Staying Upright in Rest Home Care Trial

Final Report June 2009

Report from: Ngaire Kerse, Lois Shaw & Dinah Walker. The University of Auckland
On behalf of the Tu Pakari research group (University of Auckland, AUT University,
University of Otago & Waitemata DHB)
Tu Pakari “To Stand in Confidence” Falls Prevention Group

Team Members

Professor Ngaire Kerse, General Practitioner¹
Associate Professor Clare Robertson, Epidemiology²
Associate Professor Denise Taylor, Physiotherapist³
John Parsons, Physiotherapist¹
Madeleine Calder, Registered Nurse⁴
Liz Binns, Physiotherapist³
Jenni Mace, Occupational Therapist³
Juliet Rosie, Physiotherapist³
Stephanie Woodley, Physiotherapist²
Lois Shaw, Research Nurse¹
Dinah Walker, Research Nurse¹
Professor John Campbell, Geriatrician²

1. School of Population Health and School of Nursing, University of Auckland
2. School of Medicine, University of Otago
3. Physical Rehabilitation Research Centre, AUT University
4. Independent consultant, Waitemata District Health Board

Physiotherapists implementing exercise programme:

Ineke Riley-Stohl
Sue Kohut
Fraser Wilkins
Sorcha Roberts
Juliet Rosie

IT Data Manager: Simon Moyes¹
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Executive summary

Falls are a major public health issue for older people, and those in residential care falls most frequently and are at the highest risk for injury from falls. Costs related to fall and injury management are disproportionately spent in residential care. There is little evidence that exercise alone is effective in residential care and some trials show an increase in falls as a result of exercise. Multifactorial programmes do not consistently reduce falls in residential care, however exercise seems to be a necessary component in those that have been successful. A promising exercise programme has been developed based on the Otago Exercise Programme and a successful programme used in Germany as part of a multifactorial intervention has been adapted for New Zealand use. It would be of great benefit to know whether exercise, delivered as a single intervention, is more or less effective than a multifactorial facility based intervention, or whether the combination of the two is better than each delivered individually.

Aims:
1) To refine an exercise programme aimed at preventing falls in residential care and test its effect on strength and balance (impairments of these two biological parameters are closely related to an increased risk of falls)
2) To establish feasibility for a large 2x2 factorial randomised controlled trial that will test the question “Does a multifactorial programme reduce falls in New Zealand rest homes or is an exercise programme alone sufficient to reduce falls?”

Study design.
A 2x2 factorial design was piloted to determine whether it was possible to recruit facilities and residents to a study where the facility was randomised to a) a multifactorial intervention or 2) usual care and the residents were randomised to 1) an Upright exercise programme aimed to improve balance and lower leg strength (intervention group) or to 2) a seated exercise programme (acting as a control)

Population
Overall, 70 residents (68% response rate) greater than 65 years of age, not in a palliative care or respite programme, agreed to participate in 4 rest homes located in Auckland New Zealand. Written informed consent was obtained from residents and/or their family members. Baseline demographics and functional mobility was recorded: gait speed, balance, timed chair stands, medications, previous falls and comorbidities. Rest homes were randomised to receive a multifactorial intervention or continue as usual. Participating residents were randomised to receive upright (intervention) or seated (control) exercises.

Interventions
The upright exercise programme consisted of strength, balance, sensory integration and dual tasking exercises, progressing over time. They were delivered by a physiotherapist in two sessions of one hour each per week over a 6 month period. The seated exercises classes were of the same duration and timing and consisted of flexibility and game type exercises.

The multifactorial intervention consisted of a training programme for a falls champion. Resources and training given to the champion included: environmental audit, risk assessment information, fact sheets for nurses doctors, caregivers, allied health professionals and managers, a DVD of case studies for caregivers, best practice guidelines, an implementation guide for a falls prevention and management programme, and a training package for caregivers. Hip protectors were supplied free of charge for all enrolled residents in multifactorial homes, and Vitamin D was recommended for all, with GP support obtained.

**Follow up.**
All residents were visited every 2 months by an independent assessor who asked about potential side effects including aches and pains and fatigue. Falls records were obtained from the established systems at all homes every 2 months. At the six months follow up all residents were revisited by a trained research nurse blinded to their randomisation status and their functional mobility was reassessed.

**Results.**
During the trial 14 (18%) of participants died, or were transferred out of the resthomes. Fifty-three people were able to complete the follow-up measures, but not all were able to complete every reassessment task. Average attendance at the upright exercise classes was 60% of the available classes and 55% of available seated classes. Attention to staff encouraging residents to attend classes may have increased attendance. A process evaluation provided valuable information about views towards, and uptake of the programmes.

Overall, there was no impact of the upright activities on the functional mobility measures of the residents apart from 10 people improving their time to walk 10 metres in the upright group compared with 4 in the seated control group (p < 0.007). Considering the impact of the multifactorial programme, there was a significant increase in the number of residents using Vitamin D in intervention homes compared with control homes (96% vs 56% respectively) and more people in intervention homes were wearing hip protectors at follow up in intervention homes (23% in intervention homes vs 0 in control homes). There was no difference in fall rates between groups.

**Summary**
The study showed that residents and homes could be recruited, enrolled and complete all parts of the study protocol. The interventions tested were acceptable. Greater staff encouragement could potentially have increased resident participation in the exercise classes. A 2x2 factorial trial to rigorously test these
two interventions is feasible. The use of more sensitive measures of functional mobility that a larger number of frail older people could complete may have increased the chance of detecting improvement as a result of the upright exercises.

Further evaluation of both the exercise programme and the multifactorial programme are needed prior to wider dissemination.
Introduction

Falls
At least 1/3 of all older people fall every year with serious personal and societal consequences\(^1\)\(^2\). Injury is common with hip fracture occurring in 1-2% percent of falls\(^3\). Falls are even more frequent in residential care.

Falls and residential care
Reported fall rates for residential care (0.2 – 3.6 falls per bed per year) are 3 times that of those in the community\(^4\), up to 61% of residents fall\(^5\) and hip fracture occurs at 10.5 times the rate observed for those living in private homes\(^6\)\(^7\). The Auckland Falls and Injury Prevention Pilot Study (FIPPS) showed that after 18 months 52% of a representative sample of residents had fallen and 40% of falls caused injury of some sort\(^8\). Only 15% of those who fracture their hip regain their pre-injury functional level, placing a large burden of care on staff.

Almost a third of all hospital costs for women 80 years and over result from a fall including the total direct cost of hip fracture from hospitalisation, recovery and residential care; $NZ 41,684,460 (1995 dollars). ACC data show that $187 million was spent over 2 years on falls for older people; $14.7 million on fractures and dislocations, 2/3 of the cost of all claims for falls for older adults in residential care (unpublished data, personal communication, Mooch Williams, ACC). There is a great need to intervene in residential care to reduce falls and currently there is no evidence based intervention that has been systematically tested and introduced into rest homes to reduce falls and injuries from falls in New Zealand.

Preventing falls: successful interventions
There are some successful multifactorial interventions undertaken overseas that prevent falls in residential care. These programmes have incorporated: lower limb strengthening and balance retraining exercises, falls champions to raise awareness of falls prevention and educate staff and residents, environmental hazard reduction, medical assessments and hip protectors\(^9\)\(^10\). It is not clear which parts of these interventions are most effective, although two trials that included comprehensive geriatric assessment seemed to be more effective\(^10\)\(^11\). Other multifactorial programmes have not been successful\(^12\) and the only published systematic review shows that programmes are not consistently successful regardless of their components\(^13\), meaning that widespread dissemination of multifactorial programmes would be premature. The only trial conducted in New Zealand was unsuccessful\(^12\) and there are important staffing and funding differences between the residential care context in New Zealand and overseas (personal communication Clemens Becker, Germany). In New Zealand on
average 20-25% of staff members in residential care are registered nurses (pers comm. Martin Taylor, Members Survey report, 2008) in contrast to a mandated 50% of staff in German residential care facilities being registered nurses. The funding mechanisms and assessment criteria for entry to care differ between the nations and the amount of stress within the industry differs, meaning that is not possible to simply replicate successful programmes from overseas within the New Zealand context without further careful evaluation.

Exercise
Closer examination of the published trials involving exercise as a single intervention shows confusing results. Table 1 is a plot of a summary of data from a systematic review, recently updated, which shows that combining results from the top two trials (Shimada and Sivonen14 15) indicates that falls can be reduced by exercise programmes that concentrate on gait, strength and balance exercise16. Adding a third trial with similar exercises17 tipped the combined result back towards a more neutral overall picture.

Table 1 Gait, strength and balance exercise trials

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Intervention Total</th>
<th>Usual care Total</th>
<th>Rate ratio IV, Random, 95% CI</th>
<th>Rate ratio IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shimada 2004</td>
<td>-0.83 0.47</td>
<td>15</td>
<td>11 23.7%</td>
<td>0.53 [0.21, 1.34]</td>
</tr>
<tr>
<td>Sivonen 2004</td>
<td>-0.32 0.43</td>
<td>20</td>
<td>7 20.0%</td>
<td>0.40 [0.17, 0.63]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td>35</td>
<td>16 49.7%</td>
<td>0.45 [0.24, 0.65]</td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 0.21, df = 1 (P = 0.65); I² = 0%
Test for overall effect: Z = 2.48 (P = 0.01)

| Activity programmes delivered in residential care involving balance training and lower limb strengthening may lead to a reduction in subsequent falls14 15 and of the promising multifactorial interventions, those that involved such exercise programmes were successful9 10.

The picture becomes more complex however when other types of activity are considered (Table 2). Exercise programmes that used combinations of exercise modalities, such as foot flexion exercises, seated balloon activities were not successful in reducing falls, and in fact may have increased falls17-20 as the summary diamond for these group of trials is on the side that favours usual care. This suggests
that much care should be taken to select, develop and test new programmes in the setting in which they will be disseminated. It should not be assumed that all exercise is beneficial.

Table 2 Effect of combination exercise modalities

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>log(Rate ratio)</th>
<th>SE</th>
<th>Total Interv</th>
<th>Total Usual</th>
<th>Weight</th>
<th>Rate ratio N, Random, 95% CI</th>
<th>Rate ratio N, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faber 2006</td>
<td>0.26</td>
<td>0.1</td>
<td>64</td>
<td>90</td>
<td>59.6%</td>
<td>1.32 [1.09, 1.51]</td>
<td></td>
</tr>
<tr>
<td>Murrow 1994</td>
<td>0.28</td>
<td>0.17</td>
<td>97</td>
<td>97</td>
<td>30.0%</td>
<td>1.32 [0.95, 1.55]</td>
<td></td>
</tr>
<tr>
<td>Rosenthal 2008</td>
<td>-0.2</td>
<td>0.32</td>
<td>91</td>
<td>100</td>
<td>15.6%</td>
<td>0.82 [0.44, 1.55]</td>
<td></td>
</tr>
<tr>
<td>Schoenfelder 2000</td>
<td>1.03</td>
<td>7</td>
<td>9</td>
<td>7</td>
<td>14.9%</td>
<td>2.72 [1.42, 4.09]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td></td>
<td>261</td>
<td>284</td>
<td>100.0%</td>
<td>1.37 [1.01, 1.85]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: \( \tau^2 = 0.05 \), \( \chi^2 = 6.99, \text{df} = 3 (P = 0.07); I^2 = 57\% \)

Test for overall effect: \( Z = 2.03 (P = 0.04) \)

Exercise programmes have the potential to prevent falls as they are aimed to impact the substantial risk factor related to poor strength and mobility. Multifactorial programmes, on the other hand, are designed to address more than one risk by offering the right intervention to those with the matching risk profile. Some are guided by individual risk assessment. Much care should be taken in selecting and developing components for the multifactorial interventions, and supply of the necessary resources will be key to enabling the strategies to reduce falls. Taking Vitamin D also reduces falls in residential care\(^{21-23}\).

