

Physical Activity and Depression In Nursing Home Patients – A Pilot Study

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In memriam
”mormor”
Maja Lisa Johansson

Du är alltid med mig

Abstract

Background.

The human population is getting older and the need for health care especially tailored for the very old will increase. The prevalence of depressive disorders among patients in nursing homes is estimated to 32 % compared to 13 % in the general population over 60 years of age. A study on how an activity programme could affect nursing home residents' physical functioning and well-being was designed. We added a depression rating scale to see how physical activity could affect depressive symptomatology, since physical activity is known to be effective in depressions in other age groups.

Material and methods.

A randomised controlled trial was carried out with 56 residents from six nursing homes. They were randomised to either an intervention or a control group. The intervention consisted of an individually tailored programme including extra physical activity with physical therapist, occupational therapist and "extra" activities on the ward. Age, gender and length of stay in the nursing home were recorded for each patient at baseline. Further, they were evaluated with Montgomery Aasberg Depression Rating Scale (MADRS), the Berg scale, Swedish translation of the Clinical Outcome Variables (S-COVS), Mini Mental Status Examination (MMS) and Philadelphia Geriatric Centre Morale Scale at baseline and after three months.

Results.

The patients of the intervention group improved significantly regarding their physical ability as measured by the Berg scale. The score on MADRS also dropped more in the intervention group compared with the control group, but this difference was not of statistical significance.

Discussion and Conclusion.

Balance function was significantly improved after three months of activity, and we saw a tendency that patients improved regarding depressive symptoms. However, several factors could have influenced the results of the present study such as selection bias, a too large test manual, a high drop out rate and too few participants. More research is important in this interesting and important field.

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1. Introduction

The human population all over the world is getting older. High birth and death rates have now switched to low birth and death rates. United Nations estimates that in some countries like Sweden and Norway in Northern Europe, the amount of people over the age of 60 will increase from 20 % (Norway) and 23 % (Sweden) in 2002 to 32 % (Norway) and 38 % (Sweden) in 2050. (1). The amount of people aged 80 and older will increase even more, as seen in figure 1 for year 2025.

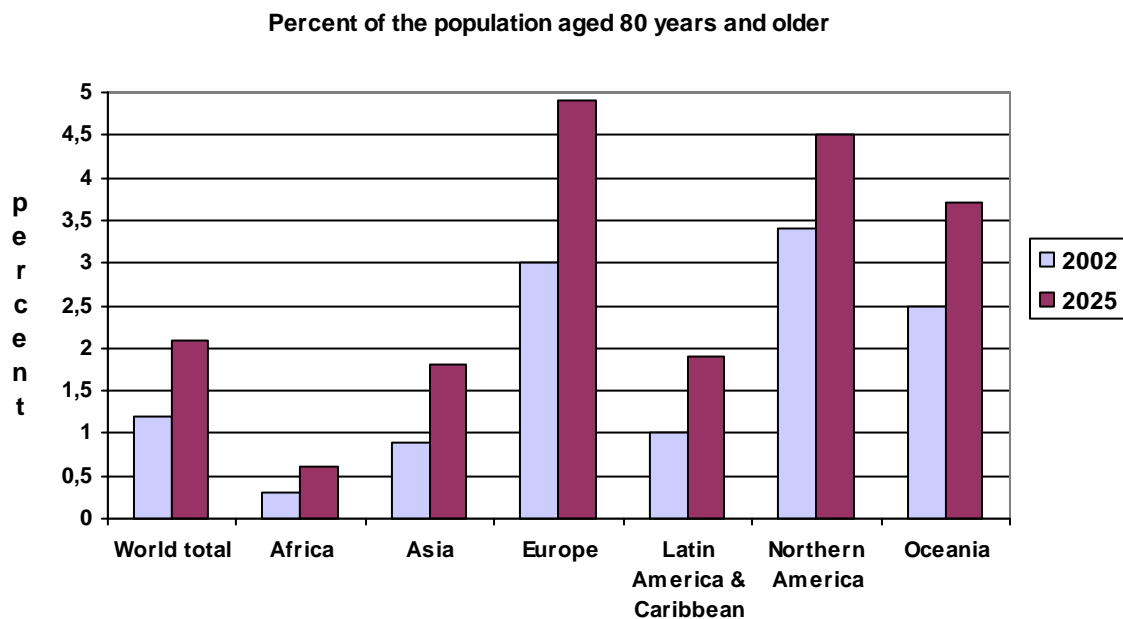


Figure 1: Based on information from U.S. Census Bureau, [http:// www.census.gov/ipc/prod/wp02/tabA-07a.xls](http://www.census.gov/ipc/prod/wp02/tabA-07a.xls) and <http://www.census.gov/ipc/prod/wp02/tabA-07b.xls>

With a growing older population, the need for health care, especially tailored for the very old above 80 years of age, will increase. The demand for safe nursing home care of good quality will increase as well. The residents in nursing homes will be very old and frail suffering from a variety of chronic disorders leading to helplessness, such as dementia due to Alzheimer's disease and stroke, Parkinson's disease, cardiovascular disorders, Chronic Obstructive Pulmonary Disease (COPD) and osteoporosis. It is calculated that today about 75-80 % of people in nursing homes have dementia, and many of those have secondary symptoms of anxiety, depression and psychosis (2). On average each patient suffers from four to five chronic diseases.

Studies have shown that the prevalence of clinical significant depression (depressive disorder) among patients in nursing homes is 32 % compared to 13 % in the general population over 60

years of age living at home. The prevalence rates are lower when it comes to “major depression”, but they show the same tendencies, namely 5 % in the nursing homes and 2 % in the elderly population living outside the nursing homes (3).

Epidemiological studies have shown that depression in the elderly is strongly associated to physical diseases that cause functional impairment, and there is reason to believe that there is an association also between depression and lack of physical activity (4). The relationship between physical activity and psychological symptoms has been studied in other age groups, showing that intervention with physical activity is more effective than no treatment and as effective as traditional therapy such as antidepressants or behavioural-cognitive therapy among depressed patients (5). Studies have also been carried among older adults, one showing that physical activity led to a 30 % decline in depression as measured with a depression scale (6). However, the participants in this trial had a mean age of “only” 64 years, and were not specifically living in nursing homes.

A study from Lund, Sweden, focusing on how physical activity could increase the level of daily functioning among nursing home residents has been designed. The department of geriatric medicine at Ullevål University Hospital, Oslo, Norway was invited to take part in the study. For this study, carried out in nursing homes in Oslo, we decided to add a depression rating scale to the measurements of the study in order to examine whether physical activity could have any influence on depressive symptomatology in this population. This must be considered a pilot study, since we do not know from the literature, what effect physical activity could have on depression in this very old age group.

