Pain reduction after a multidisciplinary education programme for elderly women with osteoporosis – a pilot study

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Abstract

- **Background and aim:** Pain and fear of future fractures are major problems for many women suffering from osteoporosis. We examined the changes after a multidisciplinary education programme on pain, physical- and social function.
- **Design:** a prospective one-group observational study with five days intervention and follow-up at three and twelve months post treatment.
- **Material:** Forty-nine women (mean age 74 years) recruited from GP to a hospital specialised in rheumatology, were enrolled in the study. Mean lumbal T-score was –2.9. The participants had at least one previous verified vertebrae fracture.
- **Method:** The outcome variables pain and physical- and social function were assessed by means of the SF-36- questionnaire at baseline and after three months and after twelve months after five days intervention. The analyses were performed by multivariate methods for longitudinal studies.
- **Result:** The mean score at baseline regarding social function, physical function and pain was 65, 45 and 35, respectively. The mean pain improvement score (95 percent confidence interval) at three months was 7.4 (2.7-12.2) and at twelve months 10.1 (4.6-15.5) compared with the baseline score.
- **Conclusion:** Elderly women experience significant reduction in pain after participating in a multidisciplinary education programme and the improvement lasts at least one year.
- **Keywords:** prospective observational study, multidisciplinary education, osteoporosis, pain.

Introduction

Osteoporosis is characterised by low bone mass density and microarchitectural deterioration of bone tissue. The enhanced bone fragility increases the risk of fractures, which occur most commonly in vertebrae, wrists and hips (1). In Norway, the prevalence of osteoporosis is estimated to be 19 percent in postmenopausal women, which is among the highest in the western world (2). Given that every year approximately 9 000 hip fractures, 15 000 wrist fractures and 140 000 vertebral compression fractures in a population of about four million people are associated with osteoporosis, this condition has considerable economic consequences. For the individual patient, a fracture causes acute pain that may become chronic. Furthermore, the patient's awareness of the higher fracture risk may cause them to be afraid of moving around, which reduces their physical activity. This in turn has a negative influence on the patient's way of life at home, at work and during leisure time.

> Patient education with a multidisciplinary approach may reduce pain significantly.

The primary goals of treatment are to increase bone density and prevent further bone loss, as well as to teach the patient to avoid situations that increase the risk of fractures. Drugs and nutritional supplements are given to improve bone density, and physical activity is thought to prevent bone loss and improve general health (3). In addition, being physically fit can improve balance and thus prevent falling and other situations that increase the risk of fracture. Patient education programmes have been found to improve compliance as regards the taking of drugs and nutritional supplements (4). Multifactor interventions that modify environmental risk factors, exercise programmes, physical aids and medication have been found to be effective in reducing the risk of hip fracture (3, 4).

To the best of our knowledge, there are very few studies on whether patient education programmes influence other aspects of health, like pain and functioning, in patients with osteoporosis. A pilot study to evaluate the effects of an education programme in four patients has had promising results with respect to pain modification and greater self-sufficiency (6). An editorial by Gold et al all the way back in 1989, highlighted patient education as an essential part of successful management of osteoporosis (7). In other chronic diseases, like rheumatoid arthritis, patient education programmes aimed at reducing the fear of pain and facilitating physical activity have been found to be effective (8). It therefore seemed worthwhile to try out and evaluate a similar programme for patients with osteoporosis.

The aim of the present study was to investigate whether a multidisciplinary education programme could reduce pain, improve physical and social functioning among elderly women with severe osteoporosis.

Materials and methods

Patients

The study was performed in springtime at a regional rheumatologic hospital in the eastern part of Norway, which serves approximately 180 000 inhabitants. Information about the project was disseminated through local newspapers and a local radio station. Information folders and application forms were sent to all general practitioners (GPs), who referred the patients to the hospital.

Before inclusion in the study, the subjects were screened for bone mineral density (BMD) by dual x-ray absorptiometry (DXA). Women with a T score equal to or less than 2.5 standard deviations below the reference values for hip or lumbar spine, and at least one verified previous vertebral fracture were included in the study. Furthermore they had to be older than 60 and able to get around indoors without a walking device. Forty-nine women (mean age 74 years) were enrolled in the study. Their characteristics are given in Table 1.

