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Prevention and Rehabilitation

Whole body vibration improves symptoms of diabetic peripheral neuropathy

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ABSTRACT

Whole Body Vibration (WBV) is an innovative therapy that may be effective for reducing chronic pain associated with diabetic peripheral neuropathy (DPN), Current treatments for DPN pain have demonstrated questionable efficacy and significant risk of adverse events. Preliminary research has indicated that WBV may be effective for controlling chronic pain symptoms of DPN. METHODS: 20 participants (9 male, 11 female), 58.51 ± 10.69 years old, and BMI of 33.60 ± 8.20 kg/m2 were randomly assigned to a sham-treatment (n = 8) or WBV treatment (n = 12) group in a pre-post design. Pain was assessed with a 10-point verbal analog pain scale (VAS). Treatment consisted of three sessions/week with at least one day between sessions, 12 min/session (four bouts of 3 min), for four weeks. Control was established with a sham vibration protocol for two weeks in which the participants were blinded to the treatment. RESULTS: VAS scores of the treatment group decreased significantly at both 2 and 4 weeks ($p = 0.019$). The treatment group was found to have a significantly lower VAS score than the controls at two weeks ($p = 0.033$). After cessation of WBV vibration treatment, participants reported reduced DPN-related pain from 1 to 5 weeks later.

Conclusion: WBV is effective for reducing DPN-associated pain over a two- and four-week interval. This was the first study to demonstrate this using a sham vibration control. We further saw a persistence in pain reduction beyond the day of treatment, indicating a potential chronic effect of WBV treatment.

1. Introduction

Diabetic peripheral neuropathy (DPN) is characterized by sporadic numbness and frequently debilitating pain in the periphery elicited by hyperglycemia-induced damage to the primary afferent nociceptors leading to hyperexcitability in the central neurons and generation of spontaneous nerve impulses in the periphery (Veves et al., 2008; Schmader, 2002). Concurrent damage to proprioceptive nerves impairs balance and mobility, increasing fall risk. (Schmader, 2002; Vinik et al., 2008). Diminished mobility and chronic pain significantly worsens quality of life, leading DPN sufferers to become increasingly sedentary (Kriska et al., 1991; Tolle et al., 2006; Stewart et al., 2007), thereby augmenting diabetic symptoms and worsening the neuropathy. Patients caught in this vicious cycle of DPN need an effective and affordable treatment (Kriska et al., 1991; Meyer-Rosberg et al., 2001).

To date, all treatments available for DPN are pharmaceutical and purely palliative in nature (Vinik and Mehrabyan, 2004; Veves et al., 2008; Guastella and Mick, 2009; Tolle et al., 2006; Possidente and Tandan, 2009). Of these treatments, those approved treatments by the FDA are linked to serious, often dose-limiting, side-effects, which may become more detrimental than the original pathology, including lethargy, dizziness, somnolence, and increased fasting plasma glucose values (Veves et al., 2008; Tolle et al., 2006; Possidente and Tandan, 2009). Limited efficacy of pharmaceutical interventions requires that up to 90% of patients receive two or more medications, compounding potential side-effects, while patient satisfaction rate is only 27% (Tolle et a 2006; Possidente and Tandan, 2009). These treatments can be prohibitively expensive with direct medical costs representing approximately 27% of all diabetes-associated healthcare costs. (Tolle et al., 2006). There exists a clear need for an effective, low-cost alternative to pharmaceuticals.

Whole body vibration therapy (WBV) represents an affordable non-invasive, non-pharmaceutical treatment. Preliminary case-

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Table 1
Subject characteristics.

	n	Age	BMI(kg/m^2)
Vibration	12	56.8 ± 11.0	34.1 ± 9.2
Non-vibration	8	57.5 ± 7.9	33.7 ± 4.6
Crossover	5	59.0 ± 8.0	32.9 ± 5.9
Total	20	58.8 ± 10.2	33.9 ± 7.8

studies have demonstrated promising short- and long-term efficacy (Hong, 2011; Hong et al., 2013) with limited contraindications. Unique among current therapies, early WBV research has indicated both acute and chronic pain mediation. Combined with the relative dearth of controlled-trails, there is an apparent necessity for further research in this area (Robinson et al., 2018). The purpose of this experiment was to further test the short-term and long-term efficacy of whole body vibration (WBV) as a pain reduction modality for the symptoms of diabetic peripheral neuropathy using a placebo-controlled experimental design.

