Medication Adherence

Patient education in groups increases knowledge of osteoporosis and adherence to treatment: A two-year randomized controlled trial

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1. Introduction

A large number of studies have demonstrated that pharmacological therapy is effective in preventing fractures in patients with osteoporosis; however, non-adherence to such therapy is a well-recognized problem attenuating the effect on bone mineral density (BMD) [1] and fracture protection [2,3]. The term adherence recognizes the patient’s right to choose and implies that the relationship between the patient and the health care provider must be a partnership that draws on the abilities of each [4]. In contrast, the term compliance, i.e. the consistency and accuracy with which a medication regimen is continued, has been criticized as it may imply that the prescriber issues instructions and the patient should follow the doctor’s order [5,6].

Treatment complexity, i.e. concurrent use of multiple medications with different dosage schedules or requirements, is a predictor of non-adherence [7,8]. Moreover, patient factors such as age, lack of knowledge and awareness about osteoporosis [9], anticipation of adverse events [10,11] and distance from the clinic have been shown to be significant barriers to adherence [4]. Factors related to the health care professionals such as inadequate understanding of drug dependence and the patient-physician relationship [12] may also affect adherence.

Previous studies have demonstrated that knowledge alone does not ensure healthier behaviour e.g. adherence to osteoporosis medication and to calcium and vitamin D supplements, maintenance of recommended exercise programs, or reduction in smoking and alcohol intake [13–18]. However, increased patient participation in medical decision-making may lead to improved adherence rates and outcomes [19,20]. Since the patient’s health beliefs are related to adherence behaviour, a consideration of patient preferences may be particularly important in maximizing adherence to treatment self-efficacy [10]. A patient educational programme is one way of involving patients in medical decision-making.

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ABSTRACT

Objective: Non-adherence to pharmacological treatment in osteoporosis is a well-recognized problem. We hypothesized that a group-based educational programme would increase patients’ knowledge and level of adherence with medical treatment.

Methods: A total of 300 patients (32 men aged 65 ± 9 years and 268 women aged 63 ± 8 years), recently diagnosed with osteoporosis, were randomised to either an osteoporosis school programme (four classes of 8–12 participants over four weeks) or a control group. Teaching was multidisciplinary, based on patients’ experiences and background and designed to encourage empowerment. Patients’ knowledge about osteoporosis and adherence to treatment was assessed with self-completed questionnaires at baseline and after 3, 12, and 24 months.

Results: There were no significant differences at baseline between the two groups with respect to knowledge score or level of adherence. At two years’ follow-up, the improvement in knowledge score was 2 [0–4] points (median [25–75 percentiles]) in the school group and 0 [0 to 2] in controls (p < 0.001) and self-reported adherence to pharmacological therapy was significantly higher in the school group (92%) compared to the control group (80%), p < 0.001.

Conclusion: The programme increased knowledge about osteoporosis and increased self-reported adherence to pharmacological treatment over a period of two years.

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Few studies have examined the effects of patient education programmes on knowledge and adherence to osteoporosis therapy in a randomised design. A program of motivational interviewing and cognitive behavioural techniques applied by telephone demonstrated a significant difference in level of adherence between the intervention group (69.8%) and a national sample of patients treated with risedronate sodium (40.5%) after six months’ follow-up [21]. In a randomised study, a program offering continuous nurse-monitoring significantly increased adherence to therapy by 57% compared with no monitoring [22]. Patient education combined with personal information on Dual-energy X-ray Absorptiometry (DXA scan) results significantly increased calcium and vitamin D intake [16,23,24]. Women in the intervention group were significantly more likely to report that they had modified their diet, calcium, and vitamin D intake than women in the control group, who were not exposed to education [23]. In contrast, no improvement in self-reported adherence to osteoporosis treatment was seen after 12 months in patients issued with an educational leaflet compared with patients following general practice [25]. In the Chronic Disease Self-Management Program (CDSMP) of the Stanford University School of Medicine, patients meet up in groups. This program is taught by either a patient or a health care professional together with a patient. CDSMP is one of the few general patient education programmes with demonstrated effects and documented theoretical base and educational methods [26,27]. However, very few studies have addressed multidisciplinary teams teaching patients with osteoporosis, and examined the effect on patients’ adherence to pharmaceutical treatment [28]. Inspired by situated learning, it is suggested that in order for professionals to comprehend what patients in everyday life experience as meaningful, and how they orientate their knowledge and learning about diseases, we have to understand the conduct of everyday life, they try to realise [29,30].

