A Comparison of Two Short Education Programs for Improving Low Back Pain-Related Disability in the Elderly

A Cluster Randomized Controlled Trial

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Study Design. Cluster randomized clinical trial.

Objectives. To assess the effectiveness of 2 minimal education programs for improving low back pain (LBP)-related disability in the elderly.

Summary of Background Data. No education program has shown effectiveness on low back pain (LBP)-related disability in the elderly.

Methods. A total of 129 nursing homes (6389 residents) in northern Spain were invited to participate in the study. The actual participants were 12 nursing homes randomly assigned to 3 groups and 661 subjects. An independent physician gave a 20-minute talk with slide projections summarizing the content of the Back Book (active management group), the Back Guide (postural hygiene group), and a pamphlet on cardiovascular health (controls). Disability was measured with the Roland-Morris questionnaire (RMQ). Blind assessments were performed before the intervention, and 30 and 180 days later. The effect of the intervention on disability was estimated by generalized mixed linear random effects models.

Results. Mean age of participants ranged between 79.9 and 81.2 years. Disability improved in all groups, but at the 30-day assessment the postural education group showed an additional improvement of 1.1 (95% confidence interval, 0.2–1.9), RMQ points and at the 180-day assessment 79.9 and 81.2 years. Disability improved in all groups, but

Low back pain is one of the most frequent disorders in industrialized countries with a lifetime prevalence rate of over 70%.1–3 A large part of the social costs and impairment of health-related quality of life are attributable to functional disability caused by back pain.4–7 Improvement of disability is especially important for elderly people in whom low back pain is associated with self-reported difficulties to perform tasks needed for daily life.8 Back pain-related disability can lead to a decrease in general activities and quickly affect their general health status. However, improvement of disability in the elderly is difficult. A randomized controlled trial in older Americans with chronic low back pain showed that a self-management program lasting 15 hours over 6 weeks had no advantage over wait-list control for improving pain, general health, and self-care attitudes, although a small beneficial effect on disability was suggested.9 In French and British adults of working age seeking medical care for low back pain, adding the Back Book, a booklet that promotes maintaining the greatest possible degree of physical activity and avoiding bed rest, to standard treatment improved disability to a larger extent that not giving it or giving a pamphlet on postural hygiene. However, in Dutch patients with subacute low back pain, giving the patients a booklet based on the Back Book reinforced by a 20-minute individual conversation tailored according to individual psychosocial prognostic factors showed no advantages over usual care.10

The objective of this study was to compare the effectiveness of 2 brief health education programs with different contents for improving low back pain-related functional disability in the elderly people recruited among nursing home residents. The intervention strate-

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The study protocol was approved by the institutional review boards of the participating centers and all patients gave written informed consent for the use of his/her data regarding presenting complaints and results of outcome assessments.

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subset of subjects with LBP when entering the study, postural education had no advantages over controls, while an additional improvement of 3.0 (95% confidence interval, 1.5–4.5) RMQ points at the 180-day assessment was observed in the active education group.

Conclusion. In institutionalized elderly, the handing out of the Back Book supported by a 20-minute group talk improves disability 6 months later, and is even more effective in those subjects with LBP.

Key words: nonspecific low back pain, education programs, functional disability, elderly. Spine 2007;32:1053–1059
gies included the hand-out of an information booklet and a 20-minute group talk with slide projections summarizing its content.

Methods

Study Population. All 129 nursing homes in 3 different healthcare areas of Asturias (northern Spain) and their residents aged 65 years or older were invited to participate voluntarily and altruistically in a cluster randomized clinical trial, in which participants were followed up for 6 months. Exclusion criteria were cognitive impairment, visual impairment, or functional illiteracy that prevented the completion of pain, disability, and quality of life questionnaires; inflammatory rheumatic disease, such as spondyloitis or rheumatoid arthritis, malignancy within the previous 5 years, and fibromyalgia or any disease that might probably be associated with a fatal outcome within the next 12 months.

The study protocol was approved by the institutional review boards of the participating centers and all patients gave written informed consent for the use of their data regarding complaints and results of outcome assessments.

Randomization. Nursing homes were included according to the order in which responses to the invitation to take part in the study were received. Randomization to the 3 study groups was performed blindly according to a random numbers table prepared before recruitment of nursing homes. Immediately after enrollment, a consecutively numbered, opaque, and sealed envelope containing an allocation number was opened.

