The utility of whole body vibration exercise in haemodialysis patients: a pilot study

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Abstract

Background: Exercise improves physical capacity in patients with end-stage renal disease on haemodialysis (HD), but few patients engage in it. Whole-body vibration exercise (WBVE) is a novel protocol that has been shown to benefit frail elderly patients’ rehabilitation. We assessed the utility of WBVE before HD sessions and tested methods to inform the design of a randomized controlled trial (RCT).

Methods: Physical condition and quality of life were assessed at enrolment and repeated 2 weeks later in a pilot study of 49 patients undergoing regular HD. All patients then undertook 8 weeks of WBVE, thrice weekly for 3 min, after which the assessments were repeated and results compared (paired t-tests). Further assessments were made after a 4-week layoff. Patients completed a post-study questionnaire about their experiences of using WBVE. The reproducibility of WBVE and effects on measures of functionality, muscle strength, indirect exercise capacity, nutritional status, bone health and quality of life were recorded to undertake a power calculation for an RCT.

Results: Of 49 patients enrolled, 25 completed all assessments. The dropout rate was high at 49%, but overall, WBVE was an acceptable form of exercise. Functionality as assessed by the 60-s sit-to-stand test (STS-60) improved significantly by 11% (P = 0.002). Some quality of life domains also improved significantly. All improvements were maintained 4 weeks after discontinuing WBVE.

Conclusions: WBVE was acceptable, safe, easily incorporated into the routine of HD and was associated with useful improvements in physical function sufficient to justify a RCT.

Key words: chronic renal failure, exercise, haemodialysis, physical activity, quality of life, vibration exercise

Introduction

Patients with end-stage renal disease (ESRD) experience significant musculoskeletal problems, including a rapid functional and physical decline after initiation of haemodialysis (HD) [1]. Reduced physical capacity results from a decline in strength, a decline aerobic capacity [2] and muscle wasting [3], along with enforced immobility during treatment. In addition, ESRD causes mineral and bone disorder (MBD) with abnormal calcium and...
phosphorus metabolism associated with parathyroid disease, along with exaggerated osteoporosis [4]. As a result, ESRD patients rapidly become frail and increasingly dependent.

A recent systematic review of exercise programmes in patients with chronic kidney disease reported that the strongest evidence found in patients on HD was in benefits to physical fitness, muscle strength and quality of life [5]. An earlier mini-review also highlighted that a physical exercise programme can improve general health, including a reduction in weight, improved muscle strength, lowered cholesterol and triglycerides, increased cardiac output and greater physical exercise capacity in ESRD patients [6]. Many of these benefits will also reduce the risk of heart disease, which is greater for people with renal disease than among the general population [7]. Furthermore, routine exercise enhances feelings of self-esteem, maintains independence and reduces depression and anxiety [8]. Failure of exercise programmes often results from the basic logistics of arranging sessions and equipment around HD sessions and transport times [9]. Despite evidence of a significant benefit, the majority of ESRD patients fail to achieve an adequate amount of aerobic or weight-bearing physical exercise [10].

Previous studies and exercise programmes in ESRD have used exercise bicycles during HD or gentle exercises during HD (designed to build muscle). Factors that contributed to sustainable exercise programmes included dedicated exercise professionals, encouragement to exercise intradialytically, committed dialysis and medical staff, adequate physical requirements of equipment and space, interesting and stimulating programmes and a sustainable economic cost. However, compliance with the exercise protocols can be poor [6]. Whole-body vibration exercise (WBVE) is a novel exercise protocol designed to prevent the loss of muscle strength and bone mineralization during the immobility and weightlessness of space flight [11], a situation similar to HD. Vibration exercise uses high-frequency vibration of muscle groups causing positive feedback of the spinal reflex arc and resulting in high levels of muscle contraction to motor unit recruitment otherwise only achievable by heavy weight lifting. There can be multiple physiological benefits from vibration exercise, including cardiovascular effects, bone health and muscle strength [12–18]. Vibration exercise may be an ideal exercise intervention incorporated into routine HD sessions in clinical practice with the potential to dramatically improve strength, bone health, function and quality of life. We have been unable to find any previously published studies on the use of vibration plates in the HD population and, hence, evidence of its acceptability and effectiveness compared with other exercise modalities in this population remains to be established.