In summary, it is known that patients can benefit from medical treatment of osteoporosis, but patients’ adherence to treatment can be problematic; it is still unclear whether patient education can resolve some of these problems. In the current study, we hypothesized that participation in an osteoporosis-specific multidisciplinary group-based patient education programme (Table 1) would increase both patients’ knowledge about osteoporosis and their adherence to treatment. This paper presents the final study results after two years’ follow-up. The results at three months’ follow-up have been reported previously [31].

2. Patients and methods

This randomized controlled trial comprised 300 patients who were diagnosed with osteoporosis and had started on specific pharmacological therapy within the previous year. Consecutive patients were invited to participate in the study by doctors and nurses in the outpatient clinic of the Department of Endocrinology. Patients were allocated consecutively in blocks of eight to either the intervention (group-based education programme, i.e. ‘school group’) or the ‘control group’. Patients were identified prospectively in the clinic. Patients unable to participate in mild physical exercise or suffering from psychiatric illness or cognitive disturbances were excluded from the study (Fig. 1).

Details of the study design have been presented previously (Table 1) [31]. In brief, the school group participated in classes of 8–12 patients, comprising a total of 3–4 h a week over four weeks (a total of 12 h). The programme was conducted by a multidisciplinary team of physicians, dieticians, physiotherapists, and nurses and was adjusted according to the individual patient’s background and needs in order to strengthen competence and empowerment [32–34]. Multidisciplinary collaboration was defined as working together in such a manner that the knowledge and skills of the participants synergistically influenced the outcome of patient care. Collaboration involved mutual respect for the unique contribution that each profession gives to health care. The relationship between patients and health professionals was built on shared expertise and on the philosophy of empowering patients [35]. In each session the teaching took as a starting point the patients’ individual experiences and needs. In order to understand patients’ lives and personal learning, the teaching team focussed on how patients conducted their every day life in and across various contexts such as home, social activities, workplace etc. [30,36]. The patients set their personal goals and the professionals supported the patients in making choices about handling osteoporosis in daily life. Participants in the school group were also invited to participate in a computerized support programme, in which patients were contacted once a month for four months and asked about pain, quality of life and physical activity. After one year, participants in the school group were invited for 2-h brush-up course, in the same groups as in the initial sessions. The control group was asked to continue with osteoporosis therapy as prescribed and follow their usual daily activities. They were offered control visits at GP or clinic as appropriate.

At inclusion into the study, participants in both groups were offered a medical consultation in the osteoporosis outpatient clinic (approximately 1 h), and again at three months (approximately 10–15 min). Patients in the control group with previous vertebral or hip fracture were offered instruction in an exercise programme by the physiotherapist.

Participants were included in the study after verbal and written informed consent. The study was approved by the Ethics Committee (No. 20010172) and performed in accordance with the Helsinki Declaration II. This study was also reported to the ClinicalTrials.gov (NCT00414154).

2.1. Questionnaires

Participants’ knowledge about osteoporosis was tested before randomization and at 3, 12 and 24 months using a validated, self-administered, multiple-choice questionnaire – PAVIOS [37] – that included topics such as risk factors, symptoms, DXA-scans and treatment options, as well questions on civil status, education, working experience and employed in the healthcare system. The score range on the PAVIOS questionnaire is 0–28, where a higher score reflects greater knowledge.