In doing these kinds of studies, one has to adjust the physical activity to this older age-group, keeping in mind that normal biological ageing involves a reduction in the reserve capacity of the body (7). For instance, the ability of the heart to increase in frequency and stroke volume is decreased. Other impairments that may come with age are osteoporoses, weaker tendons, lumbago and reduced balance (8). Therefore the personnel working in the nursing homes should tailor individual programmes for the participants.

The quality of Scandinavian nursing home care has been lively debated in media lately. This is a subject that is important for many people, but not always prioritised when it comes to investing money. My motivation to take part in this study includes an interest in this age group, and a feeling of responsibility to give them the best possible care in their last years of life.

2. Theory

2.1 Demographics

As mentioned in the introduction, the United Nations estimates that the world's older population (aged over 80) will experience a major increase in the coming years. The population in total will increase by 27 %, and the population over 80 years of age will increase by 113 % from 2002 to 2025 (9). The later a person is born, the longer he or she can expect to live. In Norway today, the mean living age is 80,2 years for women and 74,3 years for men. A girl born in 1994 can expect to live for 8,4 more years the comparable figure for boys is 6,7 years (10).

2.2 The Nursing Home Population

When trying to characterize the typical nursing home patient, one soon realizes that the most typical is that he or she has multiple diseases. Actually, in one nursing home study, 87 % of the patients suffered from more than one disease, most commonly diseases from the musculoskeletal systems such as sequela after fractures, mental disorders (mostly dementia) and diseases of the cardiovascular system (11). In this study the mean age of the patients was $82,5 \pm 9,5$ years, the mean stay in the nursing home was 1,8 years, and 78 % lived less than three years in the institution. The same study compared nursing home patients with patients living at home receiving in-home nursing and found high prevalence of depression and depressive mood symptoms in both groups, but significantly higher prevalence of depression ($p < 0,001$) among the nursing home patients. Dementia was diagnosed in 41 % of the nursing home patients, although mental tests showed that probably 72 % suffered from dementia (11). It is estimated that one half to two thirds of somatic nursing home patients have a dementia disorder (12).

Another very common diagnosis, but not always diagnosed or properly treated is depression. One systematic literature review found that up to 31% of the patients in hospitals and nursing homes suffered from depression, as compared to 19 % in the total elderly population (3). As will be discussed in chapter 2.3.3 it is important to be aware of the different or "atypical" manifestations of depression among older people (2), as this will be of critical importance in diagnosing depression (13).

The need for nursing home care is also influenced by non-medical factors. Some older people experience loneliness and isolation, the social network might be poor and due to new and

modern family structures it might be difficult for the family to take care of the older family member (12).

2.3 Depression in the older population

2.3.1 Definition of depression

According to ICD-10, depressive episodes are divided into mild, moderate or severe depressive episodes. The difference between the three levels of severity is illustrated in *table 1 and 2*.

Table 1: Depressive symptoms

| Major symptoms | Other usual symptoms |
|--------------------------------|---|
| Depressive mood | Reduced concentration |
| Loss of interest and happiness | Reduced self esteem and self trust |
| Loss of energy | Feeling of guilt, feeling of inferiority |
| Tiredness | Sad and pessimistic thoughts about the future |
| Reduced activity | Plans about, or actions of self punishment or suicide |
| | Sleep problems |
| | Loss of appetite |

Table 2: Severity

| Mild | Moderate | Severe |
|---|---|--|
| Two of the major symptoms in <i>table 1</i> AND two of the other symptoms | Three of the major symptoms in <i>table 1</i> AND three of the other symptoms | Three of the major symptoms in <i>table 1</i> AND four of the other symptoms |

This is the “definition” of depression, but when it comes to evaluating if an older person is depressed; it turns out to be more difficult as the signs of depression in elders might be both atypical and difficult to differentiate from symptoms of grief or loneliness, or in some cases from dementia (2).

2.3.2 Prevalence and risk factors of depression

The one-year prevalence of depressive episode in the general population is estimated to be 7-10 % (14). The prevalence for older people is higher. For patients that receive in-home nursing care the prevalence is about 20 %, and for nursing home patients 15-25 % is estimated to be depressed. Half of the depressed elderly patients experience the first depression in old age, whereas the other half has suffered from depressions earlier in life (16).

The risk factors for depression in the general population and the older population have similarities and differences. There are psychosocial and biological risk factors. Probably, child and adolescence experiences will be significant for some patients, but in our time troubles with mastering or coping are central causes for many lighter depressions. The more complex the society becomes, the more insufficient people will feel (14). Also, low educational level, loss of one or both parents before 15 years of age, unsolved conflicts, sexual abuse, stress economical worries, traumas, unstable relationships and absence of an intimate, close person are important risk factors. For the older population, retirement, sorrow, loss of independence and autonomy, isolation, role changes, multiple medical problems, financial difficulties, loss of function and loss of close friends and relatives will be of special importance. Heredity is the biological risk factor important in both groups. In the older population vascular changes in the central nervous system, sub cortical changes in the white matter of the brain and reduced function of neurotransmitters, especially noradrenalin, serotonin and dopamine will be the major biological risk factors. Also, medication might be of importance (fat soluble beta-blockers, corticoids, H2-blockers and benzodiazepines) (16).

2.3.3 Symptoms of depression in the older population – atypical depression

Depression among older people is more often than in the younger population associated with atypical symptoms. The symptoms are usually not that obvious or clear, and the picture might have another appearance. This makes the diagnostic process harder. Symptoms like hypochondria, agitation, restlessness, worrying, anxiety and contact seeking might overwhelm the picture. Asthenic depression with retardation, psychomotor slowness and loss of initiative might be difficult to separate from normal ageing or dementia. Another important type of depression is the depression that mimics a dementia condition with reduced attention, reduced concentration, learning difficulties and reduced short time memory. The patient might seem disoriented, passive and helpless. This picture has usually been called pseudodementia, but a better name would be “depression with symptoms resembling dementia”. The differentiation from dementia might be difficult, and memory tests or tests on orientation are not very useful. However, more important is to evaluate the person’s language abilities and ability to orientate in the room. In for example Alzheimer’s disease, these symptoms are prominent, but never in depression. Another way to differentiate between these two diseases might be to introduce antidepressant medications for a while. A reduction of the symptoms could indicate depression and not dementia. On the other hand it is important to follow up a patient with depression and cognitive symptoms and memory loss, because depression in high age might

be the first sign of dementia (2). Lastly, one should not forget that dementia and depression might occur at the same time.

