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## Testing the efficacy of a motor analogy designed to promote safe landing by older adults who fall accidentally: A randomized control study

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## TITLE PAGE

### Title

Testing the efficacy of a motor analogy designed to promote safe landing by older adults who fall accidentally: A randomized control study

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Original

1  
2  
3 **TESTING THE EFFICACY OF A MOTOR ANALOGY DESIGNED TO PROMOTE**  
4 **SAFE LANDING BY OLDER ADULTS WHO FALL ACCIDENTALLY:**  
5 **PROTOCOL FOR A RANDOMIZED CONTROL STUDY**  
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11 **ABSTRACT**  
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14 **Introduction:** Falling is associated with adverse effects on the health of older people. The  
15 majority of research into falls among older people has focused on prevention, with less  
16 attention to ‘how to fall safely’. Previous research suggests that motor analogies can be used  
17 to promote safe landing by young adults; however, the efficacy of this technique for older  
18 people remains unknown. This study aims to determine whether a motor analogy is useful for  
19 promoting safe falling in the older adult population.  
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28 **Methods and analysis:** The study adopts a randomized, controlled, single-blinded study  
29 design. People 65 years and older will be randomly allocated to a control condition or a motor  
30 analogy condition. They will receive an unexpected nudge in a forward, backward, or sideways  
31 direction (randomised order), which will initiate a fall (i.e., a simulation of an unexpected fall).  
32 Participants in the motor analogy condition will be instructed to ‘land like a feather’, whereas  
33 participants in the control condition will be instructed to ‘land safely’. The primary outcome  
34 parameters are maximum impact force (normalised by mass) applied to different body  
35 segments during impact and fracture risk ratio of wrists and hips. A 2-way MANOVA will be  
36 conducted to examine differences between the motor analogy and control conditions as a  
37 function of the different variables.  
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51 **Ethics and dissemination:** The University of Waikato Human Research Ethics Committee  
52 (Health 2021#45) has granted ethical approval. Outcomes will be disseminated through  
53 publication in peer-reviewed journals and presentations at conferences.  
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**Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12621001189819.

Registered on 6 September 2021.

**Keywords:** Older adults; Falls; Safe landing; Motor analogy

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- Single-blinded randomised controlled trial (the research assistant and participants are blinded to the conditions, but not the lead investigator)
- Investigates a promising novel method for reducing fall-related injuries in older adults
- The proposed method can be easily implemented alongside fall prevention programs or into health services attended by older adults.
- One limitation of this study is that frail older adults who do not pass the Physical Activity Readiness Questionnaire (PARQ+) are excluded from the study.

## INTRODUCTION

Accidental falls can adversely affect the health of older people and are second only to traffic incidents as the most common cause of death.<sup>1</sup> Millions of older adults fall each year. Not only are falls associated with high personal costs, such as reduced well-being, but also health care sectors are heavily burdened.<sup>2,3</sup> For instance, every year in New Zealand 18% of the total cost of injury is due to falls.<sup>4</sup> The government estimates that by the year 2025 fall related injuries will cost the country around \$418 million dollars annually.<sup>5</sup> Researchers and health care professionals have investigated various interventions to reduce the occurrence of falls; nevertheless, it is estimated that around 30-60% of older adults fall unexpectedly annually.<sup>6</sup> The complex nature of falls, combined with intrinsic (e.g., impaired balance, reduced cognitive status, poor vision, etc.) and extrinsic (e.g., slippery floors, loose rugs, poor lighting, etc.) risk factors, increases the difficulty of establishing effective fall prevention interventions.<sup>7</sup>

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3 In a systematic review and meta-analysis of multifactorial fall prevention programs,  
4 Hopewell et al. (2020) found that prevention programs may reduce fall rates, but have little to  
5 no effect on other fall-related consequences, such as fractures, hospital admission or medical  
6 attention and health-related quality of life.<sup>8</sup> To address the multidimensional nature of falls and  
7 to mitigate their negative effects on health, complementary approaches are needed to  
8 accompany fall prevention interventions. Consistent with this position, a small number of  
9 researchers have proposed that fall-related injuries can be reduced by learning ‘how to land  
10 safely’ when a fall occurs.<sup>9</sup> <sup>10</sup> A systematic review by Moon and Sosnoff <sup>10</sup> revealed that only  
11 thirteen studies have investigated safe landing techniques, and that most of the studies (12 out  
12 of 13) tested young adults rather than older adults. Landing techniques varied according to the  
13 direction of fall. For instance, to land safely from sideways falls, participants were instructed  
14 to use the martial arts technique of roll and slap.<sup>11-14</sup> Different techniques were instructed for  
15 forward (e.g., “land with a slightly flexed elbow angle”)<sup>15</sup> and backward (e.g., “bend the hips  
16 and knees”) falls.<sup>16</sup>

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36 Older adults generally learn more slowly than younger adults and fail to reach similar  
37 levels of expertise,<sup>17-19</sup> so their capacity to learn a different assortment of safe landing  
38 techniques that can be used appropriately when falling is questionable. For example, age-  
39 related declines in the ability to store and manage information (via working memory) <sup>19</sup> <sup>20</sup> make  
40 comprehension of explicit instructions (e.g., how to land safely) more challenging during  
41 learning. Additionally, older adults generally display impaired reaction times,<sup>21</sup> <sup>22</sup> which  
42 increases the difficulty associated with selecting and executing the appropriate technique  
43 during a fall. It takes approximately 0.3 seconds to recover balance when falling from standing  
44 height, with impact occurring after approximately 0.7 seconds if recovery is not possible,<sup>23</sup> so  
45 there is minimal opportunity between the balance recovery phase and impact with the ground  
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3 (i.e., 0.4 seconds) for older people to explicitly choose (and use) an appropriate safe landing  
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6 technique.

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Consequently, an approach to landing safely is required that involves less explicit information about technique and can be processed more quickly (i.e., less resource demanding). Motor analogies may achieve this goal. Analogies leverage a concept that is already well known by the learner in order to convey the complex structure of the motor skill.<sup>24 25</sup> Motor analogies are often used to teach movement skills to novices by comparing the movements with a similar, well-known concept, such as, “imagine you are putting a cookie in a cookie jar on a high shelf” (for a basketball free-throw)<sup>26</sup> or “strike the ball while bringing the bat up the hypotenuse of a triangle” (for a table tennis topspin forehand).<sup>24</sup> Such analogies are thought to promote implicit motor learning, which seeks to minimise accrual of conscious knowledge of the underlying rules governing the mechanics of movements.<sup>27 28</sup> Implicit motor learning has been shown to impose fewer demands on cognitive resources than explicit motor learning<sup>27 29</sup><sup>30</sup> and, importantly, has been shown to result in better learning by older adults.<sup>31 32</sup>

Motor analogies have been shown to be beneficial for skill learning in the older adult population, resulting in preserved skill level over time and robust performance under dual-task conditions.<sup>32</sup> They have also been used in rehabilitation settings to improve dynamic balance<sup>33</sup> and walking by Parkinson<sup>34</sup> and stroke<sup>35</sup> patients. These advantages have been attributed to the simplicity of retrieving analogies from memory<sup>36</sup> and the role they play in rapidly deploying attention during movement.<sup>37</sup> The potential for analogies to depute for explicit instructions, facilitate development of mental representations in long term memory,<sup>38</sup> reduce the demands associated with processing information (i.e., lower reliance on working memory)<sup>29 39-41</sup> and hasten processing time<sup>28</sup> makes them a compelling choice for learning safe landing strategies.

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3 Masters et al.<sup>42</sup> sought to develop a simple motor analogy that promotes safe landing in  
4 the event of a fall. They conducted focus group discussions with older fallers, physiotherapists,  
5 occupational therapists, martial artists, gymnasts, dancers, parkour enthusiasts, and health and  
6 safety experts. Analysis of the focus group transcripts revealed three common themes that were  
7 used to describe safe landing: ‘soft’, ‘silent’, ‘slow’. Based on these themes, two motor  
8 analogies with potential to promote soft, slow, silent landing were identified: *land like a*  
9 *snowflake* or *land like a feather*. In a previous experiment, we found that instructions to ‘land  
10 like a snowflake’ caused young adults to land more safely than control instructions (‘land on  
11 the ground’) when self-initiating falls.<sup>43</sup> In a second experiment, we found that instructions to  
12 ‘land like a feather’ caused young adults to land more safely than control instructions (‘land  
13 safely’) when falling unexpectedly.<sup>44</sup> To evaluate the quality of the landings, we attached  
14 inertial measurement units (IMU) to different body segments of participants and extracted  
15 measures that we used to calculate impact force and wrist fracture risk ratio. Participants  
16 allocated to the motor analogy condition landed with less force and were less likely to fracture  
17 a wrist (i.e., lower wrist fracture ratio) than participants allocated to the control condition,  
18 regardless of fall direction (forward, backward, sideways). These results suggest that  
19 participants allocated to the motor analogy condition were better able to adapt their movements  
20 to land safely.

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45 One of the main limitations of these studies was that the motor analogies were tested in  
46 a young population; it is yet to be seen whether motor analogies can be used to promote safer  
47 landing by older people. It is well-known that ageing is associated with progressive loss of  
48 functional capacity.<sup>45</sup> For instance, older people often show a decline in functional balance,<sup>46</sup>  
49 ability to learn skills,<sup>47</sup> and motor planning.<sup>48</sup> Hence, to account for individual differences in  
50 balance status in the proposed study, the primary researcher (a physiotherapist) will administer  
51 a short version of the Balance Evaluation Systems Test (Mini-BESTest), which is a clinical  
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3 balance tool used for identifying balance dysfunction.<sup>49</sup> Participants will also complete an  
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5 Activities-specific Balance Confidence (ABC) scale, which is a valid and reliable self-  
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7 estimation tool for assessing the balance status of older adults with respect to falling.<sup>50 51</sup>  
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10 Furthermore, the Movement Specific Reinvestment Scale (MSRS)<sup>52</sup> will be administered to  
11  
12 gain insight into individual differences in movement planning; the propensity that older people  
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14 have for movement specific reinvestment has been linked to a need for more time to “plan”  
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16 future movements.<sup>53</sup> Alongside the biomechanical variables used for assessing safe landing,  
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18 the assessment of functional balance (Mini-BESTest, ABC scale) and propensity for  
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20 reinvestment (MSRS) will provide valuable information to understand the effectiveness of our  
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22 motor analogy with respect to older adults.  
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27 The goal of this research is to determine whether older people land more safely (i.e.,  
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29 with less risk of injury) when they are encouraged to use a motor analogy, ‘land like a feather’,  
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31 if they fall. Based on our previous experiments, we hypothesise that:  
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- 34 • Maximum acceleration (impact force normalised by mass) of various body segments  
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36 (upper arms, wrists, hands, hips, thighs, and legs) will be significantly lower across all  
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38 fall directions (forward, backward, sideways) in the motor analogy condition compared  
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40 to the control condition  
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- 43 • Fracture risk ratio (ratio of force at impact divided by the load necessary to cause a  
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45 fracture) of the hips and wrists will be significantly lower in the motor analogy  
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47 condition compared to the control condition  
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## 51 52 **METHOD**

### 53 **Study design**

54 This study is a randomized, controlled, single-blinded study for participants aged 65 years and  
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56 older. The University of Waikato Human Research Ethics Committee (Health 2021#45)  
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58 approved the study protocol. After assessment of cognition, functional balance, and physical  
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3 activity readiness, participants will be randomly allocated to a motor analogy condition or a  
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5 control condition.  
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### 8 **Population**

9 The study population will be older adults without leg and/or foot amputation who are able to  
10 stand and ambulate without walking aids. Participants will be required to have the ability to  
11 stand without help for 1 minute and to walk without a walking aid for 6 meters. Furthermore,  
12 all participants should be able to communicate in English, with no psychiatric or neurological  
13 impairments that prohibit participation. To screen for dementia, a score above 3 on the Mini-  
14 Cog test will be required. The Mini-Cog test has been validated for dementia screening (a score  
15 between 1 to 3 is considered “possibly impaired”, and a score above 3 is considered “probably  
16 normal”).<sup>54</sup> To screen for physical activity limitations, the researcher will administer a physical  
17 activity readiness questionnaire (PARQ<sup>+</sup>). The PARQ<sup>+</sup> offers safe screening of older adults  
18 prior to engaging in exercise or physical activity.<sup>55 56</sup> Participants who answer ‘yes’ to 2 or  
19 more of the PARQ<sup>+</sup> questions (i.e., require a doctor consultation for physical activity) will be  
20 excluded.  
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### 38 **Randomisation procedure and Blinding**

