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Effect of a Group Exercise Program Compared with a Home-Based Exercise Program on Physical Activity in Community-Dwelling Elderly. Study Protocol for the GET-PACE

Randomized Control Trial

Final project

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Abstract

Background: The elderly population is increasing faster than before, so does non-communicable diseases. The benefits of physical activity are well established, but the level of physical activity still decreases with age. It is necessary to find affordable and feasible ways to promote and educate the elderly to continue or start living an active life. The primary objective is to investigate if a group exercise program will change the physical activity level of community-dwelling elderly. The secondary objective is comparing the effect of a group-exercise program and a home-based program on the number of daily steps, functional status, risk of falling, fear of falling and depression.

Methods: Single blind randomized control trial where community-dwelling elderly are recruited through primary care electronic patient charts. Participants must be 65 years or older, retired and able to walk independently with/without a walker. Participants are excluded if staying at a geriatric center, prohibited by the physician to participate in an exercise program or having significant cognitive impairments. They will be allocated randomly to the intervention group with a group exercise program, or control group with a home-based program. The programs last eight weeks. Study investigators are blinded to the allocation. Primary outcome is physical activity, measured with the *Physical Activity Scale for the Elderly* (PASE). Secondary outcomes are number of daily steps, functional status, risk of falling, fear of falling and depression. Assessed with pedometer, Barthel index, Get Up and Go test, FES-I and HADS. We will use Repeated Measures ANOVA test to compare the outcome means between groups at baseline, one week after intervention, six and twelve months after the intervention.

Discussion: Exercise is a safe and cheap intervention that should be a standard preventative measure implemented early in primary care. Earlier studies show good short-term effects, but not much long-term information. This study wants to create an eight-week exercise program that can prepare the participants for an active life after the intervention. Findings from the GET-PACE trial could assist in implementing the *Group Exercise Training for Physical Activity in Community-dwelling Elderly* as a preventative method at primary care level.

Keywords: *Community-dwelling, elderly, physical activity, group-based, home-based*

Introduction

Elderly

The term elderly defines the population from 65 years of age and older.(1) Elderly is not a definition of a physical or mental state, it solely depends on age range, which encompasses different groups of people in different physical and cognitive states. But ageing does also include a lot of changes in the body that happens slowly and progressively over time.

In the cardiovascular system the heart surface area decreases, myocardial stiffness increases and the arteries become more rigid. These changes cause the blood pressure to increase developing hypertension, which affects two thirds of individuals older than 65 years of age. Arterial hypertension increases the risk of stroke, coronary artery disease and congestive heart failure.(2, 3) In the respiratory system the vital capacity of the lungs decreases. So does the arterial oxygen pressure, because of a mismatch of perfusion and ventilation. This is suggested to be caused by the diminishing elastic recoil of the lungs increasing chances of airway collapse. Elderly have a higher possibility to get pneumonia, primarily because of overall weaker immune system but also because of a slower mucocilliary system, decreased saliva production and swallowing difficulties.(2)

In the musculoskeletal system there is a significant atrophy of muscle cells.(4, 5) The atrophy influences both types of muscle fibers but there is a greater atrophy in the type II fast fibers compared to type I.(4) In the aging muscles there is an increased fat infiltration, diminished number of motor units and less contractile tissues.(4,5) All of this creates a negative consequence on the contractile system and the force production of the muscle.(4,5) Bone loss begins with the sex-hormone decline in both men and women, although accelerated with menopause in women.(6) In the bone matrix there is a loss of osteocytes, reducing the proliferation capacity of the periosteum.(5) In the trabecular bone both number and thickness decrease with age.(6) The more fragile bone increases the risk of fractures in the elderly.(7)

The olfactory and gustatory capacities are altered as one ages. Vision gradually worsens, while chances of developing eye conditions like cataracts and glaucoma increase and can further hurt the vision. The ability to hear is weakened, especially for high frequencies.(8, 9) As a result of the changes in the musculoskeletal system and the special senses, there is often a loss of balance. To maintain a good balance it is necessary to have a good combination of the musculoskeletal control as well as afferent information from the sensory systems.(10)

The brain also changes during ageing. The blood flow to the brain is reduced, becomes less efficient and decreases the cell-to-cell communication. Furthermore, there is a neuronal atrophy and loss of dendrites.(8) The noticeable changes include slower processing speed, sensory loss, decreased reasoning and less working memory.(8,11) The long-term memory declines in free-recall, while the memory recognition is usually maintained.(8, 9) Language is generally preserved, especially in those who continue using complex language as they get older.(9)

These changes are natural changes that will happen to everyone as they age. There is a traditional belief that elderly cannot participate in any physical activity or have to decrease the amount because of these changes, which in some cultures are seen as signs of poor health.(12) In fact, 45% of the elderly population do not reach the recommended weekly amount of physical activity, and 93% are sedentary for at least 8 hours a day.(12,13) There are many reasons for this lack of activity, among these we find the lack of knowledge on the importance of physical activity, how to execute an exercise program, environments with no public transportation or the lack of exercise facilities.(12,14) Good access to public transportation has actually been shown to be a positive factor for reducing sedentary time, because it requires the individual to walk to and from the transport.(12) *Schutzer et al.* observed that general practitioners often recommended doing more physical activity to elderly, but since they did not provide any guidance or programs, the patients did not know how to do it.(14)

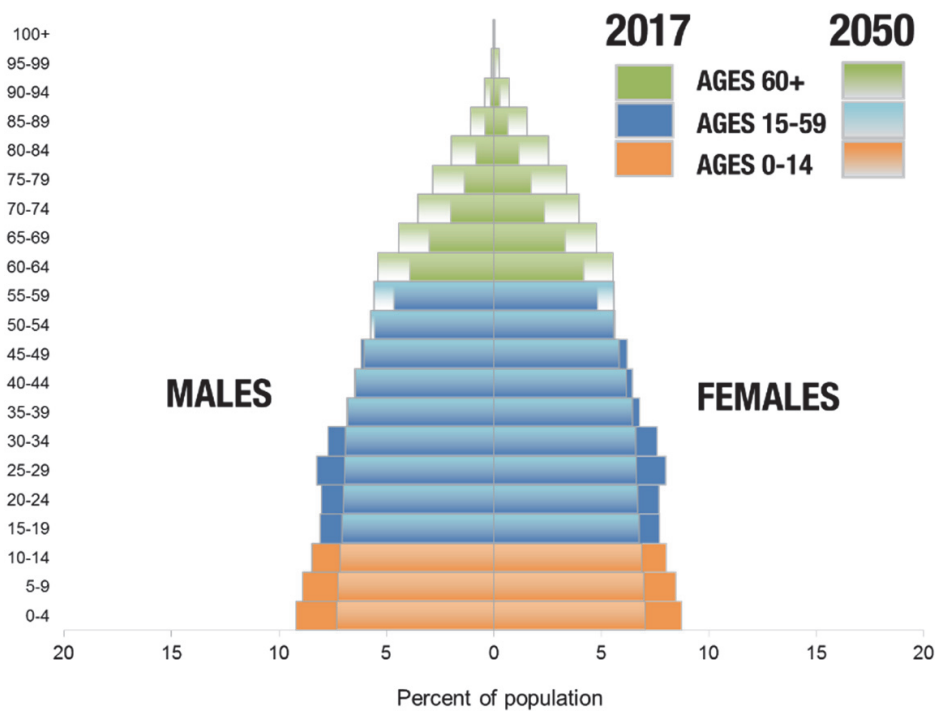


Figure 1: Population pyramid with the world population distribution in 2017 and the expected distribution in 2050. Fertility will decrease and life expectancy will continue to grow, resulting in a doubling of the population over 60 years of age. (Source: UN World Population Prospect 2017 Available at: https://population.un.org/wpp/Publications/Files/WPP2017_DataBooklet.pdf)

The current time period is unique, for the first time people all over the world can expect to live at least 60 years. From 2015 until 2050 the proportion of elderly in the world is estimated to almost double.(Figure 1) The developed countries have had a gradual increase of elderly, whereas in developing countries it has happened much quicker without time to prepare the society for the changes in population age. In 2050 80% of the elderly population will be living in low- and middle-income countries. It is therefore necessary to find affordable and easy ways to promote physical activity to help elderly stay active.(1)

Physical activity

Physical activity is defined by the World Health Organization (WHO) as “any bodily movement produced by skeletal muscles that requires energy expenditure”.(15) This could be walking, doing housework or exercise. Exercise is a subgroup of physical activity, consisting of an organized and planned program.