What New Zealand needs is the most efficient way to reduce falls.

Is it possible that exercise alone could be as successful in reducing falls in residential care as it is in the community\(^{24}\)? Many interventions are successful in the community\(^{25}\).

In Germany, including individualised strength and balance training, in the multifactorial programme reduced falls by up to 50\%\(^{9-10}\) and worked for those with dementia (Becker, unpublished data). Few multifactorial programmes without activity as a component are successful.

This project has developed an exercise programme for residential care, and will examine its effectiveness in improving balance and strength. At the same time it aims to establish feasibility for a larger RCT directly comparing the effect of a multi-component intervention with exercise alone, and with usual care.
Methods

Research Aims
Design of an exercise programme and feasibility for a RCT
The primary aims of this study are:

1) To refine an exercise programme aimed at preventing falls in residential care and test its effect on strength and balance (closely related to falls).

2) To establish feasibility for a large 2x2 factorial randomised controlled trial that will test the question “Does a multifactorial programme reduce falls in New Zealand rest homes or is an exercise programme alone sufficient to reduce falls?”

Study Design

The 2x2 factorial design is a randomised trial where rest homes have been randomised to receive a multifactorial programme or usual care. Individuals within all homes have been randomised to receive lower limb strengthening and balance retraining or usual care. The attention received during activity classes will be controlled for by a seated activity programme (control group).

Therefore for this feasibility study, rest home residents were randomly allocated to one of 4 groups:
- a) Usual care with exercise programme A (control seated exercise programme)
- b) Usual care with exercise programme B (lower leg strengthening and balance retraining)
- c) Multifactorial programme with exercise programme A (control seated exercise programme)
- d) Multifactorial programme with exercise programme B (lower leg strengthening and balance retraining)

This project took the essential steps towards developing practical and feasible falls prevention programmes for those living in residential care in New Zealand. We aimed to establish whether an exercise programme and a multifactorial programme are acceptable to staff and residents and whether the recruitment, randomisation and evaluation processes are possible within the New Zealand setting.
Population Group

Sampling framework
The sampling was done from a list of aged care facilities in the Waitemata District Health Board area. All private hospitals for continuing care, facilities under 20 beds and facilities already running the Life Programme, which incorporates an activity programme, were excluded. This left 31 potential facilities from which 4 were randomly selected to take part in the study.

Contact was made with the 4 potential facilities in March 2008 by a research team member. The study was explained and they were invited to take part. A follow up visit from the research team was made and all 4 facilities agreed to be included in the study. On a subsequent visit the Managers from all 4 facilities signed an informed consent (Appendix 1).

Exclusion criteria for residents
Residents were excluded if they were under 65 years, were admitted for palliative care, respite care, at their registered nurse's or clinical nurse coordinator's discretion, if they were unable to give informed consent and relatives were uncontactable to do so on their behalf, or if they were not in the facility at the time(s) of recruitment.

Recruitment of residents:
Recruitment of residents commenced 5th June 2008 and completion of recruitment occurred on the 15th July 2008. In facilities that had agreed to take part each resident was personally invited to participate.

Informed consent
Residents who were invited and agreed to take part in the study signed an informed consent (Appendix 2). Next of kin were contacted for those older people who were unable to consent due to cognitive impairment. Consent given on behalf of those residents, was given both verbally and in writing to the research staff (Appendix 3).

All residents who agreed or refused to take part in the study were recorded on an Inclusion Form and those who were excluded were recorded on an Exclusion Form (Appendix 4). Table 3 shows the successful recruitment within the 4 homes. The overall response rate was 68%, that is 68% of all eligible and invited residents participated.
Table 3 Response rate within the 4 homes

<table>
<thead>
<tr>
<th>Homes</th>
<th>Total in home</th>
<th>Agreed</th>
<th>Refusals</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>27</td>
<td>20</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>B</td>
<td>32</td>
<td>19</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>C</td>
<td>25</td>
<td>15</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>D</td>
<td>26</td>
<td>16</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>

**Overall response rate - 68%**

Baseline data collection
Baseline data were collected on all consenting residents. Trained interviewers completed a clinical health record audit (age, gender, NHI number, date of admission, medical diagnosis, medications and falls sustained in the previous 3 months). A standard questionnaire was administered to measure pain and fatigue and cognitive status.

Observed physical function was assessed by the lower limb performance test, the gait speed test task of walking 3 metres and 10 metres. Strength was assessed with the 30-second chair stand test, and balance with the Tinetti balance test. Staff at the homes filled in a brief questionnaire containing the dependency scale, a 14 item scale used extensively in residential care surveys in New Zealand (Appendix 5).

Randomisation of participants and homes
The schedule for random allocation of individual participants to exercise or control classes, and random allocation of residential care facilities to the multifactorial intervention or to act as a control for this intervention, was computer generated and held by an investigator at a distant site who was not involved in the day to day running of the trial (MCR). After baseline assessments had been completed, the investigator sent the physiotherapist the allocation list for the participants at that rest home. After all study recruitment and baseline assessments had been completed, the allocation schedule for the multifactorial intervention was sent to the study co-ordinator so that this intervention could be implemented in two of the four rest homes. The field team assessing participants at all follow ups remained blind to exercise group and rest home intervention allocation.
Development of exercise programme
A sub-group of the research team were involved in the development of the exercise programme. The programme aimed to contain strength, balance, sensory integration and dual tasking exercises. The programme was trialled on a group of participants and modified according to their feedback and the feedback of the therapists present at the trial. A manual was developed detailing the programme and an Excel sheet was designed to be used to record the exercises performed at each session.

Exercise programme development team
- Denise Taylor
- John Parsons
- Elizabeth Binns
- Stephanie Woodley
- Juliet Rosie
- Susanne Radeck (German physiotherapist)

Training of intervention physiotherapists
Denise Taylor and Elizabeth Binns were responsible for training the physiotherapists in the content, delivery and recording of the exercises. All physiotherapists delivering the exercise programme were trained in the same way.

Implementation of exercise programme
Exercise classes were commenced in all facilities between July 17th July 2008 and 18th of August 2008 and completed January to February 2009. Classes were well received by staff and residents. Attention to engagement of staff in getting residents involvement and being ready on time for the exercise classes was addressed by the regional coordinator of quality in residential care, a partner in the trial, talking with...
and meeting staff. Attendance sheets, (Appendix 6), were completed by the physiotherapist instructors and were used to record attendance by individual participants.

**Multifactorial intervention:**
A multifactorial intervention programme for the prevention of falls in residential care was adapted for use in New Zealand from the Falls Prevention Guidelines and support materials developed by the Australian Commission on Safety and Quality in Health Care (with their permission). The basic components were adapted for New Zealand implementation:

- **A champion:** This person was nominated by each of the two homes. Training and any necessary equipment (e.g., information booklets, fact sheets for residents, for health care professionals and carers, posters, hip protectors, light meters) was provided to them. The champion was responsible for their facility's activities and coordination with the research team. Expert falls practitioners worked with champions and management on case-based education and building relationships to encourage adherence to the programme.

- **Attention to the environment:** Lighting, maintenance of walking aids and wheelchairs, attention to hazards were audited using specifically designed materials.

- **Hip protectors:** A choice of hip protectors was offered to those at moderate and high risk of falling with training for staff and residents in their effectiveness.

- **Simple risk assessment and choice of uptake:** Risk of falls is related to mobility with those who are bed bound being at lowest risk, those who are independent without assistance are at intermediate risk and those who need assistance to transfer are at the highest risk of falls and injury from falls. The champion in conjunction with registered nursing staff encouraged those at highest and intermediate risk to wear hip protectors, take vitamin D and encouraged adherence for those attending exercise classes.

- **Vitamin D supplementation:** All older residents were offered Vitamin D. An audit by the clinical nurse prompted a request for prescription of Vitamin D by the general practitioner. All general practitioners were sent information about Vitamin D prescribing.

A package comprising the contents of this programme was constructed and given to each home randomised to receive the multifactorial programme. The package comprised:

- Falls Prevention Guidelines 2008 preventing falls and harm from falls in older people, Australian Commission on Safety and Quality in Health Care, 2008.
- Fact sheets for Residents, Nurses, Doctors, Allied Health Professionals, Health Managers and Support Staff.
- Falls Prevention Poster
- Quick reference guide for the above guidelines
- Implementation guide for the above the guidelines
- “Falls are not for me” cartoon booklet
- DVD Taking steps to prevent falls in older people
- Teaching manual for the falls champion to use as a teaching resource
- CD with all the above resources on it

The programme was implemented with staged training and support as follows.

Training of Champions and Managers
The training day for champions and managers was conducted on Thursday, August 28th, 2008 on the AUT Campus. The training was for the two facilities that were randomised to the multifactorial intervention, and covered all aspects of this approach. For each facility, a champion and a manager was selected by the facility, and attended the training day. The purpose of both being present was to ensure support for the champion from the facility's management, and for knowledge of the programme to be known widely in the facility.

The objectives for the attendees are outlined below.

The objectives for this training day were that by the end of the day's programme the participants would:
- Have been introduced to the “Orange Box” – a resource tool for falls prevention and injury prevention for residential aged care facilities
- Have been briefed on standard falls prevention strategies
- Have reviewed assessment tools for falls risk and compared this with their existing tools
- Have gained more knowledge about intrinsic and extrinsic factors as reasons why an older person is at risk of falling
- Have the opportunity to use the prepared training kit. How it works was explained the them
- Have gained an understanding of the role of the champion and manager in falls prevention
- Have received information on the role exercise and mobility plays in falls prevention, and gained an appreciation of this
✓ Have received and shared information on injury prevention, including hip protectors and medication
✓ Have had the opportunity to see the Implementation Guide for the programme and consider progression of their facility through the range of activities
✓ Have gained more understanding and depth of knowledge about post falls management linking this to incident reporting, and the importance of measurement in quality improvement

The programme and presentation topics for the day were as set out in the Table 4.