#### 39 Randomisation procedure

40 All participants who fulfil the inclusion criteria will be randomly assigned to either the motor  
41 analogy condition or the control condition using a random generator computer program. The  
42 randomization procedure (and outcome) will only be available to the lead investigator, who  
43 will not share this information with the participants or the research assistant.  
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#### 50 Blinding

51 The research assistant who will be delivering the nudge that causes the participant to fall onto  
52 the padded surface will be blind to whether the participant has been allocated to the motor  
53 analogy condition or the control condition. Participants will not be informed about the  
54 experimental condition to which they have been assigned (motor analogy or control).  
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3 Participants will also be blind to the direction in which they will be nudged  
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5 (forward/backward/sideways).  
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### 8 **Measurements and instrumentation**

9 A 2D video camera (Canon, 25 frames per second) and Delsys Trigno™ (Delsys Inc., Natick,  
10 MA) inertial measurement units (IMU) will be used for data collection. The video camera will  
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12 be positioned 3 meters from the left side of participants on a tripod (height 1.3 meters). The  
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14 researcher will place IMU sensors on 15 different body segments. Acceleration data from the  
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16 IMU sensors will be recorded at a frequency of 148.15 Hz using EMGworks Acquisition  
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18 software (Version 4.5.4). A hand-held dynamometer (MyoMeter, M550; range: 0-50 kg) will  
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20 be used to record the force applied when nudging participants to initiate each fall.  
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### 26 **Procedure**

27 Eligible participants will be invited to the human performance science lab at the University of  
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29 Waikato for a data collection session that will last around 70-80 minutes. Figure 1 provides a  
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31 flow diagram to illustrate the stages of data collection. Each consecutive component of the  
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33 diagram is described in the subsequent section (e.g., Demographics, Questionnaires, Sensor  
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35 placement etc).  
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#### 40 **Demographics**

41 At the beginning of the data collection session, demographic information will be collected: age,  
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43 gender, height (cm), mass (kg), history of fall, walking aids, and educational level.  
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#### 46 **Questionnaires**

47 Two psychometric questionnaires will be administered:  
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51 1. Activities-specific Balance Confidence (ABC) scale: This 16-item scale assesses confidence  
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53 in ability to maintain balance during a range of indoor and outdoor functional activities (e.g.,  
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55 “How confident are you that you will not lose your balance or become unsteady when you walk  
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57 around the house?”). The items of the scale are rated from 0% (lowest level of confidence) to  
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3 100% (highest level of confidence). This scale is a valid and reliable tool for measuring balance  
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5 confidence in older adults.<sup>57</sup>  
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9 2. Movement Specific Reinvestment Scale (MSRS): This scale comprises 10 items divided into  
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11 two subscales. The Conscious Motor Processing subscale measures propensity to consciously  
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13 control movements (e.g., “I try to think about my movements when I carry them out”). The  
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15 Movement Self-consciousness subscale measures propensity to monitor “style” of movement  
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17 (e.g., “I am self-conscious about the way I look when I am moving”). The items are rated on a  
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19 6-point Likert scale from strongly disagree (1) to strongly agree (6). Thus, cumulative scores  
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21 range from 10 to 60, with higher scores reflecting higher propensity for movement-specific  
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23 reinvestment. The MSRS has been shown to have high internal consistency and test–retest  
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25 reliability.<sup>58</sup>  
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### 30 Sensor placement

31 Fifteen IMU sensors will be attached over the following body segments using double-sided  
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33 tape: head, chest (aligned with the sternum), lower back (aligned with L3), upper arms (dorsal),  
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35 wrists (dorsal), hands (dorsal), hips (greater trochanter) thighs (lateral), lower legs (lateral).  
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38 Figure 2 demonstrates the placement of the IMU sensors on the participants.  
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### 41 Mini-BESTest

42 The researcher will administer a short version of the Balance Evaluation Systems Test (Mini-  
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44 BESTest), which is a standardized clinical balance tool used to assess functional balance.<sup>59-62</sup>  
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47 This test has a maximum score of 28 points, with higher scores indicating better balance.  
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### 50 Crossword puzzle

51 Participants in the motor analogy condition will be required to complete a three-word  
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53 crossword puzzle designed to prime them about how feathers land on the ground: soft, slow,  
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55 silent (Figure 3, Panel A). Participants in the control condition will be asked to complete a  
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57 similar crossword puzzle that uses names of birds as neutral primes: swallow, shag, swan  
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59 (Figure 3, Panel B).  
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### Experimental conditions

Participants in the motor analogy condition will be instructed to “land like a feather”, whereas participants in the control condition will be instructed to “land safely”. They will stand on a surface-level platform (27cm x 32cm) facing a fully padded landing area. A research assistant will apply a gentle impulse (nudge) to the left shoulder of participants, who will be instructed to fall in the direction in which the nudge is applied. The nudge will be applied in a forward, backward, or sideways direction. Order of fall direction will be randomized using a random order generator. The research assistant will be blinded to condition (motor analogy/control) and each nudge will be applied using a hand-held dynamometer. The force required to initiate each fall will be recorded and used as a covariate in the statistical analysis to control for potential differences in nudge force. To reduce the likelihood that participants will anticipate the nudge, they will be required to count backwards in 3’s during each trial (a concurrent secondary task). Nudges will occur at variable time points during counting. The experimental procedure will be repeated twice (with a different order of falls on each occasion). Hence, each participant will fall six times during the experimental procedure.

### Public involvement Statement

Initially, people with an interest in falling (e.g., older adults, health care professionals, physiotherapists, fall experts etc) were consulted about safe landing via focus groups. Key themes were used to design motor analogies with potential to facilitate safe landing in the event of a fall. After testing the efficacy of the motor analogies using young adults, we consulted with fall prevention leaders in NZ about testing the analogies in older adults. We also engaged with the community through fall prevention classes and retirement homes, with a goal to determine the level of interest that older adults have in safe landing, and to take their feedback into account when designing the proposed study. We plan to disseminate our findings among fall prevention leaders and interested older adults who have provided us with their contact information.

### Primary outcome

The acceleration data recorded by the IMUs will be exported in excel format and processed using Matlab (R2017b, MathWorks Inc., Natic, USA). Start of fall (Start) and end of fall (End) will be extracted from a one-dimensional signal magnitude acceleration vector (SMV) of the lower back unit. Figure 4 displays exemplar data from a backward fall.

To determine the beginning and end of a fall, a threshold will be calculated using a 100 ms moving window applied to the SMV data. Subsequently, the relative standard deviation (RSD) of the windows will be calculated. The generated RSDs will be averaged and used as a threshold for identifying the start and the end of the fall for each trial. RSD has previously been used to compute thresholds for identifying cancer cells,<sup>63</sup> optic-nerve signals,<sup>64</sup> and in various human motion dynamics studies.<sup>65</sup> The start of the fall will be defined as the trench before the SMV reaches its maximum value ( $SMV_{max}$ )<sup>66 67</sup> outlined by the SMV crossing the threshold. The end of the fall will be defined as the SMV crossing the threshold after it reaches its maximum value ( $SMV_{max}$ ). The start and end of fall identification method will be verified using the video recordings. Maximum acceleration ( $SMV_{max, g}$ ) will be extracted from all 15 IMUs.

The fracture risk of different body parts depends on the severity of the impact and the capacity of the bones to resist the impact.<sup>68</sup> Therefore, fracture risk ratio will be defined as the ratio of force at impact divided by the load necessary to cause a fracture.<sup>69 70</sup> To calculate the force applied to the wrists and hips, the SMV of the wrist units at time of impact will be multiplied by the scaling factors for the forearm and femoral head mass (%mass) provided by Dumas et al.,<sup>71</sup> and then multiplied by 9.807 (convert g to  $m/s^2$ ). Finally, the force applied to the participant's wrist and hip IMUs will be divided by the load required to fracture the radius bone and femur head based on cadaveric studies.<sup>72</sup>

### Sample size

Sample size estimation was conducted using a customisable statistical spreadsheet (xSampleSize.xlsx, www.sportsci.org). Sample size requirements were calculated from standard two-tailed hypothesis equations using an 80% power ( $\beta = 0.20$ ), and 5% significance level ( $\alpha = 0.05$ ). We used data from our previous research with young adults (smallest difference=0.22 m/s<sup>2</sup>; within subject SD= 0.28 m/s<sup>2</sup>; between subject SD=0.32 m/s<sup>2</sup>) for the calculations, with maximum acceleration (impact force normalised by mass) as our primary outcome. The calculations resulted in a minimum group size of 32 participants per condition. To account for 20% attrition rate, this study aims to recruit 38 participants per condition.

### Data integrity and analysis

The lead investigator will monitor data integrity by regularly examining data files for omissions and errors. The demographics, questionnaire scores, and outcome measures will be used to compare the conditions (motor analogy vs control). The means and SD of variables will be calculated and differences between the conditions will be examined using IBM SPSS Statistics 25 (IBM SPSS Statistics Software). A two-way between-groups multivariate analysis of variance (MANOVA) will be conducted to explore the effect of condition (motor analogy, control) and fall direction (forward, backward, sideways) on the following variables of interest:  $SMV_{max}$  (g) of the 15 IMUs located on the body segments displayed in Figure 2. Significant main effects and interactions will be further scrutinised using analysis of variance (ANOVA) of variables separately. To control for the multiplicity problem caused by conducting multiple statistical tests, the Benjamini–Hochberg (B-H) method will be used to control the alpha level using successive modified Bonferroni corrections.<sup>73</sup> All participants will be included in the analyses and will be given an anonymous participation ID to protect confidentiality. Only study investigators will have access to the raw data. All datasets used or analysed during this study will be available from the corresponding author upon reasonable request.

## DISCUSSION

Falls can cause significant health problems for older adults and can result in frailty, immobility, and decline in functional ability. The use of motor analogies to promote safe(r) landing is promising approach that has potential to reduce the severity of injuries that occur during accidental falls. In this paper, we described the methodology for a randomized controlled single-blinded study that investigates the efficacy of using a motor analogy to promote safer landing by older adults.

The project requires work with older people; hence, extreme caution is required to ensure the safety of our participants. One of the conditions of participation in this study is that participants can walk without assistance for at least 6 meters (twice the length of the 3-meter walk test in the Min-BESTest) in a controlled laboratory environment. Older people who cannot walk for 6 meters without assistance, or stand without a walking aid for at least one minute, will be excluded from the study. Thus, the exclusion criterion requires the participants to be comfortable when walking and standing independently. Additionally, we will administer the PARQ<sup>+</sup> and participants who answer 'yes' to 2 or more of the questions will be excluded. The PARQ<sup>+</sup> is sensitive to underlying conditions, such as osteoporosis, cardiovascular problems, respiratory disease, previous surgery, arthritis, chronic conditions, high blood pressure, back problems, stroke, etc. Therefore, if a participant is not in a healthy physical condition, they will not participate. This approach therefore excludes frail older adults from our participant pool, which is necessary due to the risk of injury associated with our fall intervention.