Table 3: Atypical depression among elderly.

| | |
|---------------------------------|--|
| Vague depression: | The patient has slight symptoms, especially the feeling of sadness is not so obvious, but the loss of function might be great. Be aware of the risk of suicide. |
| Agitated depression: | The patient is restless, worried, angry, clinging and not least demanding. |
| Hypochondriac depression: | Patient is obvious of being somatically ill, usually afraid of having a cancer. Pain and disease is usually referred to the stomach or the face. |
| Masked depression: | No signs of reduced mood, but somatic complaints. |
| Dementia resembling depression: | Concentration difficulties, reduced attention, cognitive impairment as reduced memory, and loss of orientation. |
| Asthenic depression: | The patient has no initiative and does not care for her- or himself |
| Genuine atypical depression: | The patient has symptoms like appetite and weight increase, increased need of sleep and a feeling of heavy arms and legs |
| Vascular depression: | Often together with cognitive impairment. Difficult to treat and tendency to relapse. With MR, there are changes in the white matter of the brain, probably because of vascular changes. |

The different types of atypical depressions according to Engedal, are listed in table 3 (2). Because of the atypical symptoms the diagnostic methods used for diagnosing depression do not always fit for diagnosing depression in an older person. This will be discussed more thoroughly in 2.3.4. Another difference from younger patients is that structural changes in the brain are more often found by means of CT or MR in the older age group (16).

2.3.4 Diagnostic possibilities and difficulties

As discussed above, it is not always easy to diagnose a depression in an older person. It is sometimes necessary to observe the patient over a period of time. A thorough history, both somatic and psychiatric is important, keeping in mind that somatic illnesses might be the triggering factor for a depression (2). A family history, cognitive status and risk factors for depression are important factors to evaluate. Another important way of getting more information is to interview a person that knows the elderly well, for instance a close relative, focusing on changes in the person's behaviour. Often, the family has noticed behavioural

changes (13). Standardized rating scales such as Montgomery-Aasberg Depression Rating Scale (MADRS), Geriatric Depression Scale (GDS) or Hamilton Depression Scale (HDS) can be used, but one has to be aware of that some of these scales are not tailored for all elder persons (2). Even though rating scales do not always fit for this age group, they might be very useful in evaluating effect of treatment and progression (13). For MADRS, the most used scale in the Nordic countries, a score of six and below is considered to be a normal result indicating that no depression is present, whereas a score between seven and 19 represent mild degree of depression, 20-34 moderate degree of depression and 35 and above severe degree of depression (17).

Often, the older patients do not satisfy all the diagnostic criteria of depression according to ICD-10 or other diagnostic systems despite being in need of therapy. If therapy is not given, the prognosis can be poor, and the depression has a tendency to become chronic (13).

2.3.5 Therapies used for treating depression in the older population

There are four major forms of treatment: Anti depressant medication, Electroconvulsive Therapy (ECT), psychotherapy and environmental therapy. It is usually most effective to combine different therapies, such as psychological and drug treatment (13).

Many antidepressant medications are on the market and the most important ones are Tricyclic Antidepressants (TCA), Selective Serotonin-Reuptake Inhibitors (SSRI) and related medications, Receptor antagonists (Mianserin and Mirtazapin), MonoAmine Oxidase Inhibitors (MAOI) and Reversible Inhibitors of Monoamine oxidase A (RIMA). The different medications have somewhat different pharmacological mechanism and effect. TCAs have been used for a long time with very good effect but they may have serious side effects. TCAs affect many signal systems, and especially its central anticholinergic and antiadrenergic effect may cause problems in older persons. The central anticholinergic effect may give loss of memory, disorientation and psychosis; antiadrenergic effect may give orthostatic hypotension, and have a negative effect in a person with a heart failure. TCAs should not be given to persons with a serious ongoing heart disease, and one should avoid prescribing them to patients over 80 years of age, and especially if the patient suffer from dementia. In Alzheimer's disease one of the main biochemical disturbances is loss of acetylcholine. SSRIs and related medications have similar effects as TCA, but do not affect as many neurotransmitter systems and therefore have fewer side effects. These are usually a good first choice in the elderly. SSRIs are also effective in anxiety and in agitated persons with dementia. MAOI is especially indicated for treating atypical depression. RIMA have fewer

side effects than TCAs, but they should not be combined with SSRIs to avoid the serotonergic syndrome. Receptor antagonists could be a good choice for some patients, especially when sleep disturbances are prominent (2).

Depending on the type of depression it is also possible to add other types of medications like anticonvulsants, antipsychotics (agitation and anxiety) and lithium (bipolar cycling and recurrent depressions) (18).

ECT is indicated for severe depressions or in resistant depression (two different antidepressants fail to have effect). It is also effective in depressions in persons suffering from Parkinson's disease. ECT should not be given until three months after a myocardial or cerebral infarction, severe lung disease, uncontrolled hypertension, aortic or carotid aneurysms or when increased intracranial pressure is present, but these contraindications are relative when ECT is given as a life saving treatment (2).

Information to the patients about depression and empathic listening is not the same as psychotherapy, but a very important complement to pharmacological therapy. Information about the disease, follow-up and encouragement are good strategies. We do not know exactly how well psychotherapy works in the elder but so far studies show that it has good effect, as good as biological treatment (2).

When it comes to environmental therapy and its effect on depression in the elderly, the scientific evidence is not fully understood, but it seems that depressed patients benefit from meeting other people, getting out, eating with others, go for trips and participate in activities (2). However, in the beginning of a therapy, regardless of which one is chosen, it is usually important to focus on encouragement and care and then gradually increase the expectations and demands, when one sees that the therapy works (18).

To what extent the various treatment options are used in the nursing home setting varies, but at least when it comes to medications, studies show that the need for treatment is greater than the actual use. In one study carried out in nursing homes in Norway, one found that 23 % of the residents were on antidepressants because of a depression, whereas another study showed that 32 % actually suffered from clinical significant depression, needing treatment (3, 13). When it comes to the environmental- and psychotherapy one found that the nursing home care providers did not have enough time or skills to give these kinds of therapies. This was

probably also the reason for not giving enough medication. The personnel working with the residents daily did not have enough time to discover and then report the depressions to a doctor (13).