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>PRESENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction - The Box turns Orange!</td>
<td>Madeleine Calder</td>
</tr>
<tr>
<td>Step 1 – Involve the person and their carers</td>
<td></td>
</tr>
<tr>
<td>Role of the champion and the manager – Exploring the box, a diary too</td>
<td>Madeleine Calder / John Parsons / Ngaire Kerse</td>
</tr>
<tr>
<td>Standard falls prevention strategies in brief</td>
<td>Madeleine Calder</td>
</tr>
<tr>
<td>Assessment – sharing tools – reporting incidents</td>
<td>Ngaire Kerse, John Parsons, Madeleine Calder</td>
</tr>
<tr>
<td>Fall prevention interventions – Intrinsic factors – Medications</td>
<td>Ngaire Kerse</td>
</tr>
<tr>
<td>Extrinsic factors – The environment</td>
<td>Jenni Mace</td>
</tr>
<tr>
<td>How the training tool kit works – Let’s Recap on Intrinsic factors</td>
<td>John Parsons</td>
</tr>
<tr>
<td>Mobilisation, functional activities and exercises</td>
<td>Denise Taylor</td>
</tr>
<tr>
<td><strong>Injury Prevention Prescription</strong> - Vitamin D and hip protection</td>
<td>Ngaire Kerse</td>
</tr>
<tr>
<td>Hip protectors</td>
<td>Liz Binns</td>
</tr>
<tr>
<td>Post falls – incident reporting, measuring - see the Implementation Guide</td>
<td>John Parsons and Madeleine Calder</td>
</tr>
</tbody>
</table>

The champion and manager were supplied with an Orange Box for their respective facilities and had the opportunity to examine the contents over the course of the day. The resources were primarily for the use of the champion in educating the residents and staff about falls prevention and injury prevention. Further meetings at regular intervals were conducted to support the champion and manager over the course of the next 6 months. The presenters were available as resources for the facilities during the period of the pilot study.

The multifactorial programme began in the two intervention facilities after the training day on August 28th 2008. The implementation of recommended changes were the responsibility of the management
under the advice of the champion, and according to the availability of funding for each facility. Ongoing support was supplied by the regional residential care quality advisor along with falls problem solving meetings and telephone support on a regular basis for the champions.

**Control homes** The two rest homes randomised to usual care continued with usual processes and practices.

6months Follow up Questionnaire
Follow up questionnaires were administered to all those completing the trial. The same assessment of mobility was completed at 6 months follow up as at baseline. During the trial period 4 participants died, 2 were transferred to dementia units outside the study homes and 8 were transferred to private hospital level of care.

Adverse events monitoring
Adverse events were monitored on all participants every 2 months by an independent research assistant not otherwise involved in the trial. Adverse events such as pain, fatigue and changes in sleep were recorded. (Appendix 7). Falls data were gathered from the falls register in each facility at 2 and 4 monthly intervals, from the time exercise classes started.

Data Entry
All baseline questionnaires and the dependency scale questionnaire and 6 month measures were entered into an Access database program. All measures recorded at 6 months have been entered.

Analysis
Data were analysed on an intention to treat basis using Stata 8.0 (StataCorp, College Station, TX). To compare changes in the physical assessment measures from baseline to six months for the upright exercise class participants with those attending the seated (control) exercise classes, we used logistic and linear regression models. In each model we adjusted for clustering on individual rest home, the value of the measure at baseline, and whether or not the rest home received the multifactorial intervention.
We used linear regression models to compare adherence (the proportion of available classes attended) in the two types of exercise classes, and in the multifactorial intervention versus the control homes, adjusting for clustering on individual rest home. At the six month follow up we also compared the number of participants prescribed vitamin D tablets in the multifactorial intervention versus the control homes, adjusting the model for individual rest homes, the two types of exercise classes, and whether or not vitamin D was prescribed at baseline. Similarly we compared the number of participants wearing hip protectors in the two types of intervention homes, adjusting the model for individual rest homes, the two types of exercise classes, and whether or not hip protectors were used at baseline.

We used a negative binomial regression model to compare the rate of falls during the six months of the trial in those attending the upright exercise classes with the control (seated) exercise classes, and participants in the homes receiving the multifactorial intervention with those in the control homes. In this model we adjusted for clustering on individual rest home and the time each individual resident was monitored for falls (until withdrawal from the study, death or for six months).
Results

Sixty-eight older persons were successfully recruited to the trial with an acceptable response rate (68%). During the follow up period 4 people died, 8 people were transferred to hospital level care, 2 were transferred to a dementia unit and a number of people ranging between 29-53 completed various levels of the follow up measures at 6 months. This shows that it is possible to invite, recruit and follow older people in residential care in a falls prevention trial with a complex design.

Table 5 shows the characteristics of the sample at baseline. The four homes recruited participants with significant levels of dementia with an average of 4.1- 5.9 (normal 7 and above) on the AMTS dementia screen\(^{26}\). Participants also had many co-morbidities and had resided at the rest homes on average more than 5 years. The median time in the home was 55.9 months (Table 6), with the longest staying resident enrolled in the trial was in the rest home for over 50 years.

Table 5. Baseline characteristics of trial participants by individual rest home

<table>
<thead>
<tr>
<th></th>
<th>Rest home 1 (n=20)</th>
<th>Rest home 2 (N=19)</th>
<th>Rest home 3 (n=14)</th>
<th>Rest home 4 (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women, n (%)</td>
<td>18 (90)</td>
<td>13 (68)</td>
<td>12 (86)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>87.1 (5.1)</td>
<td>86.8 (7.0)</td>
<td>83.3 (8.5)</td>
<td>82.6 (8.1)</td>
</tr>
<tr>
<td>Time since admission (months)</td>
<td>78.9 (84.6)</td>
<td>69.2 (65.8)</td>
<td>89.0 (75.5)</td>
<td>107.1 (166.4)</td>
</tr>
<tr>
<td>Number of medical conditions</td>
<td>5.7 (3.3)</td>
<td>5.6 (2.0)</td>
<td>6.8 (2.3)</td>
<td>6.1 (2.3)</td>
</tr>
<tr>
<td>Number of prescribed medications</td>
<td>10.0 (3.5)</td>
<td>8.7 (4.0)</td>
<td>10.6 (3.3)</td>
<td>11.0 (3.8)</td>
</tr>
<tr>
<td>Abbreviated mental test score, (AMTS). (range 0–10, higher scores indicate better cognition)</td>
<td>4.1 (3.4)</td>
<td>4.8 (3.1)</td>
<td>4.5 (3.0)</td>
<td>5.9 (3.1)</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation) unless indicated otherwise.

Table 6 shows the sample grouped by randomisation status. The average age was 85 years (sd 7.2) and the sample comprised 75% women. The spread of baseline characteristics between the groups was even. In this table both the median (mid point person) and the mean (average) differ because the long stayers (up to 50 years) are relative outliers and make the average high. The median is a more useful comparison statistic in this case. The number of prescribed medications is high indicating the high level of co-morbidity in this sample, with 6 medical conditions per person on average.

Over the six month intervention period between 48 and 54 exercise classes were delivered within the homes. Compliance with exercise groups was modest with over 50% of classes that were available attended. There appeared to be slightly more exercise classes attended in multifactorial homes for the Upright exercises (intervention) than those attended in control homes.
Table 6. Baseline characteristics by exercise group and home intervention

<table>
<thead>
<tr>
<th></th>
<th>Upright exercise classes n=35</th>
<th>Control (seated) exercise classes n=33</th>
<th>Multifactorial intervention homes n=33</th>
<th>Control homes n=35</th>
<th>Total n=68</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women, n (%)</td>
<td>29 (83)</td>
<td>22 (67)</td>
<td>25 (76)</td>
<td>26 (74)</td>
<td>51 (75)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>84.0 (7.7)</td>
<td>86.6 (6.8)</td>
<td>85.4 (7.7)</td>
<td>85.2 (6.8)</td>
<td>85.3 (7.2)</td>
</tr>
<tr>
<td>Time since admission (months)</td>
<td>90.7 (127.0)</td>
<td>77.9 (65.6)</td>
<td>77.6 (69.6)</td>
<td>91.0 (124.9)</td>
<td>84.5 (101.4)</td>
</tr>
<tr>
<td>Median (range) time since admission (months)</td>
<td>54.0 (6, 688)</td>
<td>62.5 (0, 224)</td>
<td>53.7 (5, 260)</td>
<td>60.2 (0, 688)</td>
<td>55.9 (0, 688)</td>
</tr>
<tr>
<td>Number of medical conditions</td>
<td>6.1 (2.4)</td>
<td>5.8 (2.7)</td>
<td>6.1 (2.2)</td>
<td>5.9 (2.9)</td>
<td>6.0 (2.6)</td>
</tr>
<tr>
<td>Number of prescribed medications</td>
<td>10.3 (3.5)</td>
<td>9.7 (3.9)</td>
<td>9.5 (3.8)</td>
<td>10.4 (3.6)</td>
<td>10.0 (3.7)</td>
</tr>
<tr>
<td>Abbreviated mental test score (AMTS), (range 0–10, higher scores indicate better cognition)</td>
<td>4.9 (3.0)</td>
<td>4.6 (3.4)</td>
<td>4.7 (3.0)</td>
<td>4.9 (3.3)</td>
<td>4.8 (3.2)</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation) unless indicated otherwise.

While staff were not told which type of exercises that the two groups were completing, it is possible that they realised through observation that they were systematically different and those in the multifactorial homes were more encouraging about attendance for those in the Upright classes than staff were in the control homes.

Table 7. Proportion of available exercise classes attended

<table>
<thead>
<tr>
<th></th>
<th>Multifactorial intervention Homes</th>
<th>Control homes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upright exercise classes (n=33)</td>
<td>0.64 (0.31)</td>
<td>0.54 (0.36)</td>
</tr>
<tr>
<td>Control (seated) classes (n=33)</td>
<td>0.54 (0.37)</td>
<td>0.55 (0.39)</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation) proportion of exercise classes attended (sum of number of classes attended/total classes available during trial). P=0.722 associated with multifactorial intervention versus control homes and P=0.803 associated with Upright exercise classes versus control (seated) classes in regression model (dependent variable proportion of available classes attended).

There were some residents who attended very few classes while others attended the majority. Participants with dementia were able to complete the activities with only occasional behavioural problems. On many occasions staff did not have residents ready for the classes and attendance
increased with greater visibility of the physiotherapists visits to the homes. Upright exercises were successfully progressed in every class.

Process evaluation of uptake and acceptability of the programmes.

Introduction
This evaluation forms a core phase of the ACC funded study to establish the feasibility of a multifactorial programme to reduce falls within aged residential care facilities within New Zealand. It complements and contextualises the quantitative findings of the randomised control trial (RCT) within four facilities in Auckland.

Methods
The primary objectives of the process evaluation were to describe constraints and enablers to participation in the trial from the perspective of staff and residents.
This evaluation was undertaken following the completion of the exercise programme and the follow-up data collection phase of the RCT. It involved face to face or phone semi-structured interviews and focus groups with staff, residents and residents designated family members. In addition a phone interview was undertaken with the clinical director of the organisation with overall control over one of the facilities.
The two facilities randomly assigned as part of the RCT to implement the multifactorial programme were called Rest Home 1 and Rest Home 2.
The evaluation sought to examine the impact of the multifactorial and / or exercise programme on clinical practice within the facility and to determine the factors that enhanced or diminished the effect of the components of the programme. In addition, the attitudes of staff and management towards the components of the programme were explored. These were:

- An increased focus on medication management for residents
- The delivery and content of the education package developed and delivered as part of the RCT
- The provision of hip protectors for all residents
- The impact of the designated falls champion
- The exercise programme developed and delivered as part of the RCT
- An increased focus on auditing of the physical environment
- An increased focus on retrospective, critical and team based analysis of falls among residents

The interviews with residents allowed consideration of their experience of the impact of the programme on the services delivered. Purposive sampling was used to ensure that those interviewed fulfilled the following criteria: attended the exercise programme and showed definite improvements; attended the exercise programme and did not improve with exercises; did not participate in the classes.
The resident interviews explored the following areas: information concerned with reducing the risk of falling; hip protectors; changes to practice following falls (if applicable); experience of exercise programme.