In studies that examine older people, criteria often are designed to exclude those with cognitive impairments. However, previous studies have reported that motor learning interventions can be effective for people with cognitive and/or communicative impairments.<sup>74</sup> In this study, we therefore attempt to include a sample that is more representative of older



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3 adults. A mini cognition test (Mini-Cog) will be administered to assess the likelihood of  
4 dementia. A score between 1 to 3 is considered “possibly impaired”, and a score above 3 is  
5 considered “probably normal”.<sup>54</sup> Only participants who score below the cut-off point of 3 will  
6 be excluded; hence, this will provide us an opportunity to assess the effect of motor analogies  
7 on older adults within different ranges of cognition, which is consistent with our ultimate goal  
8 to develop a simple solution for safe landing that is applicable to the widest possible audience.  
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17 **AUTHORS’ CONTRIBUTIONS** The idea and rationale that underpins the work was  
18 generated by R.S.W.M.; S.O. is a PhD student who is supervised by R.S.W.M. (Chief  
19 Supervisor), L.U. (Secondary Supervisor), and K. H-L. (Secondary Supervisor); S.O. wrote the  
20 manuscript with support from R.S.W.M., L.U., and K. H-L.; all of the authors have advised on  
21 study design and methodology, and will contribute to analysis, interpretation and dissemination  
22 of the findings.  
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31 **FUNDING** This work is part of a programme of research led by R.S.W.M., which is supported  
32 by a charitable donation from Freemason’s New Zealand.  
33  
34  
35

36 **AWARD/GRANT NUMBER** N/A  
37  
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39 **COMPETING INTERESTS** None declared  
40  
41

42 **PROTOCOL AMENDMENTS** Any change to the protocol will be communicated with the  
43 University of Waikato Human Research Ethics Committee (Health) and the Australian New  
44 Zealand Clinical Trials Registry (ANZCTR).  
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#### 50 **FIGURE CAPTIONS:**

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53 Figure 1: Flow diagram of the data collection session.  
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56 Figure 2: Positioning of inertial measurement units on different body segments.  
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Figure 3: Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

Figure 4: Signal magnitude vector (SMV) of the lower back inertial measurement unit during an unexpected backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

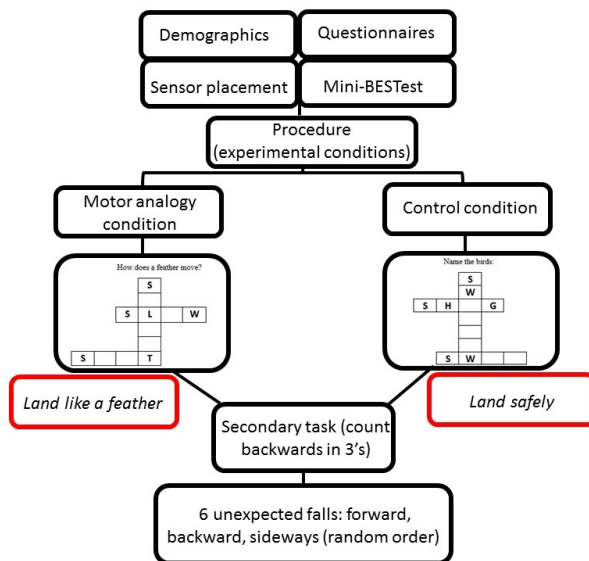
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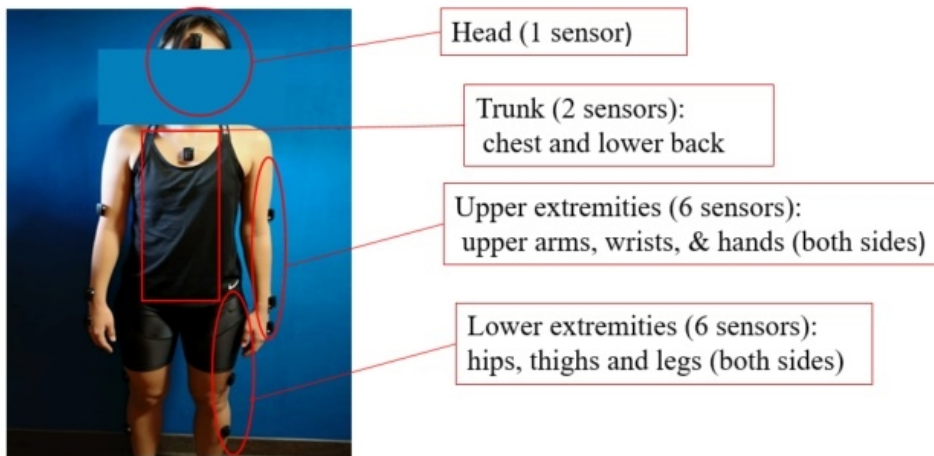
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Flow diagram of the data collection session.

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Positioning of inertial measurement units on different body segments

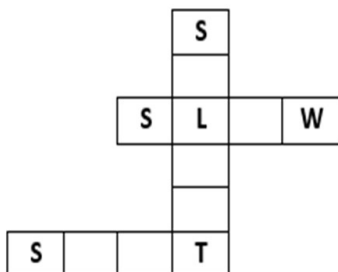
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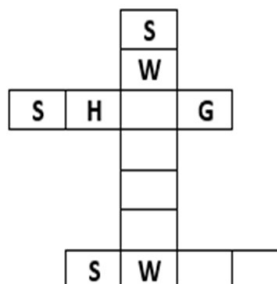
**Panel A**

How does a feather move?



**Panel B**

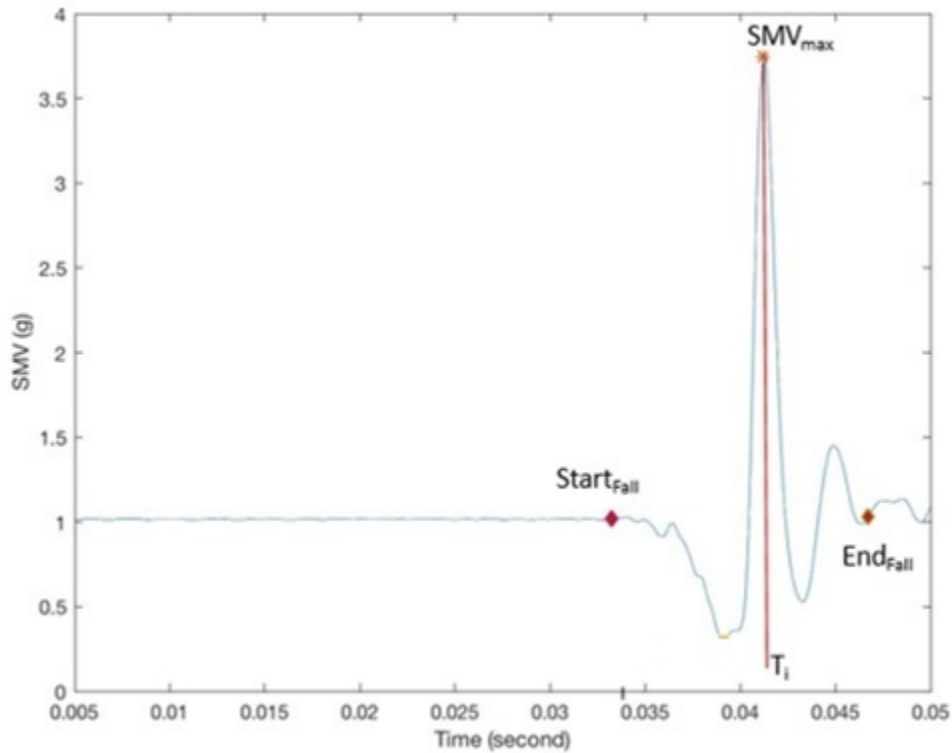
Name the birds:



Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

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Signal magnitude vector (SMV) of the lower back inertial measurement unit during an unexpected backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

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Section/item	Item #	Description	Page #
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 15
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-7
	6b	Explanation for choice of comparators	3-7
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9-11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1)	9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	8-9

	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Lead investigator ; 11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
Figure			15
References		Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	16-19

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## TITLE PAGE

### Title

Testing the efficacy of a motor analogy designed to promote safe landing by older adults who fall accidentally: A study protocol for a randomized control study

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1  
2  
3 **TESTING THE EFFICACY OF A MOTOR ANALOGY DESIGNED TO PROMOTE**  
4 **SAFE LANDING BY OLDER ADULTS WHO FALL ACCIDENTALLY: A STUDY**  
5 **PROTOCOL FOR A RANDOMIZED CONTROL STUDY**  
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10  
11 **ABSTRACT**  
12

13  
14 **Introduction:** Falling is associated with adverse effects on the health of older people. The  
15 majority of research into falls among older people has focused on prevention, with less  
16 attention to ‘how to fall safely’. Previous research suggests that motor analogies can be used  
17 to promote safe landing by young adults; however, the efficacy of this technique for older  
18 people remains unknown. This study aims to determine whether a motor analogy is useful for  
19 promoting safe falling in the older adult population.  
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28 **Methods and analysis:** The study adopts a randomized, controlled, single-blinded study  
29 design. People 65 years and older will be randomly allocated to a control condition or a motor  
30 analogy condition. They will receive a nudge in a forward, backward, or sideways direction  
31 (randomised order), which will initiate a fall. The nudge will occur at variable (randomised)  
32 time points, so participants will not be aware of when they will fall. Participants in the motor  
33 analogy condition will be instructed to ‘land like a feather’, whereas participants in the control  
34 condition will be instructed to ‘land safely’. The primary outcome parameters are maximum  
35 impact force (normalised by mass) applied to different body segments during impact and  
36 fracture risk ratio of wrists and hips. A 2-way MANOVA will be conducted to examine  
37 differences between the motor analogy and control conditions as a function of the different  
38 variables.  
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54 **Ethics and dissemination:** The University of Waikato Human Research Ethics Committee  
55 (Health 2021#45) has granted ethical approval. Outcomes will be disseminated through  
56 publication in peer-reviewed journals and presentations at conferences.  
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3 **Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12621001189819.  
4  
5 Registered on 6 September 2021.  
6  
7

8 **Keywords:** Older adults; Falls; Safe landing; Motor analogy  
9

## 10 11 12 **STRENGTHS AND LIMITATIONS OF THIS STUDY** 13

- 14 • Single-blinded randomised controlled trial (the research assistant and participants are  
15 blinded to the conditions, but not the lead investigator)  
16
- 17 • Investigates a promising novel method for reducing fall-related injuries in older adults  
18
- 19 • The proposed method can be easily implemented alongside fall prevention programs or  
20 into health services attended by older adults.  
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- 22 • One limitation of this study is that frail older adults who do not pass the Physical  
23 Activity Readiness Questionnaire (PARQ+) are excluded from the study.  
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## 31 32 **INTRODUCTION** 33

34 Accidental falls can adversely affect the health of older people and are second only to traffic  
35 incidents as the most common cause of death.<sup>1</sup> Millions of older adults fall each year. Not only  
36 are falls associated with high personal costs, such as reduced well-being, but also health care  
37 sectors are heavily burdened.<sup>2,3</sup> For instance, every year in New Zealand 18% of the total cost  
38 of injury is due to falls.<sup>4</sup> The government estimates that by the year 2025 fall related injuries  
39 will cost the country around \$418 million dollars annually.<sup>5</sup> Researchers and health care  
40 professionals have investigated various interventions to reduce the occurrence of falls;  
41 nevertheless, it is estimated that around 30-60% of older adults fall unexpectedly annually.<sup>6</sup>  
42 The complex nature of falls, combined with intrinsic (e.g., impaired balance, reduced cognitive  
43 status, poor vision, etc.) and extrinsic (e.g., slippery floors, loose rugs, poor lighting, etc.) risk  
44 factors, increases the difficulty of establishing effective fall prevention interventions.<sup>7</sup>  
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3 In a systematic review and meta-analysis of multifactorial fall prevention programs,  
4 Hopewell et al. (2020) found that prevention programs may reduce fall rates, but have little to  
5 no effect on other fall-related consequences, such as fractures, hospital admission or medical  
6 attention and health-related quality of life.<sup>8</sup> To address the multidimensional nature of falls and  
7 to mitigate their negative effects on health, complementary approaches are needed to  
8 accompany fall prevention interventions. Consistent with this position, a small number of  
9 researchers have proposed that fall-related injuries can be reduced by learning ‘how to land  
10 safely’ when a fall occurs.<sup>9</sup><sup>10</sup> A systematic review by Moon and Sosnoff<sup>10</sup> revealed that only  
11 thirteen studies have investigated safe landing techniques, and that most of the studies (12 out  
12 of 13) tested young adults rather than older adults. Landing techniques varied according to the  
13 direction of fall. For instance, to land safely from sideways falls, participants were instructed  
14 to use the martial arts technique of roll and slap.<sup>11-14</sup> Different techniques were instructed for  
15 forward (e.g., “land with a slightly flexed elbow angle”)<sup>15</sup> and backward (e.g., “bend the hips  
16 and knees”) falls.<sup>16</sup>

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36 Older adults generally learn more slowly than younger adults and fail to reach similar  
37 levels of expertise<sup>17-19</sup>, so their capacity to learn a different assortment of safe landing  
38 techniques that can be used appropriately when falling is questionable. For example, age-  
39 related declines in the ability to store and manage information (via working memory)<sup>19</sup><sup>20</sup> make  
40 comprehension of explicit instructions (e.g., how to land safely) more challenging during  
41 learning. Additionally, older adults generally display impaired reaction times<sup>21</sup><sup>22</sup>, which  
42 increases the difficulty associated with selecting and executing the appropriate technique  
43 during a fall. It takes approximately 0.3 seconds to recover balance when falling from standing  
44 height, with impact occurring after approximately 0.7 seconds if recovery is not possible<sup>23</sup>, so  
45 there is minimal opportunity between the balance recovery phase and impact with the ground  
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3 (i.e., 0.4 seconds) for older people to explicitly choose (and use) an appropriate safe landing  
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6 technique.