2.3.6 Physical activity as a therapy for depression, what do we know?

The effect of physical activity has been shown to be more effective than no treatment and as effective as “regular” anti depressive treatments when it comes to mild or moderate degree of depression. As the expenses for anti depressive therapies increase, efficient self-therapy might be of importance. Intervention studies have shown that physical activity creates a feeling of well-being after the session, better sleep, better problem solving capacity and muscle relaxation. They have also shown that physically active people has less tendency to get a depression than the physically inactive (5).

In one study, researchers found that in patients aged 20-45 with *mild to moderate* depression, aerobic class exercise was effective and as many as 47 % reduced their score on a depression rating scale. The higher the intensity of the aerobic activity, the better result. The frequency (three or five times a week) did not seem to matter. This study gave the advice that everyone should “engage in ≥ 30 minutes of moderate-intensity physical activity on most and preferably all days of the week to reduce their risk of early death and morbidity of diseases such as cardiovascular disease”. The same advice was also given when it came to depressions (19).

Another study with older patients between 50 and 75 years with *major* depressions showed that exercise has as good effect on depressions as medications (20). A study with older patients with *poorly responsive* depressive disorders showed that these patients would have a modest improvement of depressive symptoms, and “should be encouraged to attend group exercise activities” (6). Possible explanations for these positive effects have been put forward. The *anthropologic* explanation is that the man was made to hunt and collect things, and the western lifestyle with its physical inactivity is unhealthy. The *temperature hypothesis* says that a small and temporary increase in the temperature (approximately one degree Celsius), has a good psychological effect. The *biochemical* explanation is that the body produces endorphines during exercise and these together with increasing levels of serotonin and noradrenaline during training is the reason for the anti depressive effect. The *psychological* hypothesis is that training creates a feeling of mastering or distraction (5).

2.4 Physical activity and elderly people

2.4.1 Ageing and consequences for physical activity

Most cells in the body undergo ageing processes. There is a gradual shrinking of the active tissue (e.g. muscle) that is exchanged to a more passive connective tissue. This is the situation for muscle tissue and hormonal glands and the result of these changes is that the body contains less active cells. Also, changes in the circulatory system with reduced oxygen supply and reduced leave of waste products and changes in the enzymatic activity are changes that appear in the older body. Physical activity will have a positive effect on these changes for instance because of better blood and oxygen supply, at the same time however, physical activity might be more difficult for the older person with the mentioned “natural” changes. Another aspect of ageing is that it includes for many people a more sedentary daily life and this will have a major effect on the physical condition. Physical activity is important for all people to keep up a healthy effective body. In fact, if an older person keeps the body in activity, he or she might have a better working body than a much younger person without exercise (8).

Although an older person might suffer from painful joints, stiffness and muscle pain, it is important to remember that inactivity usually worsens the symptoms, and exercise is usually effective in relieving them (8).

2.4.2 Exercise suited for the older population

One should divide exercise into two groups; “natural” and purposeful exercise. The “natural” exercise includes walking to the supermarket or playing with the grandchildren. In purposeful exercise the patient wants to achieve a better physical condition. This might include walking, jogging, bicycling or strength training. The important thing is not how much you train, but that you train. This means that regular training whether it is walking 30, or 40 minutes per day does not make a big difference. When it comes to restrictions, researchers agree that there are a few contraindications of increasing physical activity in the elderly such as unstable angina pectoris, suspected myocardial infarction, uncontrolled arrhythmia and heart block. Persons with chronic diseases should visit a doctor before starting with physical activities (21).

3. The Nordic intervention study of physical and daily activities among elderly nursing home residents

3.1 Background and design of the study, participants and measurements

The study was originated in Sweden, and the motivation was as follows “During the last decade resources directed towards rehabilitation efforts in long term elderly care in Sweden have been scarce. Despite the fact that rehabilitation has been proven to contribute to positive change, physiotherapy and occupational therapy have not been highly prioritised and the number of therapists is not sufficient. Frail elderly persons in need of care seem to be a neglected group. The study intends to fill a gap in knowledge related to the effect of enhanced ADL-training, physical and daily activities and staff education in a nursing home setting, based on a theory- and evidence-based intervention programme in a Swedish health care context.” (22).

This is a randomised controlled trial and a multi-centre study carried out in nursing homes in three Swedish cities, Finland and Norway. The inclusion criteria are: Age over 65 years, need of daily assistance in a minimum of one Personal or basis Activity of daily Living (P-ADL), ability to understand verbal instruction, willingness to participate, and expected stay in the nursing home during the intervention period. Exclusion criteria: Terminal stage of disease (22).

The intervention is based on an *individually tailored* program including activities with physiotherapists and occupational therapists. It is supposed to test the impact of these activities on functions like ADL, physical capacity and self rated well-being (22). These parameters will be tested at baseline, after three months with intervention and last time after another three months (i.e. six months after starting).

4. The pilot study of physical activity and depressive symptomatology

When the Nordic study was in the start phase in Oslo, Norway, we decided to add a parameter in order to find out how physical activity and daily training would affect depression and depressive symptoms. We therefore added the MADRS scale at baseline and after three months. In this study we only evaluated the participants at baseline and after three months, and did not use all results from the original study. Further, we were fully aware of the fact that not only patients with clinical significant depression were included in this additional study of physical activity and depression. Calculation of statistical power was not possible to carry out, and therefore, this study must be considered to be a pilot study. The main purpose of the study

was thus, to explore whether there was any tendency that physical activity could influence in a positive way on depressive symptomatology. If so, the results could possibly be used to calculate the statistical power of a future controlled trial.

4.1 Method

4.1.1 Design

This is a study based on the project described in chapter 3.1. It is a randomised controlled clinical trial carried out over a period of three months, with registrations at baseline and after three months.

4.1.2 Participants

The participants were recruited from six nursing homes in Oslo, using the same inclusion and exclusion criteria as in the Nordic study: Age over 65 years, need of daily assistance in a minimum of one Personal Activity of Daily Living (P-ADL), ability to understand verbal instruction, willingness to participate, and expected stay in the nursing home during the intervention period. To be sure that the participants were competent to give written consent, a score on the Mini Mental State Examination (MMSE) of above 18 was preferred. The only exclusion criterion was: Terminal stage of disease. Out of 72 residents that were recruited, 56 were finally randomised into two groups; one intervention and one control group. We do not know the reasons for why 16 patients were not randomised, but the most important factor was that in some of the nursing homes the time between screening examination and the start of the intervention period was too long (several months), and in this waiting time patients decided to leave the study.

4.1.3 Intervention

The intervention group was offered a tailored activity programme, whereas the control group received regular care, during three months. The “extra” activity in the intervention group included extra time with a physiotherapist, extra time with an occupational therapist and an individually tailored activity programme including different kinds of activities that were discussed with the resident. To document the intervention, every resident had a diary where the staff noted all activities on a daily basis. Examples on activities were balance training, coordination, instructions on self-training, movement, walking, light weight lifting, reading groups, games, singing, hand crafting, religious meeting and much more.