Table 1

<table>
<thead>
<tr>
<th>Lesson plan for the osteoporosis school.</th>
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<tbody>
<tr>
<td><strong>Day 1</strong></td>
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<tr>
<td><strong>Introduction: facts about osteoporosis</strong></td>
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<tr>
<td>Nurse and physiotherapist</td>
</tr>
<tr>
<td>Fracture and pain</td>
</tr>
<tr>
<td>Physiotherapist</td>
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<tr>
<td>DXA scanning</td>
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<tr>
<td><strong>Nurse</strong></td>
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</table>
Data on adherence were collected using a separate questionnaire comprising nine questions on adherence (how, when and how often the patient took their osteoporosis medication), satisfaction with doctors’ explanation of treatment, the importance of the price level of the medicine and side effects, and a further 19 questions concerning the patient’s medical history and daily life (family history of osteoporosis, previous fracture, medication, distance to pharmacy, problems related to collecting the medicine at the pharmacy, marital status, monthly income) [38]. In the present study, adherence was defined as patients taking their medicine correctly at the appropriate time; patients who changed to another osteoporosis drug were considered to be adherent. Data on adherence were obtained via self-completed questionnaires that patients returned to the research team at 3, 12 and 24 months. Questionnaires were handed out to patients at inclusion into the study but were sent and returned by post at the 3, 12 and 24 months follow-ups.

2.2. Statistical analyses

All statistical analyses were performed using SPSS version 16. Differences between groups were analysed using Mann-Whitney and chi-square tests. Changes from baseline regarding knowledge score were calculated by simple subtraction and evaluated using Wilcoxon’s test. Spearman’s correlation test was used to evaluate associations between variables in the knowledge about osteoporosis questionnaire. Crude analysis of adherence to therapy was performed using Kaplan-Meyer plot and Log rank test; adjustment for confounders was performed using Cox-regression. p-Values less than 0.05 were considered significant.

3. Results

The majorities (89%) of the 300 study participants were women and median age was 64 years (range 45–81). The gender distribution in the current study is similar to the male/female ratio for patients attending the outpatient osteoporosis clinic. There were no significant differences between the intervention and control group with respect to patient age, gender, level of education, employed in the healthcare system or the PAVIOS knowledge score 22 [18–24] (median percentile 25–75); see [31] for further details. The study completion rate was also similar between the two groups (Fig. 1).

The change from baseline in knowledge score at three months was significantly higher in the school group (3 [1–5] points) than in the control group (0 [–2 to 2] points) [31] and the knowledge score remained significantly higher in the school group at both 12 and 24 months (Fig. 2; Table 2). Monthly income and marital status were not significantly associated with knowledge about osteoporosis. Most patients (96% in the school group and 89% in the control group, p < 0.05) expressed high satisfaction with the doctors’ explanation of treatment at three months (Table 2), and the level of satisfaction increased in both groups throughout the study.

Fig. 1. Flow chart on participants in the study.
Adherence with pharmacological therapy at 24 month was significantly higher in the school group compared to the control group (92% vs. 80%, \( p = 0.006 \)) (Table 2). Due to the small number of non-adherent patients, the study had limited power to analyze predictors of non-adherence. However, there were no significant differences between adherent and non-adherent patients with respect to knowledge about osteoporosis, access to the pharmacy, family history of osteoporosis, monthly income, marital status or previous fractures. Similarly, there was no association between adherence and patients' satisfaction with doctors' explanations about medication, dose regimen, side effects from medication, baseline knowledge score or change in knowledge score.