TABLE 1 **Patient characteristics at inclusion in the study. No of patients = 49**

Characteristics	Mean (SD)
Age in years (SD)	74.0 (5.1)
T score (SD)	
DXA lumbar spine	-2.9 (1.1)
DXA femur	-2.5 (0.9)
Education	N
<10 years	41
>10 years	5
Missing	3

Procedures

The study was a prospective observational study with five days intervention and one year follow up. The patients were enrolled consecutively and divided into four groups, each comprising 11 to 14 participants, on the basis of the date of enrolment. This was done because only a limited number of patients could take part in the study at one time. The four groups all followed the same education programme. The patients were assessed at the time of inclusion and after three and twelve months.

The patients were hospitalised for five days in a hospital specialised in treating patients suffering from inflammatory rheumatic diseases. The Hospital has a department for patient education. The educational programme developed for this study was based upon the Hospitals model. During the hospitalitation they were encouraged to spend time together in the evenings in order to get to know each other and exchange experiences of living with osteoporosis. Social events were held on two evenings.

Ethics

At the time of inclusion the patients were informed about the study and their rights to withdraw from the study at any time during the project period having no consequences for further treatment at the hospital. They all signed in for using their data anonymously.

Multidisciplinary education program

The patients followed the program during their stay in hospital. The program started in the morning with lectures lasting from 9.00 to 10.30, followed by a period of physical activity lasting approximately 30 minutes, such as going for a walk outdoors, or doing easy exercises for legs, balances and low back in order to dear to move their body. The timetable show 60 minutes for physical activity, but in praxis they spent approximately 30 minutes doing these activities. After lunch further lectures were given from 13.00 to 15.00.

The lectures were given by a rheumatologist, a psychologist, an occupational therapist, an occupational assistant, a nurse, a dietician, a social worker, a psychiatric nurse and a physiotherapist. They all had approximately three years of experience running education programmes for patients with rheumatoid arthritis and ankylosing spondylitis.

The education programme (for details, see Appendix) focused on different aspects of the disease, such as the pathogenesis, appropriate medication and pain management strategies. There were no special method highlighted concerning pain management, on the opposite they were encouraged to pick up advices which they thought were relevant for their own situation. The pati-

ents also performed body awareness and relaxation exercises, and various kinds of physical activity. They were taught a number of strategies for solving problems like limitations of physical and social functioning, the availability of welfare benefits, the risk of falling indoors and outdoors and the risk of malnutrition. During their stay they were also encouraged to alternate between activity and rest several times a day, in order to establishing good habits that would continue when they returned home.

The lectures were based on interactive learning and discussions on problem-solving strategies. Thus the health professionals would present a topic and then ask the group members for their opinions and experiences. The patients would then describe their individual problems and discuss their problem-solving strategies. The health professionals participated in the discussions by contributing their expertise. As they went home, the patients received handouts containing the main points of the lectures with space for their own notes. They also recieved some simple exercises for the legs which they could do on their own at home.

Outcome measures

The 36-item Short-Form Health Survey (SF-36) was used to assess outcomes (9). The questionnaire is a generic health-related quality of life instrument. It assesses eight health dimensions: physical function, role physical, bodily pain, general health, vitality, social function, role emotional, and mental health. In the proposal we decided to assess bodily pain question no 7 and 8 (2 items), physical function question no 3 (10 items) and social function question no 6 and 10 (2 items). We chose these three dimensions because we knew from clinical experience that these patients after fracturing often were afraid of pain caused by new fractures due to falling when going out.

The raw scores were coded and recalibrated according to standard procedures, and the items were summed and transformed to scales from 0 (poor) to 100 (best) (9). All but one patient filled in the questionnaire on their own.