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Consequently, an approach to landing safely is required that involves less explicit information about technique and can be processed more quickly (i.e., less resource demanding). Motor analogies may achieve this goal. Analogies leverage a concept that is already well known by the learner in order to convey the complex structure of the motor skill.<sup>24 25</sup> Motor analogies are often used to teach movement skills to novices by comparing the movements with a similar, well-known concept, such as, “imagine you are putting a cookie in a cookie jar on a high shelf” (for a basketball free-throw)<sup>26</sup> or “strike the ball while bringing the bat up the hypotenuse of a triangle” (for a table tennis topspin forehand).<sup>24</sup> Such analogies are thought to promote implicit motor learning, which seeks to minimise accrual of conscious knowledge of the underlying rules governing the mechanics of movements.<sup>27 28</sup> Implicit motor learning has been shown to impose fewer demands on cognitive resources than explicit motor learning<sup>27 29</sup><sup>30</sup> and, importantly, has been shown to result in better learning by older adults.<sup>31 32</sup>

Motor analogies have been shown to be beneficial for skill learning in the older adult population, resulting in preserved skill level over time and robust performance under dual-task conditions.<sup>32</sup> They have also been used in rehabilitation settings to improve dynamic balance<sup>33</sup> and walking by Parkinson<sup>34</sup> and stroke<sup>35</sup> patients. These advantages have been attributed to the simplicity of retrieving analogies from memory<sup>36</sup> and the role they play in rapidly deploying attention during movement.<sup>37</sup> The potential for analogies to depute for explicit instructions, facilitate development of mental representations in long term memory<sup>38</sup>, reduce the demands associated with processing information (i.e., lower reliance on working memory)<sup>29 39-41</sup> and hasten processing time<sup>28</sup> makes them a compelling choice for learning safe landing strategies.

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3 Masters et al.<sup>42</sup>, sought to develop a simple motor analogy that promotes safe landing  
4 in the event of a fall. They conducted focus group discussions with older fallers,  
5 physiotherapists, occupational therapists, martial artists, gymnasts, dancers, parkour  
6 enthusiasts, and health and safety experts. Analysis of the focus group transcripts revealed three  
7 common themes that were used to describe safe landing: ‘soft’, ‘silent’, ‘slow’. Based on these  
8 themes, two motor analogies with potential to promote soft, slow, silent landing were identified:  
9 *land like a snowflake* or *land like a feather*. In a previous experiment, we found that instructions  
10 to ‘land like a snowflake’ caused young adults to land more safely than control instructions  
11 (‘land on the ground’) when self-initiating falls.<sup>43</sup> In a second experiment, we found that  
12 instructions to ‘land like a feather’ caused young adults to land more safely than control  
13 instructions (‘land safely’) when falling unexpectedly.<sup>44</sup> To evaluate the quality of the landings,  
14 we attached inertial measurement units (IMU) to different body segments of participants and  
15 extracted measures that we used to calculate impact force and wrist fracture risk ratio.  
16 Participants allocated to the motor analogy condition landed with less force and were less likely  
17 to fracture a wrist (i.e., lower wrist fracture ratio) than participants allocated to the control  
18 condition, regardless of fall direction (forward, backward, sideways). These results suggest that  
19 participants allocated to the motor analogy condition were better able to adapt their movements  
20 to land safely.

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45 One of the main limitations of these studies was that the motor analogies were tested in  
46 a young population; it is yet to be seen whether motor analogies can be used to promote safer  
47 landing by older people. It is well-known that ageing is associated with progressive loss of  
48 functional capacity.<sup>45</sup> For instance, older people often show a decline in functional balance<sup>46</sup>,  
49 ability to learn skills<sup>47</sup>, and motor planning.<sup>48</sup> Hence, to account for individual differences in  
50 balance status in the proposed study, the primary researcher (a physiotherapist) will administer  
51 a short version of the Balance Evaluation Systems Test (Mini-BESTest), which is a clinical  
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3 balance tool used for identifying balance dysfunction.<sup>49</sup> Participants will also complete an  
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5 Activities-specific Balance Confidence (ABC) scale, which is a valid and reliable self-  
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7 estimation tool for assessing the balance status of older adults with respect to falling.<sup>50 51</sup>  
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10 Furthermore, the Movement Specific Reinvestment Scale (MSRS)<sup>52</sup> will be administered to  
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12 gain insight into individual differences in movement planning; the propensity that older people  
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14 have for movement specific reinvestment has been linked to a need for more time to “plan”  
15  
16 future movements.<sup>53</sup> Alongside the biomechanical variables used for assessing safe landing,  
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18 the assessment of functional balance (Mini-BESTest, ABC scale) and propensity for  
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20 reinvestment (MSRS) will provide valuable information to understand the effectiveness of our  
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22 motor analogy with respect to older adults.  
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27 The goal of this research is to determine whether older people land more safely (i.e.,  
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29 with less risk of injury) when they are encouraged to use a motor analogy, ‘land like a feather’,  
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31 if they fall. Based on our previous experiments, we hypothesise that:  
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- 34 • Maximum acceleration (impact force normalised by mass) of various body segments  
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36 (upper arms, wrists, hands, hips, thighs, and legs) will be significantly lower across all  
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38 fall directions (forward, backward, sideways) in the motor analogy condition compared  
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40 to the control condition  
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- 43 • Fracture risk ratio (ratio of force at impact divided by the load necessary to cause a  
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45 fracture) of the hips and wrists will be significantly lower in the motor analogy  
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47 condition compared to the control condition  
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## 51 **METHOD**

### 52 **Study design**

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54 This study is a randomized, controlled, single-blinded study for participants aged 65 years and  
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56 older. After assessment of cognition, functional balance, and physical activity readiness,  
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58 participants will be randomly allocated to a motor analogy condition or a control condition.  
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3 The start and end date for data collection are anticipated to fall between 01/07/2022 and  
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5 30/12/2022.  
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### 8 **Population**

9 The study population will be older adults without leg and/or foot amputation who are able to  
10 stand and ambulate without walking aids. Participants will be required to have the ability to  
11 stand without help for 1 minute and to walk without a walking aid for 6 meters. Furthermore,  
12 all participants should be able to communicate in English, with no psychiatric or neurological  
13 impairments that prohibit participation. To screen for dementia, a score above 3 on the Mini-  
14 Cog test will be required. The Mini-Cog test has been validated for dementia screening (a score  
15 between 1 to 3 is considered “possibly impaired”, and a score above 3 is considered “probably  
16 normal”).<sup>54</sup> To screen for physical activity limitations, the researcher will administer a physical  
17 activity readiness questionnaire (PARQ<sup>+</sup>). The PARQ<sup>+</sup> offers safe screening of older adults  
18 prior to engaging in exercise or physical activity.<sup>55 56</sup> Participants who answer ‘yes’ to 2 or  
19 more of the PARQ<sup>+</sup> questions (i.e., require a doctor consultation for physical activity) will be  
20 excluded.  
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### 38 **Randomisation procedure and Blinding**

#### 39 Randomisation procedure

40 All participants who fulfil the inclusion criteria will be randomly assigned to either the motor  
41 analogy condition or the control condition using a random generator computer program. The  
42 randomization procedure (and outcome) will only be available to the lead investigator, who  
43 will not share this information with the participants or the research assistant.  
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#### 50 Blinding

51 The research assistant who will be delivering the nudge that causes the participant to fall onto  
52 the padded surface will be blind to whether the participant has been allocated to the motor  
53 analogy condition or the control condition. Participants will not be informed about the  
54 experimental condition to which they have been assigned (motor analogy or control).  
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3 Participants will also be blind to the direction in which they will be nudged  
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5 (forward/backward/sideways).  
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### 8 **Measurements and instrumentation**

9 A 2D video camera (Canon, 25 frames per second) and Delsys Trigno™ (Delsys Inc., Natick,  
10 MA) inertial measurement units (IMU) will be used for data collection. The video camera will  
11  
12 be positioned 3 meters from the left side of participants on a tripod (height 1.3 meters). The  
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14 researcher will place IMU sensors on 15 different body segments. Acceleration data from the  
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16 IMU sensors will be recorded at a frequency of 148.15 Hz using EMGworks Acquisition  
17  
18 software (Version 4.5.4). A hand-held dynamometer (MyoMeter, M550; range: 0-50 kg) will  
19  
20 be used to record the force applied when nudging participants to initiate each fall.  
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### 26 **Procedure**

27 Eligible participants will be invited to the human performance science lab at the University of  
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29 Waikato for a data collection session that will last around 70-80 minutes. Figure 1 provides a  
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31 flow diagram to illustrate the stages of data collection. Each consecutive component of the  
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33 diagram is described in the subsequent section (e.g., Demographics, Questionnaires, Sensor  
34  
35 placement etc).  
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#### 40 **Demographics**

41 At the beginning of the data collection session, demographic information will be collected: age,  
42  
43 gender, height (cm), mass (kg), history of fall, walking aids, and educational level.  
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#### 46 **Questionnaires**

47 Two psychometric questionnaires will be administered:  
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51 1. Activities-specific Balance Confidence (ABC) scale: This 16-item scale assesses confidence  
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53 in ability to maintain balance during a range of indoor and outdoor functional activities (e.g.,  
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55 “How confident are you that you will not lose your balance or become unsteady when you walk  
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57 around the house?”). The items of the scale are rated from 0% (lowest level of confidence) to  
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3 100% (highest level of confidence). This scale is a valid and reliable tool for measuring balance  
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5 confidence in older adults.<sup>57</sup>  
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9 2. Movement Specific Reinvestment Scale (MSRS): This scale comprises 10 items divided into  
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11 two subscales. The Conscious Motor Processing subscale measures propensity to consciously  
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13 control movements (e.g., “I try to think about my movements when I carry them out”). The  
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15 Movement Self-consciousness subscale measures propensity to monitor “style” of movement  
16  
17 (e.g., “I am self-conscious about the way I look when I am moving”). The items are rated on a  
18  
19 6-point Likert scale from strongly disagree (1) to strongly agree (6). Thus, cumulative scores  
20  
21 range from 10 to 60, with higher scores reflecting higher propensity for movement-specific  
22  
23 reinvestment. The MSRS has been shown to have high internal consistency and test–retest  
24  
25 reliability.<sup>58</sup>  
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### 30 Sensor placement

31 Fifteen IMU sensors will be attached over the following body segments using double-sided  
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33 tape: head, chest (aligned with the sternum), lower back (aligned with L3), upper arms (dorsal),  
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35 wrists (dorsal), hands (dorsal), hips (greater trochanter) thighs (lateral), lower legs (lateral).  
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38 Figure 2 demonstrates the placement of the IMU sensors on the participants.  
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### 41 Mini-BESTest

42 The researcher will administer a short version of the Balance Evaluation Systems Test (Mini-  
43  
44 BESTest), which is a standardized clinical balance tool used to assess functional balance.<sup>59-62</sup>  
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47 This test has a maximum score of 28 points, with higher scores indicating better balance.  
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### 50 Crossword puzzle

51 Participants in the motor analogy condition will be required to complete a three-word  
52  
53 crossword puzzle designed to prime them about how feathers land on the ground: soft, slow,  
54  
55 silent (Figure 3, Panel A). Participants in the control condition will be asked to complete a  
56  
57 similar crossword puzzle that uses names of birds as neutral primes: swallow, shag, swan  
58  
59 (Figure 3, Panel B).  
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### Experimental conditions

Participants in the motor analogy condition will be instructed to “land like a feather”, whereas participants in the control condition will be instructed to “land safely”. They will stand on a surface-level platform (27cm x 32cm) facing a fully padded landing area. A research assistant will apply a gentle impulse (nudge) to the left shoulder of participants, who will be instructed to fall in the direction in which the nudge is applied. If the nudge does not yield a fall the trial will not be repeated (the subsequent trial in the sequence will be initiated). The nudge will be applied in a forward, backward, or sideways direction. Order of fall direction will be randomized using a random order generator. The research assistant will be blinded to condition (motor analogy/control) and each nudge will be applied using a hand-held dynamometer. The load cell will be placed on the participant’s shoulder and the research assistant will apply a nudge via the surface of the dynamometer. The integral of the force with respect to time will be calculated (i.e., impulse). The impulse required to initiate each fall will be recorded and used as a covariate in the statistical analysis to control for potential differences in nudge force. To reduce the likelihood that participants will anticipate the nudge, they will be required to count backwards in 3’s during each trial (a concurrent secondary task). Nudges will occur at variable time points during counting. To familiarise participants with the experimental procedure, one practice trial will be conducted. The direction of the fall during the practice trial (forward, backward, sideways) will be randomised across participants. Afterwards, the experimental procedure will be repeated twice (with a different order of falls on each occasion). Hence, each participant will fall six times during the experimental procedure.