Interventions. An independent physician, blinded to the recruitment or assessment of patients, gave a 20-minute talk with slides projection summarizing an information booklet distributed to each participant at the session. Contents of the booklets varied according to the study groups: 1) in the active management education group, the Back Manual (transculturally adapted Spanish version of the Back Book)12,13 was handed out; 2) in the postural education group, a Back Guide with norms of healthy posture (postural hygiene)14 applicable to daily life was handed out; and 3) in the control group, a similar pamphlet with general norms for cardiovascular health centered on recommendations for lowering cholesterol and control of blood pressure was given. Booklets in the education groups were similar in size, color, and length. Slide projections used in the talks are available in Spanish from the authors.

All talks were given by the same physician, who agreed to give training talks in 10 nursing homes from other healthcare areas, the content of which was the same as that given to the control group. Before the study, it was confirmed that he had no preformed opinion on the comparative effectiveness of active or postural education strategies for back-related problems; moreover, he was told that a similar effect for both education interventions was foreseen. After the last talk, he was asked if he had an opinion on the comparative effectiveness of the education programs. Additionally, another physician was present during the first and last talks in the 3 study groups in order to assess whether or not any difference in the formal aspects of the presentation was noted.

Outcome Assessments. Subjects were evaluated immediately before the session, and 30 and 180 days later. Pain intensity, functional disability, fear avoidance beliefs, and health-related quality of life were measured at each of these time points. Pain intensity was measured with a 10-cm visual analog scale (VAS, 0 = no pain, 10 = worst possible pain). Low back pain-related functional disability was the primary outcome variable and was measured using a Spanish validated version of the Roland-Morris questionnaire (RMQ),15 in which disability is scored from 0 to 24 points (better to worse). FAB were measured using a Spanish validated version of the fear avoidance beliefs questionnaire.17 Only the 5 questions regarding fear avoidance beliefs about physical activity were used (FAB-Phys), with scores ranging from 0 (= no fear avoidance beliefs) to 30 (highest possible fear avoidance beliefs). The subscale on fear avoidance beliefs about work (FAB-Work) was excluded because all participants were retired. Quality of life was measured using the SF-12 questionnaire.18 Both the physical component summary (PCS) and the mental component summary of SF-12 are normalized for the Spanish general population (mean, 50; standard deviation, 10); PCS and MCS reference scores range from 2.86 (worst possible) to 71.67 (best possible physical quality of life), and from 11.61 (worst possible) to 71.24 (best possible mental quality of life), respectively. At the first assessment, the following variables were recorded: age (date of birth), sex, education level (5 categories), current low back pain (“no” or “yes” if VAS ≥1), duration of the low back pain episode, categorized as chronic when the episode lasted more than 3 months19 and presence of other chronic disabling conditions requiring constant medical treatment. The use of medication for either low back pain or chronic disorders was also recorded.

All questionnaires were self-administered and completed by the subject on his/her own in the absence of healthcare staff or third parties. Completed self-report instruments were collected by auxiliary personnel unrelated to the study. Data were entered in a database at a coordination centralized office by 2 administrative assistants who double-checked that data entered coincided with ratings of the VAS, Roland-Morris, FAB-Phys, and SF-12 questionnaires.

Power Calculation. It was assumed that the average baseline scores for functional disability would be 8 RMQ points, with an estimated cluster size of 35 subjects, and an interclass correlation of 0.1. In order to detect a difference of 2 points that has been cited as the cutoff point for a minimal clinically important change,20 with an alpha error of 0.05, a beta error of 0.20, and a 5% loss to follow-up, a sample size of 654 subjects was required. Assuming that 40% of the residents in the nursing homes would agree to participate in the study and would not meet any exclusion criteria, it was decided to recruit a minimum of 1600 residents.

Statistical Analyses. Frequencies were calculated for categorical variables. For continuous variables, mean and standard deviation (SD) were calculated at the individual level, whereas means and ranges between clusters were calculated at cluster level. Improvement of functional disability was defined as scores of the Roland-Morris questionnaire at baseline minus scores at the corresponding follow-up, so that positive values reflect improvement and the higher the value, the higher the improvement. The intraclass correlation coefficient was estimated for improvement of disability.21 Because of the cluster design, to estimate the effect of the independent variable on the improvement of disability, generalized mixed linear random
effects models were used after adjusting for possible confounding factors.  

In all the models, intervention (active education, postural education, control) was the independent variable. Education intervention was coded as “dummy variables,” and “control” was used as the reference in all the models, so that the effect size reflects the difference between experimental (active or postural) interventions and control. At the design phase, it was decided that variables with imbalances between groups at the preintervention assessment would be included in the models as potential confounders. A backward strategy was used; those variables that when eliminated produced a change of $\geq 10\%$ of the effect size were considered confounding variables. Finally, the analyses and regressions were repeated, this time restricting them only to those subjects who had low back pain at the study entry.