The Global Recommendations Of Physical Activity for Health presented by the WHO in 2011 recommend 150 minutes of moderate-intensity or 75 minutes of vigorous aerobic activity per week for adults and elderlies. The activity time does not have to be continuous, but it is advised to do at least periods of 10 minutes to bring a health impact. In addition, it is recommended to do muscle strengthening exercises at least two times per week.(16) For elderly it is also recommended to include balance training and fall prevention exercises three times a week to counterwork poor mobility and decrease the risk of falling. If for some health reason it is not possible to do the recommended amount, they should do as much as tolerated.(16) It is important to say that positive results are obtained also without reaching the 150 minutes since some physical activity is better than none.(17)

A great element of physical activity is the low risk of injury and adverse effects, as long it is done correctly. We must separate the physical activity done with the intention to improve health and the physical activity done in vigorous activity and in a sports setting. The risk of injury is much higher in a sport setting with unpredictable risk factors, while the activity done for health improvement are in a relatively controlled environment which decreases this risk. A population which might have an increased risk of injury following physical activity are those who already have a musculoskeletal disease. In these cases, the participant could stay away from the type of activity that might aggravate the condition and aim for other types of exercise. In any other cases, physical activity is shown to be safe for all population, as long as it is started at a low level and with a gradual and controlled increase in load.(18)

The importance of physical activity

A broadly accepted theory for the importance of physical activity for the human being is that we are equipped with a unique genome that only allow for balanced gene expression when presented to an environment of physical activity. In the case of a level of activity below the set threshold, the gene expression may change and can facilitate diseases, such as cancer and diabetes.(18) Physical activity is one of many factors, yet it is a factor that can be easily influenced and changed.

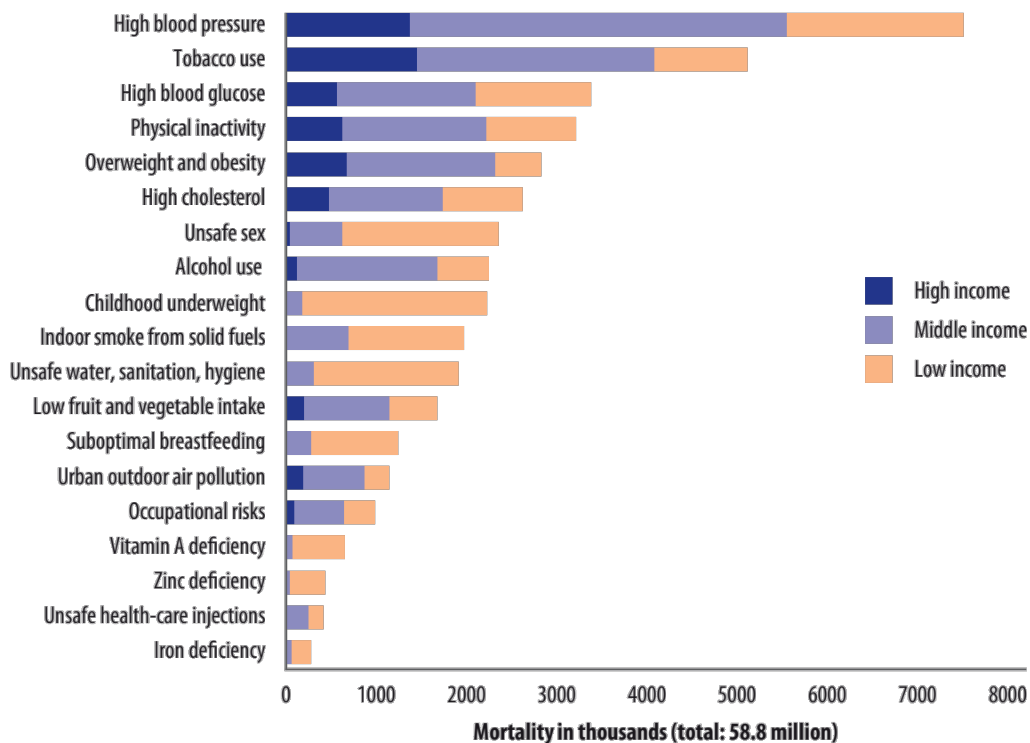


Figure 2: the major mortality risk factors. Presented by the country income level. Physical activity is found as the fourth risk factor. (Source: WHO global Health Risk Report 2009.)

In 2009 the WHO published *The Global Health Risk Report*, where we could find “lack of physical activity” listed as the fourth biggest risk factor for mortality.(19) There are numerous studies showing the importance of physical activity in preventing non-communicable diseases and chronic conditions. Doing vigorous physical activity at least two times per week decrease chances of stroke and cardiovascular disease, in fact, a two-hour energetic walk per week could prevent 30% of the cases.(20, 21)This is because physical activity regulates the major risk factors for cardiovascular disease, for example by lowering the blood pressure, decreasing lipoprotein levels and regulating the insulin sensitivity and inflammation levels.(18,20) Interestingly, there is no need for weight loss to experience the advantages of physical activity, but it will indeed be a natural result when consistent activity is performed.(21)

Regular physical activity has also demonstrated a significant positive effect for some types of cancer, especially colon cancer, which is the third most common cancer in middle to high-income countries.(21,22) *Booth et al.* demonstrated that the least active individuals have almost 50% higher chance of cancer than the most active individuals.(21) A Cochrane review of physical activity as a treatment for chronic pain showed limited evidence on physical activity's positive effect on pain. Nevertheless, it did not have any recorded negative effects. Additionally, it showed statistically significant positive results for physical function after the session.(23)

Physical activity is not only important for physical health but also for mental health. Depression and anxiety disorders are the most common mental illnesses, as a consequence, depression is also one of the greatest causes of disability.(18, 24) Physical activity works both as prevention and treatment, and is a great low-cost intervention available to everyone.(18,25) Numerous studies have concluded that physical activity can be just as good as psychotherapy and medication, however, there is no consensus on the amount or intensity needed.(18) The effect is not only prominent in cases of illness but also for a general mental functioning, including the feeling of well-being, sleep and stress. Individuals with a lower physical activity level will have a stronger stress reaction in an acute stress situation when compared to more active counterparts. (26) Individuals increasing their activity levels experience feeling better about themselves and their physical health. The feeling of well-being is an important factor related to motivation, those who experience more well-being will also continue doing more physical activity. (27)

Importance of physical activity in elderly

Mortality due to communicable diseases has been decreasing steadily during the last century leading to a higher life expectancy. However, there has been an increase in non-communicable diseases which now is major factor of morbidity and mortality in our society.(28) The elderly population of today do not have better health during their older days. Even though the severe disability is decreasing in high-income countries, the level of mild to moderate disability is constant.(1) This means that more people are living longer, but are not able to take advantage of these years because of disability.

Physical activity is not only a prevention for disease, but most importantly it allows individuals to live a more independent life for longer by preventing disability. Falls are the second cause of accidental deaths in the world, and 30-35% of elderly have at least one fall per year.(29, 30) Even though a fall accident do not cause immediate death it can cause long-lasting comorbidities that lead to disability and loss of independence or eventually early death.(30) Additionally, the fear of falling can prevent individuals to continue participating in daily activities and might cause isolation and by this further decrease the physical status. Activity is therefore extremely important for elderly to help maintain and

improve their functional and cognitive status.(31) For fall reduction any type of exercise has shown to be effective, but strength training has shown particularly good outcomes.(18, 32) Moderate to vigorous physical activity improves sleep quality as well as reducing the self-reported fatigue in elderly, it is also protective against sleep-disorders. (33, 34) Maintaining or even improving balance and functional status in elderly is important because it allows them to live more independently thus enjoying a higher quality of life.

Social support is one of the most important factors for taking part and continuing doing physical activity. This includes encouragement from family and friends, but also the support from the instructor as motivational and cheerful during the exercise setting.(35, 36, 37) Interventions implementing education on how to start exercising and including follow-up support might be more effective in motivating for physical activity.(38) A low to moderate intensity is suggested, as well as adapting the program to the individual's needs.(37, 39)

Group exercise intervention applied for elderly

Group exercise is a session done with several people together with an instructor showing the exercises and helping the participants if needed. Various studies have demonstrated that the exercise effect is bigger in elderly when done in a group setting, especially in relation to fall reduction and reducing the fear of falling.(40, 41) Over 60% of elderly participants appreciate the social contact of a group training and enjoy seeing familiar faces during the sessions, as well as having a feeling of belonging in the group.(35, 39) A systematic review on group exercise as fall prevention showed a decrease in the number of falls and additionally an increase in well-being and mental health after participating in the group training, as well as decreasing the feelings of isolation and depression. (42)

