COMMENTARY

COMMENTARY ON "EFFECTS OF UPPER LIMB VIBRATORY STIMULATION TRAINING ON MOTOR SYMPTOMS IN PARKINSON'S DISEASE: AN OBSERVATIONAL STUDY"

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Published Jul 29, 2024. DOI: 10.2340/jrm.v56.40920. J Rehabil Med 2024; 56: jrm40920

We read with great interest the article by Varalta et al. (1). The authors did an impressive job of delving into the problems faced by Parkinson's patients, as tremor is a difficult PD symptom that greatly impairs manual abilities and daily activities. However, we are writing to share our concerns regarding this recent study published in the Journal of Rehabilitation Medicine. While the study shows interesting findings concerning the potential benefits of vibratory stimulation training for tremor reduction and motor functionality in Parkinson's disease (PD) patients, several drawbacks should be addressed to ensure a thorough understanding of the intervention's efficacy.

First, there is a mismatch between the title and the methodology section of the study. The paper's title highlights the vibratory machine's impact on tremor and upper limb motor functions, yet the study also assesses cognitive function, as found in the methodology section. As a result, the title should be updated to reflect this broader scope.

Additionally, the study's title indicates that it is an observational study, meaning no active intervention was given by the researcher and merely observing natural outcomes without manipulating any variable. In contrast, the methodology section of the study indicates an intervention (upper limb vibratory stimulation training) was applied to the participants, and outcomes were measured before and after the intervention. This study design is consistent with that of a clinical trial (experimental study). In an observational study, individuals are monitored without changing the study setting or the subjects themselves. Researchers watch and gather data on people's features and results without intervening. However, a clinical trial is a research study that evaluates the efficacy and safety of medicinal, surgical, or behavioural therapies on a group of participants and measurements are taken before and after the intervention to assess its effects (2). Moreover, as no control group is present in this study, and only one group is receiving an intervention, the design of this study can be considered as a single-arm uncontrolled pre–post study design (3).

Second, there is a mismatch between the introduction and methodology of the study. The introduction does not include the background of cognitive impairment in Parkinson's disease, and even the objective of the study is only to evaluate the effects of an upper limb (UL) vibratory rehabilitation programme using a specific device (Armshake®, Move It GmbH, Bochum, Germany) on tremor and motor functionality in patients with PD but the methodology section has incorporated a scale for assessing cognitive dysfunction as well. It is necessary to establish and explain the importance of testing cognitive function in Parkinson's disease. Furthermore, the paper should also explain why there is a possibility of changes in cognitive performance simply by giving treatment for improving upper limb motor functions of Parkinson's disease.

Furthermore, the study has made no mention of the sampling procedure. While such studies do not include randomization into separate groups, precise sampling procedures must be used to guarantee that the research population is suitable and representative of the larger patient population for which the intervention is designed (4).

Additionally, neither the reliability nor the validity of the outcome measures used are mentioned. This is a significant omission since these measures ensure that the tools employed are both reliable and valid (5). This information is routinely included in clinical studies to increase the reliability and robustness of the findings.

Lastly, the study fails to effectively address potential confounding variables such as treatment status or disease severity, which may impact treatment outcomes. Including these characteristics as covariates in the analysis, or stratifying the sample by disease stage, would improve the study's rigour.

Addressing the mentioned drawbacks, such as revising the title, explaining the relationship between motor and cognitive functions, reporting the reliability and validity of outcome measures, providing background on cognitive dysfunction, and detailing the sampling methodology, would improve the study's validity. This would help us gain a better grasp of the effectiveness of vibratory stimulation training in treating motor symptoms in PD patients.

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RESPONSE TO THE COMMENTARY ON "EFFECTS OF UPPER LIMB VIBRATORY STIMULATION TRAINING ON MOTOR SYMPTOMS IN PARKINSON'S DISEASE: AN OBSERVATIONAL STUDY"

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First of all, we would like to thank Mebanpynjop Dohtdong and colleagues for their interest in and comments on our recent article (1).