We aimed to provide pilot data on the utility of WBVE in ESRD patients undergoing HD in order to inform the planning of a definitive, multicentre, randomized controlled trial (RCT).

Our specific objectives were to assess

i. The acceptability of WBVE in patients with ESRD undergoing HD sessions.
ii. The practical issues involved in enabling patients to exercise three times a week for a 3-min duration using WBVE.
iii. The value of the outcome measures chosen in determining the effect of WBVE on functionality, muscle strength, indirect exercise capacity, nutritional status, bone health and quality of life of patients on HD.
iv. The magnitude of the effect, if any, on each of these measures.
v. The number of patients required to test the utility of WBVE in an RCT.

### Materials and methods

#### Study design

This prospective pilot study compared each patient to his/her baseline following an 8-week intervention period. Patients undertook a training session with the measurement techniques then underwent a baseline assessment (result 1), which was repeated in 2 weeks (result 2). Thereafter patients received the exercise intervention of WBVE three times a week, prior to receiving dialysis, for 8 weeks, after which the assessments were repeated (result 3). A further assessment was conducted 4 weeks after completing the exercise programme to estimate any residual effects (result 4). This design allowed each patient to act as his/her own control by comparing the mean of results 1 + 2 with result 3 (paired t-test) and, separately, results 3 and 4 (paired t-test).

#### Setting and participants

Patients were recruited at three hospital sites across National Health Service (NHS) Fife where patients receive HD. We aimed to recruit 40 patients with a mix of ages, dialysis vintages and genders, expecting that ~30 would complete the study intervention and assessments. All ESRD patients in NHS Fife currently receiving HD were deemed eligible for inclusion. Patients were excluded for the following reasons: consistent hyper-hypotension, recent cardiac event (in the preceding 6 weeks), known aortic aneurysm (of any size), unstable angina or significant vascular disease, current infectious illness, poorly controlled diabetes, active liver disease, breathlessness at rest with visible signs of peripheral oedema, physical disability including unilateral or bilateral amputation, pacemaker dependence, osteoporosis or history of low-trauma fragility fractures and persistent hyperkalaemia before HD. The study was given a favourable opinion from the North of Scotland NHS Research Ethics Committee.

#### Measurements

We specifically measured

i. Sit-to-stand (the number of repeated manoeuvres that can be achieved in 60 s (STS-60)).
ii. Standing equilibrium measured as a score out of 28 using the Tinetti balance assessment tool [19].
iii. Hand grip strength of the dominant hand using a dynamometer (lbs). Following a practice attempt the mean was calculated from two further attempts.
iv. Duke Activity Status Index (DASI), which correlates with peak oxygen uptake (Peak VO₂) [20].

#### Nutrition assessments

a. Skinfold calipers to estimate the proportion of body fat and lean body mass (two sites: biceps, triceps) using the equations of Durnin and Womersley [21].

b. Calf circumference.

c. Upper arm circumference.

#### Bone health

a. Alkaline phosphatase (ALP), calcium adjusted, phosphate, parathyroid hormone (PTH) (from routinely collected blood measures).

b. Protein catabolic rate (from routinely collected blood measures).

c. Urea reduction ratio (URR) measured pre- and 8-weeks post-exercise only.
The physical measures were made by one observer (N.D.) who was blinded to previous results. Blood pressure before and after each exercise session was monitored for safety. In addition, blood results were monitored monthly for calcium, phosphate, PTH, ALP, full blood count (FBC) and protein catabolic rate to monitor dialysis adequacy.

Quality of life

We assessed quality of life using the 12 disease-specific domains from the self-administered short form of the Kidney Disease Quality of Life (KDQOL-SF) questionnaire [22]. The domains were burden of kidney disease (BD), symptoms listed (SL), effects of kidney disease (EKD), sleep overall (SO), health overall (HO), satisfaction with care (SWC), cognitive function (CF), quality of social interaction (QSI), quality of social support (QSS), dialysis staff encouragement (DSE), work status (WS) and sexual function (SF). The item scores contributing to each domain were transformed into a 0–100 scale, with lower values indicating a poorer health state.