Home-based intervention applied for elderly

A home-based exercise program is a program delivered to the participants where they manage the program themselves to do at home. It is a safe, easy and affordable way of doing exercise.(43) Home-based program has been found to be preferred by the elderly compared to working out at a center and it gives good adherence after ending the study period.(43, 44) In a two-year follow-up study the adherence level of the home-based group were double the center-based group.(44) Even though a home-based program is done at home by the participants itself, the intervention usually includes a contact element at the beginning or even during the intervention. This could be face-to-face sessions, home visits or regular telephone calls. This element is important for giving correct information, motivate and to learn the exercises.(37) In the previous mentioned study, the adherence level dropped significantly at 1 year follow-up after ending the regular follow-up that they had previously done. In

the case of home-based programs regular telephone calls as check-ups could be useful and affordable to keep up the adherence rate.(44)

Knowledge gap

A Cochrane review on community interventions for increasing physical activity concluded that there is a lack of studies presenting results of increased physical activity after finishing the study period, and that multi-component community interventions did not increase the physical activity level of the population. (45) These interventions were trying to target the entire population of an area and did not specifically use exercise as an intervention. Foster et al. concluded that exercise programs designed to increase physical activity levels cause moderate short and mid-term increase.(38) But both reviews presented numerous limitations about the included studies such as being too short in duration or not using the adequate measuring tool. Studies continue using unvalidated questionnaire and scale measurements instead of the International Physical Activity Questionnaire (IPAQ). Physical Activity Scale for the Elderly (PASE) or accelerometers. (38,45)

The studies have a lack of intention-to-treat analysis and a lack of reproducibility because they fail to present the intervention clearly as well as important information like how it is performed and who will deliver it. Some interventions are too difficult to execute in a normal practice because of either being a particularly individualized intervention or because of the high-cost. Most studies are done with white population in middle to high-income areas. There is not enough studies done on other population groups, and it is necessary to propose a low-cost study protocol to make it possible to execute the study with different populations and acquiring cost-effective data.(38)

This randomized control trial will investigate the short and the long-term effects on the level of physical activity of community-dwelling elderly after participating in a group exercise program or home-based program. Physical activity will be measured by using the validated PASE. And the trial will also have a focus on educating the participants so that they can stay active after completing the intervention period.

Hypothesis

Null hypothesis. An eight-week group exercise program does not have any effects on the physical activity of community-dwelling elderlies.

Alternative hypothesis. An eight-week group exercise program does have an effect on the physical activity of community-dwelling elderlies.

Objectives

Primary

- To investigate if a group exercise program will change the physical activity level of the community-dwelling elderlies.

Secondary

- To investigate if the group exercise program will influence the number of steps per day.
- To compare the effect on functional status between the group-exercise program and the home-based group.
- To determine the effect of the group exercise program and home-based program on the risk of falling, fear of falling and anxiety and depression levels.

Methods

Study design

The study will be a two-arm randomized control trial that includes an intervention and a control group with an 1:1 allocation. All the participants will have to sign an informed consent to participate in this trial.

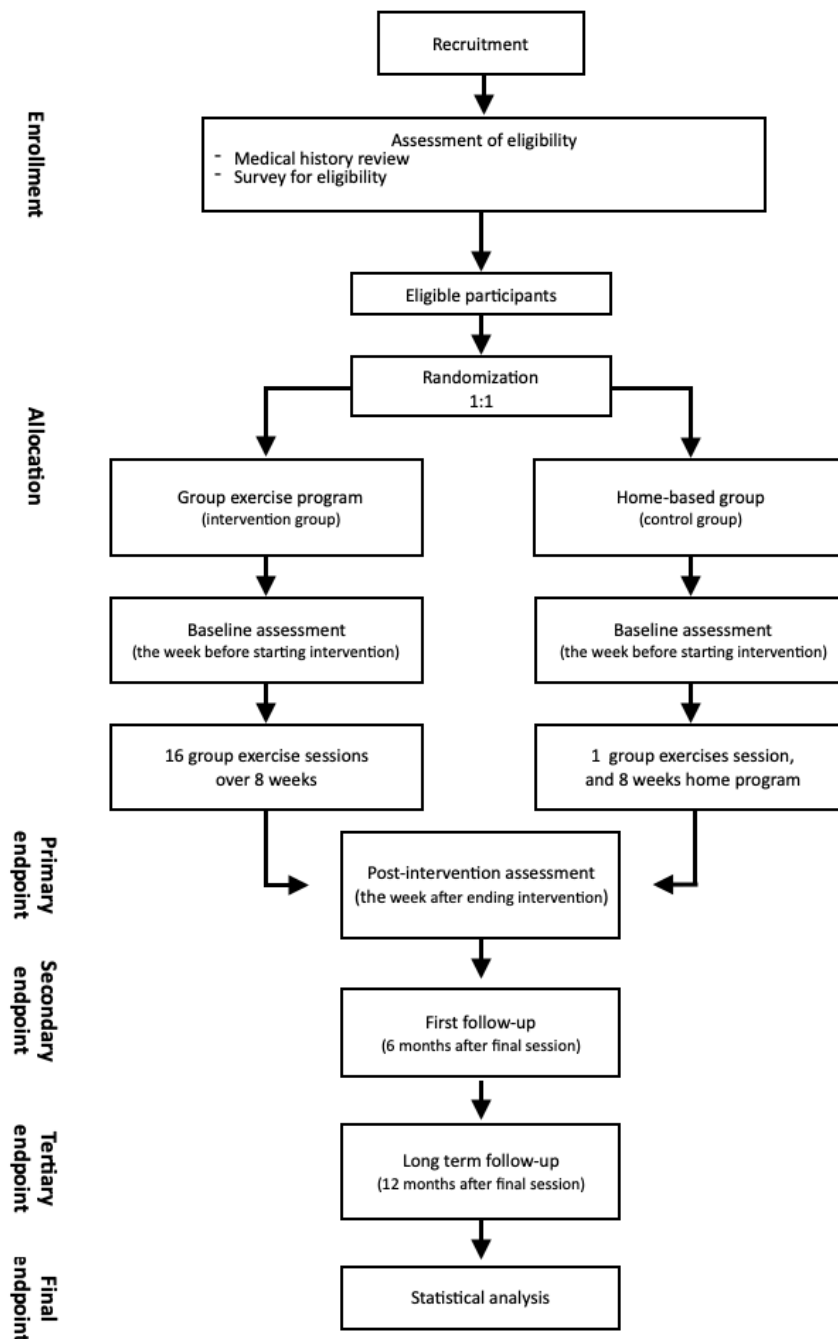


Figure 3: Flow diagram of the enrollment, allocation and follow-up period.

Study setting

The study will be done at a primary care level and the exercise program will require an open space with a suitable size that allows for setup and execution of the exercise circuit. Studies have shown that to achieve good adherence it is important that the location is easily accessible for the elderly.(46) This means that the designated space should be close to the homes of the participants and that good and affordable transportation methods are available or provided.

Sample size

To our knowledge there is no set Minimal Clinical Important Difference (MCID) stated in the scientific literature for the PASE. We could expect a change in the PASE-score between 17-25 points. This was the observed change in a prospective observational study where PASE was used to measure physical activity in lung cancer patients.(47)

Recruitment

An information letter will be sent out to everyone aged 65 years or older in the designated area. The study population contact information will be retrieved from electronic patient charts in a primary care facility. With the information letter we will include a reply card, that those who are interested in participating can return. When the reply card is returned, they will receive the informed consent to sign, as well as a basic questionnaire covering demographic information like age, sex, education, BMI, marital status, chronic diseases and number of active medications.

Eligibility criteria

Inclusion criteria

The eligible participants must meet all of the following criteria: 1) Community-dwelling of 65 years of age or older; 2) Retired; 3) Able to walk independently with or without an assistive device; 4) Able to follow instructions.

Exclusion criteria

Exclusion criteria includes: 1) Living in a geriatric center or staying at a hospital; 2) Prohibited by the general practitioner to participate in an exercise program; 3) Demonstrating a significant cognitive impairment; 4) Incapable of giving consent.

Randomization

The participants will be allocated randomly to the two study arms by using 1:1 ratio simple randomization. The randomization will be carried out by a researcher using an online number-randomization program, where each participant will get a number and these numbers will be allocated in different groups. By using this program, we can plot in the number of participants and ensure that the two groups have an equal number of participants.

Blinding

The study will be a single-blinded trial. Researchers involved in the enrollment, allocation and assessment will be blinded to the group allocations. Participants cannot be blinded because it is difficult in the case of an exercise intervention.

Group exercise program for the intervention group

Name and description

The intervention group will participate in an eight-week long group exercise program, with two sessions per week and 16 sessions in total. The program consists of a warm up, two different circuit exercise programs and a cool down.

Materials

- Chairs
- Dumbbell weights
- Medicine balls
- Aerobic step
- Pedometer and daily log diary

Procedure

Warm up	The sessions will start with a five minutes full body warm up. The participants will be sitting on a chair, and no equipment is needed. The warm-up exercises are: (1) Overhead arm raises, (2) Overhead arm reach, (3) Dynamic back stretch, (4) Shoulder rolls, (5) Open-the-door, (6) Trunk rotation, (7) Stepping, (8) Side tapping, (9) Ankle rotation. <i>(See annexes 1)</i>
Circuit exercise program	The program consists of a circuit of six different exercises focused on full body muscle strengthening. At the beginning of each session the participants will be asked to go into pairs and will go through the entire circuit with the chosen partner. Some of the exercises are done helping each other while others are done together at the same time.