Data analyses

The mean scores of the transformed values of the SF-36 scales were calculated at baseline and during follow-up three and twelve months after intervention. Next, longitudinal analyses were performed by means of the generalised estimation equation (GEE). GEE is a multivariate method for correlated data that allows analysis of repeated unbalanced design (10), which means that we can **adjust** for individual differences in data at baseline. An initial model was constructed, which included the following covariates: age, level of education, T-scores for lumbar spine and hip, number of falls and baseline SF-36 score for each dimension. It also included the test number of baseline and follow-up coded as dummy variables. This method takes the correlated structure of the data into account, and enables the whole follow-up to be used in the same model. The initial model was reduced by backwards reduction if the p value of the covariate was more than 0.2 and if the elimination of the covariate caused only minor changes (<10 percent) of the coefficient between the outcome and the independent variable. The longitudinal analyses were performed by means of the statistical software SPIDA (11).

Results

The mean descriptive scores at baseline and three and twelve months after intervention are shown in figure 1. They indicate an improvement in pain score after three months that lasted until twelve months, and improved mean scores for physical and social function at three months, although these had declined at twelve months, though not to baseline.

The results of the multivariate analyses of bodily pain and physical and social function are shown in table 2. Highly significant associations were found between the score of each dimension and the corresponding scores at baseline ($p<0.001$). Improvements in bodily pain scores and physical and social function score were observed at both three and twelve months compared with baseline (figure 1). The multivariate analyses indicated that bodily pain ($p=0.002$) and physical activity ($p<0.001$) improved in score from baseline to three-month follow-up (figure 1). Only bodily pain ($p<0.001$) improved in score from baseline to twelve-month follow-up. No improvements of statistical significance in social function were seen.

The minimum and maximum score at baseline were respectively for pain 10 and 75, for physical function 5 and 88, and for social function 25 and 87.5.

Table 2 shows differences in score when adjusted with covariates. These differences are not very different from differences shown in figure 1. Though, we will give some comments on the femur T-score. A statistically significant positive association ($p=0.002$) was found between the femur T-score and the SF-36 social function dimension. The association between the femur T-score and bodily pain was of borderline significance ($p=0.07$), the coefficient between SF-36 regarding bodily pain and femur T-score

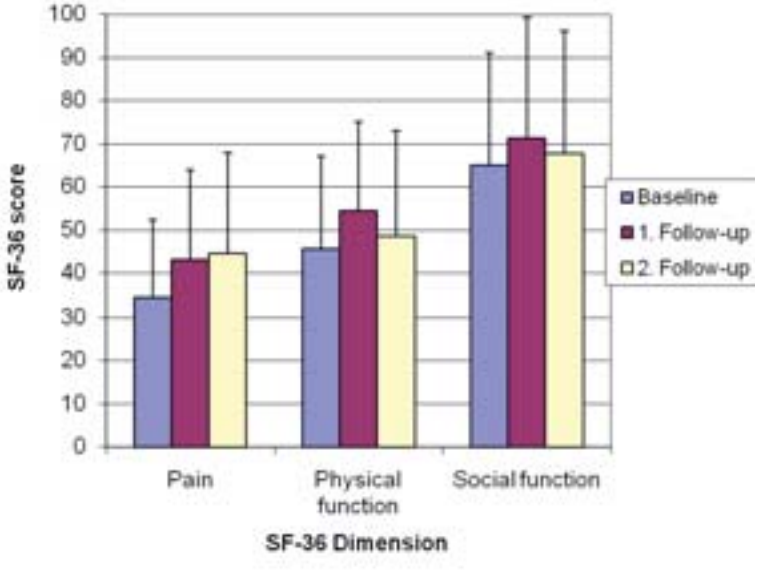

FIGURE 1 The mean scores (bars) and corresponding standard deviation (vertical lines) of the SF-36 dimensions pain, physical function and social function at baseline (1) and after three (2) and twelve months (3).