Once the nursing homes had been randomized into the 3 study groups, it turned out that one of the homes assigned to the active education group was fractioned into 3 organizational units, and it was necessary to do the intervention separately in each one of them. For this reason, it was decided to analyze the results by considering each unit as a separate cluster. However, a sensitivity analysis joining the 3 units as one cluster was also performed.

Analyses were performed with SPSS (version 12.0) and Stata (version 8.0; Stata Corp., College Station, TX) statistical programs.

Role of the Funding Sources. In order to do this study, the Kovacs Foundation funded the Spanish transcultural adaptation of the Back Book (“Manual de la Espalda”) that was used in the active education group, and owns the Spanish copyright. For the same purpose, the Kovacs Foundation also developed, and owns the copyright of the booklet used in the postural education group (Back Guide, “Guía de la Espalda”). The funding sources had no involvement in the study design, collection, analysis and interpretation of data, writing of the report, or in the decision to submit the paper for publication.

Results

Recruitment and interventions were performed between October 6, 2003 and November 25, 2004. The required sample size was reached with the first 10 nursing homes that accepted to participate in the study (total number of residents, 1647). Of these, 4 were randomized to the active education program (664 residents), 3 to the postural intervention (672 residents), and 3 to the control group (311 subjects). However, 12 clusters were analyzed because one home assigned to the active education program was fractioned into 3 separate units.

A total of 661 (40.1\%) of 1647 residents were willing to participate. They were distributed as follows: 233 in the active education group (35.1\% of subjects in the corresponding nursing homes), 199 (29.6\%) in the postural education group, and 241 (77.5\%) in the control group. Twelve subjects (active education 1, postural education 10, control 1) were excluded before starting the intervention because of cognitive impairment (n = 9), spondylitis (n = 2), and cancer (n = 1). A flow chart of the study population in accordance with CONSORT guidelines for trials randomized by clusters is shown in Figure 1.

Baseline assessment

<table>
<thead>
<tr>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
<th>Low Back Pain: Y completed in 1 home* Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Control</td>
<td>Control</td>
<td>Control</td>
<td>Control</td>
<td>Control</td>
</tr>
</tbody>
</table>

Figure 1. Flow chart of the study.
back pain; the episode was chronic in about 35% of cases. Between 43% and 61% were taking drug medication for low back pain and more than 50% were taking medication for other chronic illnesses.

Changes in VAS, Roland-Morris Questionnaire, FAB-Phys, and PCS and MCS SF-12 at the 30-day and 180-day assessments are shown in Table 2. Disability improved in all groups compared with baseline data. Results of the generalized mixed linear random effect model after adjusting for significant variables at baseline, including use of medication for low back pain, education level, and scores of the Roland-Morris questionnaire, and PCS and MCS SF-12, showed an additional improvement of functional disability of 1.1 (95% confidence interval [CI] 0.2–1.9) in the postural education group at the 30-day assessment, and an improvement of 2.0 (95% CI, 0.5–3.4) in the active education group at the 180-day assessment (Table 3). When only those subjects with low back pain at the study entry were analyzed, postural education had no advantage compared with the control group at follow-up, whereas the active education group showed an additional improvement of disability of 3.0 (95% CI 1.5–4.5) at the 180 day evaluation (Table 3). A subgroup analysis joining the 3 units of the nursing home in which interventions were performed separately provided consistent results (data not shown).

At the end of the study the physician who gave the talks continued to have no opinion with respect to the