Finally corroborating information concerning the integration of the multifactorial programme into clinical practice within the facilities was gathered. This included physical audits for evidence of material supplied as part of the programme (posters, information sheets for residents, family and staff) and chart audits of resident’s clinical notes to determine compliance with medication management, falls reporting, hip protector use and exercise class attendance.

The details of the data collected at these facilities during the evaluation are shown in Table 8.

Data analysis of interview and focus group data

Detailed notes were taken during the focus groups and interviews to allow for recording of themes arising during these interactions. These notes were analysed for apparent themes by an experienced independent researcher. Analysis of the transcripts was performed and themes identified by a process of repeated review. The data were organised into initial codes, by a process of in-vivo coding. Following this, higher codes were developed that encompassed these initial codes and provided insight into the identified themes. Appropriate text segments were then assigned to each category.

Table 8. Participants in a process evaluation of the multifactorial and exercise interventions to prevent falls in rest home care.

<table>
<thead>
<tr>
<th></th>
<th>Rest Home 1</th>
<th>Rest Home 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus group with carers</td>
<td>5 attendees (4 caregivers and physiotherapist)</td>
<td>8 attendees (7 caregivers and manager)</td>
</tr>
<tr>
<td>Face to face interview with champion</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Face to face interview with manager</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Face to face interview with selected residents</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Chart audit</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Environmental audit</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Throughout the process there was continuous revision and refinement of the categories and themes. This was undertaken using a constant approach and involved each item being checked and compared with the rest of the data to establish analytical categories.
Results
The results will be presented with the findings from the interviews and focus groups combined. Where contextually relevant the data from the chart and environmental audits will be discussed. Analysis of the interview and focus group transcripts revealed the presence of the following main categories among the participants:

<table>
<thead>
<tr>
<th>Changes in practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>The role of the Champion</td>
</tr>
<tr>
<td>Successes and areas of difficulty for the programme components. This consisted of:</td>
</tr>
<tr>
<td>- Education</td>
</tr>
<tr>
<td>- Falls meetings</td>
</tr>
<tr>
<td>- Environment</td>
</tr>
<tr>
<td>- Medication use</td>
</tr>
<tr>
<td>- Exercises</td>
</tr>
<tr>
<td>- Hip protectors</td>
</tr>
</tbody>
</table>

Changes in practice
The markedly different experiences at the two facilities were apparent on examination of the transcripts. This appeared universal among management, caregivers and residents. Rest Home 2 appeared to integrate the aspects of the programme far more readily into the standard clinical practice and operations of the facility. Transcripts show that Rest Home 1 appeared to find it more of a challenge to alter practice at a resident-caregiver level than the staff at Rest Home 2. This may have been due to the small size of Rest Home 2 and the stable and experienced workforce in place. The change in practice at Rest Home 2 was apparent to the caregivers, staff and management.

‘The programme has really changed the way that caregivers work with residents. It has been a real eye opener and has led to definite improvements.’ Nurse Manager, Rest Home 2.

‘The whole picture has changed. There have been areas of extreme improvement and areas of slight improvement.’ Falls champion, Rest Home 2.

‘We are now confident to walk residents whereas we were not before. We would put them in wheelchairs. Learnt to step back and see if they can do more for themselves.’ Caregiver, Rest Home 2.

In addition the change in emphasis towards a more proactive approach to management of falls was apparent at Rest Home 2.
‘More aware of intrinsic and extrinsic factors and far more aware of trip hazards.’ Caregiver, Rest Home 2.

The staff at Rest Home 1 reported more localised success from the programme.

‘I think the only real change is with the exercises. They have been great and have made a real difference.’ Caregiver, Rest Home 1.

‘The hip protectors and the exercise I think are the main things that have changed for the better.’ Falls Champion, Rest Home 1.

Interviews with selected residents did not show any perceived change in practice at either facility other than the implementation of the exercise classes.

The Role of the Champion

Once again the results obtained from the two facilities showed a discrepancy in relation to the role of the champion. The support provided by management to the falls champion appears to have been pivotal in this.

‘I was helped by a great support system. … (nurse manager) has supported me every step of the way. Lots of meetings and support.’ Falls Champion, Rest Home 2.

‘Manager handed it all over to me at the start’ Falls Champion, Rest Home 1.

‘The PT has helped me and the other caregivers but nothing from management. I was pretty much left alone to cope with it all and get it running and keep it going. I found that hard.’ Falls Champion, Rest Home 1.

The ability of the champion to affect a change in practice among their colleagues appears closely linked to this management support and to the champion’s attitude and experience.

At Rest Home 2 an experienced caregiver in a position of leadership volunteered for the role of Falls Champion. She had experience as an ACE1 trainer / assessor. Conversely the Falls Champion at Rest Home 1 had been seconded to undertake the role. This is reflected in the comments made concerning the role.

‘I don’t think I have been any good as the champion. I didn’t want it in the first place and I have been pretty much left on my own since then. I have tried hard but it is not me.’ Falls Champion, Rest Home 1.

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1 Aged Care Education – an NZQA recognised training programme for unregulated staff in aged residential care facilities.
‘There was so much for me to do and the box was huge and I was just overwhelmed. I hated doing the training. I really hated it. I couldn’t sleep and I was so nervous. I still hate it.’ Falls Champion, Rest Home 1.

Programme components

It was recognised that the role of the Falls Champion in implementing the programme components was crucial. Integral to this was the delivery of an education package to staff. This package was designed as an interactive block of six sessions of 20 minutes each. These were to be delivered each month for six months. The Falls Champions and their managers attended a day long training session that included a detailed breakdown of the education package, including the use of the prepared case studies for relating the learning objectives into practice. The integration of the training package into the facilities showed differences in relation to attendance by staff.

‘The education package is completely embedded now. All new staff will have the programme as it stands’. Falls Champion, Rest Home 2.

‘Everyone has done the programme except new people. We will get them on board as they arrive’. Nurse Manager, Rest Home 2.

‘Certificates have been given to all the staff and the night shift even managed to attend all the sessions’. Nurse Manager, Rest Home 2.

‘The training days were poor. I have only been to the one training day. Didn’t feel I saw anything else happening that was different’. Caregiver, Rest Home 1.

‘Staff have gone to the sessions but I am not sure that they have followed up on what is involved. Sometimes that says that they want more out of it.’ Falls Champion, Rest Home 1.

‘About 4 or 5 people come along to the sessions. I don’t think it has made any difference. We knew most of it already. There is nothing new really.’ Caregiver, Rest Home 1.

In addition the mode of delivery appeared to be inconsistent across the facilities, with Rest Home 2 presenting the education package as suggested, whereas Rest Home 1 appeared to offer all the sessions together in a block.
‘Sessions in 20 minute blocks are good. Wonderfully put together. Manageable bites.’
Caregiver, Rest Home 2.

‘I think that the education needed to be longer. People came in especially and it was not worth it for that time and so I would do lots of sessions together to bulk it up.’ Falls Champion, Rest Home 1.

Finally the use of the case scenarios as a learning tool appeared to differ across the two facilities.

‘The case studies are great and the way they are structured is great so you need to think it out.’
Caregiver, Rest Home 2.

‘I think that it needs to be more interesting. I just thought it was too much information and all writing.’
Caregiver, Rest Home 1.

‘I don’t remember things that are just written down. I wanted more props or participatory activities. ‘I tune out.’
Caregiver, Rest Home 1.

‘There needs to be case scenarios. We need to have things to figure out.’
Caregiver, Rest Home 1.

Falls meetings
Both facilities reported limited changes in practice relating to meetings following a fall. Such a retrospective team based activity was advocated as being of importance in changing clinical practice and in reducing falls rates among residents. When questioned about this staff from both facilities suggested that analysing incidents was already part of standard practice.

‘Always have been aware of safety issues so nothing has changed dramatically and more liable to highlight things than they were.’
Caregiver, Rest Home 2.

‘We constantly supervise the best we can. We can’t really do anything differently to be honest’
Caregiver, Rest Home 1.

‘The post fall audit has not really been an issue as we have always looked for patterns in our falls and have always had a very high reporting rate for falls historically. Always have been aware of safety issues so nothing has changed dramatically and more liable to highlight things than they were.’
Nurse Manager, Rest Home 2.
However, at Rest Home 1, there was some evidence to show that the staff could see the need to change the process for examining factors relating to a falls.

‘The falls meetings have not been pushed much. Not much of a link with them to what we want to do and what we need to do. Although I think we are getting better at looking at what happens after falls. It is always in the notes now.’ Physiotherapist, Rest Home 1.

‘I guess the thing to work on would be the post falls meetings. But only when they are needed. At the moment there is not enough analysis after a fall’. Caregiver, Rest Home 1.

Chart audits did reveal evidence of changes in practice following falls. All falls recorded in the notes had corresponding falls incident reports detailing the causative factors and corrective actions. One of the residents interviewed recalled a fall in the preceding six months. However they were unable to report any change in caregiver practice following the incident.

Environment

Attendees from both facilities reported limited success in implementing environmental audits as proscribed as part of the programme. It was felt that such auditing activity had little impact in affecting a change. In the case of Rest Home 1 this was due to planned large scale refurbishments.

‘Mainly it is the lighting. That is the problem. We are being completely rebuilt soon and so nothing major can get done’. Caregiver, Rest Home 1.

‘I did the audit thing and found the lights were bad. But we all knew that. Nothing will change though. Nothing ever does’. Falls Champion, Rest Home 1.

Rest Home 2 did report some changes in awareness of environmental hazards among staff.

‘On the whole I think that we are all far more aware of environmental hazards as part of this programme. Across the board that is. All of us, even the cleaners and kitchen staff’. Nurse Manager, Rest Home 2.

Medication use

Both facilities reported full compliance with Vitamin D prescription among residents. This was confirmed on chart audit.

Exercises

Overwhelmingly all the staff, management and residents questioned expressed the positive impact of the exercise component of the programme.
'I think the only real change is with the exercises. They have been great and have made a real difference'. Caregiver, Rest Home 1

'The exercise sessions were a huge hit'. Caregiver, Rest Home 2.

'The exercises are good. They are hard but the residents love them. The staff love them too. They can see that they help a lot'. Manager, Rest Home 1.

'I hated them at first as they made my breathing a lot worse, but now I think they are great. They are hard and they push me but my walking is better and my legs are stronger'. Resident, Rest Home 1.

The relatively high intensity of the exercises was initially seen as a barrier. However once residents and staff saw the benefits of this increased intensity it was accepted.

'Residents have more strength and confidence. But they are sometimes over confident. They have gone from 5 sit to stands to doing 20 of them. Strength has increased. Walking is quicker'. Caregiver, Rest Home 2.