Prior experience of activities, such as dancing, gymnastics, sports (e.g., rugby, surfing, parkour, etc.), martial arts (e.g., tai-Chi, judo, taekwondo, etc.) may affect participants’ landing strategies. Thus, after data collection, the experimenter will record information regarding participants’ experience of these activities (e.g., type of activity, years of participation, level of

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3 ability, type of fall strategy learned etc). This information will be used to support interpretation  
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5 of the findings of our study.  
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### 8 **Public involvement Statement**

9 Initially, people with an interest in falling (e.g., older adults, health care professionals,  
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11 physiotherapists, fall experts etc) were consulted about safe landing via focus groups. Key  
12  
13 themes were used to design motor analogies with potential to facilitate safe landing in the event  
14  
15 of a fall. After testing the efficacy of the motor analogies using young adults, we consulted  
16  
17 with fall prevention leaders in New Zealand about testing the analogies in older adults. We also  
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19 engaged with the community through fall prevention classes and retirement homes, with a goal  
20  
21 to determine the level of interest that older adults have in safe landing, and to take their  
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23 feedback into account when designing the proposed study. We plan to disseminate our findings  
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25 among fall prevention leaders and interested older adults who have provided us with their  
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27 contact information.  
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### 35 **Primary outcome**

36 The acceleration data recorded by the IMUs will be exported in excel format and processed  
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38 using Matlab (R2017b, MathWorks Inc., Natic, USA). Start of fall (Start) and end of fall (End)  
39  
40 will be extracted from a one-dimensional signal magnitude acceleration vector (SMV) of the  
41  
42 lower back unit. Figure 4 displays exemplar data from a backward fall.  
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45

46 To determine the beginning and end of a fall, a threshold will be calculated using a 100  
47  
48 ms moving window applied to the SMV data. Subsequently, the relative standard deviation  
49  
50 (RSD) of the windows will be calculated. The generated RSDs will be averaged and used as a  
51  
52 threshold for identifying the start and the end of the fall for each trial. RSD has previously been  
53  
54 used to compute thresholds for identifying cancer cells<sup>63</sup>, optic-nerve signals<sup>64</sup>, and in various  
55  
56 human motion dynamics studies.<sup>65</sup> The start of the fall will be defined as the trench before the  
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58 SMV reaches its maximum value ( $SMV_{max}$ )<sup>66 67</sup> outlined by the SMV crossing the threshold.  
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3 The end of the fall will be defined as the SMV crossing the threshold after it reaches its  
4 maximum value ( $SMV_{max}$ ). The start and end of fall identification method will be verified using  
5 the video recordings. Maximum acceleration ( $SMV_{max}$ , g) will be extracted from all 15 IMUs.  
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11 The fracture risk of different body parts depends on the severity of the impact and the  
12 capacity of the bones to resist the impact.<sup>68</sup> Therefore, fracture risk ratio will be defined as the  
13 ratio of force at impact divided by the load necessary to cause a fracture.<sup>69 70</sup> To calculate the  
14 force applied to the wrists and hips, the SMV of the wrist units at time of impact will be  
15 multiplied by the scaling factors for the forearm and femoral head mass (%mass) provided by  
16 Dumas et al.<sup>71</sup>, and then multiplied by 9.807 (convert g to  $m/s^2$ ). Finally, the force applied to  
17 the participant's wrist and hip IMUs will be divided by the load required to fracture the radius  
18 bone and femur head based on cadaveric studies.<sup>72</sup> This measurement does not include the  
19 direction of force applied to the wrist and hips; hence, it is an estimation of the fracture risk  
20 ratio.  
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### 34 **Sample size**

35 Sample size estimation was conducted using a customisable statistical spreadsheet  
36 (xSampleSize.xlsx, [www.sportsci.org](http://www.sportsci.org)). Sample size requirements were calculated from  
37 standard two-tailed hypothesis equations using an 80% power ( $\beta = 0.20$ ), and 5% significance  
38 level ( $\alpha = 0.05$ ). We used data from our previous research with young adults (smallest  
39 difference=0.22  $m/s^2$ ; within subject SD= 0.28  $m/s^2$ ; between subject SD=0.32  $m/s^2$ ) for the  
40 calculations, with maximum acceleration (impact force normalised by mass) as our primary  
41 outcome. The calculations resulted in a minimum group size of 32 participants per condition.  
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51 To account for 20% attrition rate, this study aims to recruit 38 participants per condition.  
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### 54 **Data integrity and analysis**

55 The lead investigator will monitor data integrity by regularly examining data files for omissions  
56 and errors. The demographics, questionnaire scores, and outcome measures will be used to  
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3 compare the conditions (motor analogy vs control). The means and SD of variables will be  
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5 calculated and differences between the conditions will be examined using IBM SPSS Statistics  
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7 25 (IBM SPSS Statistics Software). A two-way between-groups multivariate analysis of  
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9 variance (MANOVA) will be conducted to explore the effect of condition (motor analogy,  
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11 control) and fall direction (forward, backward, sideways) on the following variables of interest:  
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13  $SMV_{max}$  (g) of the 15 IMUs located on the body segments displayed in Figure 2. Significant  
14  
15 main effects and interactions will be further scrutinised using analysis of variance (ANOVA)  
16  
17 of variables separately. To control for the multiplicity problem caused by conducting multiple  
18  
19 statistical tests, the Benjamini–Hochberg (B-H) method will be used to control the alpha level  
20  
21 using successive modified Bonferroni corrections.<sup>73</sup> All participants will be included in the  
22  
23 analyses and will be given an anonymous participation ID to protect confidentiality. Only study  
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25 investigators will have access to the raw data. All datasets used or analysed during this study  
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27 will be available from the corresponding author upon reasonable request.  
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### 33 **Ethics and dissemination**

34 The University of Waikato Human Research Ethics Committee (Health 2021#45) approved the  
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36 study protocol. The results of the trial will be submitted to international peer-reviewed journals  
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38 and presented at conferences.  
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### 42 **DISCUSSION**

43 Falls can cause significant health problems for older adults and can result in frailty, immobility,  
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45 and decline in functional ability. The use of motor analogies to promote safe(r) landing is  
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47 promising approach that has potential to reduce the severity of injuries that occur during  
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49 accidental falls. In this paper, we described the methodology for a randomized controlled  
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51 single-blinded study that investigates the efficacy of using a motor analogy to promote safer  
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53 landing by older adults.  
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3 The project requires work with older people; hence, extreme caution is required to  
4 ensure the safety of our participants. One of the conditions of participation in this study is that  
5 participants can walk without assistance for at least 6 meters (twice the length of the 3-meter  
6 walk test in the Min-BESTest) in a controlled laboratory environment. Older people who  
7 cannot walk for 6 meters without assistance, or stand without a walking aid for at least one  
8 minute, will be excluded from the study. Thus, the exclusion criterion requires the participants  
9 to be comfortable when walking and standing independently. Additionally, we will administer  
10 the PARQ<sup>+</sup> and participants who answer ‘yes’ to 2 or more of the questions will be excluded.  
11 The PARQ<sup>+</sup> is sensitive to underlying conditions, such as osteoporosis, cardiovascular  
12 problems, respiratory disease, previous surgery, arthritis, chronic conditions, high blood  
13 pressure, back problems, stroke, etc. Therefore, if a participant is not in a healthy physical  
14 condition, they will not participate. This approach therefore excludes frail older adults from  
15 our participant pool, which is necessary due to the risk of injury associated with our fall  
16 intervention.  
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36 In studies that examine older people, criteria often are designed to exclude those with  
37 cognitive impairments. However, previous studies have reported that motor learning  
38 interventions can be effective for people with cognitive and/or communicative impairments.<sup>74</sup>  
39 In this study, we therefore attempt to include a sample that is more representative of older  
40 adults. A mini cognition test (Mini-Cog) will be administered to assess the likelihood of  
41 dementia. A score between 1 to 3 is considered “possibly impaired”, and a score above 3 is  
42 considered “probably normal”.<sup>54</sup> Only participants who score below the cut-off point of 3 will  
43 be excluded; hence, this will provide us an opportunity to assess the effect of motor analogies  
44 on older adults within different ranges of cognition, which is consistent with our ultimate goal  
45 to develop a simple solution for safe landing that is applicable to the widest possible audience.  
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**AUTHORS' CONTRIBUTIONS** The idea and rationale that underpins the work was generated by R.S.W.M.; S.O. is a PhD student who is supervised by R.S.W.M. (Chief Supervisor), L.U. (Secondary Supervisor), and K. H-L. (Secondary Supervisor); S.O. wrote the manuscript with support from R.S.W.M., L.U., and K. H-L.; all of the authors have advised on study design and methodology, and will contribute to analysis, interpretation and dissemination of the findings.

**FUNDING** This work is part of a programme of research led by R.S.W.M., which is supported by a charitable donation from Freemason's New Zealand.

**AWARD/GRANT NUMBER** N/A

**COMPETING INTERESTS** None declared

**PROTOCOL AMENDMENTS** Any change to the protocol will be communicated with the University of Waikato Human Research Ethics Committee (Health) and the Australian New Zealand Clinical Trials Registry (ANZCTR).

#### **FIGURE CAPTIONS:**

Figure 1: Flow diagram of the data collection session.

Figure 2: Positioning of inertial measurement units on different body segments.

Figure 3: Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

Figure 4: Signal magnitude vector (SMV) of the lower back inertial measurement unit during a backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

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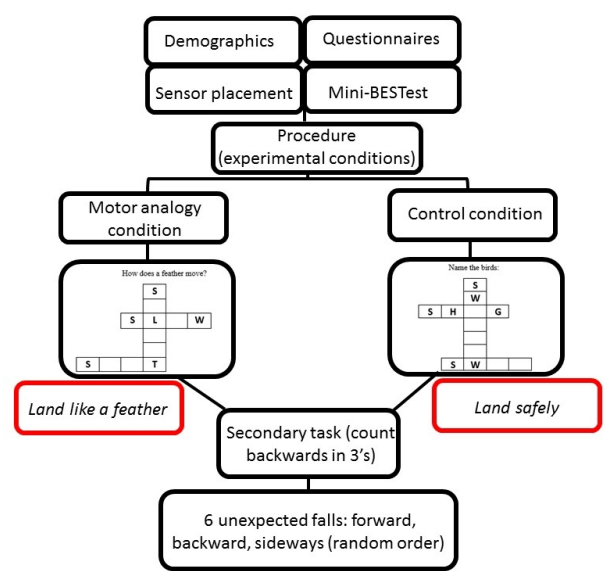
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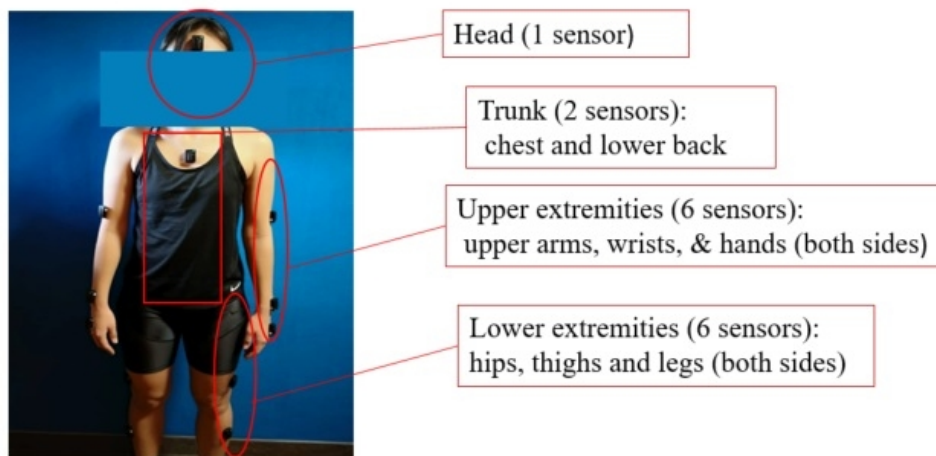
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Flow diagram of the data collection session.

