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Physiological, psychological and functional changes with whole body vibration exercise in the elderly: FEVER methodology and protocols

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ABSTRACT

Background: The FEVER (Frail Elderly Vibration Exercise Response) study aims to address a paucity of research focusing on the use of Whole Body Vibration (WBV) by frail elderly who, with the highest levels of dependence and fall-related hospitalisation/mortality, potentially stand to benefit most from such accessible exercise.
Methods: FEVER is an open, randomised feasibility study, consisting of multiple parallel arms and a longitudinal element. Rest-home residents aged 70+ years will be recruited, and assigned to a WBV-exercise group (WBV), a simulated-WBV-exercise group (SIM), or a control group (CON). WBV- and SIM-participants will undergo thrice-weekly sessions (<20-min each, including 1:1 ratio of exercise:rest) for a 16-week exercise intervention period, whilst CON-participants will receive no intervention beyond normal care. WBV-exercise will start with 5 * 1-minute sessions (6 Hz, 2 mm amplitude), progressing to 10 * 1-minute sessions at which time Hz/amplitude can be increased if desired. During WBV-exercise, participants will maintain an isometric knee flexion of ~20° (±5°), to dampen WBV further up the body.
Results: Outcomes will include assessments of functionality (primary outcome), Quality of Life, bone health and cardiovascular function. Measures will be conducted at baseline, 8-weeks and 16-weeks of the intervention, and 3-, 6- and 12-months post-intervention. As a protocol paper, there are no specific results to present; our current purpose is to share the study design with the scientific community.
Conclusions: The FEVER study aims to investigate the beneficial effects of WBV-exercise in the frail elderly, ascertain an effective training regime and for the first-time identify a time-line of detraining.

1. Rationale

The frail elderly (predominantly rest home residents, aged 70+ years) often exhibit poorer health and a higher burden of care than more-mobile/less-dependent healthy elderly. Their increased frailty means they are unable to exercise conventionally and gain the associated health and functional benefits, leading to reduced physical function and independence and culminating in a decreased Quality of Life (QoL). Consequently, falls and associated fractures are a particularly serious threat to the health and well-being of frail elderly, causing trauma, pain, impaired function, a loss of confidence in day-to-day living, a loss of independence, and even death [1]. The consequences of a fall are far reaching in the elderly, affecting not only their own lives but also those of relatives and carers; as the number of older New Zealanders increases, so too does the incidence of falls and ultimately the financial-burden placed on the public health system. Prescribed exercise interventions have been found to be successful in addressing these issues [2], but are often costly to run, labour-intensive, require highly skilled/trained practitioners and do not always encourage compliance.

At present in New Zealand there is no prescribed exercise intervention aimed at preventing falls or increasing physical function (or treating diseases such as sarcopenia and osteoporosis) in the frail elderly. This is because the frail elderly cannot undertake conventional exercise at an intensity to provide health benefits, and show the lowest compliance rates for such exercise [3]. Currently, the sole treatment prescribed for elderly New Zealanders, with respect to bone health and fall-prevention, is increased dietary calcium coupled with supplementation of vitamin D at 1.25 mg/month to decrease fractures from a fall. Consequently, a requirement exists for an easily accessible, widespread and cost-effective means of exercising the frail elderly safely, which will produce gains in QoL, physical function and a decreased risk/number of falls, yet still encourage a high level of compliance in this population.

Easy to use and relatively cheap to purchase, the demands of WBV exercise are minimal for both participant and practitioner — taking part in WBV exercise can be as simple as standing on a platform with knees flexed at approximately 20° for 1-minute bouts interspersed with 1-minute rest periods — making it an easily accessible activity for

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those with mobility problems or limited cognitive ability. Whole Body Vibration (WBV) has been deemed a safe and effective means of enhancing muscular strength and bone health in various populations, including sedentary persons [4] and the healthy/mobile elderly aged 60–75 years old [5,6]. Mechanical stresses to the bone caused by WBV are thought to enhance bone loading (stimulating osteogenesis), thus increasing bone mineral density and bone health [5,6]. With some studies showing no improved bone health as a result of WBV interventions [7–9], there remains a lack of clarity on the effects of WBV on this parameter. However, the Tonic Vibration Reflex proposes that WBV-stimulated muscle contractions and elevated localised blood flow can enhance anabolic hormone levels, further strengthening the musculoskeletal system [10], thus not just affecting bone health but also muscle strength and physical function. Moreover, WBV interventions in post-menopausal women and the healthy/mobile elderly (aged 60–75 years old) have brought about improvements in lower-limb muscular strength and associated functional performance and quality of life [5,6]. However, there is a paucity of research focusing specifically on the institutionalised, frail elderly who, with the highest levels of dependence and the highest rate of fall-related hospitalisation and mortality, would stand to benefit most from a well-developed, accessible treatment prescription utilising WBV exercise.