'Some not at full capacity and have been able to be pushed more'. Falls Champion, Rest Home 2.

'People complained of a lot of pain at the start but that got a lot easier as time went on'. Caregiver, Rest Home 2.

'They have been great. I didn’t think it would work. I thought they were too hard and it was hard getting people there at the start. A lot of people didn’t like it and stopped and a lot have kept at it'. Physiotherapist, Rest Home 1.

'I have heard a lot of feedback from residents about their legs being a lot stronger'. Caregiver, Rest Home 1.

The integration of the exercise programme in the format it had been developed for the RCT was an issue of concern in Rest Home 2. Due to its small size it had no designated physiotherapy resource and so sustainability beyond the duration of the trial was problematic. Conversely in Rest Home 1, the exercise programme had already been embedded into the role of the physiotherapist.
Hip Protectors

The provision of hip protectors to all residents was inconsistent across the two facilities. At Rest Home 1 staff reported an almost universal acceptance of hip protectors by residents. It was suggested that this was due to the caregiver staff advocating their use in a consistent manner. This was seen as a real success by the staff and was one of the benefits of the programme. Rest Home 2 reported very low rates of hip protector use among residents. It was seen as the only component of the programme where they had not shown any success. However it appeared that staff had made a decision not to advocate for hip protector use among residents.

‘They take away a lot of independence. A lot of our residents wear continence products and having hip protectors decreases their confidence and independence. Also they are so uncomfortable and don’t fit right’. Caregiver, Rest Home 2.

Summary of process evaluation

The evaluation assists with contextualisation of the findings of the main phase of the study. It also informs the further development necessary to implement the multifactorial programme across the diversity of aged residential care facilities that would be used in a larger trial. The variability seen between these two participating homes in 1) uptake of and 2) attitudes to the programme means that further field testing is needed in a controlled study prior to widespread dissemination of either programme. The need to ensure management buy-in to the programme and the integral role of the falls champion in driving all aspects of the programme at a clinical level is shown to be of extreme importance. In addition the relationship between the management and the falls champion also appears to be crucial to implementing the systemic changes required for successful implementation of the programme.

Impact of the programme on physical measures and falls

Balance at baseline in the two groups was on average poor. A score of 2 of a maximum of 5 (the 4-test balance score) at baseline declined in both groups to 1.6 after the 6 month follow up period with no significant differences between the seated and Upright exercise groups. Fewer participants were able to complete the 6 month balance test (n=53) than had been able to complete it at baseline (n=68). Looking at one aspect of the balance test, the semi-tandem stand, the amount of time that participants were able to hold this position declined in both groups and there were no differences between the groups. Similarly there was no impact of the exercise programme on walking speed, as shown by the result for the 3 and 10 metre walk tests (Table 8). There was a trend towards improvement in chair stand tests. In the Upright exercises group (intervention) the number of chair stands completed in 30 seconds
increased and time to complete five chair stands decreased representing an improvement in function and general lower limb strength. In the seated exercises group the trends in change in activity were in the opposite direction (Table 8). These changes did not reach statistical significance (P = 0.1) perhaps because fewer people were able to fully complete these tests.

Table 9. Physical assessment measures at trial entry and 6 months

<table>
<thead>
<tr>
<th></th>
<th>Upright exercise classes</th>
<th>Control (seated) exercise classes</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-test balance score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(score range 0–5, lower scores indicate poorer balance)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=68)</td>
<td>2.1 (1.2)</td>
<td>1.9 (1.5)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=53)</td>
<td>1.6 (1.4)</td>
<td>1.6 (1.3)</td>
<td>0.779</td>
</tr>
<tr>
<td>Semi-tandem stand time (seconds) (range 0–10 seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=67)</td>
<td>6.5 (3.9)</td>
<td>5.8 (4.7)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=46)</td>
<td>5.7 (5.0)</td>
<td>4.9 (4.8)</td>
<td>0.570</td>
</tr>
<tr>
<td>Time to walk 3 m (seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=65)</td>
<td>7.2 (8.5)</td>
<td>5.8 (3.1)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=43)</td>
<td>5.8 (2.9)</td>
<td>6.4 (3.7)</td>
<td>0.756</td>
</tr>
<tr>
<td>Time to walk 10 m (seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=65)</td>
<td>20.0 (16.4)</td>
<td>21.3 (17.8)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=43)</td>
<td>18.5 (9.5)</td>
<td>23.5 (20.8)</td>
<td>0.639</td>
</tr>
<tr>
<td>Number of chair stands in 30 seconds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=41)</td>
<td>6.9 (2.3)</td>
<td>6.7 (2.2)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=29)</td>
<td>8.2 (3.6)</td>
<td>5.8 (1.9)</td>
<td>0.110</td>
</tr>
<tr>
<td>Time for 5 chair stands (seconds)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=39)</td>
<td>21.0 (6.5)</td>
<td>22.9 (7.7)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=26)</td>
<td>18.6 (6.6)</td>
<td>23.8 (5.7)</td>
<td>0.101</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation).

*P value associated with Upright exercise classes versus seated exercise classes at 6 months (participants with both assessments completed only).

The potential impact of the programme on physical function was examined by counting those who improved or stayed the same as a result of the programme. There was no differential impact observed between the two groups in the balance tests or the chair stand tests. When examining the 10 metre walk test there were more people who improved in the upright group than in the seated exercise group. This was the only statistically significant difference between the two groups that was observed in the assessment of improvement over time. The result of those who did not improve or stay the same are presented in Table 10.
### Table 10. Improvement/same in physical assessment measures at 6 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Upright exercise classes</th>
<th>Control (seated) exercise classes</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-test balance score (n=53)</td>
<td>17 (61)</td>
<td>15 (60)</td>
<td>0.845</td>
</tr>
<tr>
<td>(score range 0–5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Semi-tandem stand time (range 0–10 s)</td>
<td>15 (71)</td>
<td>15 (63)</td>
<td>0.623</td>
</tr>
<tr>
<td>(n=45)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to walk 3 m (n=41)</td>
<td>7 (33)</td>
<td>6 (30)</td>
<td>0.791</td>
</tr>
<tr>
<td>Time to walk 10 m (n=41)</td>
<td>10 (48)</td>
<td>4 (20)</td>
<td>0.007</td>
</tr>
<tr>
<td>Number of chair stands in 30 s (n=23)</td>
<td>7 (33)</td>
<td>5 (42)</td>
<td>0.721</td>
</tr>
<tr>
<td>Time for 5 chair stands (n=24)</td>
<td>6 (46)</td>
<td>7 (64)</td>
<td>0.777</td>
</tr>
</tbody>
</table>

Values are number of participants (%) with both baseline and 6 months assessment results. Remainder had scores or times that were worse at 6 months than at baseline.

*P value associated with Upright exercise classes versus control (seated) exercise classes at 6 months (participants with both assessments completed only).

Examining falls and potential effect of the two types of intervention on falls showed that there were no statistically significant differences in rate of falls between the group receiving upright exercises compared with the group receiving seated exercises. Nor was there any significant difference in fall rates between those living in homes continuing with usual care practice and those living in homes undergoing the multifactorial intervention.

### Table 11. Numbers of falls and follow up times at 6 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Upright exercise classes</th>
<th>Control (seated) exercise classes</th>
<th>Multifactorial intervention homes</th>
<th>Control homes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of falls (falls per person year) in previous 3 months</td>
<td>2.97</td>
<td>3.88</td>
<td>4.48</td>
<td>2.40</td>
<td>3.41</td>
</tr>
<tr>
<td>Total time falls monitored (person months)</td>
<td>176</td>
<td>160</td>
<td>162</td>
<td>174</td>
<td>336</td>
</tr>
<tr>
<td>Total number of falls during trial</td>
<td>33</td>
<td>39</td>
<td>37</td>
<td>35</td>
<td>72</td>
</tr>
<tr>
<td>Number (%) of participants with ≥1 falls during trial</td>
<td>16 (48)</td>
<td>15 (48)</td>
<td>13 (42)</td>
<td>18 (58)</td>
<td>31</td>
</tr>
<tr>
<td>Rate of falls (falls per person year) during trial</td>
<td>2.25</td>
<td>2.93*</td>
<td>2.74</td>
<td>2.41†</td>
<td>2.57</td>
</tr>
</tbody>
</table>

*Incident rate ratio from negative binomial regression model for number of falls in Upright exercise class group versus control exercise class group 0.75, 95% confidence interval 0.42 to 1.33, P=0.321; †multifactorial intervention versus control homes 1.10, 95% confidence interval 0.98 to 1.24, P=0.108.

Examining potential effects of the multifactorial intervention on receipt of falls and injury preventive treatments showed that use of Vitamin D by residents in intervention homes increased from 60% to 96% of all residents. There was an increase in Vitamin D use in control homes. This differential change in medication use was statistically significant. Hip protector use was greater in multifactorial homes at four
months (relative risk 2.46, 95% CI 1.81-3.35), although closer examination showed that this was evident in one home only (Table 12).

Table 12. Residents with hip protectors and vitamin D prescribed at baseline and follow up.

<table>
<thead>
<tr>
<th></th>
<th>Multifactorial intervention homes</th>
<th>Control homes</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hip protectors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=68)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4 months (n=53)</td>
<td>7 (23)</td>
<td>0</td>
<td>*0.003</td>
</tr>
<tr>
<td><strong>Vitamin D</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial entry (n=68)</td>
<td>20 (61)</td>
<td>14 (40)</td>
<td></td>
</tr>
<tr>
<td>6 months (n=53)</td>
<td>25 (96)</td>
<td>15 (56)</td>
<td>†0.001</td>
</tr>
</tbody>
</table>

Values are number of trial participants (% of total participants from these homes).

*P value associated with multifactorial intervention versus control homes at 4 months (participants followed up at 4 months only).

† P value associated with multifactorial intervention versus control homes at 6 months (participants followed up at 6 months only).
Discussion
This study was successful in proving that a 2x2 factorial trial comparing two different interventions aimed at decreasing falls is feasible. The homes entered the trial and residents were recruited with an acceptable response rate. The multifactorial programme has been developed and trialled in two homes with a good effect on Vitamin D prescribing and hip protector use.

The exercise programme has been developed, taught to physiotherapists not previously familiar with it and trialled with over 30 residents. The participation rates in the classes were acceptable with the recognition that increased staff awareness and cooperation may be needed in the larger trial to promote attendance at classes. In Germany there were volunteers available to assist in bringing residents to classes and assist with class processes. This could be a potential strategy to promote participation in a larger trial.

Most participants completed the trial and expected follow up rates are available for a power calculation to estimate how many participants will be needed to show an impact on falls in a larger trial.

The measures use in the trial for assessment of outcomes were largely acceptable. However, they may need to be examined in more detail considering that fewer participants than ideal were able to complete the measures at follow up.

The participants.
The sample had been living in rest home care for a surprisingly long time. This may have been because those who chose (and their families who chose for them) to participate may have been those with a long relationship with the rest home. The longest staying resident had been in the home for over 50 years. This is possible for some individuals with intellectual disability or long term mental illness. Participants may also have been those more likely to fall who were more interested in the topic of the study. The group of older people in rest home care are frail, have a high prevalence of dementia and many co-morbidities. This sample is similar to other studies in New Zealand residential care. It was particularly pleasing to be able to involve those with dementia in the programmes and find that they were able to participate.