Week 1: The sessions of the first week will be focused on learning the correct technique for each exercise. During the first session the physiotherapist will give some important information including: 1) recommend taking at least one long walk per week; 2) engaging in all the physical activity that they feel capable of doing; 3) Use heavier weights during the sessions when they are able to do the demanded repetitions and set within the timeframe or if it feels too easy; 4) To wear the pedometer every day during the week before an assessment; 5) The number of steps should be written down in the diary every day.

These two sessions will not be done as a circuit, instead the physiotherapist will demonstrate the exercises one by one. After showing one exercise the participants will repeat it. Every exercise is done with a light weight, 6 repetitions and 2 sets.

Week 2-3: As the participants are familiarized with the exercises, they will start doing it in a circuit. The participants will go into pairs and each pair will start at a different station with different exercises. They will have 2 minute at each station where they will try to do the number of repetitions and sets as stated in the program. 10 repetitions, 2 sets and only 1 circuit.

Week 4-6: They will continue as before but changing to 8 repetitions, 2 sets and 2 circuits.

Week 7-8: Increase the circuit to 2 rounds with 10 repetitions and 2 sets.

(See: annexes 2)

Cool down stretches

The cool down will consist of light stretching to help the patient relax after the exercise program. Each stretch will be held for 30 seconds. It consist of stretching of the hamstrings, quadriceps, upper back, chest, arms, triceps and neck.

(See: annexes 3)

Who

All the sessions will be carried out by the same physiotherapist to favor comfort, trust and consistency for the participants.

How

Every session is carried out by the physiotherapist present at the designated space. The physiotherapist should be motivating, enthusiastic and encouraging the participants to do their best. Safety of the participants will be monitored at all times.

Where

An open space in a primary center or public gymnasium available in the community. Easily accessible and preferably close to the participants living area.

When and how much

Two sessions per week for eight weeks, which means 16 sessions in total. Participants will also be encouraged to take at least one long walk per week.

The entire program can be found in the annexes. This program is an ideal program. Considering the individual differences of the participants some adjustments can be made to ensure the safety of the participants.

Home-based exercise program for the Control group*Name and description*

The control group will participate in a home-based exercise program including one introduction lecture.

Material

For the session:

- Chairs
- Dumbbell weights
- Medicine ball
- Aerobic step

Material needed for the home-based program:

- Printed copy of the exercise program
- Pedometer and daily log diary
- A chair
- Dumbbell weights or another object like a water bottle
- Medicine ball or a normal ball
- Aerobic step or a staircase

*Procedure***Introduction lecture**

Firstly, the physiotherapist will hand out the printed copies and give some basic information about the program: 1) The pedometer should be worn every day of the week before the assessment and number of steps should be registered in the diary; 2)The programs should be done two days a week; 3) Encourage to go on a longer walk at least once a week; 4) Alternative objects can be used at home,

Home-based program

such as water bottles instead of weights. But always try to challenge yourself; 5) Try to stay as active as possible.

Secondly, the physiotherapist will present the exercise program. They will start by doing the warm-up together. (See annexes 1)

Then the strengthening exercises will be presented one by one and the participants will execute them together with the physiotherapist. They will do 6 repetitions of each exercise. (See annexes 4)

To finish up the program the cool-down stretches will be demonstrated and performed. (See annexes 3)

The participants will do the same at home, starting with the warm-up, doing one of the two possible strengthening programs and finishing with the cool-down stretches.

Who

One physiotherapist will do the introduction lecture.

How

The first session will be carried out by a physiotherapist at the designated space. The rest of the sessions will be the participants responsibility to do at home.

Where

The session will be done in an open space in a primary center or public gymnasium available in the community. Easily accessible and preferably close to the participants living area. The rest of the program will be done at the participants home.

When and how much

One group session with the physiotherapist during the first week of the study. Thereafter, they are recommended to do two muscle strengthening sessions per week using the hand-out exercise program, as well as going for at least one long walk per week.

The entire program can be found in the annexes. This program is an ideal program. Considering the individual differences of the participants some adjustments can be made for the safety of the participants.

Outcomes

Primary outcome

The primary outcome is the physical activity of community-dwelling elderly. This is objectively measured with the Physical Activity Scale for the Elderly(PASE). It is easily administered by interview and takes into account all the occupational, household and leisure activities during one week. The activities are logged as never, seldom(1-2 days/week), often(3-4 days/week) and mostly(5-7 days/week). The scores are from 0-400 and are calculated by a fixed activity weight and frequency values for every activity which is found in the PASE scoring form.(48) *(See annexes 5)*

Secondary outcomes

Number of steps per day will be measured by wearing a pedometer. The pedometer is handed out during the baseline assessment and participants are asked to carry the pedometer on the waistline during the week before every assessment. Data will be registered during waking hours, participants will only remove the pedometer for sleeping and bathing. Every day they will log the number of steps in the diary. On the assessment days the daily numbers of step will be collected and will be used to find the average number of steps for the last week.

Functional status will be measured with the Barthel Index. Barthel index measures ten simple activities of daily living (ADLs), and the maximum score is 100. It has shown to be useful in identifying individuals at risk of not being able to live independently.(49) *(See annexes 6)*

Risk of falling. Will be assessed with the Get Up and Go Test. This test is recommended by the American and the British Geriatrics Society to identify risk of falling. The participant has to sit on a chair, stand up, walk three meters, turn around, walk back and sit back down on the chair. The participants are allowed to walk with assistive device if necessary. The cut-off point for a normal test performance in community-elderly individuals is suggested to be at twelve seconds. (50)

The fear of falling will be measured using the FES-I questionnaire. This questionnaire encompasses 16 daily activities, and the participants must answer how concerned they are about falling on a scale from 1-4 during each of the activities. Where 1=not concerned at all and 4=very concerned, the maximum score is 64.(51) *(See annexes 7)*

To measure anxiety and depression we will use the Hospital Anxiety and Depression Scale (HADS). This scale is not only used for in-hospital patients but is also recommended for a general elderly

population. Each component is scored between 0-3, and the total sum is calculated and thereafter divided into three degrees: normal, borderline case and case.(52) (*See annexes 8*)

Assessment

Baseline assessment. Will be done the week before starting the intervention.

Post-intervention assessment. Will be done the week after ending the intervention.

First follow-up assessment. Six months after the end of the intervention.

Last follow-up assessment. At twelve months after the end of the intervention

Statistical analysis

The normality in all variables will be tested by using the Shapiro-Wilk test. As physical activity data usually is non-parametric, we will probably be using non-parametric tests.(53) We will perform a descriptive analysis where categorical variables will be summarized as counts and percentages. Quantitative variables will be summarized using mean, median, range and standard deviation(SD).(54)

We will perform comparisons of different participant characteristics by intervention/control group. To assess statistically significant differences of a quantitative variable between the two groups, we will use the Mann-Whitney's Test. The Fisher's exact test will be used to determine differences in percentages of categorical variables between the groups.

All analyses regarding outcomes will be conducted on an intention-to-treat basis. We will evaluate mean differences in outcome variables between groups at the different follow-up assessments. If the variables follow a normal distribution, we will use the repeated measures ANOVA test. Otherwise, we will use a mixed effects linear model. We will elaborate a graph with the mean and standard deviation at the different timepoints for the different groups and outcomes.(55)

All tests will be two-tailed and the level of significance will be set at $p < 0.05$. We will be using IBM SPSS Statistics software to carry out the statistical analysis.

Ethics

The study will be evaluated by the Ethical Committee of the Institution before being started. The development of the study is in accordance with the rules of good clinical practice and the set principles of the Helsinki Declaration (World Medical Association 1989).

An informed consent will be requested by all of the participants in the study. If not signed, the participant will be excluded from the study. The informed consent can be found attached in the annexes. (*See: annexes 9*)

Limitations

The limitations of the study are:

- Using PASE to assess physical activity makes the study vulnerable to recall bias. Participants in the intervention group might be more motivated or aware of their weekly physical activity and therefore report differently than their control counterparts.
- Our study may also suffer from selection bias. People that are concerned about their health and physical activity may be more prone to enroll in the study.
- Another source of bias is the Hawthorne effect(observer effect). Participants are likely to change their weekly physical activity when they know their steps are being tracked or when they have to report their activity at the end of the week.
- The last follow up is at one year after the end of the intervention period, which provides limited long-term results.
- Eight weeks for the intervention period may be too short to get significant changes in the outcomes. Doing more physical activity is a major lifestyle change, which can be hard to influence in a short time period.
- Difficulty of doing a high intensity exercise program in an elderly population which might not give the best possible results in eight weeks.
- Increasing physical activity is closely related to the motivation of the participants, but we have not included any assessment of motivation.
- We have also not included any type of motivational interviews to increase the motivation for the lifestyle change.