2. Methods

Twenty participants completed the study including 9 men and 11 women previously diagnosed with diabetic peripheral neuropathy (Table 1). Participants were recruited through local diabetes support groups, community education programs and private practices. Both insulin and non-insulin dependent diabetics were included; gender or ethnic group did not restrict the participant population. Written informed consent was obtained from each participant prior to participation and this study was reviewed and approved by Willamette University's Institutional Review Board.

Participants were randomly assigned to either the vibration treatment group or the sham-vibration control group upon entry into the study. After two weeks of treatment, participants in the placebo group were invited to cross over to the treatment group permitting an additional within-subjects analysis. Participants remained blinded to the nature of the sham-vibration.

2.1. Treatment protocol

2.1.1. Whole-body vibration group

WBV (Turbosonic, TT2590) was administered (Standing with knees slightly flexed) three sessions/week with at least one day between sessions, 12 min/session (four bouts of 3 min), for four weeks. Vibrating platform forces progressed from 0.5 g up to 1.0 g at a frequency of 25 Hz. At this frequency the vibration and sound of the machine were palpable and audible to the participant.

2.2. Sham-vibration control group

Participants in this group were given the same schedule of therapy as the vibration group but received sham vibration in which an audible high-pitched humming sound played through the speakers on the WBV machine, having negligible amplitude and creating no effective vibration stimulus.

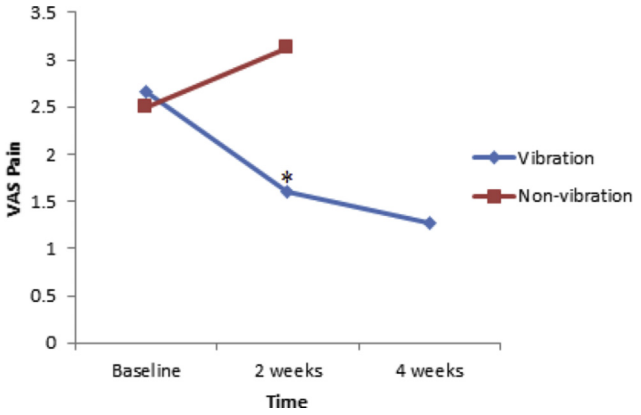

Fig. 1. Trends in VAS pain (1–10 scale). Asterisk (*) denotes statistical significance with a 95% confidence interval.

2.3. Subjective pain assessment

During each treatment day, participants completed a questionnaire to determine the intensity of their pain just before and within 5 min after vibration treatment. The difference in these values was assessed as the acute change in pain. After the initial treatment, and again at two and four weeks, participants were also asked to report the duration of pain reduction after their previous vibration treatment; this was assessed as the "persistence of pain reduction". Pain was assessed using a verbal analog scale (VAS) of 0–10. Additionally, six weeks after the cessation of vibration therapy, participants were asked to report how long it took for their pain to return; this was assessed as the "time to return to pain".

2.4. Data analysis

Paired t-tests were used to detect differences in VAS pain between control and treatment groups. T-tests were also performed to detect differences within the treatment group from baseline to 4 weeks. Alpha was set at 0.05 and all statistical analyses were conducted with SPSS for Windows statistical software (version 19, SPSS, Inc, Chicago, IL). Data are presented as means ± SE. Variables were tested for assumption of normality.

3. Results

There was a chronic decrease in VAS pain following two weeks of whole body vibration therapy in the vibration group ($p = 0.019$) (Table 2) as well as at four weeks ($p = 0.013$). The difference was significant between the groups at two weeks ($p = 0.033$). A significant acute decrease in VAS pain was identified in the treatment group ($p = 0.016$) but not in the control group (Fig. 1), although a trend towards decrease was observed in this group ($p = 0.080$).

The reported persistence of pain reduction increased after two weeks of WBV ($p = 0.045$) and the trend continued to be significant at four weeks ($p = 0.041$) compared with the placebo group,

Table 2
Chronic changes in VAS Pain.