The exercise programme
This programme did not result in a marked change in physical function measures. This was probably because not enough participants were able to complete the 6 month follow up assessments. The
number able to complete the follow up assessments was less than estimated and less than desirable meaning that a type 2 error is possible, where there is a difference between the groups but there are insufficient numbers completing the trial to show the difference. There were some trends towards improved function in chair stands and walking speed in the Upright exercise group compared with the control seated exercise group. This trial was powered to show a change in the chair stand test, however only half those needed to show a change were able to complete both baseline and 6 month follow up assessments. A larger study with falls as an outcome is needed to test this activity programme to an adequate standard to justify widespread dissemination. It is possible that falls can reduce without significant change in balance and gait, depending on how balance and gait are measured.

The activities were planned twice weekly. Other programmes have been planned for three times a week or more episodes of activity\textsuperscript{16}, however the optimum frequency of activity episodes per week are not entirely clear.

Compliance with this exercise programme was relatively high with participants completing on average over 50% of classes. Other programmes proven to be effective in reducing falls had high participation rates, such as 75% of intervention groups exercising at least three times a week for the Otago Exercise Programme\textsuperscript{24}.

\textit{The multifactorial programme.}
The evaluation of the programme showed that the programme had an impact on the way staff approached the staff-resident interactions in at least one of the homes. The role of the champion was key in instigating and supporting change. The difference between how the champion operated between the two homes means that ways to assist the champion in ongoing change management need to be developed and delivered during the larger trial. This has been described in other programmes and aspects of the evaluation point the way towards more training for the champions about change processes in organisations. The strategies that relied on audit (Vitamin D) were straightforward in implementation. The strategies relying on resident cooperation were less well taken up (Hip protector compliance was low). Environmental changes were more difficult to document.

\textbf{Summary}
Overall the multifactorial programme was feasible and acceptable. This pilot study paves the way for a larger 2x2 factorial trial testing the questions “do exercises prevent falls in residential care?”, “does a
multifactorial programme reduce falls?” and “which programme is more effective and cost efficient?”.

The feasibility study has not proven that the activity programme improves physical measures, however meaningful change in physical measures can be difficult to achieve and the optimal outcome of falls prevention has previously been achieved without marked change in balance and gait. Overall the study has achieved its goals and the information generated will make a contribution to seeking further funds to conduct the definitive trial comparing these two approaches to falls prevention.

Further evaluation is needed of both the exercise programme and the multifactorial intervention prior to wider dissemination.
References


Appendices
1. Consent Form For Management
2. Consent Form For Participant
3. Consent Form For Proxy
4. Exclusion, Inclusion Forms
5. Baseline Questionnaire
6. Physiotherapist Record Sheets
7. 2 month/4 month adverse event questionnaire
The residents have been invited to participate in a study about staying upright while living in rest homes. Prevention of falls is important to maintain independence. The project aims to find out whether doing activities to increase strength and balance make a difference to lower leg function. We also want to see whether the rest home having a champion to emphasise falls prevention is acceptable to other staff and residents.

Introduction
This research is being undertaken by the University of Auckland in partnership with the AUT University and the University of Otago. This pilot study will find out whether offering older people in rest homes regular activities makes a difference:

- To lower leg function
- To balance

The research team hopes to recruit about 70 older people aged 65 + from four rest homes in Auckland. It is really important that everyone helps with the study so that we can see if it useful for all older people in rest homes.

Your decision to have your residential care facility take part in this study is completely voluntary.

What to expect?
- We would like to talk to your residents about their health and well being and ask them to do some simple tasks like a timed walk and standing up out of a chair. The interview will take approximately 45 minutes and be completed at your rest home. The interview would happen now and after 6 months.
• We would also like your residents to undertake an exercise programme twice a week for 6 months.
• We would also like to review medical records of enrolled residents at the rest home and record the medications. This information would only be used for the study and be kept safe.

This study is a randomised controlled trial and will find out whether certain types of exercises increase lower leg function.
• Some participants will do exercises standing up and using some weights. Others will do seated exercises concentrating on flexibility. The choice of which exercises they do is made by chance and about half of the participants will do each type of exercises.
• A physiotherapist will come to the rest home to deliver the activity programmes free of charge.
• Your rest home may or may not have a champion to emphasise falls prevention who will teach staff, check the environment and suggest falls prevention strategies to staff and your doctor. The choice of whether your rest home has the champion or not is made by chance. Training is provided for the champion free of charge and resource packages to assist in programme delivery are supplied free of charge.
• You do not have to take part in this study, it is your choice. Whether you choose to take part or not will make no difference to the care delivered at the rest home of from the GP.
• You are able to opt out at any time. Please feel free to discuss taking part with the staff at the home or the GP.

Information Sharing
• The information collected as part of this study may be used to improve health services for older people by being combined with information collected as part of other studies about falls.
• This would only occur with the explicit approval of ethics review committees governing this research and after all information identifying individuals has been removed.

Confidentiality & Your Rights
• Everything you and your staff say will be strictly confidential. No material that could personally identify you, your staff or your rest home will be used in any reports on this study. Your GP will be informed of your participation in this study. Only the research team will have access to the list of people who were involved in the research. These will not be given to anyone else. All researchers on the project will have signed confidentiality agreements. The study files and all other information that you provide will remain strictly confidential.
• You do not have to answer all the questions in the interview and you can stop at anytime.
• You will receive notice from the research team when information about this research has been published.

The project has been funded by the Accident Compensation Corporation New Zealand (ACC)

The project has received ethical approval from the Northern X Regional Ethics Committee

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact your professional organisation.

To get involved
• Your participation in this important research would be appreciated. We would like to involve all rest homes invited to participate. If you want further information please contact:

Lois Shaw and Dinah Walker
Stay Upright Trial Phone: 09 373 7599 X 83030
Department of General Practice & Primary Health Care
School of Population Health Facsimile: 09 373 7624
University of Auckland Email: l.shaw@auckland.ac.nz
Private Bag 92 019, Auckland 1142 Email: dinah.walker@auckland.ac.nz

ACC Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Accident Compensation Act 2001. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

Study Investigators
The principal investigators for this study are:

Associate Professor Ngaire Kerse
Department of General Practice &

Associate Professor Denise Taylor
Health & Rehabilitation Research Centre
I have read and I understand the information sheet dated 28th Feb 2008 for management taking part in the staying upright in rest home care study.

- I have had the opportunity to discuss this study with the investigator. I am satisfied with the answers I have been given.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw my rest home from the study at any time.
- I understand that my participation in this study is confidential and that no material that could identify my rest home will be used in any reports on this study.
- I understand that the treatment, or investigation, will be stopped if it should appear harmful.
- I understand the compensation provisions for this study.
- I understand the residents will be contacted and followed up in 6 months.
- I have had time to consider whether to take part.

Y/N I wish to receive a copy of the aggregated result. I understand that there may be a significant delay between data collection and the publication of the study results.

Rest Home Name ________________________________

I ___________________________ (print full name)
of ____________________________ (print rest home address)

hereby consent to take part in the Staying Upright study

_____________________________  Signature of Rest Home manager

_____________________________  Date
You are invited to participate in a study about staying upright while living in rest homes. Prevention of falls is important to maintain independence. The project aims to find out whether doing activities to increase strength and balance make a difference to lower leg function. We also want to see whether the rest home having a champion to emphasise falls prevention is acceptable to other staff and residents.

Introduction
This research is being undertaken by the University of Auckland in partnership with the AUT University and the University of Otago. The study will find out whether offering older people in rest homes regular activities makes a difference:

- To lower leg function
- To balance

The research team hopes to recruit about 70 older people aged 65 + from four rest homes in Auckland.

What to expect?
- We would like to talk to you about your health and well being and ask you to do some simple tasks like a timed walk and standing up out of a chair. The interview will take approximately 45 minutes and be completed at your rest home. The interview would happen now and after 6 months.
• We would also like you to join in an exercise programme twice a week for 6 months.
• We would also like to review your medical record at the rest home and record your medications. This information would only be used for the study and be kept safe.
• We would like to visit you again to talk about your health and well being and ask you to do some simple tasks like a timed walk and standing up out of a chair. This study will find out whether a certain type of exercise increases lower leg function by deciding by chance (that is like the toss of a coin) who will get the type of exercises and then seeing what changes there are to function.

• Some participants will do exercises standing up and using some weights. Others will do seated exercises concentrating on flexibility. The choice of which exercises you do is made by chance and about half of the participants will do each type of exercises.
• Your rest home may or may not have a ‘champion’, that is a rest home staff member specially trained to help prevent falls. That person will: emphasise falls prevention, teach all staff, check the environment, suggest falls prevention strategies to staff and your doctor. The choice of whether your rest home has the champion or not is made by chance. If you are in a home with the champion you will be offered Vitamin D, one tablet a month to help strengthen muscles and increase bone strength.
• You do not have to take part in this study, it is your choice. Whether you choose to take part or not will make no difference to the care you receive at the rest home of from your GP.
• You are able to opt out at any time. Please feel free to discuss taking part with your family, whanau, friends, the staff at the home or your GP.

Information Sharing
• The information collected as part of this study may be used to improve health services for older people by being combined with information collected as part of other studies about falls.
• This would only occur with the explicit approval of ethics review committees governing this research and after all information identifying individuals has been removed.

Confidentiality & Your Rights
• Everything you say will be strictly confidential. No material that could personally identify you will be used in any reports on this study. Your GP will be informed of your participation in this study. Only the research team will have access to the list of people who were involved in the research. These will not be given to anyone else. All researchers on the project will have signed confidentiality agreements.
The study files and all other information that you provide will remain strictly confidential.

- You do not have to answer all the questions in the interview and you can stop at anytime.
- You will receive notice from the research team when information about this research has been published.

The project has been funded by the Accident Compensation Corporation New Zealand (ACC)

This study has received ethical approval from the Northern X Regional Ethics Committee
If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act:

Telephone (NZ wide): 0800 555 050
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)
Email: advocacy@hdc.org.nz

To get involved
- Your participation in this important research would be appreciated. We would like to involve all older adults invited to participate including the very old, the unwell and frail.
- Please let the nurse know that you are interested
- If you would like to participate, the nurse will review your record and ask you to undertake the interview. If not, we will not contact you again.
- If you want further information please contact:

Lois Shaw and Dinah Walker
Stay Upright Trial
Department of General Practice & Primary Health Care
School of Population Health
7624
University of Auckland
Private Bag 92 019, Auckland 1142

Phone: 09 373 7599 X 83030
Facsimile: 09 373 7624
Email: l.shaw@auckland.ac.nz
dinah.walker@auckland.ac.nz

ACC Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Accident Compensation Act 2001. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

Study Investigators, The principal investigators for this study are:

Assoc Prof Ngaire Kerse
Department of General Practice & Primary Health Care
School of Population Health
University of Auckland
Private Bag 92019, Auckland
Tel: (09) 373 7599 Ext. 84467

Assoc. Prof. Denise Taylor
Health and Rehabilitation Research Centre
Faculty of Health & Environmental Sciences
AUT University
North Shore Campus
Private Bag 92006, Auckland 1142
Tel: (09) 921 9680
I have read and I understand the information sheet dated May 30th 2008 for residents taking part in the staying upright in rest home care study.