Calendar

		STUDY PERIOD (February 2020 – August 2021)							
		Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	$-t_1$	0	Base-line	Week 1	Week 8	Week 9	Month 6	Month 12	t_x
ENROLMENT:									
Information letter	X								
Informed consent	X								
<i>Inclusion and exclusion criteria</i>	X								
Allocation		X							
INTERVENTIONS:									
<i>8 week group exercise program</i>				←————→					
<i>8 week home exercise program</i>				←————→					
ASSESSMENTS:									
<i>Demographic information</i>	X								
<i>Physical activity</i>			X			X	X	X	
<i>Number of steps</i>						X	X	X	
<i>Functional status</i>			X			X	X	X	
<i>Risk of falling</i>			X			X	X	X	
<i>Fear of falling</i>			X			X	X	X	
<i>Anxiety and depression</i>			X			X	X	X	
OTHER:									
<i>Statistical analysis</i>									X

Figure 4: Calendar of the study period

Role of the investigators

The role of the investigators is to administer the research in an objective way to obtain high-quality and reproducible results. The main researchers will have to plan the study, recruit researchers, prepare all the paperwork as well as doing the final work and presenting the results. The main researchers are the responsible for all the aspects of the study, including that it is done in an ethical and approved manner. There will be other researchers responsible for the recruitment process and to control the eligibility criteria. When this is done another researcher will do the randomization. Blinded physiotherapists will be responsible for all of the assessment, and two other physiotherapists will be responsible for their own group of participants, either the group exercise training or the home-based

training. Finally, there will be a statistician doing the statistical analysis who will be also blinded to the group allocation of the participants. The investigators will not participate in any other aspect of the study than the one provided above.

Resources

All the resources needed to conduct this study are presented in the table below. (*figure 5*)

Study resources	
<i>Fungible material</i>	<ul style="list-style-type: none"> – Step diary – Printed exercise program for control group – Printed questionnaires and scales
<i>Non-fungible material</i>	<ul style="list-style-type: none"> – Chairs – Dumbbell weights – Medicine ball – Aerobic step – Pedometer
<i>Human resources</i>	<ul style="list-style-type: none"> – Physiotherapists – Researchers – Statistician

Figure 5: Table of necessary resources

Annexes

1. Warm-up

The only material needed is a chair



Overhead arm raises	<ul style="list-style-type: none"> – Start with the arms relaxed on the side of the body – Slowly raise the arms out from the body and up above the head. Keep the shoulders relaxed. – Slowly lower the arms until they are in a relaxed position next to the body again. <p><i>Repeat 5 times</i></p>
Overhead arm reach	<ul style="list-style-type: none"> – Start with the arms relaxed next to the body – Reach your right arm straight up to the ceiling – Lower it slowly – Repeat with the other arm <p><i>Repeat 5 times with each arm</i></p>
Dynamic back stretch	<ul style="list-style-type: none"> – Keep the arms straight in front of you, with the back of the hands touching – Slide down between the legs with the hands guiding, as far as you feel comfortable. – Slide slowly back up again <p><i>Repeat 8 times</i></p>
Shoulder rolls	<ul style="list-style-type: none"> – Keep the arms next to your body – Roll shoulder backwards – Reverse and roll the shoulders forwards <p><i>Repeat 8 times each direction</i></p>
Open-the-door	<ul style="list-style-type: none"> – With your right arm, reach over to the left side in a grabbing motion – Pull the arm in a straight line to the opposite side until the arm is completely straight – just like you are opening a door – Repeat with the other arm <p><i>Repeat 8 times each arm</i></p>
Trunk rotation	<ul style="list-style-type: none"> – Keep hands up, palms facing forward. – Rotate the body to the right – Then rotate to the left <p><i>Repeat 8 times</i></p>
Stepping	<ul style="list-style-type: none"> – Keep hands relaxed next to the body – Lift the right knee up – Lower the right knee – Repeat with the left knee – Move the arms together with the stepping, in a marching movement <p><i>Repeat 10 times each leg</i></p>
Side tapping	<ul style="list-style-type: none"> – Keep the hands on the thighs – Tap the right leg out to the side, without turning the rest of the body – Bring the right leg back to center – Repeat with left leg <p><i>Repeat 10 times each leg</i></p>
Ankle rotations	<ul style="list-style-type: none"> – Cross the right leg over the left leg – Rotate the ankle in one direction – Rotate the ankle in the opposite direction – Repeat with the left leg <p><i>Rotate 5 times each direction</i></p>

2. Group exercise program






Group exercise program – first session of the week

All the exercises will be done in pairs.

The participants will have 2 minutes at each exercise station, and 45sec off to switch station. They have to try to do the repetition and sets that is given, but at the 2 minute mark they will switch exercise station independently if the number is reached or not.



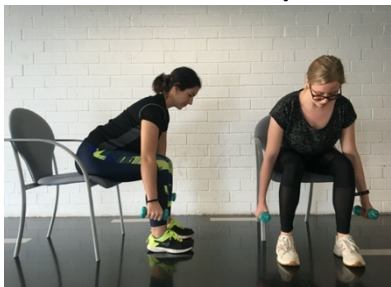
Name	How to perform it	Repetitions, sets and circuits
<p style="text-align: center;">Sit to Stand</p> 	<p>Material: 2 chairs facing</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair, keeping the back straight 2. Stand up from the chair – <i>if needed use the arm rests to push up or hands on the thighs</i> 3. Do two high fives with the partner while standing 4. Slowly sit down again <p>To the standing up easier you could use:</p> <ul style="list-style-type: none"> – Arms straight out in front of you to help getting the weight forwards – Using the chairs arm rests or hands on the thighs to help push up <p>To make it harder:</p> <ul style="list-style-type: none"> – Have the arms crossed over the chest while standing up – Changing the surface to a unstable foam mat. 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">High Steps with overhead weight</p> 	<p>Material: 2 chairs facing, 1 dumbbell</p> <ol style="list-style-type: none"> 1. Sit on the chair with a straight back and with the arms above the head, one of the participants holding the dumbbell. 2. Lift the knee straight up, and at the same time lower the dumbbell to touch the knee 3. Repeat two times on each leg, then pass the weight on to the partner. 4. The partner without the weight will do the same thing as the one holding the weight. <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight or no weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – Standing position 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>





<p style="text-align: center;">Shoulder Press</p> 	<p>Material: 2 chairs facing, 2 dumbbells per person</p> <p>The pair will do this at the same time together</p> <ol style="list-style-type: none"> 1. Sitting in a chair with a straight back, and the feet on the ground at shoulder-width. 2. Hold dumbbells at shoulder height and the palms facing forward. 3. Push the arms upwards and extend the elbows to lift the dumbbells above the head. 4. Lower the arms slowly back to initial position. <p>To make it easier:</p> <ul style="list-style-type: none"> – Light weights <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – Standing position 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">Seated Rows</p> 	<p>Material: 2 chairs facing, a pair of dumbbells per person</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair, with the feet together on the floor. 2. Bend forward at the hip. 3. Hold the dumbbells in each hand, palms facing towards the back, and keep the arms parallel to the legs. 4. Lift the dumbbells up by bending the elbows to 90 degrees while squeezing the shoulder blades together. 5. Lower slowly back to starting position. <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight <p>To make it harder</p> <ul style="list-style-type: none"> – Heavier weight 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">Overhead Triceps</p> 	<p>Material: 2 chairs facing, 1 dumbbell</p> <ol style="list-style-type: none"> 1. The partners raise the arms above the head: one holding the dumbbell and the other keeping the palms together. 2. Bend the elbows so that the arms go behind the head – avoid opening up the elbows, keep them close to the head 3. Extend the arms back above the head and forward. 4. Pass the dumbbell to the partner and repeat <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>


	<p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – Standing position 	
<p style="text-align: center;">Biceps Curls</p>  	<p>Material: 2 chairs facing, a pair of dumbbells per person</p> <ol style="list-style-type: none"> 1. Sit on the chair, keeping the back straight and feet shoulder-width apart on the floor. 2. Hold the dumbbells and have the palms facing forward. 3. Lift the weights towards the shoulders by flexing the elbows – keep the elbows as still as possible don't move them behind the body 4. Lower the dumbbells slowly as you return to the original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Less weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – 2 normal full curls, followed by 3 halfway curls. 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">Diagonal Russian Twist</p>  	<p>Material: 2 chairs next to each other, medicine ball or dumbbell</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair with the leg closest to the partner straightened and the other foot on the ground. Keep the back straight 2. One of the partners holds the medicine ball, the other one keeps the palms together. 3. Straighten the arms and lift them diagonally away from the straightened leg. 4. Lower the arms, still keeping them straight, diagonally to the side of the straight leg. 5. Do 8 repetitions and pass the medicine ball to the partner 6. Switch seat to work the other side <p>To make it easier:</p> <ul style="list-style-type: none"> – No weight or less weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – More repetitions 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>