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Positioning of inertial measurement units on different body segments

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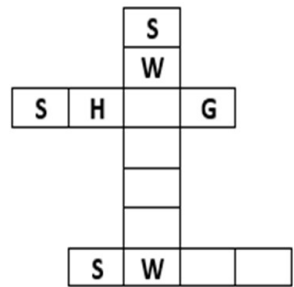
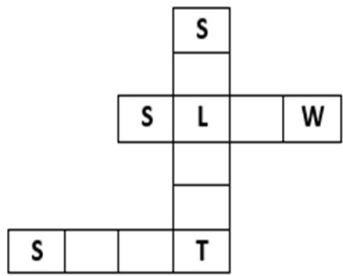
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**Panel A**

**Panel B**

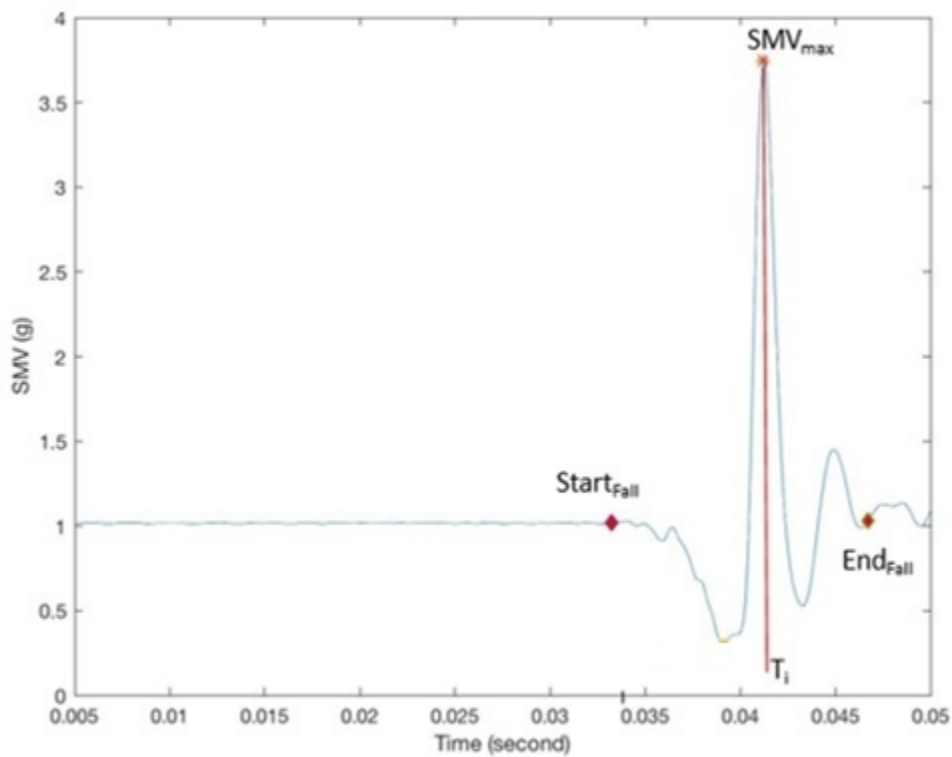
How does a feather move?

Name the birds:



Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

338x190mm (96 x 96 DPI)



Signal magnitude vector (SMV) of the lower back inertial measurement unit during an unexpected backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

127x100mm (96 x 96 DPI)

Section/item	Item #	Description	Page #
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 15
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-7
	6b	Explanation for choice of comparators	3-7
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9-11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1)	9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	8-9



	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Lead investigator ; 11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
Figure			15
References		Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	16-19

# BMJ Open

## Testing the efficacy of a motor analogy designed to promote safe landing by older adults who fall accidentally: A study protocol for a randomized control study

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## TITLE PAGE

### Title

Testing the efficacy of a motor analogy designed to promote safe landing by older adults who fall accidentally: A study protocol for a randomized control study

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1  
2  
3 **TESTING THE EFFICACY OF A MOTOR ANALOGY DESIGNED TO PROMOTE**  
4 **SAFE LANDING BY OLDER ADULTS WHO FALL ACCIDENTALLY: A STUDY**  
5 **PROTOCOL FOR A RANDOMIZED CONTROL**  
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10  
11 **ABSTRACT**  
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13  
14 **Introduction:** Falling is associated with adverse effects on the health of older people. The  
15 majority of research into falls among older people has focused on prevention, with less  
16 attention to ‘how to fall safely’. Previous research suggests that motor analogies can be used  
17 to promote safe landing by young adults; however, the efficacy of this technique for older  
18 people remains unknown. This study aims to determine whether a motor analogy is useful for  
19 promoting safe falling in the older adult population.  
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28 **Methods and analysis:** The study adopts a randomized, controlled, single-blinded study  
29 design. People 65 years and older will be randomly allocated to a control condition or a motor  
30 analogy condition. They will receive a nudge in a forward, backward, or sideways direction  
31 (randomised order), which will initiate a fall. The nudge will occur at variable (randomised)  
32 time points, so participants will not be aware of when they will fall. Participants in the motor  
33 analogy condition will be instructed to ‘land like a feather’, whereas participants in the control  
34 condition will be instructed to ‘land safely’. The primary outcome parameters are maximum  
35 impact force (normalised by mass) applied to different body segments during impact and  
36 fracture risk ratio of wrists and hips. A 2-way MANOVA will be conducted to examine  
37 differences between the motor analogy and control conditions as a function of the different  
38 variables.  
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54 **Ethics and dissemination:** The University of Waikato Human Research Ethics Committee  
55 (Health 2021#45) has granted ethical approval. Outcomes will be disseminated through  
56 publication in peer-reviewed journals and presentations at conferences.  
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3 **Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12621001189819.

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5 Registered on 6 September 2021.

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8 **Keywords:** Older adults; Falls; Safe landing; Motor analogy

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10  
11 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 12  
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14
- 15 • Single-blinded randomised controlled trial (the research assistant and participants are
  - 16 blinded to the conditions, but not the lead investigator)
  - 17
  - 18 • Investigates a promising novel method for reducing fall-related injuries in older adults
  - 19
  - 20 • The proposed method can be easily implemented alongside fall prevention programs or
  - 21 into health services attended by older adults.
  - 22
  - 23 • One limitation of this study is that frail older adults who do not pass the Physical
  - 24 Activity Readiness Questionnaire (PARQ+) are excluded from the study.
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32 **INTRODUCTION**

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35 Accidental falls can adversely affect the health of older people and are second only to traffic  
36 incidents as the most common cause of death.<sup>1</sup> Millions of older adults fall each year. Not only  
37 are falls associated with high personal costs, such as reduced well-being, but also health care  
38 sectors are heavily burdened.<sup>2,3</sup> For instance, every year in New Zealand 18% of the total cost  
39 of injury is due to falls.<sup>4</sup> The government estimates that by the year 2025 fall related injuries  
40 will cost the country around \$418 million dollars annually.<sup>5</sup> Researchers and health care  
41 professionals have investigated various interventions to reduce the occurrence of falls;  
42 nevertheless, it is estimated that around 30-60% of older adults fall unexpectedly annually.<sup>6</sup>  
43  
44 The complex nature of falls, combined with intrinsic (e.g., impaired balance, reduced cognitive  
45 status, poor vision, etc.) and extrinsic (e.g., slippery floors, loose rugs, poor lighting, etc.) risk  
46 factors, increases the difficulty of establishing effective fall prevention interventions.<sup>7</sup>  
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3 In a systematic review and meta-analysis of multifactorial fall prevention programs,  
4 Hopewell et al. (2020) found that prevention programs may reduce fall rates, but have little to  
5 no effect on other fall-related consequences, such as fractures, hospital admission or medical  
6 attention and health-related quality of life.<sup>8</sup> To address the multidimensional nature of falls and  
7 to mitigate their negative effects on health, complementary approaches are needed to  
8 accompany fall prevention interventions. Consistent with this position, a small number of  
9 researchers have proposed that fall-related injuries can be reduced by learning ‘how to land  
10 safely’ when a fall occurs.<sup>9</sup> <sup>10</sup> A systematic review by Moon and Sosnoff <sup>10</sup> revealed that only  
11 thirteen studies have investigated safe landing techniques, and that most of the studies (12 out  
12 of 13) tested young adults rather than older adults. Landing techniques varied according to the  
13 direction of fall. For instance, to land safely from sideways falls, participants were instructed  
14 to use the martial arts technique of roll and slap.<sup>11-14</sup> Different techniques were instructed for  
15 forward (e.g., “land with a slightly flexed elbow angle”)<sup>15</sup> and backward (e.g., “bend the hips  
16 and knees”) falls.<sup>16</sup>

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36 Older adults generally learn more slowly than younger adults and fail to reach similar  
37 levels of expertise<sup>17-19</sup>, so their capacity to learn a different assortment of safe landing  
38 techniques that can be used appropriately when falling is questionable. For example, age-  
39 related declines in the ability to store and manage information (via working memory) <sup>19</sup> <sup>20</sup> make  
40 comprehension of explicit instructions (e.g., how to land safely) more challenging during  
41 learning. Additionally, older adults generally display impaired reaction times<sup>21</sup> <sup>22</sup>, which  
42 increases the difficulty associated with selecting and executing the appropriate technique  
43 during a fall. It takes approximately 0.3 seconds to recover balance when falling from standing  
44 height, with impact occurring after approximately 0.7 seconds if recovery is not possible<sup>23</sup>, so  
45 there is minimal opportunity between the balance recovery phase and impact with the ground  
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3 (i.e., 0.4 seconds) for older people to explicitly choose (and use) an appropriate safe landing  
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6 technique.

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Consequently, an approach to landing safely is required that involves less explicit information about technique and can be processed more quickly (i.e., less resource demanding). Motor analogies may achieve this goal. Analogies leverage a concept that is already well known by the learner in order to convey the complex structure of the motor skill.<sup>24 25</sup> Motor analogies are often used to teach movement skills to novices by comparing the movements with a similar, well-known concept, such as, “imagine you are putting a cookie in a cookie jar on a high shelf” (for a basketball free-throw)<sup>26</sup> or “strike the ball while bringing the bat up the hypotenuse of a triangle” (for a table tennis topspin forehand).<sup>24</sup> Such analogies are thought to promote implicit motor learning, which seeks to minimise accrual of conscious knowledge of the underlying rules governing the mechanics of movements.<sup>27 28</sup> Implicit motor learning has been shown to impose fewer demands on cognitive resources than explicit motor learning<sup>27 29</sup><sup>30</sup> and, importantly, has been shown to result in better learning by older adults.<sup>31 32</sup>

Motor analogies have been shown to be beneficial for skill learning in the older adult population, resulting in preserved skill level over time and robust performance under dual-task conditions.<sup>32</sup> They have also been used in rehabilitation settings to improve dynamic balance<sup>33</sup> and walking by Parkinson<sup>34</sup> and stroke<sup>35</sup> patients. These advantages have been attributed to the simplicity of retrieving analogies from memory<sup>36</sup> and the role they play in rapidly deploying attention during movement.<sup>37</sup> The potential for analogies to depute for explicit instructions, facilitate development of mental representations in long term memory<sup>38</sup>, reduce the demands associated with processing information (i.e., lower reliance on working memory)<sup>29 39-41</sup> and hasten processing time<sup>28</sup> makes them a compelling choice for learning safe landing strategies.



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3 Masters et al.<sup>42</sup>, sought to develop a simple motor analogy that promotes safe landing  
4 in the event of a fall. They conducted focus group discussions with older fallers,  
5 physiotherapists, occupational therapists, martial artists, gymnasts, dancers, parkour  
6 enthusiasts, and health and safety experts. Analysis of the focus group transcripts revealed three  
7 common themes that were used to describe safe landing: ‘soft’, ‘silent’, ‘slow’. Based on these  
8 themes, two motor analogies with potential to promote soft, slow, silent landing were identified:  
9 *land like a snowflake* or *land like a feather*. In a previous experiment, we found that instructions  
10 to ‘land like a snowflake’ caused young adults to land more safely than control instructions  
11 (‘land on the ground’) when self-initiating falls.<sup>43</sup> In a second experiment, we found that  
12 instructions to ‘land like a feather’ caused young adults to land more safely than control  
13 instructions (‘land safely’) when falling unexpectedly.<sup>44</sup> To evaluate the quality of the landings,  
14 we attached inertial measurement units (IMU) to different body segments of participants and  
15 extracted measures that we used to calculate impact force and wrist fracture risk ratio.  
16 Participants allocated to the motor analogy condition landed with less force and were less likely  
17 to fracture a wrist (i.e., lower wrist fracture ratio) than participants allocated to the control  
18 condition, regardless of fall direction (forward, backward, sideways). These results suggest that  
19 participants allocated to the motor analogy condition were better able to adapt their movements  
20 to land safely.