<table>
<thead>
<tr>
<th>Variable</th>
<th>Active Education</th>
<th>Postural Education</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment at 30 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability (Roland Morris)</td>
<td>3.5 (2.6)</td>
<td>3.3 (2.4–4.1)</td>
<td>4.0 (3.3)</td>
</tr>
<tr>
<td>Intensity of pain (VAS)</td>
<td>1.9 (1.8)</td>
<td>1.9 (1.7–2.2)</td>
<td>1.9 (2.1)</td>
</tr>
<tr>
<td>FAB physical</td>
<td>16.9 (1.7)</td>
<td>16.9 (16.4–17.7)</td>
<td>19.0 (0.9)</td>
</tr>
<tr>
<td>PCS SF-12</td>
<td>38.9 (7.2)</td>
<td>38.5 (36.5–40.6)</td>
<td>34.6 (8.3)</td>
</tr>
<tr>
<td>MCS SF-12</td>
<td>50.2 (3.6)</td>
<td>50.8 (50.8–52.8)</td>
<td>56.4 (7.3)</td>
</tr>
<tr>
<td>Improvement of disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All subjects</td>
<td>(n = 232)</td>
<td>1.1 (0.5–1.8)</td>
<td>3.1 (2.4–3.7)</td>
</tr>
<tr>
<td>Subjects with low back pain</td>
<td>1.8 (1.3–2.3)</td>
<td>2.1 (1.3–3.8)</td>
<td>4.7 (3.9–5.6)</td>
</tr>
<tr>
<td>Assessment at 180 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability (Roland Morris)</td>
<td>3.0 (2.7)</td>
<td>3.2 (1.7–4.5)</td>
<td>4.4 (3.6)</td>
</tr>
<tr>
<td>Intensity of pain (VAS)</td>
<td>0.7 (1.5)</td>
<td>0.7 (0.3–1.1)</td>
<td>1.2 (1.7)</td>
</tr>
<tr>
<td>FAB physical</td>
<td>16.2 (1.3)</td>
<td>16.9 (16.5–17.2)</td>
<td>18.5 (1.0)</td>
</tr>
<tr>
<td>PCS SF-12</td>
<td>41.5 (7.0)</td>
<td>40.9 (37.4–44.3)</td>
<td>36.0 (6.7)</td>
</tr>
<tr>
<td>MCS SF-12</td>
<td>58.9 (3.0)</td>
<td>58.9 (58.7–59.5)</td>
<td>57.7 (3.0)</td>
</tr>
<tr>
<td>Improvement of disability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All subjects</td>
<td>1.5 (0.9–1.3)</td>
<td>1.4 (0.8–3.6)</td>
<td>2.7 (1.8–3.6)</td>
</tr>
<tr>
<td>Subjects with low back pain</td>
<td>3.1 (2.5–3.8)</td>
<td>3.2 (2.2–5.4)</td>
<td>5.0 (4.0–6.0)</td>
</tr>
</tbody>
</table>
comparative effectiveness of the intervention strategies, and the physician who audited the first and last talks given to each group did not detect any difference.

**Discussion**

In institutionalized elderly subjects, an active education strategy based on a 20-minute group talk and the hand-out of the Back Book determined an improvement in functional disability of 3 RMQ points at 6 months. The postural education program was also associated with an improvement at 1 month, but that improvement was clinically irrelevant and it had disappeared at 6 months. The size effect of the active management education program is modest, being just above the cutoff for a minimal clinically important change. However, few treatments have shown to improve disability, especially in the elderly, and this program required only a 20-minute group talk and the handing out of a booklet, which is likely to be cheaper than other treatments for low back pain which have shown even smaller effects. For instance, that effect is approximately 3 times the one shown by spinal manipulation on patients seeking health care for low back pain.

The small number of clusters may account for the differences among the study groups with regard to baseline scores of some variables. However, results of regression analysis indicate that these differences did not affect the validity of the results obtained. Some subjects did not fill out the questionnaires at the follow-up assessments, although, in general, the percentage of subjects that completed all instruments at 3 and 6 months was higher in the postural education group than in the active intervention and control groups (Figure 1).

If the physician who gave the talks had experienced a greater degree of enthusiasm or confidence in one of the 3 interventions, he could probably have influenced the results. However, this seems unlikely for 3 reasons: 1) the speaker was told that in elderly subjects, active or postural education interventions would probably have a similar effect, 2) he had an indifferent opinion with regard to the intervention either before or after the study, and 3) the independent observer did not notice any difference between the speaker’s attitude during the talks. Furthermore, the speaker only saw the subjects while giving the talk and he had no further contact with attendees, nor did he have access to outcome assessments.

Results from this study are consistent with those obtained in studies carried out in the United Kingdom and France with the hand-out of the Back Book to subjects of working age, but are not in agreement with recent data of a Dutch study in which provision of a similar booklet to acute patients 18 to 65 years old was accompanied by a 20-minute psychosocial intervention tailored to each patient and delivered by the general practitioner. Differences in the results obtained may be related to the intervention strategy, characteristics of the study sample, recruitment of subjects from nursing homes versus general practices, or differences in sociocultural factors that may be relevant in patients with low back pain.

All of the clinical variables improved in all groups at follow-up, and some of them showed a clinically relevant degree of improvement. For instance, at 6 months pain had improved between 1.9 and 2.7 VAS points, and low back pain-related disability had improved even in the control group, in which patients did not know that they were taking part in a study on that issue and in which the talk and pamphlet focused on cardiovascular health. These findings suggest the importance of unspecific effects (placebo, Hawthorne, regression to the mean, etc.), and reinforces the need for having a control (“sham”) group in clinical trials, even in those assessing different education programs.