4.1.4 Data collection

The following data was collected at baseline: Age, gender and length of stay in the nursing home, and the following data both at baseline and at three months: The Berg balance scale score, Swedish translation of the Clinical Outcome Variables Score (S-COVS), Mini Mental Status Examination (MMSE) score, Philadelphia Geriatric Centre Morale Scale score and Montgomery Aasberg Depression Rating Scale (MADRS) score. The Berg scale and S-COVS scores were the primary outcome variables. For the original study, more tests were included, but will not be discussed here. Physiotherapists and one medical student, not working in the nursing homes and that did not participate in the intervention programme tested the patients and collected all the data.

4.1.5 Measurements

MMSE measures cognitive function in various psychological areas such as short time memory, language, orientation for time, place and situation, visuo-spatial function and abstract thinking. The test has a maximum score of 30. A score of 24 and below is usually considered to be a sign of cognitive impairment among elders above 80 years of age. One inclusion criteria was that the MMSE score should preferably be 18 or above. The Berg balance scale includes 14 items (e.g. moving from sitting to standing, stand on one leg, turn 360 degrees), all testing balance function. The S-COVS scale measures mobility and ambulation. This instrument consists of 13 items that can be scored from one to seven points, representing from complete dependence (1 point) to independence or normal function with or without an assistive device (5–7 point) (23, 24). The Philadelphia Geriatric Centre Morale Scale has 17 yes or no questions evaluating feeling of agitation, attitude towards own aging and loneliness. MADRS is a grading scale where ten different aspects of a depressive illness are judged. The items can be scored from zero to six points and usually the evaluation is done by interviewing the patient. It is possible to get an objective view of the severity of a depression and also to evaluate efficiency of treatment using MADRS. According to Snaith et al a score of 0-6 is defined as no depression, 7-19 is mild depression, 20-34 is moderate depression and 35-60 is severe depression (17).

4.1.6 Statistics

SPSS 12 version was used for the database and statistical analysis. For comparing means of the scores on the scales we have used students t-test with 2-tailed significance values. For comparing frequencies we have used chi-square and Fishers exact test.

4.1.7 Ethical considerations

The study was carried out in accordance with the Helsinki declaration, and was approved by the Regional Committee for Medical Research, Eastern Norway. Written informed consent was obtained from all the participants. All were judged to be competent.

4.2 Results

4.2.1 Baseline characteristics

This chapter will describe the characteristics of the participants.

Table 4 shows characteristics of the residents, separated by gender. It shows that the only significant difference between women and men is, not surprisingly, the age.

Table 4. Characteristics of the participants by gender.

| | Women (n=43) | Men (n=13) | P value |
|--|--------------|-------------|---------|
| Age in years, mean (s.d.) | 88,2 (5,7) | 80,2 (7,3) | <0,001 |
| Stay in the nursing home in months, mean (s.d.)* | 29,1 (35,0) | 20,5 (16,3) | 0,42 |
| MMSE score, mean (s.d.) | 23,6 (4,1) | 23,3 (3,1) | 0,80 |
| Berg score, mean (s.d.) | 24,6 (16,8) | 21,2 (18,9) | 0,54 |
| SCOVs score, mean (s.d.) | 59,5 (18,6) | 50,5 (18,1) | 0,13 |
| Philadelphia Morale Scale score, mean (s.d.) | 10,9 (3,5) | 11,8 (3,4) | 0,42 |
| MADRS score, mean (s.d.)** | 5,7 (6,4) | 7,2 (10,2) | 0,54 |
| 0-6 = no depression, number | 31 | 8 | |
| 7-19 = light depression, number | 8 | 4 | |
| 20-34 = moderate depression, number | 3 | - | |
| ≥ 35 = severe depression, number | - | 1 | |

* Data on stay in nursing home was collected in 36 women and 12 men

**Data on MADRS score was collected in 42 women and 13 men

The 56 residents were randomised to two groups; one intervention group and one control group. Table 5 shows age, length of stay in the nursing home and gender distribution, and the results at baseline on the tests for the two groups. As can be seen from the table, the two groups did not differ significantly regarding any measures, although 10 in the intervention group had a score on MADRS above 7, compared to 6 in the control group.

Table 5: Characteristics of the intervention- and control group.

| | Intervention group (n=28) | Control group (n=28) | P value |
|--|---------------------------|----------------------|---------|
| Women, number, (%) | 21, (75,0) | 22 (78,6) | 0,76 |
| Men, number, (%) | 7, (25,0) | 6, (21,4) | 0,76 |
| Age, mean (s.d.) | 86,5 (6,7) | 86,1 (7,3) | 0,84 |
| Stay in the nursing home, months, mean (s.d.)* | 23,4 (19,8) | 29,7 (38,3) | 0,49 |
| MMSE score, mean (s.d.) | 23,1 (3,9) | 23,9 (4,0) | 0,48 |
| Berg score, mean (s.d.) | 23,5 (16,2) | 24,0 (18,7) | 0,92 |
| SCOVs score, mean (s.d.) | 59,6 (17,7) | 56,0 (19,9) | 0,39 |
| Philadelphia Morale Scale score, mean (s.d.) | 11,2 (3,7) | 10,9 (3,4) | 0,76 |
| MADRS score, mean (s.d.)** | 7,1 (9,1) | 4,9 (5,0) | 0,25 |
| 0-6 = no depression, number | 18 | 21 | |
| 7-19 = mild depression, number | 7 | 5 | |
| 20-34 = moderate depression, number | 2 | 1 | |
| ≥ 35 = severe depression, number | 1 | - | |

*data collected from 48 participants

**data collected from 55 participants

Of the 55 residents that were examined with MADRS, 16 (29 %) scored seven or above, and according to Snaiths et al's definition they could be considered suffering from depression. Four out of 55 (7,3 %) had a moderate or severe depression. According to the general view in geriatric psychiatry, patients with a MADRS score of 15 and above are in most cases in need of treatment (2). Seven (12,7 %) scored 15 and above on MADRS.

4.2.2 Efficacy of the intervention programme

In the original Nordic multi-centre study, MMSE, Berg scale, S-COVs and Philadelphia Geriatric Centre Morale Scale (and more) were defined as outcome variables to test whether the intervention programme could be beneficial compared to non-intervention. We added MADRS as a new secondary outcome.