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45 One of the main limitations of these studies was that the motor analogies were tested in  
46 a young population; it is yet to be seen whether motor analogies can be used to promote safer  
47 landing by older people. It is well-known that ageing is associated with progressive loss of  
48 functional capacity.<sup>45</sup> For instance, older people often show a decline in functional balance<sup>46</sup>,  
49 ability to learn skills<sup>47</sup>, and motor planning.<sup>48</sup> Hence, to account for individual differences in  
50 balance status in the proposed study, the primary researcher (a physiotherapist) will administer  
51 a short version of the Balance Evaluation Systems Test (Mini-BESTest), which is a clinical  
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3 balance tool used for identifying balance dysfunction.<sup>49</sup> Participants will also complete an  
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5 Activities-specific Balance Confidence (ABC) scale, which is a valid and reliable self-  
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7 estimation tool for assessing the balance status of older adults with respect to falling.<sup>50 51</sup>  
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10 Furthermore, the Movement Specific Reinvestment Scale (MSRS)<sup>52</sup> will be administered to  
11  
12 gain insight into individual differences in movement planning; the propensity that older people  
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14 have for movement specific reinvestment has been linked to a need for more time to “plan”  
15  
16 future movements.<sup>53</sup> Alongside the biomechanical variables used for assessing safe landing,  
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18 the assessment of functional balance (Mini-BESTest, ABC scale) and propensity for  
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20 reinvestment (MSRS) will provide valuable information to understand the effectiveness of our  
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22 motor analogy with respect to older adults.  
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27 The goal of this research is to determine whether older people land more safely (i.e.,  
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29 with less risk of injury) when they are encouraged to use a motor analogy, ‘land like a feather’,  
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31 if they fall. Based on our previous experiments, we hypothesise that:  
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- 34 • Maximum acceleration (impact force normalised by mass) of various body segments  
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36 (upper arms, wrists, hands, hips, thighs, and legs) will be significantly lower across all  
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38 fall directions (forward, backward, sideways) in the motor analogy condition compared  
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40 to the control condition  
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- 43 • Fracture risk ratio (ratio of force at impact divided by the load necessary to cause a  
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45 fracture) of the hips and wrists will be significantly lower in the motor analogy  
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47 condition compared to the control condition  
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## 51 **METHOD**

### 52 **Study design**

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54 This study is a randomized, controlled, single-blinded study for participants aged 65 years and  
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56 older. After assessment of cognition, functional balance, and physical activity readiness,  
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58 participants will be randomly allocated to a motor analogy condition or a control condition.  
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3 The start and end date for data collection are anticipated to fall between 01/07/2022 and  
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5 30/12/2022.  
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### 8 **Population**

9 The study population will be older adults without leg and/or foot amputation who are able to  
10 stand and ambulate without walking aids. Participants will be required to have the ability to  
11 stand without help for 1 minute and to walk without a walking aid for 6 meters. Furthermore,  
12 all participants should be able to communicate in English, with no psychiatric or neurological  
13 impairments that prohibit participation. To screen for dementia, a score above 3 on the Mini-  
14 Cog test will be required. The Mini-Cog test has been validated for dementia screening (a score  
15 between 1 to 3 is considered “possibly impaired”, and a score above 3 is considered “probably  
16 normal”).<sup>54</sup> To screen for physical activity limitations, the researcher will administer a physical  
17 activity readiness questionnaire (PARQ<sup>+</sup>). The PARQ<sup>+</sup> offers safe screening of older adults  
18 prior to engaging in exercise or physical activity.<sup>55 56</sup> Participants who answer ‘yes’ to 2 or  
19 more of the PARQ<sup>+</sup> questions (i.e., require a doctor consultation for physical activity) will be  
20 excluded.  
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### 38 **Randomisation procedure and Blinding**

#### 39 Randomisation procedure

40 All participants who fulfil the inclusion criteria will be randomly assigned to either the motor  
41 analogy condition or the control condition using a random generator computer program. The  
42 randomization procedure (and outcome) will only be available to the lead investigator, who  
43 will not share this information with the participants or the research assistant.  
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#### 50 Blinding

51 The research assistant who will be delivering the nudge that causes the participant to fall onto  
52 the padded surface will be blind to whether the participant has been allocated to the motor  
53 analogy condition or the control condition. Participants will not be informed about the  
54 experimental condition to which they have been assigned (motor analogy or control).  
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3 Participants will also be blind to the direction in which they will be nudged  
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5 (forward/backward/sideways).  
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### 8 **Measurements and instrumentation**

9 A 2D video camera (Canon, 25 frames per second) and Delsys Trigno™ (Delsys Inc., Natick,  
10 MA) inertial measurement units (IMU) will be used for data collection. The video camera will  
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12 be positioned 3 meters from the left side of participants on a tripod (height 1.3 meters). The  
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14 researcher will place IMU sensors on 15 different body segments. Acceleration data from the  
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16 IMU sensors will be recorded at a frequency of 148.15 Hz using EMGworks Acquisition  
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18 software (Version 4.5.4). A hand-held dynamometer (MyoMeter, M550; range: 0-50 kg) will  
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20 be used to record the force applied when nudging participants to initiate each fall.  
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### 26 **Procedure**

27 Eligible participants will be invited to the human performance science lab at the University of  
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29 Waikato for a data collection session that will last around 70-80 minutes. Figure 1 provides a  
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31 flow diagram to illustrate the stages of data collection. Each consecutive component of the  
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33 diagram is described in the subsequent section (e.g., Demographics, Questionnaires, Sensor  
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35 placement etc).  
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#### 40 **Demographics**

41 At the beginning of the data collection session, demographic information will be collected: age,  
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43 gender, height (cm), mass (kg), history of fall, walking aids, and educational level. For the  
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45 history of fall the following questions will be asked: Have you fallen and if so, how many times  
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47 in the past year? Have you experienced a near fall? If so, how many times in the past year?  
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49 Have you visited a hospital, family doctor or another healthcare professional because of a fall  
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51 in the past year?  
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#### 55 **Questionnaires**

56 Two psychometric questionnaires will be administered:  
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3 1. Activities-specific Balance Confidence (ABC) scale: This 16-item scale assesses confidence  
4 in ability to maintain balance during a range of indoor and outdoor functional activities (e.g.,  
5 “How confident are you that you will not lose your balance or become unsteady when you walk  
6 around the house?”). The items of the scale are rated from 0% (lowest level of confidence) to  
7 100% (highest level of confidence). This scale is a valid and reliable tool for measuring balance  
8 confidence in older adults.<sup>57</sup>  
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17 2. Movement Specific Reinvestment Scale (MSRS): This scale comprises 10 items divided into  
18 two subscales. The Conscious Motor Processing subscale measures propensity to consciously  
19 control movements (e.g., “I try to think about my movements when I carry them out”). The  
20 Movement Self-consciousness subscale measures propensity to monitor “style” of movement  
21 (e.g., “I am self-conscious about the way I look when I am moving”). The items are rated on a  
22 6-point Likert scale from strongly disagree (1) to strongly agree (6). Thus, cumulative scores  
23 range from 10 to 60, with higher scores reflecting higher propensity for movement-specific  
24 reinvestment. The MSRS has been shown to have high internal consistency and test–retest  
25 reliability.<sup>58</sup>  
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### 39 Sensor placement

40 Fifteen IMU sensors will be attached over the following body segments using double-sided  
41 tape: head, chest (aligned with the sternum), lower back (aligned with L3), upper arms (dorsal),  
42 wrists (dorsal), hands (dorsal), hips (greater trochanter) thighs (lateral), lower legs (lateral).  
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45 Figure 2 demonstrates the placement of the IMU sensors on the participants.  
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### 50 Mini-BESTest

51 The researcher will administer a short version of the Balance Evaluation Systems Test (Mini-  
52 BESTest), which is a standardized clinical balance tool used to assess functional balance.<sup>59-62</sup>  
53 This test has a maximum score of 28 points, with higher scores indicating better balance.  
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### Crossword puzzle

Participants in the motor analogy condition will be required to complete a three-word crossword puzzle designed to prime them about how feathers land on the ground: soft, slow, silent (Figure 3, Panel A). Participants in the control condition will be asked to complete a similar crossword puzzle that uses names of birds as neutral primes: swallow, shag, swan (Figure 3, Panel B). Crossword puzzles have been used in research to activate concepts/primes.<sup>63</sup>

### Experimental conditions

Participants in the motor analogy condition will be instructed to “land like a feather”, whereas participants in the control condition will be instructed to “land safely”. They will stand on a surface-level platform (27cm x 32cm) facing a fully padded landing area. A research assistant will apply a gentle impulse (nudge) to the left shoulder of participants, who will be instructed to fall in the direction in which the nudge is applied. If the nudge does not yield a fall the trial will not be repeated (the subsequent trial in the sequence will be initiated). The nudge will be applied in a forward, backward, or sideways direction. Order of fall direction will be randomized using a random order generator. The research assistant will be blinded to condition (motor analogy/control) and each nudge will be applied using a hand-held dynamometer. The load cell will be placed on the participant’s shoulder and the research assistant will apply a nudge via the surface of the dynamometer. The integral of the force with respect to time will be calculated (i.e., impulse). The impulse required to initiate each fall will be recorded and used as a covariate in the statistical analysis to control for potential differences in nudge force. To reduce the likelihood that participants will anticipate the nudge, they will be required to count backwards in 3’s during each trial (a concurrent secondary task). Nudges will occur at variable time points during counting. To familiarise participants with the experimental procedure, one practice trial will be conducted. The direction of the fall during the practice trial (forward, backward, sideways) will be randomised across participants. Afterwards, the

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3 experimental procedure will be repeated twice (with a different order of falls on each occasion).  
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5 Hence, each participant will fall six times during the experimental procedure.  
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9 Prior experience of activities, such as dancing, gymnastics, sports (e.g., rugby, surfing,  
10 parkour, etc.), martial arts (e.g., tai-Chi, judo, taekwondo, etc.) may affect participants' landing  
11 strategies. Thus, after data collection, the experimenter will record information regarding  
12 participants' experience of these activities (e.g., type of activity, years of participation, level of  
13 ability, type of fall strategy learned etc). This information will be used to support interpretation  
14 of the findings of our study.  
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### 23 **Public involvement Statement**

24 Initially, people with an interest in falling (e.g., older adults, health care professionals,  
25 physiotherapists, fall experts etc) were consulted about safe landing via focus groups. Key  
26 themes were used to design motor analogies with potential to facilitate safe landing in the event  
27 of a fall. After testing the efficacy of the motor analogies using young adults, we consulted  
28 with fall prevention leaders in New Zealand about testing the analogies in older adults. We also  
29 engaged with the community through fall prevention classes and retirement homes, with a goal  
30 to determine the level of interest that older adults have in safe landing, and to take their  
31 feedback into account when designing the proposed study. We plan to disseminate our findings  
32 among fall prevention leaders and interested older adults who have provided us with their  
33 contact information.  
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### 50 **Primary outcome**

51 The acceleration data recorded by the IMUs will be exported in excel format and processed  
52 using Matlab (R2017b, MathWorks Inc., Natic, USA). Start of fall (Start) and end of fall (End)  
53 will be extracted from a one-dimensional signal magnitude acceleration vector (SMV) of the  
54 lower back unit. Figure 4 displays exemplar data from a backward fall.  
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3 To determine the beginning and end of a fall, a threshold will be calculated using a 100  
4 ms moving window applied to the SMV data. Subsequently, the relative standard deviation  
5 (RSD) of the windows will be calculated. The generated RSDs will be averaged and used as a  
6 threshold for identifying the start and the end of the fall for each trial. RSD has previously been  
7 used to compute thresholds for identifying cancer cells<sup>64</sup>, optic-nerve signals<sup>65</sup>, and in various  
8 human motion dynamics studies.<sup>66</sup> The start of the fall will be defined as the trench before the  
9 SMV reaches its maximum value ( $SMV_{max}$ )<sup>67 68</sup> outlined by the SMV crossing the threshold.  
10 The end of the fall will be defined as the SMV crossing the threshold after it reaches its  
11 maximum value ( $SMV_{max}$ ). The start and end of fall identification method will be verified using  
12 the video recordings. Maximum acceleration ( $SMV_{max, g}$ ) will be extracted from all 15 IMUs.  
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27 The fracture risk of different body parts depends on the severity of the impact and the  
28 capacity of the bones to resist the impact.<sup>69</sup> Therefore, fracture risk ratio will be defined as the  
29 ratio of force at impact divided by the load necessary to cause a fracture.<sup>70 71</sup> To calculate the  
30 force applied to the wrists and hips, the SMV of the wrist units at time of impact will be  
31 multiplied by the scaling factors for the forearm and femoral head mass (%mass) provided by  
32 Dumas et al.<sup>72</sup>, and then multiplied by 9.807 (convert g to  $m/s^2$ ). Finally, the force applied to  
33 the participant's wrist and hip IMUs will be divided by the load required to fracture the radius  
34 bone and femur head based on cadaveric studies.<sup>73</sup> This measurement does not include the  
35 direction of force applied to the wrist and hips; hence, it is an estimation of the fracture risk  
36 ratio.  
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### 50 **Sample size**