TABLE 2 **Results of multivariate analyses of SF-36 scores as the dependent variable by the GEE method (95 percent confidence intervals in parentheses).**

	SF-36 dimension		
Covariate	Bodily pain	Physical function	Social function
Follow-up vs Baseline			
3 months (N=48)	7.4 (2.7-12.2)	8.5 (3.8-13.3)	5.6 (-2.2-13.5)
12 months (N=47)	10.1 (4.6-15.5)	3.7 (-1.1-8.4)	2.2 (-5.7-10.2)
Baseline score (N=49)	0.92 (0.78-1.1)	0.87 (0.77-0.98)	0.76 (0.65-0.86)

was 0.34 (95 percent confidence interval: -0.01-0.69), but the femur T-score was not significant for physical function (p=0.5). At three and twelve months 24 patients had pain scores that were ≥ 10 points better than baseline. Eleven women experienced an improvement of ≥ 20 points at three months and 13 women an improvement of ≥ 20 points at twelve months.

One person had a vertebral fracture after the intervention and did not meet to the first follow up (informed by phone call), but met at one year follow up. Two persons dropped out of the study at twelve month follow up; one was becoming dizzy (age-related) and one had had a stroke.

Discussion

In the present study patients with severe osteoporosis were found to have reduced pain and improved physical and social function three months after following an education programme. A year later they still had reduced pain.

However, some of the results must be interpreted with caution. Firstly, the study lacks a control group, and therefore the improvements may be associated with factors other than the education programme. For example, attention may have a positive impact on health. However, it seems unlikely that the attention the patients received during the hospital stay would explain improvements observed several months later. Improvements may also be related to the natural course of the disease. However, as osteoporosis is a progressive disease, health is likely to decline rather than improve over the years, and our patients were over 70 years of age (mean 74 years). Thus, the improvements may have been greater than our results show. A control group could have confirmed our assumption of deterioration.

Secondly, the 'regression to the mean effect' must be considered (12). The patients were recruited by GPs, and since patients are more likely to consult a doctor during a bad period, those with poor health may have had a greater probability of being referred to the study than those with good health. We tried to adjust for this effect by including outcome score at baseline and time since fracture as covariates. However, when these were included we found only minor changes in the improvement in outcome score between baseline and follow-up. Finally, the SF-36 score at both follow up was highly correlated with the score at baseline (12). We therefore believe that the regression effect does not explain the improvement found in outcome scores.

The choice of statistical warrants some comments. In this study we had repeated measurements of the outcome in addition to covariates that had to be taken into account. Alternatively we cold have used a paired test, such as the paired t-test. A paired test would have several shortcomes compared with the GEE-method. First, we could only have made pairwise comparisons, for example results at baseline compared with follow-up number one and two separately. Secondly, this test cannot adjust for confounding covariates. Adjustments for confounders could be obtained using ANOVA for repeated measurements. This method, however, presumes a balanced design and the results are frequently difficult to interpret. The GEE-method solves all these concerns, and the regression coefficients can be interpreted as regression coefficient of ordinary least square regression. Alternatively, linear mixed model (LMM) could be used, but in these settings LMM and GEE are interchangeable.

The SF-36 is considered to be a reliable instrument. We consider it unlikely that when answering the questions at follow-up the patients were influenced by their previous answers, because it would have been too difficult to remember answers given months before. The SF-36 is a generic instrument that makes it possible to compare impact on health across different diagnostic groups as well as with that of the general population (9). The low pain score (meaning much pain) at baseline (mean score=35) in the present study indicates that these women had as much pain as a group of women with rheumatoid arthritis (mean score = 38) (13). The findings for both these groups differ considerably from the data for an age- and sex-matched Norwegian reference group that had a mean score of 60 (14). As regards to physical and social function, our group did not differ much from this reference group at three or twelve months.

The internal validity we consider as good in accordance to collect data when screening all patients for BMD at inclusion and using SF-36 for measurements. But on the other hand the lack of a control group does questionnaire the internal validity, since the randomised control trial (RCT) is the gold standard of intervention studies.

In the present study patients experienced improvements in pain and physical and social function up to one year after participating in a multidisciplinary education programme. The fact that the effects lasted for a whole year is a promising sign. We did not make systematic records of changes in behaviour according to what they had learned from the education program, but at follow-up some of the patients spontaneously reported positive changes. For example, one patient had travelled alone by train to visit relatives and had been to the theatre, while another had started to take walks alone after having been introduced to hip protectors. Another patient said she had made a car journey of several hours to another part of the country together with her daughter. These examples of behavioural changes may illustrate a reduced fear of falling and of fracturing.