Vibration exercise

The WBVE equipment (ifit Pro) is programmable and has safety hand grips. The WBVE comprised three sessions of 3 min/week, with a graded introduction to achieve 3 min of maximum isometric exercise. The ‘dose’ of exercise was a pragmatic choice, as was the length of the intervention and the period of layoff. The vibration plate was set at a frequency of 50 Hz and a vertical displacement of 10 mm, in line with published levels of effectiveness [18]. Patients were trained in the technique by HD nursing staff proficient in the exercise protocol. Each patient exercised unsupervised (unless they requested assistance from the nursing staff) for 3 min prior to their thrice-weekly dialysis session, for a period of 8 weeks (24 sessions in total).

At the end of the study, or when patients dropped out, they were given a self-administered questionnaire to ascertain their views on and experiences with using the WBVE equipment. Acceptability of the intervention was determined using this post-study questionnaire, which asked patients whether or not they would like to continue using the device and recommend it to others.

Data analysis

Data were analysed with SPSS (version 20; IBM, Armonk, NY, USA) using parametric tests (paired and unpaired t-tests) and non-parametric tests according to the distribution of the data, which was assessed by the Shapiro–Wilk test. Paired t-tests were used to compare observed differences with a hypothesized mean difference of zero. Analysis of covariance was used to adjust for initial levels of function and explore differences due to potential confounders such as age, gender, length of time dependent on dialysis and compliance with the exercise regime. A level of 5% indicated statistical significance. We elected not to use a Bonferroni correction for multiple testing because the principal aim of our pilot study was to estimate the magnitude of the effects of vibration exercise on various measures that were likely to be interrelated.

Results

All patients receiving HD across NHS Fife (n = 162) were invited by letter to take part in the study, of which 89 (55%) expressed an interest. Of these, 27 (30%) were deemed ineligible after discussion with the patient and/or their consultant upon reviewing the exclusion criteria. Of the 62 remaining patients, 49 enrolled in the study (22 females, 27 males). Age varied from 24 to 92 years (mean 65, median 70). Months on dialysis varied from <1 to 145 months (mean 40, median 33). Subsequently, 25 patients (51%) completed all assessments and 24 (49%) withdrew (Figure 1). Those who withdrew were, on average, older by 8.4 years [95% confidence interval (CI) 0.01–16.9; P = 0.049], had a greater risk of a fall [mean difference in Tinetti score –2.4 (95% CI –0.2 to –4.7); P = 0.031] and had a poorer performance on the STS-60 test [mean difference –3.9 (95% CI 0.9 to –8.80; P = 0.11). Of those who originally joined the study, 54% of females and 48% of males completed the assessments (difference in proportions; P = 0.66).

Reproducibility

In all, 41 patients attended visits 1 and 2 (Table 1). The STS-60 was significantly greater by, on average, 1.5 events on the repeat occasion (P = 0.003), suggesting a training effect.

Quality of life

A total of 42 patients completed the KDQOL questionnaire at baseline. All but the SO domain were skewed in distribution. There were no significant differences in any of the domains between those who completed the study (n = 22) and those who withdrew (n = 20) (P > 0.08, Mann–Whitney U test). Only four of those who completed the study were currently working and only eight completed the SF question on the KDQOL. Hence, these aspects were dropped from the analysis.

Effect of WBVE

In all, 14 of the 25 patients who finished the study (56%) completed all 24 exercise sessions (three times per week for 8 weeks). A further seven patients missed only one session. The minimum number of sessions completed was 20. Following the 8-week intervention the STS-60 improved significantly by ~11% (P = 0.002) (Table 2). In an analysis of covariance, there were no significant relationships between the change of physical measures and age, gender or months on HD after allowance for the initial level of any of the physical outcome measures. The SL and HO improved significantly following the 8-week exercise period (Table 2).

The URR did not differ significantly following the 8-week exercise intervention [mean change 0.56 (SD 4.1), P = 0.49]. Markers of bone health and the protein catabolic rate did not change significantly following the 8-week exercise intervention (Table 3).

After 4 weeks of abstinence from the vibration exercise, the improvement in the STS-60 was maintained (Table 4). Only the handgrip strength showed any significant change, although that was an increase of 7% (P = 0.044). The score for SL declined marginally, indicating an increase in symptoms reported (P = 0.052). There was no significant change in the protein catabolic rate or in any of the markers of bone health (P > 0.3, data not shown).