Group exercise program – 2nd session of the week

Name	How to perform it	Repetitions and sets
<p style="text-align: center;">Ball taps</p> 	<p>Material: 2 chairs facing, medicine ball</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair with a straight back. One of the participants with the ball on the ground below. 2. The one with the medicine ball: lift the knee straight up to tap the right foot on the ball, and then lower it. 3. Repeat with the left foot 4. Perform 3 taps with each leg 5. Pass the ball to the partner 6. Partner repeat the 3 taps with each leg <p>To make it easier:</p> <ul style="list-style-type: none"> – Smaller ball – Lighter ball <p>To make it harder:</p> <ul style="list-style-type: none"> – Bigger ball – Heavier ball – Increase tapping velocity 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">Biceps curl to shoulder press</p> 	<p>Material: 2 chairs facing, two pair of dumbbells</p> <ol style="list-style-type: none"> 1. Sitting on the chair with a straight back 2. Hold the dumbbells with the palms facing forward 3. Bend the elbow to bring the dumbbells up towards the shoulders 4. Continue lifting by rotating the palms to face forward 5. Press the dumbbells up above the head as you extend the elbows 6. Slowly lower again in the same order back to starting position <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weights <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – Standing position 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>

		
<p style="text-align: center;">Step ups</p> 	<p>Material: two aerobic steps facing, a wall, possibly a medicine ball</p> <ol style="list-style-type: none"> 1. Stand in front of the aerobic step 2. Step up with the right foot – holding on to the wall if needed 3. Step up the left foot 4. If holding a ball: pass the ball on to the partner 5. Step down with the right foot first and then the left <p>To make it easier:</p> <ul style="list-style-type: none"> – No ball – Lower step <p>To make it harder:</p> <ul style="list-style-type: none"> – With a ball – Not using the wall as support – Higher step 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p style="text-align: center;">Reverse chest fly</p> 	<p>Material: 2 chairs facing, 2 pair of dumbbells</p> <ol style="list-style-type: none"> 1. Sitting normally on the chair, keeping the back straight 2. Lean forward – just as far as you can still keep the back straight 3. Hold the dumbbells and let the arms hang down by the sides 4. Keep the arms straight and open the arms until shoulder height 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p>

	<ol style="list-style-type: none"> 5. Press the shoulder blades together on the top 6. Lower the arms to original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight 	<p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p>Farmers walk</p> 	<p>Material: 2 pair of dumbbells, something to mark the 5m distance</p> <ol style="list-style-type: none"> 1. One of the partners starts holding the dumbbells parallel to the body. 2. Hold the dumbbells with a tight grip, keep the back straight and shoulder blades slightly pressed together. The weights should be quite heavy. 3. Walk to the marked 5 meters, turn around and walk back to start. 4. Then the partner do the same. <p>To make it harder:</p> <ul style="list-style-type: none"> – More weight 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p>Wall push-ups</p> 	<p>Material: A wall</p> <ol style="list-style-type: none"> 1. Place both hands on the wall, right in front of the shoulders 2. Bend the elbow to lean towards the wall 3. Keep the back straight and squeeze abdominals. 4. Stop when the forehead touch the wall 5. Straighten the arms to return to original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Stand close to the wall <p>To make it harder:</p> <ul style="list-style-type: none"> – Stand further away from the wall – Table pushups, knee pushups and normal pushups 	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p> <p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
<p>Alternative cross-crosses</p> 	<p>Material: 2 chairs facing</p> <ol style="list-style-type: none"> 1. Keep the elbows bent at shoulder height 2. Keep the back straight and squeeze the abdominal muscles 3. Lift the right knee and lower the left elbow to try to touch 4. Return to original position 5. Repeat with the opposite leg and elbow <p>To make it harder</p>	<p>Week 1: 6 repetitions x 2 sets</p> <p>Week 2-3: 10 repetitions x 2 sets x 1 circuit</p> <p>Week 4-6: 8 repetitions x 2 sets x 2 circuit</p>

	<p>– Standing position</p>	<p>Week 7-8: 10 repetitions x 2 sets x 2 circuit</p>
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3. Cool down stretches

Hold each stretch for 30 seconds.

It should be a light comfortable stretch, and it should not be painful.

Take deep breaths during the stretching.

Name	How to perform it
<p>Hamstring and calf stretch</p>	<p>Material: 1 chair</p> <ol style="list-style-type: none"> 1. Face the chair 2. Bend forward at the hip and keep the legs straight 3. Put the arm on the seat of the chair, keep the back straight <p>To stretch more:</p> <ul style="list-style-type: none"> – Bend the elbows to make the stretch more intense
<p>Quadriceps stretch</p>	<p>Material: 1 chair or a wall</p> <ol style="list-style-type: none"> 1. Hold a stable chair or the wall with one arm, keep the back straight. 2. Bend the right leg back and hold the right foot or ankle with the right hand 3. Hold it 4. Repeat with the other leg
<p>Upper back stretch</p>	<p>Material: 1 chair</p> <ol style="list-style-type: none"> 1. Sit or stand, with feet shoulder-width apart 2. Intertwine your fingers, and twist the hands so the palms are facing forwards 3. Lift the arms to chest or shoulder height 4. Press the hands away from the body, feeling the stretch of the upper back
<p>Chest and arm stretch</p>	<ol style="list-style-type: none"> 1. Stand with the legs shoulder-width apart 2. Extend the arms behind the back and intertwine the fingers. 3. Twist the hands so the palms are facing away from the body 4. Push away from the body, to feel the stretch of the chest and the arms
<p>Triceps stretch</p>	<p>Material: 1 chair</p> <ol style="list-style-type: none"> 1. Sit on the chair 2. Bring your hand above and behind the head – like you want to touch the back of the neck 3. With the other hand, hold the elbow and push it towards the head to feel a stretch 4. Repeat on the other arm
<p>Head rotation</p>	<ol style="list-style-type: none"> 1. Rotate the head towards the right for x repetitions 2. Then switch and rotate towards the left ...

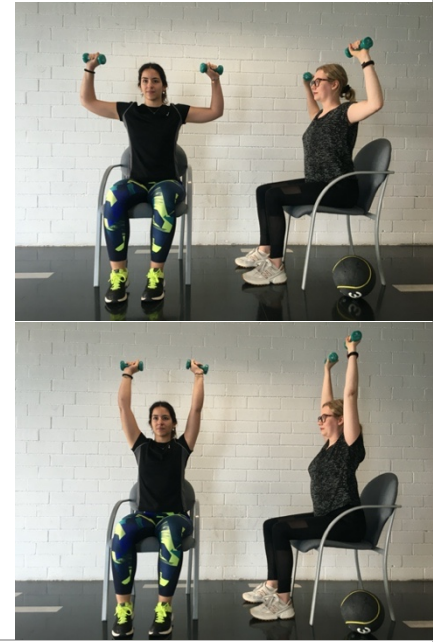

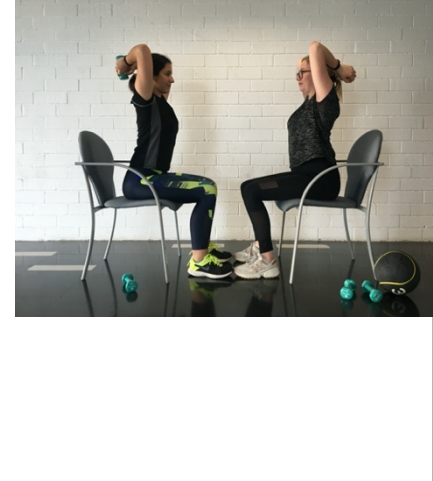
4. Home-based exercise program






Home based exercise program – 1st session of the week

The exercises can be done with dumbbells or any other heavy object you have at home, for example a water bottle.




For the medicine ball you can use a normal ball or as before, another heavy object.