Tremor is a cardinal motor symptom of Parkinson's disease (PD), affecting up to 80% of patients (2). This condition significantly impacts the quality of life, leading to disability and considerable limitations in activities of daily living (3). The Armshake® device (Move It GmbH, Bochum, Germany) is marketed in Europe specifically for treating tremor and its sequelae in patients with PD. As the Armshake® is currently in use at our clinical unit, we decided to include it in some research tasks. These activities were limited to the intended purposes specified by the manufacturer ("in-label" use) and did not include any additional interventions beyond those performed under normal conditions of device use (for clarity, we did not impose any experimental or controlled conditions but simply collected data from patients undergoing normal clinical practice). In this context, our investigation concerning the effects of Armshake® should be considered a prospective observational study (1, 4).

Motor behaviour results from a complex integration between cortical and subcortical areas, encompassing the motor, cognitive, and motivational aspects of movement (5). This close interplay (mainly based on dopaminergic projections) enables the learning, control, and expression of habitual (automatic) actions, which become dysfunctional in PD (6). Neuromotor approaches have been found to improve motor and cognitive performance in patients with PD (7–9). Therefore, we collected data on the motor and cognitive effects of the Armshake® device during our observational research activity. Considering the large number of outcome measures recorded from a sample of 20 patients with PD, we decided to present our results in 2 papers. The first deals with the effects of the Armshake® device treatment on cognition and was published in 2022 in Brain Sciences (4). This is the reason why our article recently published in the Journal of Rehabilitation Medicine (JRM) reports predominantly on the motor effects of vibratory stimulation training performed with the Armshake® (1).

In our study, we evaluated patients at 3 timepoints (i.e. before treatment, at the end of treatment, and 30 days after the end of treatment) according to some primary (i.e. the Fahn-Tolosa-Marin Tremor Rating Scale [FTMTRS]) and secondary (i.e. the Unified Parkinson's Disease Rating Scale [UPDRS]; the Purdue Pegboard test [PPT]; the Disability of the Arm, Shoulder and Hand [DASH] questionnaire; the Montreal Cognitive Assessment [MoCA]) outcomes. With regard to the reliability/validity of our outcome measures, the FTMTRS is recommended by the Movement Disorder Society to assess tremor severity because of its good overall clinimetric properties (i.e., reliability, validity, and sensitivity to change) (10). The UPDRS – part III is reported to have excellent validity and internal consistency as well as adequate ceiling effects (11). The PPT showed high test–retest reliability for measuring hand dexterity in PD. It has intraclass correlation coefficients (ICCs) $\geq$0.90 and very good interrater reliability (ICCs >0.99) (12). The DASH Italian version has good test–retest reliability (function/symptoms: ICCs=0.89; sport/music ICCs=0.75; work: ICCs=0.84) (13). The MoCA is validated for the screening of mild cognitive dysfunction in PD. It has excellent test–retest (ICCs=0.79) and interrater reliability (ICCs=0.81) (14).

As to enrolment of the study population, we applied a consecutive sampling procedure. All patients were evaluated and treated during the "ON phase" of medication (i.e., between 1 and 2.5 h after last intake). The disease stage was defined according to the Hoehn and Yahr (H and Y) scale (15). In order to address the concern regarding potential confounders, a one-way ANCOVA was conducted to determine whether disease severity might impact the primary outcome.

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We confirm the significant differences found on the FTMTRS between timepoints ($F=4.83$; $p=0.045$) after controlling for the H&Y stage.

In conclusion, we agree with Mebanpynjop Dohtdong and colleagues concerning the importance of motor-cognitive interaction mechanisms, which open to some intriguing possibilities for PD rehabilitation. From this perspective, the results of our study on 20 patients with PD treated with the Armshake® device, published in Brain Sciences and JRM, should be considered, and read, as one (1, 4).

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