Table 2

<table>
<thead>
<tr>
<th></th>
<th>School group</th>
<th>Control group</th>
<th>p-values*</th>
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<tr>
<td><strong>Drop outs, numbers</strong></td>
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<tr>
<td>Baseline</td>
<td>3</td>
<td>6</td>
<td>ns</td>
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<tr>
<td>3 months</td>
<td>1</td>
<td>7</td>
<td>ns</td>
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<tr>
<td>12 months</td>
<td>3</td>
<td>6</td>
<td>ns</td>
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<tr>
<td>24 months</td>
<td>4</td>
<td>4</td>
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<tr>
<td><strong>Knowledge score</strong></td>
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<td></td>
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<tr>
<td>3 months</td>
<td>25 [22–26]</td>
<td>22 [19–25]</td>
<td>&lt;0.001</td>
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<tr>
<td>12 months</td>
<td>24 [20–26]</td>
<td>22 [18–24]</td>
<td>&lt;0.001</td>
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<tr>
<td>24 months</td>
<td>24 [20–26]</td>
<td>22 [19–24]</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Change in knowledge score</strong></td>
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<td></td>
<td></td>
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<tr>
<td>3 months</td>
<td>3 [1–5]</td>
<td>0 [–2 to 2]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months</td>
<td>2 [0–5]</td>
<td>0 [–2 to 2]</td>
<td>&lt;0.001</td>
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<tr>
<td>24 months</td>
<td>2 [0–4]</td>
<td>0 [–2 to 2]</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Adherence rate</strong></td>
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<tr>
<td>Baseline</td>
<td>100%</td>
<td>100%</td>
<td>ns</td>
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<tr>
<td>3 months</td>
<td>100%</td>
<td>95%</td>
<td>0.006</td>
</tr>
<tr>
<td>12 months</td>
<td>95%</td>
<td>88%</td>
<td>0.006</td>
</tr>
<tr>
<td>24 months</td>
<td>92%</td>
<td>80%</td>
<td>0.006</td>
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<tr>
<td><strong>Satisfaction with doctor's information</strong></td>
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<tr>
<td>Baseline</td>
<td>95%</td>
<td>89%</td>
<td>ns</td>
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<tr>
<td>3 months</td>
<td>96%</td>
<td>89%</td>
<td>&lt;0.05</td>
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<td>12 months</td>
<td>98%</td>
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<tr>
<td>24 months</td>
<td>99%</td>
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ns = not significant. Knowledge scores and changes in score are presented as medians [25–75 percentiles].

* No adjustment for multiple comparisons was made.

4. Discussion and conclusion

The study results demonstrate a significant improvement in patient knowledge about osteoporosis and adherence with therapy after a group-based, multidisciplinary educational programme. These changes remained significant at two years, suggesting a prolonged effect of the programme.

The observed adherence rate at two years in the control group (80%) was surprisingly high compared to the rate of 62% reported in a clinical cohort of female Danish patients [38]. The high rate from the current study may reflect selection bias associated with inclusion into a clinical study. Indeed, another Danish clinical study showed compliance to hormonal replacement therapy in postmenopausal women to be in the same range (86%) [39]. In the current study, adherence in the school group increased significantly compared with that in the control group. Other studies of adherence to medication for chronic diseases have reported similar results. A group-based patient educational programme for patients with type-2 diabetes resulted in a significant decrease (by 0.4%, \( p < 0.01 \)) in HbA1c at 24 months after baseline [40]. Providing group information to Parkinson’s disease patients about the continuous dopaminergic hypothesis in order to encourage regular medicine intake and improve medication adherence was found to improve adherence significantly (by 13.4% (CI 5.1–21.7), \( p = 0.002 \)) [41]. Few disease-specific educational programmes have been tested in randomized trials; it remains to be determined which programmes are most effective and whether specific attitudes or approaches are to be preferred. The approach in the current study was multidisciplinary, based on dialogue, focussed on empowerment and situated learning, and involved patients’ everyday life and experiences. In line with this, a recent Cochrane review suggested that important innovations regarding improved adherence are more likely to occur if investigators collaborate across clinical disciplines and encourage patients to be actively involved in tackling the problem [42].

We have previously reported that our educational program significantly increased knowledge about osteoporosis at three months follow-up [31]. These short-term results are in line with other studies demonstrating that knowledge about osteoporosis increased significantly after participation in a four-day intensive multidisciplinary community educational programme [43]. Similar short-term results were seen following brief educational sessions for community or residential care-based elderly women [44]. In the current study, however, the observation period was extended to two years. Although the level of knowledge was slightly lower at the end of the study than after three months, the difference between the school and control groups remained significant. We have not been able to identify randomised controlled studies with a similar length of follow-up. The close follow-up and patients meeting in the same groups after one year probably facilitated patient-to-patient network in the groups.

Neither baseline knowledge score nor change in knowledge score was associated with better adherence in our study. Similar results were reported from a study of elderly patients after hospital discharge. Various aspects of after-care were assessed, particularly in relation to drug compliance and understanding of treatment. Of the 30 patients on regular medication, 92% of those visited at home achieved over 95% compliance, despite the fact that the majority of the elderly did not understand the purpose of their drug therapy [45]. In another study, greater knowledge about osteoporosis was found not to be associated with intention to use hormone therapy at one year, although women who knew more about osteoporosis reported fewer conflicts about making a decision regarding treatment [46].

