Moving Mindfully for Freezing of Gait

NCT05923229

Protocol

04/18/2023

Moving Forward: Protocol v1 04/18/2023

RESEARCH DESIGN AND METHODS

Note: Aim 1/Aim 2 are listed under CT Record #NCT05309083 titled Moving Mindfully for Freezing with Parkinson's

Aim 3: Conduct pilot RCT trial to evaluate feasibility and acceptability of the standardized Mindfulness-Based Walking Therapy (MBWT) program. Using the standardized MBWT manual produced from Aim 2, we will randomize 24 people with Parkinson Disease + Freezing of Gait (PD+FOG) to MBWT or FOG education group (i.e., usual care and FOG education), examining feasibility elements listed in Aim 2.

RATIONALE

Our main goal in Aim 3 is to conduct a formative evaluation of the intervention by gathering information before, during, and after a controlled pilot study. Results from this pilot will allow us to further improve the protocol and inform implementation of the intervention in a future larger trial, if warranted.

DESIGN

We will recruit and randomize 24 participants with PD+FOG to the standardized MBWT program or FOG education (12 per group). Participants in both groups will undergo three evaluations sessions: 1-4 weeks prior to the intervention (Pre-test), 1-4 weeks after the intervention (Post-test), and 14-18 weeks after the intervention (Follow-up).

The FOG education group will receive customary care from their health professional team, which may include alterations to anti-Parkinson medications, and they will receive weekly education and information on resources about FOG. For early phase RCTs that aim to determine if an intervention works at all, the NIH expert panel's discussion of comparator selection in Freedland et al., recommends a low formidability comparator such as no treatment or waitlist. For RCTs that seek to determine how well the intervention works relative to an alternative intervention, the panel recommends usual care that reflects existing clinical services, a well-established alternative intervention, or a variation of the experimental intervention. Currently there are no universal care standards for FOG thus a well-established alternative intervention is not available and it would not be feasible to test a variation of a protocol currently being developed. Thus, we have selected to utilize a usual care group that reflects existing clinical services for management of FOG.

KEY FEASIBILITY ELEMENTS, EXPECTED OUTCOMES, AND BENCHMARKS FOR MBWT

Ability to recruit our target sample. We estimate screening approximately 85 participants by phone to find 30 participants that pass the phone screen. This anticipated screening rate of 35% is based on our recent interventions. We anticipate six people will not pass screening, leaving 24 people to be randomized. We anticipate four people will decide not to participate after randomization leaving twenty participants that begin the interventions. We will track reasons for not continuing during the phone screens. *Benchmark:* (1) Recruitment of 24 participants.

Participant attendance and retention: We will collect data on why mindfulness classes are missed and reasons for drop-outs, if any. Make up classes may need to be scheduled. Benchmarks: (2) Attendance and retention of participants, defined as 80% of participants attending 80% of the sessions.

Participant adherence. Adherence for mindfulness home practice will be monitored using a paper form. The participants will note how many minutes they practiced mindfulness today. *Benchmark:* (3) Home

practice adherence, at least 70% of participants will complete at least 70% of the daily home assignments during the active intervention period. Number of home practice hours is 18 hours over the course of the mindfulness intervention.

INCLUSION/EXCLUSION CRITERIA

(These criteria will be formally reviewed during the advisory group meetings and an IRB update will be conducted before enrollment):

Participants with PD will meet the following inclusion criteria:

- diagnosed by a neurologist with idiopathic PD;
- age 50 and older;
- a score on the Hoehn & Yahr (H&Y) scale between I-IV;
- history of freezing of gait;
- able to provide informed consent;
- able to walk independently with or without an assistive device for at least five minutes;
- experience fear and/or worry in relation to their FOG; and
- stable medication regimen for two months prior to enrollment.

Participants with PD will be excluded if they have any of the following:

- evidence of dementia (Montreal Cognitive Assessment – Telephone Version < 13) to ensure understanding of materials;
- are under consideration for deep brain stimulation surgery within the next six months;
- neurologic condition other than PD;
- inability to cooperate with the protocol;
- language, visual, or hearing barriers to participation; or
- history of orthopedic or other medical problems that limit ability to participate safely in the intervention.