Before we carried out the efficacy analysis we wanted to test whether all the outcome variables could be considered as independent of each other. For this purpose we carried out a correlation analysis using the baseline data, table 6.

Table 6: Correlations of MADRS, mental and physical function at baseline.

| | Berg | S-COVS | Philadelph | MADRS | MMSE | Age | Stay |
|-------------|------|--------|------------|---------|-------|-------|-------|
| Berg score | | 0,86** | -0,26 | 0,12 | 0,08 | 0,05 | 0,2 |
| SCOVS score | | | -0,18 | -0,2 | 0,11 | 0,13 | -0,23 |
| Phil score | | | | -0,59** | -0,14 | -0,04 | 0,06 |
| MADRS score | | | | | -0,16 | -0,2 | -0,14 |
| MMSE score | | | | | | -0,2 | 0,05 |

** p<0,01

At baseline, it turned out that the score on MADRS and Philadelphia Geriatric Centre Morale Scale correlated well, -0,59 (p <0,01), and the same was the case for the S-COVS score and the score on the Berg scale, 0,86 (p<0,01). At the three months testing the correlation was -0,57 (p<0,01) for MADRS and Philadelphia Geriatric Centre Morale Scale, and 0,78 (p<0,01) for the S-COVS test and Berg scale.

Table 7 shows the efficacy analysis. In this table we have included all the outcomes, also the scales that correlated well to explore if there could be any differences for tests that nearly measured the same phenomenon.

Table 7: Results of the efficacy analysis.

| | N | Baseline Score mean (SD) | Three months score mean (SD) | Change at three months mean (SD) | Between groups difference at three months | |
|--------------------|----|--------------------------|------------------------------|----------------------------------|---|---------|
| | | | | | Value | P value |
| MADRS | | | | | | |
| Intervention group | 23 | 8,3 (9,6) | 6,7 (7,8) | 1,5 (4,5) | 1,3 | 0,28 |
| Control group | 18 | 3,9 (5,2) | 3,7 (4,3) | 0,2 (2,7) | | |
| Phil-score | | | | | Value | P value |
| Intervention group | 23 | 10,8 (3,8) | 10,6(3,3) | 0,3 (2,5) | 0,2 | 0,81 |
| Control group | 20 | 10,5 (3,5) | 10,0 (3,7) | 0,5 (2,6) | | |
| Berg-score | | | | | Value | P value |
| Intervention group | 23 | 26,0 (16,1) | 31,6 (15,9) | 5,6 (5,9) | 10,2 | <0,0001 |
| Control group | 20 | 25,8 (18,5) | 21,2 (16,8) | -4,6 (4,3) | | |
| SCOVS score | | | | | Value | P value |
| Intervention group | 23 | 60,7 (17,5) | 62,5 (15,5) | 1,8 (12,9) | 0,8 | 0,83 |
| Control group | 18 | 58,4 (19,8) | 59,4 (24,7) | 1,0 (10,1) | | |

As seen in table 7, the intervention group achieved a significant improvement in their physical status evaluated by the Bergs scale, whereas the control group declined. This difference was highly significant. The difference (improvement) between baseline and at three months using the Berg scale was also significant for the intervention group, analysed by one-sample t-test (within group difference, $p < 0,0001$). The improvement in psychological status (MADRS score) was greatest in the intervention group, compared to the control group, but this was not a statistically significant difference.

If we only include the persons that actually scored above or equal to 7 on MADRS (i.e. depressed persons) we see that the change (improvement) at three months in the intervention group is 5,4 (30 %) compared to 2,5 (17 %) improvement in the control group, using the MADRS (table 8). However, only 11 persons, nine from the intervention group and two from the control group, were included in this analysis.

Table 8: Result of the efficacy analysis (MADRS \geq 7).

| | N | Baseline Score mean (SD) | Three months Score mean (SD) | Change at three months mean (SD) | Between group difference at three months | |
|---|---|--------------------------|------------------------------|----------------------------------|--|---------|
| | | | | | Value | P value |
| MADRS\geq7 Intervention group | 9 | 17,8 (9,0) | 12,3 (10,0) | 5,4 (4,3) | 2,94 | 0,39 |
| Control group | 2 | 15,0 (8,5) | 12,5 (5,0) | 2,5 (3,5) | | |

We looked at the results for each individual during the three months follow-up, as shown in figure 2 and 3. It turned out that 12 out of 23 (52,2 %) residents in the intervention group had a lower score on MADRS at three months as compared to the score on baseline. The figures for the persons in the control group were six out of 18 (33,3 %). This difference was however not of statistical significance ($p=0,34$). When studying the persons with MADRS \geq 7 it turned out that eight out of nine 9 (88,9 %) in the intervention group lowered their score after three months, whereas one of two (50 %) in the control group lowered their score ($p=0,35$).

Figure 2: Progression for each individual in the intervention group, one coloured line per person