Very few patients in the current study had problems collecting medication from the pharmacy. Problems with access to services (including difficulties in obtaining prescriptions) have in other...
studies been mentioned as reasons for non-adherence, especially for elderly patients [47,48]. This suggests that patients of different ages and with different health conditions have different problems to cope with and require different kinds of support in order to maintain adherence.

A broad definition of adherence was applied in the current study as it was thought important to capture the spectrum of medication-taking behaviour that varies from occasional non-adherence to consistent reductions, as well as increases in dose or complete cessation of medicine (non-adherence). The strength of the study is the focus on patients’ intake of any medication (for osteoporosis); thus if patients changed their osteoporosis medication, this was considered as still being adherent to the treatment. A weakness of many studies is that the analysis is conducted in the context of one particular behaviour (treatment versus no-treatment), yet patients often have alternative treatments to consider. An individual may value a particular dose regimen, but not act on it because a second regimen is favoured more highly [49,50]. All data have been collected longitudinally and participants were randomized to study intervention and, therefore, all potential important confounders were equally distributed between the groups.

The current study also has some limitations. First, the adherence questionnaire was not validated, although it had subsequently been used in previous Danish studies. Furthermore, all data were self-reported and may therefore be overestimated [51], if participants in the school group wished to please the teaching staff. The high level of adherence could thus be due to limitations of the questionnaire. An alternative method to examine adherence to pharmacological treatment could involve a pharmacoepidemiological database [52]. However, no measures can guarantee complete accuracy [14].

Second, there might have been other factors related to adherence that were not assessed in the study. Patients in the control group with vertebral fractures were offered participation in physiotherapy classes; this, however, would tend to level out differences between the groups. Third, the multiple-choice questionnaire revealed patients’ factual knowledge about the physical and clinical aspects of osteoporosis, but it did not necessarily capture what they might have gained from participating in the programme. It is possible that patients scored highly on the questionnaire but at the same time lacked an understanding of the nature of their condition and its possible consequences. Patients may also have acquired knowledge from other sources and experiences external to the educational programme provided. Furthermore, the approach used did not allow us to examine how the individual patient interacted within the patient group, nor how the individual used the knowledge gained in his/her everyday life.

Fourth, the dropout rate was higher in the control group, and this might affect the results, although there was no significant difference in dropout rate between the groups. Finally, few patients in the current study had problems with adherence, thus limiting the study's power to analyse predictors of non-adherence; future studies could usefully focus on patients with adherence problems.

In conclusion, this randomised controlled study is to our knowledge the first study demonstrating that a multidisciplinary team, consisting of allied health professionals teaching patients in groups, can help to increase patients’ knowledge about osteoporosis and their self-reported adherence to pharmacological treatment over a period of two years. However, neither the level of knowledge at baseline nor the increase in knowledge was associated with greater adherence. This also shows that learning is not a simple transfer of knowledge. There are many factors involved in learning about and handling a chronic illness such as osteoporosis in everyday life. Further investigation into patients’ individual experiences with and gains from education programmes is needed.

4.1. Practice implications

The findings from this study suggest that patients with osteoporosis demonstrate both greater knowledge about osteoporosis and better adherence to medicine after participating in an osteoporosis-specific multidisciplinary group-based patient educational programme. This programme used dialog and shared decision-making, and it had patients’ everyday life, experiences and needs as the starting point of all lessons.

It is recommended, therefore, that health care professionals who work with patients with osteoporosis contribute to the development of programmes that focus on patient empowerment and enter treatment partnerships with their patients. The evidence behind health education shows that it is an important part of the management of patients with chronic disease, and there is a need to test these programmes in randomised settings, combined with research methods focusing on patients’ perspectives and attitudes towards the actual education programmes. While we do not believe that group-based patient educational programmes can be a substitute for individual face-to-face discussions with physicians and nurses, they can be a valuable supplement.

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