The beneficial effect of active education was noted at 6 months, but not at 1 month. This could be due to several factors. It is possible that in that group the talk was irrelevant and the effect was due to reading the Back Book or even the repeated reading of it. However, the characteristics of the study sample do not support that explanation. Postural education has been traditionally used in Spain for low back pain, which could explain that this type of information met the expectations for a physician’s talk, while active management education may have initially seemed unbelievable to the subjects in the corresponding group, so that they needed to experience its precepts directly before believing and adopting them. Finally, since active education aims at changing attitudes and behavior, it is also possible that the effects of this type of education appear more slowly.

Fear-avoidance beliefs have proved to be important factors in disability in the Anglo-Saxon and Scandinavian populations, but they are practically irrelevant in Spanish patients of working age. In this study, 30

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**Table 3. Results of the Generalized Mixed Linear Random Effects Model**

<table>
<thead>
<tr>
<th>Improvement of Functional Disability</th>
<th>Active Education Effect Size (95% CI)</th>
<th>Postural Education Effect Size (95% CI)</th>
<th>Adjusted by Baseline Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 30 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All subjects</td>
<td>-0.4 (-1.2 to 0.3)</td>
<td>1.1 (0.2 to 1.9)</td>
<td>MCS SF-12</td>
</tr>
<tr>
<td>Subjects with low back pain</td>
<td>1.1 (-0.1 to 2.3)</td>
<td>0.6 (-0.7 to 2.0)</td>
<td>Roland Morris score</td>
</tr>
<tr>
<td>At 180 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All subjects</td>
<td>1.0 (0.6 to 3.4)</td>
<td>1.1 (-0.5 to 2.7)</td>
<td>Roland Morris score</td>
</tr>
<tr>
<td>Subjects with low back pain</td>
<td>3.0 (1.5 to 4.5)</td>
<td>1.0 (-0.6 to 2.7)</td>
<td>Roland Morris score</td>
</tr>
</tbody>
</table>
and 180 days after the intervention and with respect to baseline scores, FAB had improved by a constant 11.5% in the active group, by 1.9% and 4.6% in the postural group, and had worsened by 1.4% and 0.6% in the control group. This might suggest that FAB are more relevant in Spanish elderly than in younger subjects. However, since even in the active management group the improvement of FAB was modest, it is also possible that the improvement in disability was mediated by other behavioral or cognitive mechanisms.

The percentage of subjects who accepted to participate in the study was low, especially in the education groups. Participants were elderly persons who were interested in listening to a talk on health education, despite being institutionalized and having serious restrictions in their physical quality of life. In addition, despite having other illnesses and a low physical quality of life, none of them died during the study and they had a mental quality of life that was higher than the Spanish average. Although the latter may be due to the differences between the elderly and the general Spanish population from where the average was taken, those facts may suggest a selection bias. However, since those factors emerge from the characteristics of the intervention and the population under study, they do not appear to limit the generalizability of these results to the elderly in whom this intervention is possible.

The physician who gave the talks gave only 10 previous talks on general health education in order to refine his communication skills with the elderly, and received no specific training. Since the Back Book is a standard book available in several languages, this suggests that the simple educational program that in this study has proved to be effective, could be easily generalized to the elderly in other countries. Future studies should test this hypothesis.

Conclusion

This study shows that, in elderly institutionalized subjects, a booklet on traditional postural education supported by a 20-minute group talk resulted in a clinically irrelevant improvement of functional disability at 30 days and had no better effect on subjects with low back pain than a similar control educational intervention. The same intervention focused on active management education improved disability 6 months later and had an even greater effect on subjects with low back pain. This study provides further evidence for the effectiveness of the Back Book in a population in which it is especially difficult to modify attitudes and to improve functional disability.

Key Points

- A total of 661 elderly from 12 nursing homes in Spain took part in a cluster randomized controlled trial comparing the effect of 3 education programs on LBP related disability.

- Education programs consisted of the hand-out of a booklet and a 20-minute group talk. The education programs that were compared focused on active management, postural hygiene, and a control intervention on cardiovascular health.

- Disability improved in the 3 groups. When compared with the control group, education on postural hygiene led to a statistically significant but clinically irrelevant improvement in disability at 1 month, which had disappeared at 6 months. There was no effect in subjects with low back pain.

- Education on active management led to a statistically significant but clinically irrelevant improvement in disability at 6 months. In subjects with low back pain, the improvement reached clinical relevance.

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