- I have had the opportunity to discuss this study with the investigator. I am satisfied with the answers I have been given.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing or future health care.
- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.
- I understand the compensation provisions for this study.
- I have had time to consider whether to take part.
- I agree to a follow up contact visit 6 months after the first visit.
- I know whom to contact if I have any side effects to the study.

- PTO
Y/N I wish to receive a copy of the aggregated result. I understand that there may be a significant delay between data collection and the publication of the study results.

Y/N I consent that the researcher may have access to my medical information.

Y/N I consent to my information being used for future related studies subject to approval by an accredited NZ Ethics Committee.

Y/N I consent to being contacted again after the study has finished if further research projects might interest me.

I ___________________________ (print full name)
of ___________________________ (print Rest Home)

hereby consent to take part in the Staying Upright study.

______________________________ Signature of participant

______________________________ Date
Part 7: When a participant is unable to make an informed choice

To be completed when one or more participants in a project will likely not be able to make an informed choice about whether to take part. Do not complete this section if all participants in the study will be competent to make an informed choice and give informed consent themselves. Refer to the Guidelines for information about children in research.

1. Will any of the participants have a person with them who is available and entitled to make an informed choice on their behalf if they themselves are unable to do so. yes X no

If yes, that person can make a proxy informed choice for the potential participant. Include an appropriate consent form for that person legally entitled. (Note: Where possible the incompetent person should also orally consent to the level of his or her understanding.)

If no, complete section 1.1

1.1 Is there any person interested in the potential participant’s welfare who knows the participant (eg family member/friend/whanau) and is willing and available to express a view as to what the potential participant would choose were he or she competent and fully informed about the study. yes X no

If yes, include an information sheet for the family member/friend/whanau statement as per page 24.

Please note: if it is appropriate that there be wider consultation with family, then this should be encouraged

If no, complete section 1.2

1.2 Explain why it is not possible for a potential participant to make an informed choice and why it is not possible for a proxy choice to be made or for a person interested in the potential participant’s welfare to state what the participant would choose if he or she was competent and fully informed.

Older people in rest homes may have dementia. This means they are not able to learn new information, they have poor judgement and they don’t understand the implications of making a choice.

Some older people in care do not have surviving relatives or friends that understand them and know them well. Therefore there may be no proxy to assist in decision making. There may also never have been an application to the courts for appointment of a guardian.
2. What would be the risks to the participants of taking part in this study?

There is minimal risk from undertaking the activity programmes in the trial. They are designed especially for frail older people in rest homes.

3. Could the research be carried out on people who are able to consent

Yes X

4. Explain why approval is being sought to use this participant/population/patient group.

Older people with dementia have a high fall rate and experience injury from fall more often than those without dementia. They are underrepresented in falls prevention trials and few falls prevention strategies have proven effective for those with dementia. There is an acute need to develop interventions to prevent falls and establish their effectiveness.

5. What is the potential health interest for the group of patients/population of which the participant would be a member?

If falls could be reduced, morbidity and injury associated with falls would be reduced. Quality of life would improve and care would be easier as older people would maintain function.
Staying upright in rest home care

STATEMENT BY RELATIVE/FRIEND/WHANAU

Assoc. Professor Ngaire Kerse
Dept. of General Practice &
Primary Health Care
School of Population
Health University of
Auckland Private Bag 92019
Glen Innes, Auckland
Tel 09 373 7599 ext 84467
n.kerse@auckland.ac.nz

Assoc. Professor Clare Robertson
Department of Medicine, University of Otago

Assoc. Professor Denise Taylor and Liz
Binns

Lay Title
_______Staying Upright in Rest Home Care____________

Principal Investigator
____________Ngaire Kerse__________________________

Participant’s Name
____________________________________________________________

I have read and I understand the information sheet dated May 30th 2008 for people taking part in the study designed to increase lower leg function and decrease falls. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I believe that ____________________________ (participant’s name) would have chosen and consented to participate in this study if he/she had been able to understand the information that I have received and understood.

I understand that taking part in this study is voluntary and that my relative/friend may withdraw from the study at any time if he/she wishes. This will not affect his/her continuing health care.

I understand that his/her participation in this study is confidential and that no material which could identify him/her will be used in any reports on this study.

I understand the compensation provisions for this study.

I know whom to contact if my relative/friend has any side effects to the study or if anything occurs which I think he/she would consider a reason to withdraw from the study.

I know whom to contact if I have any questions about the medication of the study.

This study has been given ethical approval by the Auckland Ethics Committee. This means that the Committee may check at any time that the study is following appropriate ethical procedures.

I/my relative/friend would like a copy of the results of the study. YES/NO
I believe my relative/friend would agree to his/her GP being informed of his/her participation in this study  YES/NO

I believe my relative/friend would agree to his/her medical records being reviewed As part of this study YES/NO

Signed: _____________________________ Date __________________________

Printed Name: ____________________________________________________________

Relationship to Participant: ________________________________________________

Address for results : _______________________________________________________  

STATEMENT BY PRINCIPAL INVESTIGATOR

I Ngaire Kerse declare that this study is in the potential health interest of the group of patients of which ____________________________ is a member and that participation in this study is not adverse to ____________________________ ’s interests.

I confirm that if the participant becomes competent to make an informed choice and give an informed consent, full information will be given to him/her as soon as possible, and his/her participation will be explained. If the participant makes an informed choice to continue in the study, written consent will be requested and if the participant does not wish to continue in the study, he/she will be withdrawn.

Signed: _____________________________ Date __________________________

Principal Investigator

(IF applicable at a later stage)

I ___________________________ (participant) having been fully informed about this study agree to continue taking part in it.

Signed: _____________________________ Date __________________________

Participant
### Inclusion Form

**Interviewer ID** ________________  
**Home/Hospital ID** ________  
**Home/Hospital Name** ____________________________  

**Start date** ________________  

<table>
<thead>
<tr>
<th>Res ID#</th>
<th>Room No</th>
<th>Name</th>
<th>Gender</th>
<th>Date of consent (refusal)</th>
<th>Date of baseline data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Total Residents Home** ________  
**Total Residents Hospital** ________  
**Total Residents Dementia** ________

### Exclusion Form

**Interviewer ID** ________________  
**Home/Hospital ID** ________  
**Home/Hospital Name** ____________________________  

**Total in Residents Home** ________  
**Total in Residents Hospital** ________  
**Total in Residents Dementia** ________

<table>
<thead>
<tr>
<th>Room</th>
<th>Potential participant initials</th>
<th>Age</th>
<th>Gender</th>
<th>under 65</th>
<th>terminally ill</th>
<th>Not in rest home at recruitment</th>
<th>Unable to contact family</th>
<th>Other reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Reason for not participating**

Version 4 18/09/2008
Participant Questionnaire

Residential Facility Number

Date

Participant Number

Interviewer Code

Study Director:
Ngaire Kerse, Denise Taylor

Project Managers:
Lois Shaw, Dinah Walker
From Medical Records

Enter number in box

1. Male 1
   1a D O B
   Female 2
   2. Date of Admission

NHI

3. Chronic Medical Conditions

3a…………………………………3b…………………………………
   3c…………………………………
   3d…………………………………
   3e…………………………………3f…………………………………
   3g…………………………………3h…………………………………

3i. Total number of medical conditions

4. All current prescribed medications

<table>
<thead>
<tr>
<th>Name</th>
<th>Dose</th>
<th>Frequency</th>
<th>Name</th>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

4a Total number of current prescribed medications
5. Number of Falls

<p>| | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
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<td>11</td>
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<td>21</td>
<td>22</td>
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<td>24</td>
<td>25</td>
<td>26</td>
<td>27</td>
<td>28</td>
<td>29</td>
<td>30</td>
</tr>
</tbody>
</table>

From an audit of medical records, 3 months prior to enrollment.

From an interview with the participant

6. PAIN AND FATIGUE

*Note to interviewer:* Read out all options to the participant

‘Have you experienced any of the following problems over the past few days?’

<table>
<thead>
<tr>
<th>Problem</th>
<th>Severity</th>
<th>Score</th>
<th>Participant’s Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have leg or foot pain? (that includes the whole area from your hip to your toes)</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild leg pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate leg pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe leg pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>2. Do you have back pain? (anywhere below your shoulder blades)</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild back pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate back pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe back pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>3. Do you have neck or shoulder pain?</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild neck pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate neck pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe neck pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>4. Do you have pain in any other part of your body?</td>
<td>Site of pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note to interviewer: Record only the worst body area, if more than one</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5. Do you have fatigue? (prompt with definition only if necessary)</td>
<td>No fatigue</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild fatigue</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate fatigue</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(some interference with activities)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe fatigue</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(definite interference with activities)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
7. ABBREVIATED MENTAL TEST SCORE
These questions are to asked to all older people participating in research and are about general cognitive functioning. Thank you for being patient with us and answering as best you can.

1=Correct

<table>
<thead>
<tr>
<th>Question</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>- must be correct</td>
</tr>
<tr>
<td>Time</td>
<td>- without looking at timepiece, correct to nearest hour</td>
</tr>
<tr>
<td>Month</td>
<td>- exact</td>
</tr>
<tr>
<td>201 Queen Street</td>
<td>- give this address, check registration, check memory at end of test</td>
</tr>
<tr>
<td>Year</td>
<td>- exact (except in Jan/Feb when previous year is OK)</td>
</tr>
<tr>
<td>Your address</td>
<td>- exact</td>
</tr>
<tr>
<td>Date of birth</td>
<td>- exact</td>
</tr>
<tr>
<td>Start of WW II</td>
<td>- exact year</td>
</tr>
<tr>
<td>Name of present Prime Minister</td>
<td>- exact</td>
</tr>
<tr>
<td>Count from 20 to 1 backwards</td>
<td>- can prompt with 20 -19 -18, but no further prompts. participant can hesitate and correct but no other errors</td>
</tr>
</tbody>
</table>

TOTAL

8. LOWER EXTREMITY TESTS (See Picture Instruction Sheet in manual)

Instructions: Start with A: Legs comfortably apart stand. If the person can hold the position for 10 seconds, ask them to attempt B: Side-by-side stand. If they manage that proceed to C, D, and E as person is able.