Post-study questionnaire replies

Post-study questionnaires were returned by 38 participants. Of 24 patients who completed the study and returned a questionnaire, 20 wished to continue using the vibration exercise device and would recommend it to others. Of 14 patients who
dropped out, 10 wished to resume using the exercise device and 12 would recommend it to others. Hence, overall, 32 patients from the potential pool of 49 participants (65%) would recommend WBVE as an acceptable form of exercise. When asked ‘In general how did you get on using the vibration exercise equipment’, most had a positive experience, for example: ‘I managed it ok. It was an easy form of exercise’; ‘Aye, it was fun’; ‘Yes, I felt a difference using it’; ‘Very easy to use and does not leave you tired and short of breath’; ‘It was ok. First couple of times was difficult due to my poor balance but after that it was ok’; ‘Good at first. Seemed to loosen by back and legs’ and ‘It was good, fine and easy to work. A couple of times after dialysis I would have liked to go on again. My legs felt good’.

However, some patients were less enthusiastic: ‘Fine until I tried it on my own, then the machine went “bananas”’; ‘Fine,
but felt I could be doing something more energetic' and 'Fed up by week 4'.

Most patients (25/38) had no problems using the device. Comments made by others included: 'I had to ensure colostomy bag was empty and dentures were secure'; 'I had to stop using it, I felt very dizzy'; 'Poor eyesight, trouble seeing buttons'; 'Unsure of where the start button was. I wasn’t too sure about all the settings. You had to be careful stepping on and off it' and 'Pressed the wrong buttons sometimes'.

For eight patients, the extra time spent in the dialysis unit was a problem, for example: 'I was held up from starting dialysis' and 'Sometimes time-wise was a problem, as we were getting shouted in for dialysis'.

**Discussion**

This study has shown that vibration exercise is a form of physical activity acceptable by most, but not all patients receiving HD. Of the 89 patients who expressed an interest in the study, 30% were considered ineligible, in keeping with a recent systematic review and meta-analysis that reported 25% as being ineligible for an exercise programme [23]. However, the dropout rate from our 8-week programme was 49%, which was higher than the average of 15% noted in the review [23]. Reasons for the discrepancy may relate to differences between studies in the severity of renal disease, patient frailty, age distribution and co-morbidities. In general, it is recognized that those enrolling in exercise programmes are fitter and younger and may already be engaged in regular leisure time activity. Our results suggested that, compared with those who remained in the programme, those who dropped out were, on average, older and likely more frail. However, these individuals may be expected to have the most to gain from a supervised, hospital-based exercise programme, and it was of interest that 10 of the 14 dropouts who returned questionnaires after the study expressed a wish to resume the vibration exercise.

Overall, the vibration exercise intensity of 3 min a day three times a week prior to the HD session was simple to deliver and safe. Of 24 patients who dropped out of the programme, 6 had an adverse event, although only one was directly related to the exercise study, where a patient experienced nausea after using the vibration exercise device (Figure 1). This is consistent with a recent systematic review of WBVE in elderly patients that found no safety concerns or serious adverse events [18].

<table>
<thead>
<tr>
<th>Test</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Change 8 weeks post-exercise</th>
<th>P-value</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
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<tr>
<td>Tinniti</td>
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<td>23.9</td>
<td>3.1</td>
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<td>STS-60 (s)</td>
<td>24</td>
<td>19.7</td>
<td>8.7</td>
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<td>Weight (kg)</td>
<td>25</td>
<td>76.2</td>
<td>16.7</td>
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<td>1.9</td>
<td>0.5–1.0</td>
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<td>Calf circumference (cm)</td>
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<td>37.6</td>
<td>4.6</td>
<td>0.10</td>
<td>0.70</td>
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<td>Upper arm circumference (cm)</td>
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<td>31.2</td>
<td>4.4</td>
<td>0.10</td>
<td>1.05</td>
<td>0.3–0.5</td>
<td>0.65</td>
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<td>Hand grip strength (lbs)</td>
<td>24</td>
<td>46.0</td>
<td>19.1</td>
<td>2.4</td>
<td>8.1</td>
<td>1.0–5.8</td>
<td>0.16</td>
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<td>Peak VO2 (mL/min)</td>
<td>20</td>
<td>20.4</td>
<td>7.0</td>
<td>0.38</td>
<td>3.56</td>
<td>1.3–2.0</td>
<td>0.64</td>
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<td>Fat (%)</td>
<td>24</td>
<td>29.5</td>
<td>8.2</td>
<td>0.4</td>
<td>1.4</td>
<td>0.1–1.1</td>
<td>0.097</td>
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<td>Fat free mass (kg)</td>
<td>24</td>
<td>53.4</td>
<td>9.9</td>
<td>–0.4</td>
<td>1.4</td>
<td>–1.0–0.1</td>
<td>0.11</td>
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Quality of life