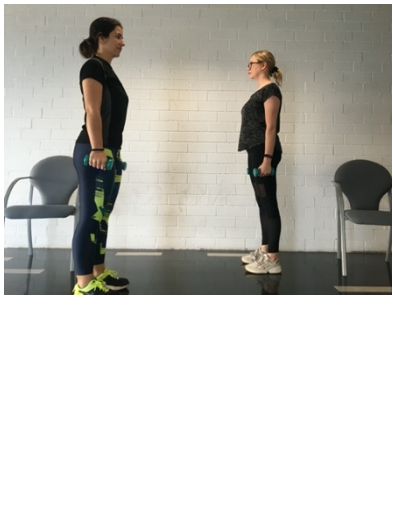
Name	How to perform it	Repetitions and sets
<p style="text-align: center;">Sit to Stand</p> 	<p>Material: 1 chair</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair, keeping the back straight 2. Stand up from the chair – <i>if needed use the arm rests to push up or hands on the thighs</i> 3. Slowly sit down again <p>To the standing up easier you could use:</p> <ul style="list-style-type: none"> – Arms straight out in front of you to help getting the weight forwards – Using the chairs arm rests or hands on the thighs to help push up <p>To make it harder:</p> <ul style="list-style-type: none"> – Have the arms crossed over the chest while standing up – Changing the surface to a unstable foam mat. 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">High Steps with overhead weight</p> 	<p>Material: 1 chair, 1 dumbbell</p> <ol style="list-style-type: none"> 1. Sit on the chair with a straight back, with the arms above the head holding the dumbbell 2. Lift the knee straight up, and at the same time lower the dumbbell to touch the knee <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight or no weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – Standing position 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Shoulder Press</p>	<p>Material: 1 chair, 2 dumbbells</p> <ol style="list-style-type: none"> 1. Sitting in a chair with a straight back, and the feet on the ground at shoulder-width. 	<p>Week 1: 6 repetitions x 1 set</p>



	<ol style="list-style-type: none"> 2. Hold dumbbells at shoulder height and the palms facing forward. 3. Push the arms upwards and extend the elbows to lift the dumbbells above the head. 4. Lower the arms slowly back to initial position. <p>To make it easier:</p> <ul style="list-style-type: none"> – Light weights <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – Standing position 	<p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Seated Rows</p> 	<p>Material: 1 chair, 1 pair of dumbbells</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair, with the feet together on the floor. 2. Bend forward at the hip. 3. Hold the dumbbells in each hand, palms facing towards the back, and keep the arms parallel to the legs. 4. Lift the dumbbells up by bending the elbows to 90 degrees while squeezing the shoulder blades together. 5. Lower slowly back to starting position. <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight <p>To make it harder</p> <ul style="list-style-type: none"> – Heavier weight 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Overhead Triceps</p> 	<p>Material: 1 chair, 1 dumbbell</p> <ol style="list-style-type: none"> 1. Raise the arms above the head holding the dumbbell 2. Bend the elbows so that the arms goes behind the head – avoid opening up the elbows, keep them close to the head 3. Extend the arms back above the head 5. Repeat <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – Standing position 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>

		
<p style="text-align: center;">Biceps Curls</p>  	<p>Material: 1 chair, 1 pair of dumbbell</p> <ol style="list-style-type: none"> 1. Sit on the chair, keeping the back straight and feet shoulder-width apart on the floor. 2. Hold the dumbbells and have the palms facing forward. 3. Lift the weights towards the shoulders by flexing the elbows – keep the elbows as still as possible don't move them behind the body 4. Lower the dumbbells slowly as you return to the original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Less weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – 2 normal full curls, followed by 3 halfway curls. 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Diagonal Russian Twist</p>  	<p>Material: 1 chair, medicine ball or dumbbell</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair with one leg straightened and the other foot on the ground. Keep the back straight 2. Hold the medicine ball 3. Straighten the arms and lift them diagonally away from the straightened leg. 4. Lower the arms, still keeping them straight, diagonally to the side of the straight leg touching the hip 5. Return and repeat. 6. Switch to do the other side of the body <p>To make it easier:</p> <ul style="list-style-type: none"> – No weight or less weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight – More repetitions 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>

Home-based exercise program – 2nd session of the week

Name	How to perform it	Repetitions and sets
<p style="text-align: center;">Ball taps</p> 	<p>Material: 1 chair, medicine ball or a stack of books</p> <ol style="list-style-type: none"> 1. Sit on the edge of the chair with a straight back, with a stack of books on the ground right in front of the chair 2. Lift the knee straight up to tap the right foot on the books, and then lower it. 3. Repeat with the left foot <p>To make it easier:</p> <ul style="list-style-type: none"> – Lower stack <p>To make it harder:</p> <ul style="list-style-type: none"> – Higher stack of books – Increase tapping velocity 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Biceps curl to shoulder press</p> 	<p>Material: 1 chair, 1 pair of dumbbells</p> <ol style="list-style-type: none"> 1. Sitting on the chair with a straight back 2. Hold the dumbbells with the palms facing forward 3. Bend the elbow to bring the dumbbells up towards the shoulders 4. Continue lifting by rotating the palms to face forward 5. Press the dumbbells up above the head as you extend the elbows 6. Slowly lower again in the same order back to starting position <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weights <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weights – Standing position 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Step ups</p> 	<p>Material: 1 step or stairs, a wall, possibly a weight</p> <ol style="list-style-type: none"> 1. Stand in front of the step 2. Step up with the right foot – holding on to the wall if needed 3. Step up the left foot 4. Step down with the right foot first and then the left 5. Second set, switch and start with the left foot <p>To make it easier:</p> <ul style="list-style-type: none"> – No ball – Lower step 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p>

	<p>To make it harder:</p> <ul style="list-style-type: none"> – Holding a ball – Not using the wall as support – Higher step 	<p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Reverse chest fly</p> 	<p>Material: 1 chair, 1 pair of dumbbells</p> <ol style="list-style-type: none"> 1. Sitting normally on the chair, keeping the back straight 2. Lean forward – just as far as you can still keep the back straight 3. Hold the dumbbells and let the arms hang down by the sides 4. Keep the arms straight and open the arms until shoulder height 5. Press the shoulder blades together on the top 6. Lower the arms to original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Lighter weight <p>To make it harder:</p> <ul style="list-style-type: none"> – Heavier weight 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Farmers walk</p> 	<p>Material: 1 pair of dumbbells or heavy bags, something to mark 5m distance</p> <ol style="list-style-type: none"> 1. Hold the dumbbells with arms hanging parallel to the body. 2. Hold the dumbbells with a tight grip, keep the back straight and shoulder blades slightly pressed together. The weights should be quite heavy. 3. Walk to the marked 5 meters, turn around and walk back to start. 4. Rest and repeat <p>To make it harder:</p> <ul style="list-style-type: none"> – More weight 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>

<p style="text-align: center;">Wall push-ups</p> 	<p>Material: a wall</p> <ol style="list-style-type: none"> 1. Place both hands on the wall, right in front of the shoulders 2. Bend the elbow to lean towards the wall 3. Keep the back straight and squeeze abdominals. 4. Stop when the forehead touch the wall 5. Straighten the arms to return to original position <p>To make it easier:</p> <ul style="list-style-type: none"> – Stand close to the wall <p>To make it harder:</p> <ul style="list-style-type: none"> – Stand further away from the wall – Table pushups, knee pushups and normal pushups 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>
<p style="text-align: center;">Alternative cross-crosses</p> 	<p>Material: 1 chair</p> <ol style="list-style-type: none"> 1. Keep the elbows bent at shoulder height 2. Keep the back straight and squeeze the abdominal muscles 3. Lift the right knee and lower the left elbow to try to touch 4. Return to original position 5. Repeat with the opposite leg and elbow <p>To make it harder</p> <ul style="list-style-type: none"> – Standing position 	<p>Week 1: 6 repetitions x 1 set</p> <p>Week 2-3: 10 repetitions x 2 sets</p> <p>Week 4-6: 8 repetitions x 3 sets</p> <p>Week 7-8: 10 repetitions x 3 sets</p>

5. PASE

PASE SCORING FORM

PASE Item	Type of Activity	Activity Weight	Activity Frequency	Weight times Frequency
2.	Walk outside home	20	a.	
3.	Light sport / recreational activities	21	a.	
4.	Moderate sport / recreational activities	23	a.	
5.	Strenuous sport / recreational activities	23	a.	
6.	Muscle strength / endurance exercises	30	a.	
7.	Light housework	25	b.	
8.	Heavy housework or chores	25	b.	
9a.	Home repairs	30	b.	
9b.	Lawn work or yard care	36	b.	
9c.	Outdoor gardening	20	b.	
9d.	Caring for another person	35	b.	
10.	Work for pay or as volunteer	21	c.	
PASE SCORE:				

Activity Frequency Values:

- Use hours per day conversion table below
- 1 = activity reported in past week, 0 = activity not reported
- Divide work hours reported in Item 10.1 by seven; if no work hours or if job involves mainly sitting with slight arm movements (Item 10.2 = 1), then activity frequency = 0.