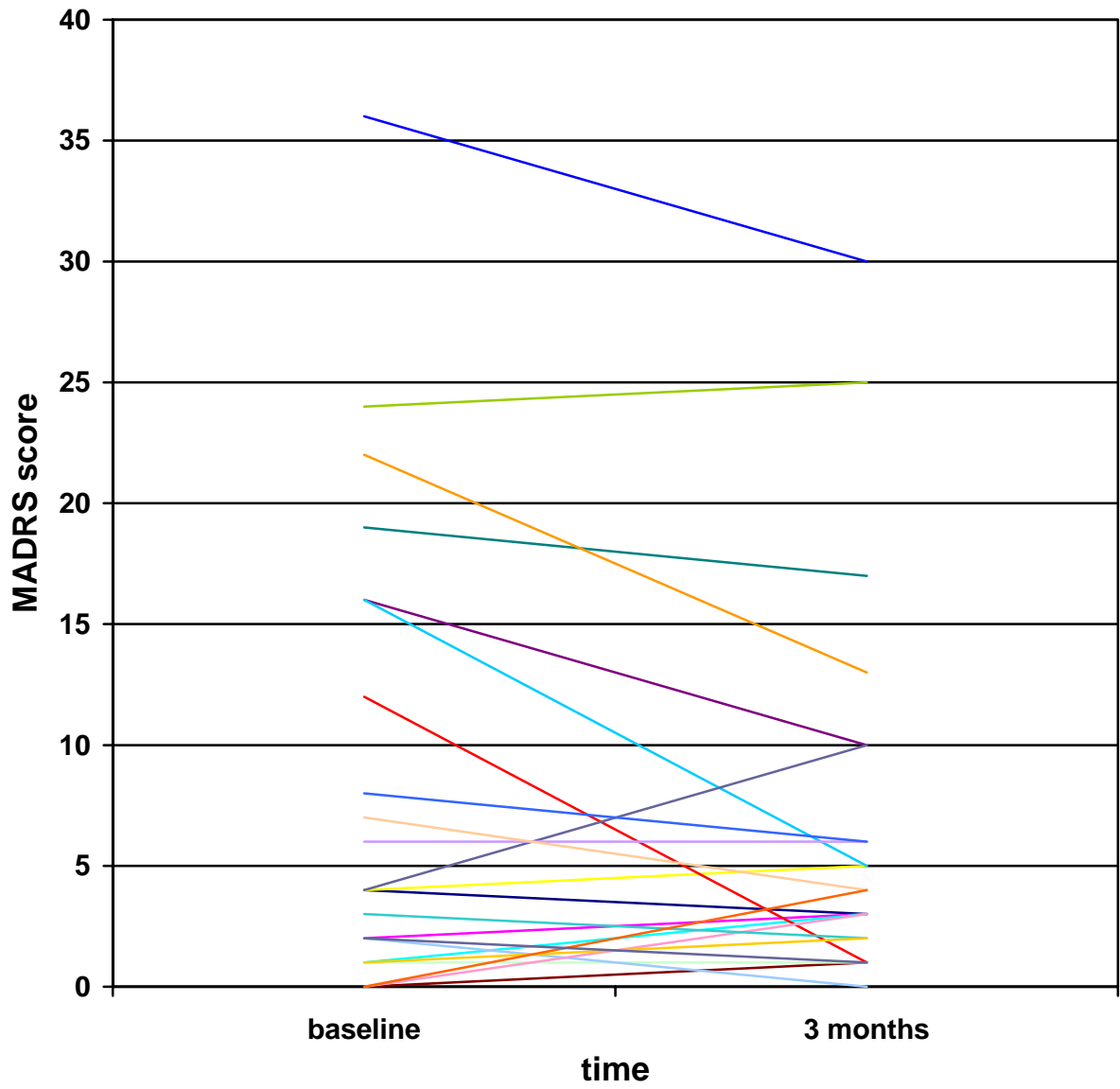
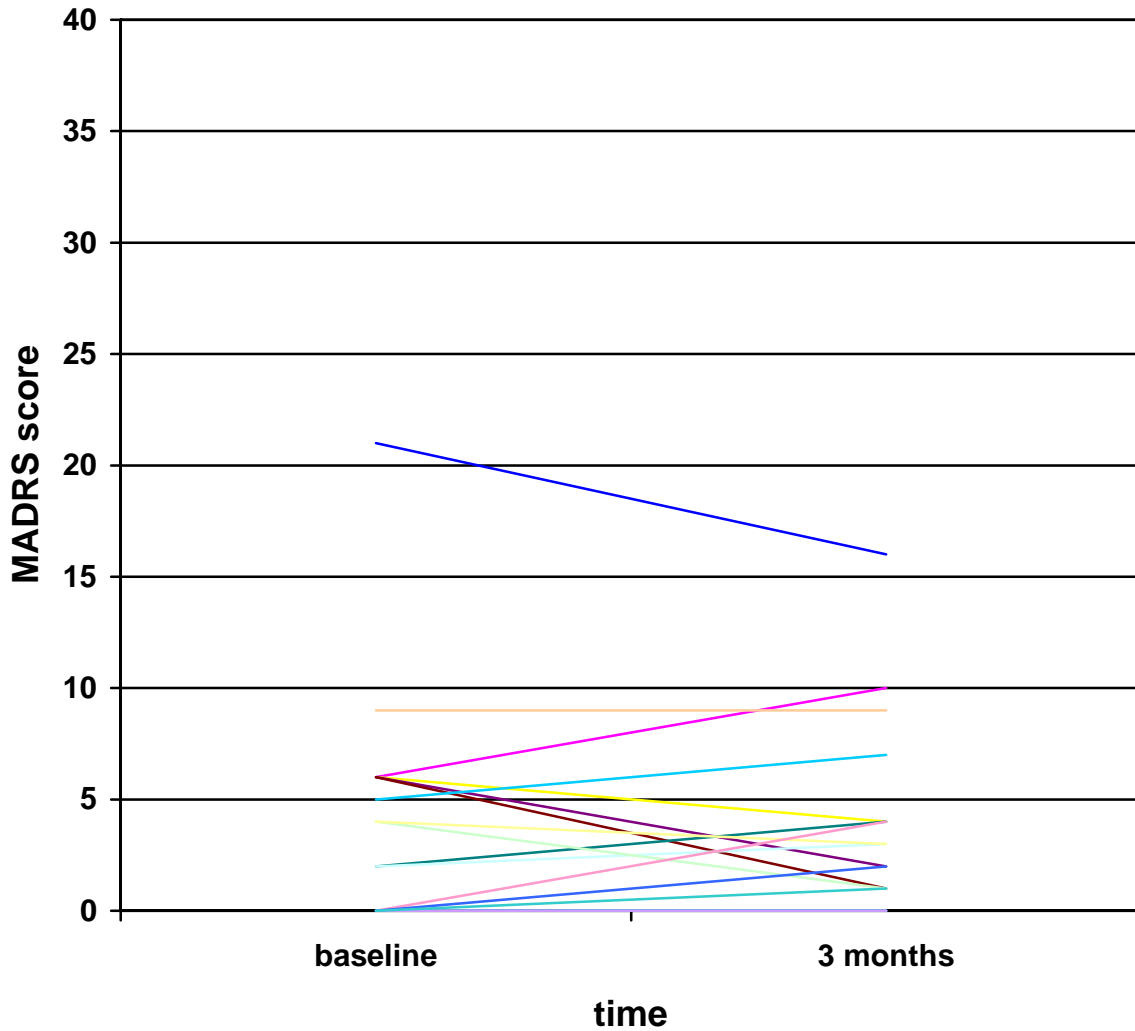


Figure 3: Progression for each individual in the control group, one coloured line per person



4.2.3 Drop-outs

During the three months trial, 14 residents (25,5 %) dropped out; five (17,9 %) in the intervention group and nine (33,3 %) in the control group (difference between the groups, $p=0,23$). The reasons for dropping out are unknown. However, the drop out rate was highest among the participants that scored between seven and 19 on MADRS, 41,7 %. See table 9.