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<th>Test</th>
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<th>SD</th>
<th>Change 8 weeks post-exercise</th>
<th>P-value</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
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<tr>
<td>BD</td>
<td>20</td>
<td>46.5</td>
<td>38.1</td>
<td>–2.2</td>
<td>22.2</td>
<td>–12.6–8.2</td>
<td>0.66</td>
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<tr>
<td>SL</td>
<td>20</td>
<td>74.2</td>
<td>21.4</td>
<td>5.7</td>
<td>12.1</td>
<td>0.0–11.3</td>
<td>0.050</td>
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<tr>
<td>EKD</td>
<td>20</td>
<td>64.7</td>
<td>24.5</td>
<td>3.4</td>
<td>14.0</td>
<td>–3.1–10.0</td>
<td>0.28</td>
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<tr>
<td>SO</td>
<td>20</td>
<td>56.5</td>
<td>22.3</td>
<td>2.2</td>
<td>13.5</td>
<td>–4.8–1.5</td>
<td>0.47</td>
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<tr>
<td>HO</td>
<td>20</td>
<td>54.5</td>
<td>23.7</td>
<td>5.5</td>
<td>10.0</td>
<td>0.8–10.2</td>
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<td>SWC</td>
<td>18</td>
<td>75.0</td>
<td>22.3</td>
<td>0.0</td>
<td>18.1</td>
<td>–9.0–9.0</td>
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<td>CF</td>
<td>20</td>
<td>81.7</td>
<td>24.3</td>
<td>–0.3</td>
<td>21.0</td>
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<td>QSI</td>
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<td>16.2</td>
<td>–3.7</td>
<td>17.4</td>
<td>–11.8–4.4</td>
<td>0.36</td>
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<tr>
<td>QSS</td>
<td>20</td>
<td>74.2</td>
<td>27.3</td>
<td>–10.6</td>
<td>25.5</td>
<td>–22.8–1.1</td>
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<td>DSE</td>
<td>20</td>
<td>85.0</td>
<td>16.5</td>
<td>0.0</td>
<td>21.8</td>
<td>–10.2–10.2</td>
<td>1.0</td>
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</tbody>
</table>

Table 2. Change in physical measures and quality of life following 8-weeks of vibration exercise (n = 25)

Table 3. Change in markers of bone health and protein catabolic rate following 8-weeks of vibration exercise (n = 25)

<table>
<thead>
<tr>
<th>Test</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Change 8 weeks post-exercise</th>
<th>P-value</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
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<tr>
<td>ALP (U/L)</td>
<td>25</td>
<td>105.60</td>
<td>55.4</td>
<td>–0.84</td>
<td>15.8</td>
<td>–7.4–5.70</td>
<td>0.79</td>
<td></td>
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<tr>
<td>Ca adjusted (mmol/L)</td>
<td>25</td>
<td>2.27</td>
<td>0.33</td>
<td>–0.003</td>
<td>0.28</td>
<td>–1.12–0.11</td>
<td>0.95</td>
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<tr>
<td>Phosphate (mmol/L)</td>
<td>25</td>
<td>1.64</td>
<td>0.46</td>
<td>–0.10</td>
<td>0.55</td>
<td>–0.33–0.13</td>
<td>0.37</td>
<td></td>
</tr>
<tr>
<td>PTH (pmol/L)</td>
<td>25</td>
<td>20.79</td>
<td>35.0</td>
<td>6.20</td>
<td>28.9</td>
<td>–5.7–18.10</td>
<td>0.29</td>
<td></td>
</tr>
<tr>
<td>Protein catabolic rate (g/day)</td>
<td>25</td>
<td>62.10</td>
<td>16.0</td>
<td>–3.90</td>
<td>15.1</td>
<td>–10.6–2.90</td>
<td>0.24</td>
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</tbody>
</table>

*aMean of visits 1 and 2 for the baseline measures. VO2, oxygen uptake.*
remaining adverse events or medical reasons for withdrawal was due to the WBVE intervention itself. However, three patients cited a perceived time constraint as a reason for withdrawal, which may be a noteworthy barrier to patient engagement with a WBVE programme delivered at the time of attendance for HD.