ACTIVITY TIME TO HOURS PER DAY CONVERSION TABLE

Days of Activity	Hours Per Day of Activity	Hours Per Day
0. Never		0
1. Seldom	1. Less than 1 hour	.11
	2. 1-2 hours	.32
	3. 2-4 hours	.64
	4. More than 4 hours	1.07
2. Sometimes	1. Less than 1 hour	.25
	2. 1-2 hours	.75
	3. 2-4 hours	1.50
	4. More than 4 hours	2.50
3. Often	1. Less than 1 hour	.43
	2. 1-2 hours	1.29
	3. 2-4 hours	2.57
	4. More than 4 hours	4.29

6. Barthel index

Barthel Index of Activities of Daily Living

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation. Refer to the Guidelines section on the following page for detailed information on interpretation.

The Barthel Index

Bowels

- 0 = incontinent (or needs to be given enema)
- 1 = occasional accident (once/week)
- 2 = continent

Patient's Score: _____

Bladder

- 0 = incontinent, or catheterized and unable to manage
- 1 = occasional accident (max once per 24 hours)
- 2 = continent (for over 7 days)

Patient's Score: _____

Grooming

- 0 = needs help with personal care
- 1 = independent face/hair/teeth/shaving (implements provided)

Patient's Score: _____

Toilet Use

- 0 = dependent
- 1 = needs some help, but can do something alone
- 2 = independent (on and off, dressing, wiping)

Patient's Score: _____

Feeding

- 0 = unable
- 1 = needs help cutting, spreading butter, etc.
- 2 = independent (food provided within reach)

Patient's Score: _____

Transfer

- 0 = unable – no sitting balance
- 1 = major help (one or two people, physical), can sit
- 2 = minor help (verbal or physical)
- 3 = independent

Patient's Score: _____

Mobility

- 0 = immobile
- 1 = wheelchair independent, including corners, etc.
- 2 = walks with help of one person (verbal or physical)
- 3 = independent (but may use any aid, e.g., stick)

Patient's Score: _____

Dressing

- 0 = dependent
- 1 = needs help, but can do about half unaided
- 2 = independent (including buttons, zips, laces, etc.)

Patient's Score: _____

Stairs

- 0 = unable
- 1 = needs help (verbal, physical, carrying aid)
- 2 = independent up and down

Patient's Score: _____

Bathing

- 0 = dependent
- 1 = independent (or in shower)

Patient's Score: _____

Total Score: _____

Scoring: Sum the patient's scores for each item. Total possible scores range from 0 – 20, with lower scores indicating increased disability. If used to measure improvement after rehabilitation, changes of more than two points in the total score reflect a probable genuine change, and change on one item from fully dependent to independent is also likely to be reliable.

7. FES-I

Now we would like to ask some questions about how concerned you are about the possibility of falling. For each of the following activities, please circle the opinion closest to your own to show how concerned you are that you might fall if you did this activity. Please reply thinking about how you usually do the activity. If you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity.

		<i>Not at all concerned</i> 1	<i>Somewhat concerned</i> 2	<i>Fairly concerned</i> 3	<i>Very concerned</i> 4
1	Cleaning the house (e.g. sweep, vacuum or dust)	1	2	3	4
2	Getting dressed or undressed	1	2	3	4
3	Preparing simple meals	1	2	3	4
4	Taking a bath or shower	1	2	3	4
5	Going to the shop	1	2	3	4
6	Getting in or out of a chair	1	2	3	4
7	Going up or down stairs	1	2	3	4
8	Walking around in the neighbourhood	1	2	3	4

9	Reaching for something above your head or on the ground	1	2	3	4
10	Going to answer the telephone before it stops ringing	1	2	3	4
11	Walking on a slippery surface (e.g. wet or icy)	1	2	3	4
12	Visiting a friend or relative	1	2	3	4
13	Walking in a place with crowds	1	2	3	4
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)	1	2	3	4
15	Walking up or down a slope	1	2	3	4
16	Going out to a social event (e.g. religious service, family gathering or club meeting)	1	2	3	4

8. HADS

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			I feel as if I am slowed down:
3		Most of the time	3		Nearly all the time
2		A lot of the time	2		Very often
1		From time to time, occasionally	1		Sometimes
0		Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			I get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much	0		Not at all
1		Not quite so much	1		Occasionally
2		Only a little	2		Quite Often
3		Hardly at all	3		Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			I have lost interest in my appearance:
3		Very definitely and quite badly	3		Definitely
2		Yes, but not too badly	2		I don't take as much care as I should
1		A little, but it doesn't worry me	1		I may not take quite as much care
0		Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			I feel restless as I have to be on the move:
0		As much as I always could	3		Very much indeed
1		Not quite so much now	2		Quite a lot
2		Definitely not so much now	1		Not very much
3		Not at all	0		Not at all
		Worrying thoughts go through my mind:			I look forward with enjoyment to things:
3		A great deal of the time	0		As much as I ever did
2		A lot of the time	1		Rather less than I used to
1		From time to time, but not too often	2		Definitely less than I used to
0		Only occasionally	3		Hardly at all
		I feel cheerful:			I get sudden feelings of panic:
3		Not at all	3		Very often indeed
2		Not often	2		Quite often
1		Sometimes	1		Not very often
0		Most of the time	0		Not at all
		I can sit at ease and feel relaxed:			I can enjoy a good book or radio or TV program:
0		Definitely	0		Often
1		Usually	1		Sometimes
2		Not Often	2		Not often
3		Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

9. Informed consent

Informed Consent

Informed Consent form for Community-Dwelling Elderlies who we are inviting to participate in this study on physical activity. The title of our research project is: Effect of a Group Exercise Program Compared with a Home-Based Exercise Program on Physical Activity in Community-Dwelling Elderly: GET-PACE Randomized Control Trial

Name of principal investigator: Lena Siqveland

Name of University: Escola Universitària de la Salut i l'Esport – EUSES, Physiotherapy UB-UdG

This Informed Consent has two parts:

1. Information sheet – to share information about the research project with you
2. Certificate of Consent – for signatures if you agree to take part

You will be given a copy of the full Informed Consent Form

Information sheet

Introduction

I am Lena Siqveland, working on my final project for my physiotherapy degree. I am doing a research on physical activity and elderly. I want to investigate if we can help community-dwelling elderlies by implementing a group exercise program for eight weeks. I am going to give you information about this project as well as inviting you to be a part of the research.

Purpose of the research

The world population is getting older than ever before, and a large amount of elderly are living a sedentary life. We have a lot of knowledge about the positive effects of living a life with physical activity. I want to develop an exercise program that not only help elderly becoming more active but also give you the knowledge to continue staying active every day of the rest of your life.

Type of Research Intervention

The intervention consists of 8 weeks of a scheduled exercise program 2 times per week. Before starting the program, we will do a baseline assessment and after the end of the program we will have 3 follow-up assessments.

Participant selection

We are inviting everyone aged 65 years or older registered in X primary health care area.

Voluntary Participation

The participation in this research is absolutely voluntary. It is your own personal choice whether to participate or not. If you chose to participate you can change your mind at any point and leave the research project.

Procedures and Protocol

You will be randomly divided into two groups. Both groups will have to do the same exercise program the difference is that one group will meet at a center during the 8 weeks to do the program together while the other group will only meet the first day, to get familiarized with the program, and then they are free to do it by themselves at home. The program will be standardized, but changes can and will be done depending on every individuals conditioning.

We will ask you to do four assessments at different points during the study. This will include a few questionnaires that you will fill out with one of the investigators and a walking test. As a part of the assessment we will also ask you to wear a pedometer on you every day during the week before the assessment to be able to count the number of steps each day.

Duration

The research takes place over 1 year and 6 months. During that time, there will first be a baseline assessment, then the exercise program will last for 8 weeks. After finishing we would like to meet you one week after the end, 6 months after and 1 year after for the final check-up.

In total, you will be asked to come 4 times for the assessment, and depending on your group, you will come 1 time or 16 times for the exercise program.

Side Effects

There are no known side effects for this intervention.

Benefits

If you participate in this research, you will have the benefit of getting an exercise program and get more experience on how to exercise properly. This program can help you get stronger and help you to live a more or maintain an independent life. You will have the opportunity to meet new people and possibly create new friendships. Looking at the big picture, your participation will help developing new prevention methods that future generations can benefit from.

Reimbursements

You will not be given any money to take part in this research.

Confidentiality

With this research, something out of the ordinary is being carried out in the community. Others in the community will most likely be aware that you are participating and they may ask you questions. We will not share the identity of any person participating in this research. All information obtained during this research is confidential. The collected information will be stored and only the investigators will have access to it.

Sharing the Results

The information we get from this research will be shared with you through a community meeting. It will also be available to the public through a scientific journal, so other people can learn from our experience. Confidential information will not be shared.

Right to Refuse or Withdraw

You do not have to participate in this study if not desired. You can also stop the participation at any point during the study, it is your choice and we will respect it.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year

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