Table 9: Drop-outs by MADRS levels.

| Group | Number of patients included in study | Number of patients at 3 months | Drop-out number; % | P value |
|--------------------|--------------------------------------|--------------------------------|--------------------|-----------------|
| Total population | 55 | 41 | 14; 25,5 | 0,23* |
| Intervention group | 28 | 23 | 5; 17,9 | |
| Control group | 27 | 18 | 9; 33,3 | |
| MADRS 0-6 | 39 | 30 | 9; 23,1 | |
| MADRS 7-19 | 12 | 7 | 5; 41,7 | |
| MADRS \geq 20 | 4 | 4 | 0 | \approx 0,2** |

* Comparing intervention group and control group

** Comparing dropout rates in group MADRS 0-6, MADRS 7-19 and MADRS \geq 20

4.3 Discussion

The main purpose of the original Scandinavian study was to examine how an individually tailored activation programme would affect ADL, physical capacity and self rated well-being in a nursing home population. In this pilot study, we wanted to look especially into the effect on depressive symptomatology as measured by the MADRS. The pilot study has not reported all data that was collected for the original study. Here we will discuss the results and also cast some light on what could be done differently in a future larger study.

4.3.1 Physical parameters

We have seen that the intervention group made a significant improvement in one of the two physical measurements, the Berg scale. At the same time, the persons in the control group reduced their score on the scale. The latter finding was unexpected. It is not likely that the persons in the control group should decline that much in their physical condition during three months. One would assume that they should stay approximately at the same level. However, regardless the decline of the control group, the intervention group made significant improvement between baseline and three months follow-up (one sample t-test), and one can conclude that physical activity has a positive impact on balance function among elderly nursing home patients. The most likely explanation for the reduction of the Berg score in the control group might be that the control persons were disappointed that nothing happened after signing up the informed consent. A way of getting around this disappointment factor is to give the control group some kind of intervention, or to assure them that they will get the intervention after the trial is ended if it had any positive effect.

We found that the other physical parameter, S-COVS, correlated well with the Berg scale both at baseline and after three months, but using this scale we found no improvement after three months. Berg and S-COVS scales measure balance and strength, respectively. One hypothesis is that the intervention programme improved balance but not strength of the elderly persons, but this is difficult to understand. It is difficult to improve balance without improving strength. A maybe more probable explanation for the difference between the two scales is that both these tests are exhausting for an older person. The evaluation with the S-COVS is carried out late in the test session and after testing for balance. Most likely, the older persons were more tired when he/she reached this point of evaluation.

4.3.2 Efficacy on depressive symptomatology

In other age groups, the effect of physical activity on depressive symptoms has been found positive. We expected to find the same results in older persons. However, we could not confirm the findings from studies with younger persons. Physical activity as a part of the treatment for depression in frail nursing home patients is still an interesting question, because we saw a tendency of effect and assume that several factors could have influenced the results in this present study. One problem is how we included the patients. Firstly the patients are not representative of a nursing home population since only those with a high score on MMSE were included. According to nursing home studies in Norway about 75 % to 80 % are demented (2). Secondly, it is possible that depressed patients will not volunteer to participate in a study that includes physical activity because a depressed person normally has loss of motivation and initiative (14, 15). Thirdly, it was not possible to change the inclusion criteria of the Nordic study. To study effect on depressive symptomatology it would be important to include enough patients with depression that means patients with a score above seven on the MADRS. We tried to analyse the results of the patients scoring above seven on MADRS separately, but the number was too small, especially in the control group to have reliable results. Besides, the drop-out rate was also highest among these patients. It is interesting to notice that we saw a tendency that the more depressed the patient was, the better was the effect of the intervention, figure 2. This means that in a new trial one should make efforts to include more patients with depression of moderate degree. In a future trial one should also consider whether the MADRS is the most appropriate scale to use. Probably other scales will be better and more reliable if one would like to include more patients with moderate degree of dementia. Scales like the Geriatric Depression Scale (GDS) is easier to score when the

persons are demented. Another possibility is to use the Cornell scale that is especially designed for patients with dementia.

We found a prevalence of depressive symptomatology of 29 %, and of major depression of 7,3 %. These figures are not that different from the prevalence found in the literature, 32 % for depression (depressive disorder) and 5 % for “major depression”, in the nursing home population (3). This prevalence rate must be considered to be high and efforts should be made to treat these patients. We therefore, believe that various treatments should be tried out such as physical activities, social activities, psychological treatment – not only drug treatment.

4.3.3 Drop-outs

A problem in this study was the drop out rates both in the intervention and especially in the control group. The highest drop out rate was found among the patients scoring seven to 19 on MADRS and in the control group, although the differences was not of statistical significance. One hypothesis for the higher drop out rate in the control group is that they might have been disappointed when they realised that they received no intervention. The dropping out is a known problem. In a previously referred article, the authors reported that 41 % of the depressed participants in an exercise group dropped out, whereas in another trial carried out with non-depressed elderly, only 17 % dropped out (6). Depressed persons have lack of initiative and must be encouraged to stay in a trial.

4.3.4. The test situation

It is important to remember how the test situation of the frail old nursing home patients can influence the results. The test manual consisted of 40 pages including 35 physical tasks, 61 questions, the MMSE, the clock drawing test and the MADRS. It took about one to two hours to complete the manual, and every person went through this at baseline and at three months. When working with such a large test manual, it is of importance that both the test administrator and the patient have a good day, and that there is time for rests. In future trials of depressed elderly persons efforts should be made to include few and not time-consuming outcome measures.

5. Conclusions

5.1 How to design a new and better study

This pilot study has taught us a lot and the knowledge will be important when designing a larger study.

The first thing to do is to change the inclusion criteria in order to include only patients with a MADRS score of seven and more and make efforts to include persons with depression of moderate degree.

Secondly, one should offer the control group either the intervention programme after the trial is ended, or better another intervention.

Thirdly, it will be important to choose a shorter test manual.

A fourth factor to keep in mind is to calculate the appropriate number of participants that is needed to confirm that an intervention programme is of significance or not. In our study the number was too small. If the improvement as measured by the MADRS is 1.5 after three months in the intervention group and 0.2 in the control group (the results in the present study), with a standard deviation of 2.7 in both group, 70 patients should be included in each group in a future study to have a significant results at $p < 0.5$ (two sided) with an 80 % power.

5.2 The future

The responses from the nursing homes and the residents have been positive. Many residents liked to be part of a project and they got an opportunity to feel important. “If this can help others...” “If this can make me stronger...” “If this can give the nurses more time...” were answers heard more than once. In a society with a growing older population, with clinical significant depression and poor quality of life, we need to find effective ways of making the last years of life as meaningful and joyful as possible. More research is needed, and not only research that evaluates drugs for depression.

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