To-date research utilising WBV to enhance health and independence in the frail elderly remains sparse, with no clear treatment prescription identified. Studies [3,11–13] have shown WBV to improve functionality, quality of life, lower-limb muscle strength and bone health of frail elderly participants, coupled with a reduced fall-risk. Ultimately, differences in participants' levels of frailty, study protocol and limitations in study design have led researchers to conclude that the clinical, social, and functional effects of long-term WBV in the frail elderly remain unknown and more research is needed in order to develop a WBV programme in the frail elderly. Furthermore, there has been neither an investigation of any lasting effects after WBV-based exercise interventions have ceased, nor any attempt to identify a time-line of detraining.

Therefore, the aims of the FEVER (Frail Elderly Vibration Exercise Response) study are to establish i) an effective WBV-based treatment prescription programme to maximise improvements in physical function and quality of life in the frail elderly, ii) if the frail elderly undergo any maintenance of, or improvement in, bone health and/or muscle strength as a result of WBV training, iii) which beneficial effects (if any) are retained post-intervention, and iv) the time-course of detraining.

2. Study design

FEVER will be an open, randomised feasibility study. The study design consists of three parallel arms, is placebo-controlled, and includes a longitudinal response element. Fig. 1 presents a schematic time-line of the study design following initial participant recruitment. The study protocol has ethical approval from the Health and Disability Ethics Committee of New Zealand (12/NTB/78), and Universal Trial Registration (UTN: U1111-11367146).

2.1. Participants

A total of 180 frail elderly volunteers (60 per group; 216 total including 20% drop out) will be recruited from rest home facilities based in the Greater Wellington Region/Urban Centre. Eligible volunteers aged 70 years and older will undergo pre-screening for inclusion and exclusion criteria (Table 1) by consultant gerontologists and Clinical Managers/GPs associated with their place of residence. Briefly, eligible participants should be assessed as having a degree of 'frailty', meaning that they are unable to undertake everyday activities unaided, as defined by the Functional Ambulation Categories outlined by Holden et al. [14]. Transportation is a particular impediment to exercise in this population group [15]; in order to minimise disruption to participants, and thus encourage compliance, all exercise and assessment sessions will be completed in-situ within rest homes where possible, with participants transported to external assessments when required (e.g., DXA). The WBV machine remains in-situ at the participating rest home for the duration of the exercise intervention.

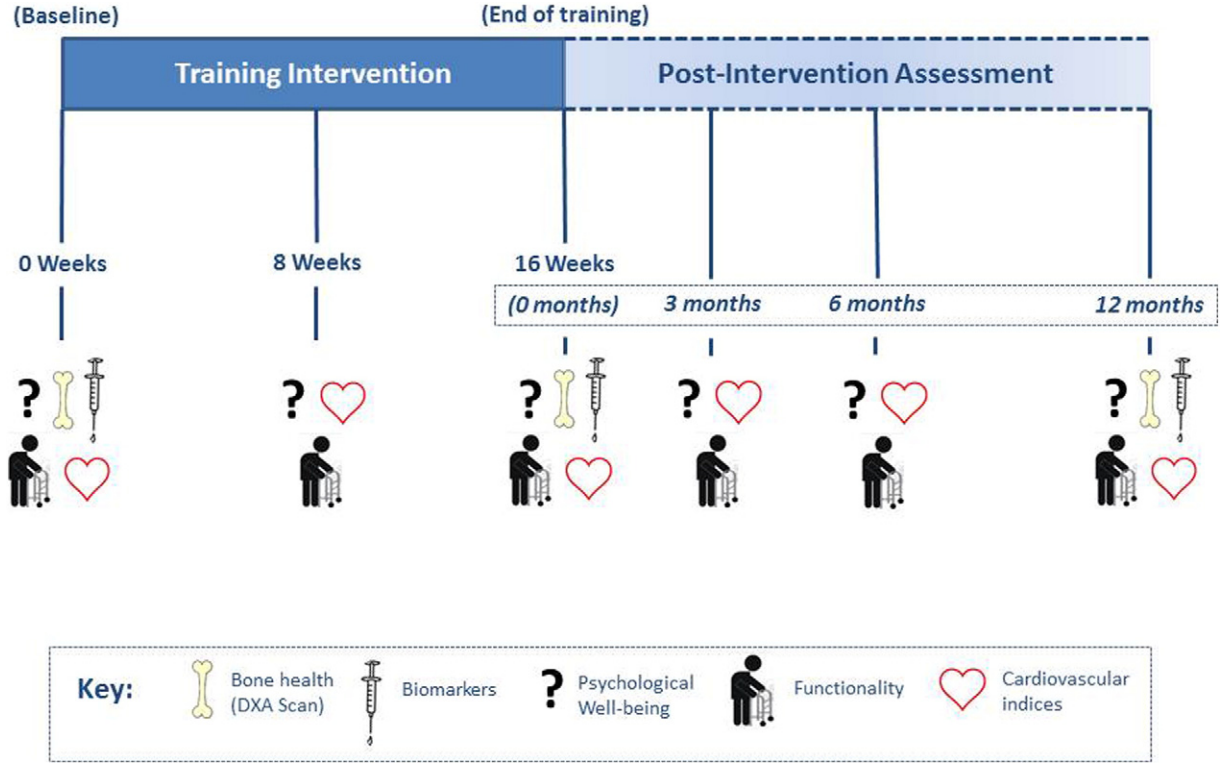

Fig. 1. Schematic time-line of the proposed study.