	Baseline	2 weeks	4 weeks	p-value
Vibration	2.7 ± 1.8 (n = 17)	1.6 ± 1.0 (n = 17)	1.26 ± 1.4 (n = 17)	p = 0.019
Non-vibration	2.6 ± 1.8 (n = 8)	3.2 ± 2.43 (n = 8)		p > 0.05

p-value indicates significant difference from baseline to two weeks.

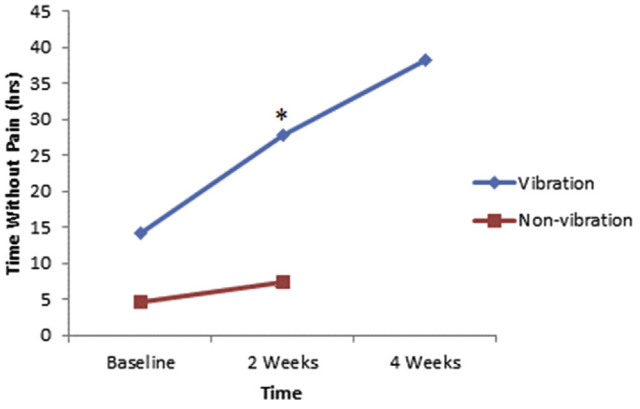

Fig. 2. Persistence of pain reduction after most recent WBV treatment. * denotes significance with a 95% confidence interval.

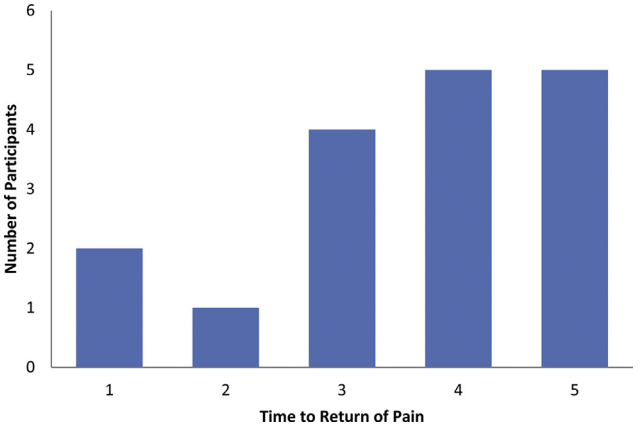

Fig. 3. Reported time to return of pain at a 6 week interview for participants in the vibration group. 6+ weeks indicates that pain had not returned at the time of the interview.

($p > 0.05$) (Fig. 2). This result was approached significance between groups at two weeks ($p = 0.095$).

At the six-week post-study follow-up interview, 10 out of 17 participants reported that their pain had taken at least three weeks to return, with five participants reporting that at six weeks pain had not yet returned (Fig. 3).

4. Discussion

The purpose of this study was to further test the efficacy of whole body vibration (WBV) as a pain reduction modality for the symptoms of diabetic peripheral neuropathy.

The significant chronic decrease in pain after both two and four weeks confirms results found in previous WBV clinical trials, and the significant difference between the vibration and placebo groups further strengthens the hypothesis that the reduction in DPN pain symptoms is directly associated with WBV (Fig. 1, Table 2) (Hong, 2011; Hong et al., 2013; Kessler and Hong, 2013). Furthermore, the significant increase in time to return to pain mirrors results found by Kessler and Hong (2013) and provides further evidence for the existence of a chronic effect of treatment (Fig. 3).

The results of this study show that WBV holds promise for filling a niche that medications have not filled: a non-pharmacological therapy that can help sufferers of painful DPN relieve their pain without reducing their ability to exercise and thus control their diabetes. With the current satisfaction rates of pharmacological therapies at an abysmal 27%, the need for therapies such as this is great and future research is warranted (Tolle et al., 2006; Possidente and Tandan, 2009). The authors suggest that the next step in this process should be a more powerful and more statistically robust controlled trial of WBV in the clinical DPN population, a more detailed investigation into the possible mechanisms by which it relieves pain and subsequently, and a full phase III clinical trial with an IDE so that the therapy can be recognized by the FDA.

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Declaration of competing interest

The authors declare no conflict of interest.

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