Of the physical measures, we noted a small but significant improvement in the STS-60 test, which was maintained 4 weeks after the vibration exercise stopped. This is consistent with traditional exercise modalities in HD patients [24, 25]. A pilot study in 22 patients attending a satellite HD unit in Australia showed a small but statistically significant improvement of 2.4 manoeuvres in the 30-s STS test following a 4-month supervised exercise intervention consisting of cycling and resistance training (P = 0.0006) [24]. Similarly, an RCT from Canada assessing two traditional exercise modalities over a 24-week intervention period showed a small improvement in the 30-s STS test of 0.8 and 2.1 manoeuvres in the cycling (n = 20) and walking groups (n = 23), respectively (P < 0.005) [25]. In our study, the post-exercise score for the Tinetti balance test also showed some improvement, although the difference was not statistically significant (P = 0.075). However, a recent systematic review found an improvement in the Tinetti score of 4.5 points (95% CI 0.95–8.11) in elderly patients following WBVE [18]. In our repeatability study, the SD of the differences in the Tinetti test was 1.5 units and the average change following 8 weeks of vibration exercise was 0.8 U. We would need 72 patients in an RCT (36 per group) to detect a difference of 1 unit at a type I error rate of 5% and a type II error rate of 20% (80% power) [26]. With this number, we would have sufficient power to detect a difference in the STS-60 of two repetitions and in the calf circumference of 0.5 cm. However, allowing for a possible dropout rate of nearly 50%, we would need to recruit ~70 patients for each group.

HO and SL were the only domains in the KDQOL questionnaire to have improved significantly following the 8-week intervention period. There were no observed differences in the other domains of the KDQOL or the other physical measurements recorded. On planning our pilot study, we had considered it unlikely to have observed a significant difference in blood chemistry.

We believe our study is the first to assess the impact of WBVE in the HD population. We did not have a control group, but our purpose was to establish the acceptability of WBVE in patients with ESRD on HD. It was a pilot study, so it was not powered to detect a given magnitude of effect on physical function. The data generated did allow us to estimate an appropriate sample size for a properly powered RCT and to test methods and evaluate recruitment, potential outcome measures, compliance and likely dropout rates. Our choice of physical outcome measures and intensity of vibration exercise was pragmatic. We chose measures of both upper and lower body attributes, though in reality we did not expect change in upper body measures, including them merely to assess any potential change in general function over the course of the study. Any improvement was expected to relate to lower limb function as assessed by the Tinetti balance test and the STS-60. However, we accept that other measures exist that may have been more appropriate in this particular population. Vibration exercise appears to be a simple passive exercise modality, easily incorporated into the HD routine and evaluated by minimal staffing and patient training. Hence we consider an RCT is now warranted, using our results to assist its planning. Such a study may be most beneficial for newly diagnosed patients, incident to dialysis, who are known to suffer early decline in physical performance that may be avoided by vibration exercise.

**Conclusion**

We have shown that WBVE has the convenience of being applied in short bursts while patients attend hospitals for HD sessions. Overall, WBVE was acceptable and safe, though we
acknowledge there can be practical issues for some patients using the devices and the modality is not suitable for all patients. Further research is justified; if it can be shown that WBVE has utility in improving physical functioning and long-term outcomes, then the exercise modality could be incorporated into routine practice. We have provided key information for planning further studies on the suitability of our methodology in a robust RCT comparing WBVE with other modalities of exercise (e.g. self-managed rather than supervised exercise) and in comparing levels of intensity of vibration exercise necessary to achieve health gain. Finally, other studies might be devised to identify the usefulness of WBVE for maintaining physical function in new patients, as the evidence suggests their function will deteriorate markedly in the months following initiation of dialysis.

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Ethics approval
This study was given a favourable ethical opinion by the National Research Ethics Service North of Scotland Committee (REC reference 14/NS/1010; IRAS Project ID 150142). Written informed consent was obtained from all study participants.

Conflict of interest statement
The NHS Fife Research and Development office provided a bursary in support of the study, contributing to research nurse costs and the purchase of equipment. The senior research advisor for the NHS Fife Research and Development office, David Chinn, is one of the co-authors of the study responsible for study design, data analysis and interpretation, writing the report and the decision to submit the article to a peer-reviewed journal.

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