor activity, generally several repetitions (e.g., perform the compound movement 10 times in a row, returning to home position after each repetition). This is the foundation of our rehabilitation approach: Physical Activity with Cognitive Engagement (PA^+).

The footpad sensor is the gatekeeper for the PA^+ exercise system. Via this sensor, the system is constantly aware of the location of the user. By requiring the user to be at a specific starting point on the footpad prior to displaying any external cues, the user must achieve the desired excursion of movement to complete the given task and return to the starting position prior to the display of the subsequent cue. Therefore, the footpad–along with the screen(s) displaying a cue–are responsible for the initiation, lap, and termination of the time stamps during a set of movements or routines. That allows a baseline measurement to be recorded at the start of each treatment session and a comparable measurement to be gained with every cue given and movement made.

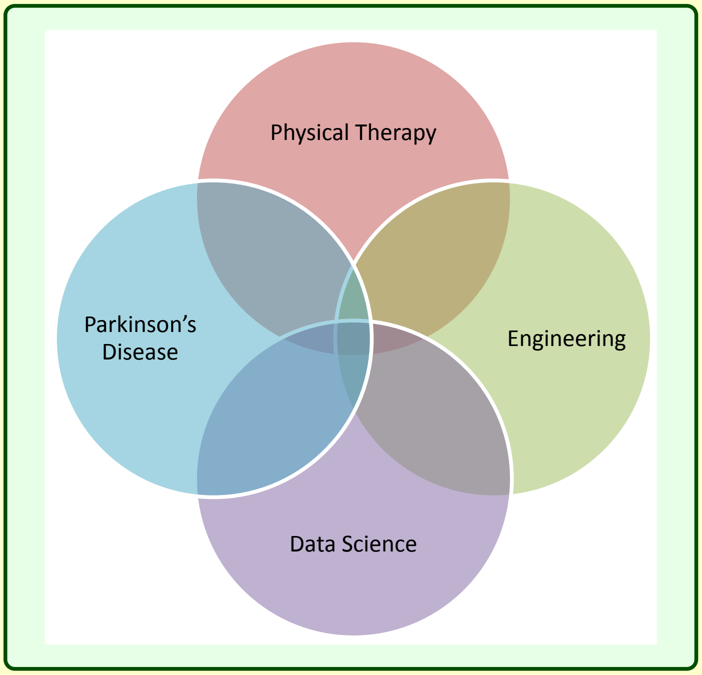
We can collect several timing variables related to PA^+: how long did it take for cognitive capture (executive function); how long did it take to touch the correct screen; how long did it take to return to home position (both feet on the pad, hands at side), etc.? In addition, we posit that if we require a varying number of repetitions (e.g., 1 time, 5 times, 10 times, or something in between), the user may have a difficult time starting and/or stopping. PD patients have a hard time getting into motion, but once moving, they have a difficult time stopping. Over time, to challenge the user, the system will adapt by varying cues, creating false-flag options, randomizing repetitions, and possibly requiring touching two correct answers with two hands. Vocalization options eventually can also be integrated (e.g., say the correct answer "tree" during each repetition of the task performance).



Physical Activity Plus Cognitive Engagement

The adaptability of the system is uniquely important. In order to successfully counter the failing routines of automaticity that occur with PD as a result of dopamine loss, constantly changing and adapting cognitive and physical challenges are necessary. For example, providing the exact same external cues to elicit the same cognitive and physical responses on a daily basis will only train the mind and the body to respond to that cue and will not provide carry over of function into everyday life.

By providing a user with external cues that require differing cognitive challenges and physical responses on a regular basis, the mind and body are forced to adapt to those changes to successfully fulfill the requests of the cues given. Then, the data collected by the system can be internally analyzed to determine the level of success the user has with the given cues and levels of difficulty, and it will adapt the given cues accordingly. This allows for the user to be challenged further if they are performing at a high level or complexity to be reduced if they are struggling. This adaptive programming by the system is key in achieving neuroplasticity in the brain and represents an important technical challenge.



Nature of Innovation

The foundation of our innovation is automata: "machines that [perform] a function according to a predetermined set of coded instructions, especially [those] capable of a range of programmed responses to different circumstances" [20]. We are building such a robot to assist PD patients with performing PT treatment, a virtual PT coach. Our system ***learns*** how to deliver a protocol relevant to time-based and functional-based assessments of the PD patient. Then, based on optional self-report data from the patient ("when did you take your medicine" or "how are you feeling today" or "how difficult was the warmup for you"), we can determine the session protocol. The system can be further customized based on the likes and culture of the PD patient (e.g., someone growing up liking Kentucky basketball may want the Coach Calipari version; an Alabama fan may want the Coach Saban version; and a country-music fan of 'Alabama' may want Randy Owen as the coach). Such customization/gamefication will increase enjoyment and ultimately increase compliance (e.g., today I feel like I want[1] 'Adam Sandler' to direct me; maybe tomorrow, I feel like I want 'Meryl Streep'). In addition, we may have an option for intensity of language for the chosen coach (*default* is polite language like Alexa/Siri; *high intensity* may contain more vulgar language "do you want today's workout to 'kick your ass'" [challenge me] or "do you want to 'phone in' today's workout" [go easy]). The point is, the system will allow the PD patient to decide.

[1] We anticipate that once we reach a critical mass, celebrities may volunteer their time to support the PD community by recording their voices. Such design will also allow localization in other languages.