51 Sample size estimation was conducted using a customisable statistical spreadsheet  
52 (xSampleSize.xlsx, [www.sportsci.org](http://www.sportsci.org)). Sample size requirements were calculated from  
53 standard two-tailed hypothesis equations using an 80% power ( $\beta = 0.20$ ), and 5% significance  
54 level ( $\alpha = 0.05$ ), critical values of the f distribution (for Multivariate analysis of variance), and  
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3 data from our previous research with young adults (smallest difference=0.22 m/s<sup>2</sup>; within  
4 subject SD= 0.28 m/s<sup>2</sup>; between subject SD=0.32 m/s<sup>2</sup>) were used for the calculation, with  
5 maximum acceleration (impact force normalised by mass) as our primary outcome. The  
6 calculations resulted in a minimum group size of 32 participants per condition. To account for  
7 20% attrition rate, this study aims to recruit 38 participants per condition.  
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### 15 **Data integrity and analysis**

16 The lead investigator will monitor data integrity by regularly examining data files for omissions  
17 and errors. The demographics, questionnaire scores, and outcome measures will be used to  
18 compare the conditions (motor analogy vs control). The means and SD of variables will be  
19 calculated and differences between the conditions will be examined using IBM SPSS Statistics  
20 25 (IBM SPSS Statistics Software). A two-way between-groups multivariate analysis of  
21 variance (MANOVA) will be conducted to explore the effect of condition (motor analogy,  
22 control) and fall direction (forward, backward, sideways) on the following variables of interest:  
23 fracture risk ratios of hips, fracture risk ratios of wrists, and SMV<sub>max</sub> (g) of the 15 IMUs located  
24 on the body segments displayed in Figure 2. Significant main effects and interactions will be  
25 further scrutinised using analysis of variance (ANOVA) of variables separately. To control for  
26 the multiplicity problem caused by conducting multiple statistical tests, the Benjamini–  
27 Hochberg (B-H) method will be used to control the alpha level using successive modified  
28 Bonferroni corrections.<sup>74</sup> All participants will be included in the analyses and will be given an  
29 anonymous participation ID to protect confidentiality. Only study investigators will have  
30 access to the raw data. All datasets used or analysed during this study will be available from  
31 the corresponding author upon reasonable request.  
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### 54 **Ethics and dissemination**

55 The University of Waikato Human Research Ethics Committee (Health 2021#45) approved the  
56 study protocol. The results of the trial will be submitted to international peer-reviewed journals  
57 and presented at conferences.  
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## DISCUSSION

Falls can cause significant health problems for older adults and can result in frailty, immobility, and decline in functional ability. The use of motor analogies to promote safe(r) landing is promising approach that has potential to reduce the severity of injuries that occur during accidental falls. In this paper, we described the methodology for a randomized controlled single-blinded study that investigates the efficacy of using a motor analogy to promote safer landing by older adults.

The project requires work with older people; hence, extreme caution is required to ensure the safety of our participants. One of the conditions of participation in this study is that participants can walk without assistance for at least 6 meters (twice the length of the 3-meter walk test in the Min-BESTest) in a controlled laboratory environment. Older people who cannot walk for 6 meters without assistance, or stand without a walking aid for at least one minute, will be excluded from the study. Thus, the exclusion criterion requires the participants to be comfortable when walking and standing independently. Additionally, we will administer the PARQ<sup>+</sup> and participants who answer 'yes' to 2 or more of the questions will be excluded. The PARQ<sup>+</sup> is sensitive to underlying conditions, such as osteoporosis, cardiovascular problems, respiratory disease, previous surgery, arthritis, chronic conditions, high blood pressure, back problems, stroke, etc. Therefore, if a participant is not in a healthy physical condition, they will not participate. This approach therefore excludes frail older adults from our participant pool, which is necessary due to the risk of injury associated with our fall intervention.

In studies that examine older people, criteria often are designed to exclude those with cognitive impairments. However, previous studies have reported that motor learning interventions can be effective for people with cognitive and/or communicative impairments.<sup>75</sup> In this study, we therefore attempt to include a sample that is more representative of older

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3 adults. A mini cognition test (Mini-Cog) will be administered to assess the likelihood of  
4 dementia. A score between 1 to 3 is considered “possibly impaired”, and a score above 3 is  
5 considered “probably normal”.<sup>54</sup> Only participants who score below the cut-off point of 3 will  
6 be excluded; hence, this will provide us an opportunity to assess the effect of motor analogies  
7 on older adults within different ranges of cognition, which is consistent with our ultimate goal  
8 to develop a simple solution for safe landing that is applicable to the widest possible audience.  
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17 **AUTHORS’ CONTRIBUTIONS** The idea and rationale that underpins the work was  
18 generated by R.S.W.M.; S.O. is a PhD student who is supervised by R.S.W.M. (Chief  
19 Supervisor), L.U. (Secondary Supervisor), and K. H-L. (Secondary Supervisor); S.O. wrote the  
20 manuscript with support from R.S.W.M., L.U., and K. H-L.; all of the authors have advised on  
21 study design and methodology, and will contribute to analysis, interpretation and dissemination  
22 of the findings.  
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32 by a charitable donation from Freemason’s New Zealand.  
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37 **AWARD/GRANT NUMBER** N/A  
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40 **COMPETING INTERESTS** None declared  
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43 **PROTOCOL AMENDMENTS** Any change to the protocol will be communicated with the  
44 University of Waikato Human Research Ethics Committee (Health) and the Australian New  
45 Zealand Clinical Trials Registry (ANZCTR).  
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50 **FIGURE CAPTIONS:**  
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53 Figure 1: Flow diagram of the data collection session.  
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56 Figure 2: Positioning of inertial measurement units on different body segments.  
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Figure 3: Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

Figure 4: Signal magnitude vector (SMV) of the lower back inertial measurement unit during a backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

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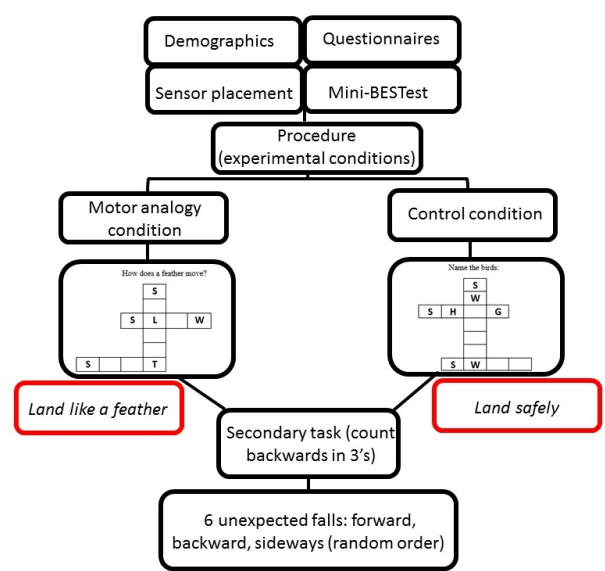
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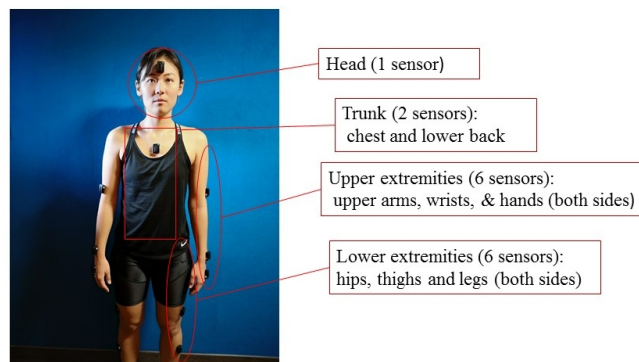
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Flow diagram of the data collection session.

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Positioning of inertial measurement units on different body segments

338x190mm (96 x 96 DPI)

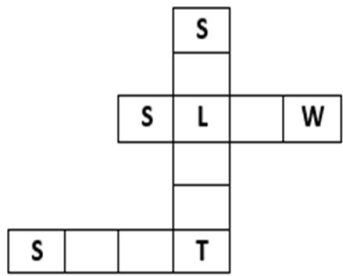
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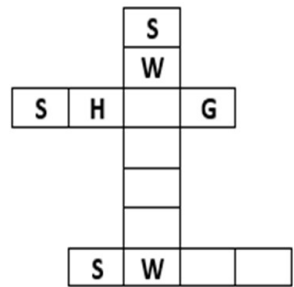
**Panel A**

How does a feather move?



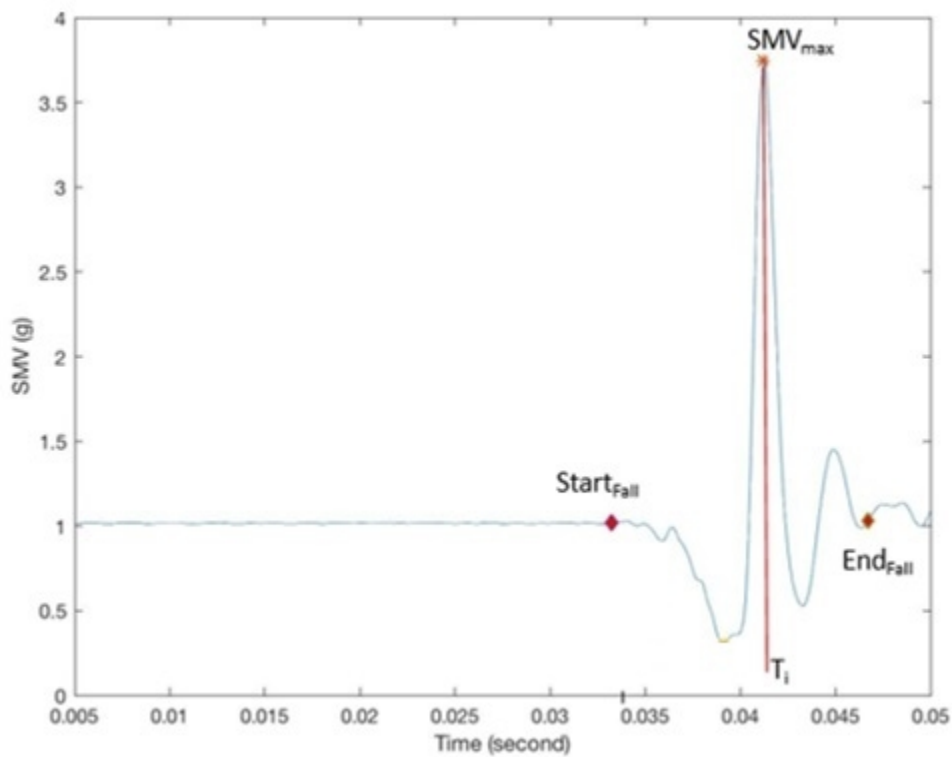
**Panel B**

Name the birds:



Crossword puzzles for priming participants. Panel A: soft, slow, silent. Panel B: swallow, shag, swan.

338x190mm (96 x 96 DPI)



Signal magnitude vector (SMV) of the lower back inertial measurement unit during an unexpected backward fall. Start of fall (StartFall), time of impact (Ti) and end of fall (EndFall) are displayed.

127x100mm (96 x 96 DPI)

Section/item	Item #	Description	Page #
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	15
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1; 15
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-7
	6b	Explanation for choice of comparators	3-7
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	9-11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8

Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see fig 1)	9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers) and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts) and how	8-9

	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA

Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Lead investigator ; 11
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
Figure			15
References		Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	16-19