A randomised study of multidisciplinary patient education in osteoporosis shows significant better knowledge about the disease in the education group than in the control group (15). It is likely to believe that our patients increased their knowledge abut the disease and how to live with it as well. Pain is a subjective feeling influenced among others by anxiousness and knowledge. Since our patients had a reduction in pain score even

> Osteoporosis may give increased pain, fear avoidance, reduced physical function and social function.

one year after the intervention it might be associated with cognitive changes. Though it is difficult to know what influenced their reduction in pain, since they were presented a package of possible solutions. On the other hand, maybe just the package-approach is the most probable reason, because suffering from the same disease does not necessarily mean they experienced the same kind of problems or the same kind of comprehensions of problem-solving.

One participant had vertebral fracture during follow-up. Our material was too small for us to judge whether this was less than expected. However, the compression fracture occurred while the patient was gardening, which she had taken up again after participating in the education programme. This indicates that there are two sides to a reduced fear of physical activity: on the one hand, physical activity promotes health, but on the other hand certain physical activities may exceed the patient's ability to keep her balance, or may increase the risk of fracturing. Since patients ability to understand general information about their own individual physical level varies considerably between patients, recommendations about physical activity should be tailored to the individual concerned.

The most positive finding in the present study was pain reduction, which was found at three months and was still present one year later. We have already argued that this may be related to the education programme rather than to the natural disease course. The next question then is whether the improved pain scores are of clinical importance for the individual. No norms have been established for what can be considered to be clinically important changes in SF-36 scores. The scale of the SF-36 is 0-100, which is similar to that of a visual analogue scale. Clinically important improvement in pain on the visual analogue scale has been set at 20-30 percent for rheumatic patients (Hagen KB 2005 personal communication), which should correspond to approximately 10 to 20 points, depending on whether the scores are high or low. In our study 24 patients had an improvement score equal to or more than 10 points at three and twelve months compared with baseline, and 13 had an improvement score equal to or more than 20 points at three and twelve months. As there are six categories for evaluating pain intensity in the SF-36, this means that about one quarter of the group had moved at least from one SF-36 category to another, for example from «severe pain» to «moderate pain». Thus the improvement in the pain score found in the present study may have been of clinical importance for several of the participants.

In conclusion, this educational programme has had promising results with respect to reduction in pain, but there are no convincing results in physical and social function in older patients with osteoporosis. The findings should be followed up by a controlled study, and we recommend that future studies should include an evaluation of changes in physical activity. It would also be of interest to examine whether patients' use of medication and health services can be influenced by an education programme. Health costs could also be one perspective illustrated.

APPENDIX **One week educational program for women with osteoporosis - 3rd floor LSR**

Time:	**Sunday**	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
07.30-08.00		Voluntary swimming	Voluntary swimming	Voluntary swimming	Voluntary swimming	Voluntary swimming
08.15-09.00		Breakfast	Breakfast	Breakfast	Breakfast	Breakfast
09.00-10.30		Psychologist: Emotions living with osteoporosis, coping strategies, pain	Rheumatologist: Osteoporosis and medical treatment	Chef: Nutrition	Social worker: Health and social rights -network	Occupational therapist: Practical advices and introduction to relevant technical devices Evaluation and closing.
10.30-11-30		Physical activity	Physical activity	Physical activity	Physical activity	Physical activity
11.30-13.00		LUNCH	LUNCH	LUNCH	LUNCH	LUNCH
13.00-14.30		Physiotherapist: Physical activity, training, relaxation, pain	Occupational therapist assistant CREATIVE ACTIVITY!!	Occupational therapist: Activity of daily Activity and fall prevention	Nurse: About medication, pain	Departure
15.00		DINNER	DINNER	DINNER	DINNER	DINNER
17.00-18.00	Arrival Registration. Completed questionnaire		Social activity conducted by nurse		Creative activity conducted by occupational therapist assistant	

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