8a. BALANCE TESTS

A. Legs comfortably apart - stand
Held for ________ sec (stop at 10)

B. Side-by-side-stand
Held for ________ sec (stop at 10) If unable, end Balance Tests

C. Semi-Tandem Stand
Held for ________ sec (stop at 10) If unable, end Balance Tests

D. Tandem Stand
Held for ________ sec (stop at 10) If unable, end Balance Tests

E. One Leg stand
Held for ________ sec (stop at 10)

Comments:
8b. GAIT SPEED TEST (See Picture Instruction Sheet in Manual)

A. Time for First Gait Speed Test (sec)
1. Time for 3 meters ________ sec
2. Time for 10 meters ________ sec
3. Aids for first walk
   None □ Cane □ Walker □ Gutter Frame □

<table>
<thead>
<tr>
<th>2. If participant did not attempt test of failed circle why</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tried but unable                                       1</td>
</tr>
<tr>
<td>Participant could not walk unassisted                   2</td>
</tr>
<tr>
<td>Not attempted, you felt unsafe                          3</td>
</tr>
<tr>
<td>Not attempted, participant felt unsafe                  4</td>
</tr>
<tr>
<td>Participant unable to understand instructions           5</td>
</tr>
<tr>
<td>Other (Specify)                                         6</td>
</tr>
<tr>
<td>Participant refused                                     7</td>
</tr>
</tbody>
</table>

Complete score sheet and go to chair stand test

B. Time for Second Gait Speed Test (sec)
1. Time for 3 meters ________ sec
2. Time for 10 meters ________ sec
3. Aids for second walk
   None □ Cane □ Walker □ Gutter Frame □

<table>
<thead>
<tr>
<th>2. If participant did not attempt test of failed circle why</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tried but unable                                       1</td>
</tr>
<tr>
<td>Participant could not walk unassisted                   2</td>
</tr>
<tr>
<td>Not attempted, you felt unsafe                          3</td>
</tr>
<tr>
<td>Not attempted, participant felt unsafe                  4</td>
</tr>
<tr>
<td>Participant unable to understand instructions           5</td>
</tr>
<tr>
<td>Other (Specify)                                         6</td>
</tr>
<tr>
<td>Participant refused                                     7</td>
</tr>
</tbody>
</table>

Complete score sheet and go to chair stand test

What is the time for the faster of the two walks?
Record the shorter of the two times
3m ________ sec
10m ________ sec

If only 1 walk done, record that time ________ sec

If the participant was unable to do the walk: □ 0 points

Comments:

Version 5 June 4th 2008 60
8c. SINGLE CHAIR STAND TEST  (See Picture Instruction Sheet in Manual)

A. Safe to stand without help  [ ] Yes  [ ] No

B. Results:
   Participant stood without using arms  [ ]  → Go to Repeated Chair Stand Test
   Participant used arms to stand  [ ]  → End test; score as 0 points
   Test not completed  [ ]  → End test; score as 0 points

C. If participant did not attempt test or failed, circle why:
   Tried but unable  1
   Participant could not stand unassisted  2
   Not attempted, you felt unsafe  3
   Not attempted, participant felt unsafe  4
   Participant unable to understand instructions  5
   Other (Specify) ________________________  6
   Participant refused  7

8d. REPEATED CHAIR STAND TEST

Ask to complete as many chair stands as possible in 30 sec. Also time the seconds for 5 chair stands

A. If five stands done successfully, record time in seconds.
   Time to complete five stands________ sec

B. Number of chair stands in 30 sec. ________

If participant did not attempt test or failed, circle why:
   Tried but unable  1
   Participant could not stand unassisted  2
   Not attempted, you felt unsafe  3
   Not attempted, participant felt unsafe  4
   Participant unable to understand instructions  5
   Other (Specify) ________________________  6
   Participant refused  7
<table>
<thead>
<tr>
<th>ID</th>
<th>21 Mobility within home</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Walks without aids………………………………… 1</td>
</tr>
<tr>
<td></td>
<td>Walks with aid of stick or walker…………………… 2</td>
</tr>
<tr>
<td></td>
<td>Walks only with help of a person………………………… 3</td>
</tr>
<tr>
<td></td>
<td>Walks only with help of two people………………………… 4</td>
</tr>
<tr>
<td></td>
<td>Moves independently in wheelchair……………………… 5</td>
</tr>
<tr>
<td></td>
<td>Bedfast, chair bound, or mainly so………………………… 6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>22 Use of toilet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gets to and uses toilet without help……………… 1</td>
</tr>
<tr>
<td>Needs reminding but manages without help……….. 2</td>
</tr>
<tr>
<td>Requires personal assistance………………………… 3</td>
</tr>
<tr>
<td>Unable to use toilet………………………………… 4</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>23 Continence (urine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continent of urine…………………………………… 1</td>
</tr>
<tr>
<td>Continent when toileted regularly…………………… 2</td>
</tr>
<tr>
<td>Incontinent on average weekly or less………………… 3</td>
</tr>
<tr>
<td>Incontinent on average every 24 hours………………… 4</td>
</tr>
<tr>
<td>Persistently incontinent of urine……………………… 5</td>
</tr>
<tr>
<td>Indwelling catheter…………………………………… 6</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>24 Continence (faeces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continent of faeces…………………………………… 1</td>
</tr>
<tr>
<td>Incontinent on average weekly or less………………… 2</td>
</tr>
<tr>
<td>Incontinent on average every 24 hours………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>25 Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to dress fully without help…………………… 1</td>
</tr>
<tr>
<td>Able to dress with a little help…………………….. 2</td>
</tr>
<tr>
<td>Needs considerable help with dressing………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>26 Feeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to eat a meal without help……………………… 1</td>
</tr>
<tr>
<td>Able to eat a meal only if food is specially prepared…………………….. 2</td>
</tr>
<tr>
<td>Unable to eat a meal without personal assistance………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>27 Self care of appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Takes care of appearance e.g. comb hair or (shave)…………………………………… 1</td>
</tr>
<tr>
<td>Requires some personal assistance………………………………… 2</td>
</tr>
<tr>
<td>Unable to manage at all………………………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>28 Showering / bathing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to without help…………………………………… 1</td>
</tr>
<tr>
<td>Unable to without help………………………………… 2</td>
</tr>
<tr>
<td>Not applicable (policy is to supervise)………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>29 Vision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can see well enough to read with or without glasses…………………………………… 1</td>
</tr>
<tr>
<td>Reduced- can read large print, watch TV very poor vision, may need guidance assistance at times…………………………………… 2</td>
</tr>
<tr>
<td>Blind or nearly blind………………………………… 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>30 Hearing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hears normal conversation without aids…………………………………… 1</td>
</tr>
<tr>
<td>Hears well with aid………………………………… 2</td>
</tr>
<tr>
<td>Deafness isolates from normal conversation………………………………… 3</td>
</tr>
<tr>
<td>Severe deafness………………………………… 4</td>
</tr>
</tbody>
</table>

| Name:………………………………………..|

<table>
<thead>
<tr>
<th>31 Speech</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expresses her' himself well…………………………………… 1</td>
</tr>
<tr>
<td>Speech impaired e.g. omits words, repeats phrases…………………………………… 2</td>
</tr>
<tr>
<td>Speech disorganised and incomprehensible…………………………………… 3</td>
</tr>
<tr>
<td>Unable to speak but can communicate…………………………………… 4</td>
</tr>
<tr>
<td>Unable to communicate…………………………………… 5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>32 Comprehension (of speech)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Able to follow and understand everyday conversation without undue difficulty…………… 1</td>
</tr>
<tr>
<td>Only understands short simple phrases…………………………………… 2</td>
</tr>
<tr>
<td>Apparently unable to make sense of verbal communication…………………………………… 3</td>
</tr>
<tr>
<td>Unable to assess…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>33 Memory</th>
</tr>
</thead>
<tbody>
<tr>
<td>No noticeable memory defect…………………………………… 1</td>
</tr>
<tr>
<td>Loss of memory for recent events- distant memory not impaired to same extent………………… 2</td>
</tr>
<tr>
<td>Loss of memory for both recent and remote events…………………………………… 3</td>
</tr>
<tr>
<td>Unable to assess…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>34 Orientation of place</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usually knows what day and year it is………………… 1</td>
</tr>
<tr>
<td>Sometimes knows what day and year it is………………… 2</td>
</tr>
<tr>
<td>Mainly confused as to day and year………………………… 3</td>
</tr>
<tr>
<td>Totally confused as to surroundings…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>35 Orientation of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usually knows what day and year it is………………… 1</td>
</tr>
<tr>
<td>Sometimes knows what day and year it is………………… 2</td>
</tr>
<tr>
<td>Mainly confused as to day and year………………………… 3</td>
</tr>
<tr>
<td>Totally confused as to day and year…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>36 Awareness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully aware of what goes on around him/her………………… 1</td>
</tr>
<tr>
<td>Sometimes unaware of what goes on around him or her…………………………………… 2</td>
</tr>
<tr>
<td>Usually unaware…………………………………… 3</td>
</tr>
<tr>
<td>Totally unaware…………………………………… 4</td>
</tr>
<tr>
<td>Unable to assess…………………………………… 5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>37 Wandering</th>
</tr>
</thead>
<tbody>
<tr>
<td>No wandering…………………………………… 1</td>
</tr>
<tr>
<td>Occasional and brief bouts of wandering………………… 2</td>
</tr>
<tr>
<td>Persistent wandering…………………………………… 3</td>
</tr>
<tr>
<td>Not applicable (immobile inactive)…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>38 Night care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rarely or never needs night attention…………………………………… 1</td>
</tr>
<tr>
<td>Needs attention sometimes during the night…………………………………… 2</td>
</tr>
<tr>
<td>Needs attention on average once a night…………………………………… 3</td>
</tr>
<tr>
<td>Needs attention more than once a night…………………………………… 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>39 Behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observes accepted social standards…………………………………… 1</td>
</tr>
<tr>
<td>Subject to bouts of behaviour that disturb but do not offend…………………………………… 2</td>
</tr>
<tr>
<td>Sometimes behaves as to cause others actual distress or discomfort…………………………………… 3</td>
</tr>
<tr>
<td>Resident</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Staying Upright in Rest Home Care

From an interview with the participant

1. Pain

*Note to interviewer:* Read out all options to the participant

‘Have you experienced any of the following problems over the **past few days**?’

<table>
<thead>
<tr>
<th>Problem</th>
<th>Severity</th>
<th>Score</th>
<th>Participant’s Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Do you have leg or foot pain? (that includes the whole area from your hip to your toes)</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>b. Do you have back pain? (anywhere below your shoulder blades to, but not including hips)</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild back pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate back pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe back pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>c. Do you have neck or shoulder pain?</td>
<td>No pain</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild pain</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate pain</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Severe pain</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>d. Do you have pain in any other part of your body?</td>
<td>Site of pain</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note to interviewer:* No pain 1 Mild pain 2

*Record only the worst body area, if more than one Moderate pain 3

*Severe pain 4

e. If **yes** to any of the pain questions, has the pain stopped you taking part in any of your usual daily activities? 1 = Yes 2 = No

If **yes** please comment.

Comments:
2. Fatigue

Do you have fatigue?  
1 = No fatigue  
2 = Mild fatigue  
3 = Moderate fatigue  
4 = Severe fatigue

*Prompt with definition only if necessary*

**Definition of Fatigue:** Any physical or mental exhaustion. **Mild and moderate fatigue** is where participant has some interference with their daily activities. **Severe fatigue** is where participant is prevented totally from completing some of their daily activities.

3. Has there been any change in your sleep in the last two months?

1 = Yes  
2 = No

If Yes please comment.

Comments:

4. Number of falls. *(From Falls Register.)*

a. **For 2 month questionnaire:** From first day of exercises to 2 months.

b. **For 4 month questionnaire:** From 2 months to 4 months.