Effects of Two Guideline Implementation Strategies on Patient Outcomes in Primary Care

A Cluster Randomized Controlled Trial

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Study Design. Cluster randomized controlled trial.

Objective. To improve quality of care for patients with low back pain (LBP) a multifaceted general practitioner education alone and in combination with motivational counseling by practice nurses has been implemented in German general practices. We studied effects on functional capacity (main outcome), days in pain, physical activity, quality of life, or days of sick leave (secondary outcomes) compared with no intervention.

Summary of Background Data. International research has lead to the development of the German LBP guideline for general practitioners. However, there is still doubt about the most effective implementation strategy. Although effects on process of care have been observed frequently, changes in patient outcomes are rarely seen.

Methods. We recruited 1378 patients with LBP in 118 general practices, which were randomized to 1 of 3 study arms: a multifaceted guideline implementation (GI), GI plus training of practice nurses in motivational counseling (MC), and the postal dissemination of the guideline (controls, C). Data were collected (questionnaires and patient interviews) at baseline and after 6 and 12 months. Multilevel mixed effects modeling was used to adjust for clustering of data and potential confounders.

Results. After 6 months, functional capacity was higher in the intervention groups with a cluster adjusted mean difference of 3.650 between the MC group and controls (95% CI = 0.320–6.979, p = 0.032) and 2.652 between the GI group and controls (95% CI = −0.704 to 6.007, p = 0.120). Intervention effects were more pronounced regarding days in pain per year with an average reduction of 16 (GI) to 17 days (MC) after 6 months (12 and 9 days after 12 months) compared with controls.

Conclusion. Active implementation of the German LBP guideline results in slightly better outcomes during 6 months follow-up than its postal dissemination. Results are more distinct when practice nurses are trained in motivational counseling.

Key words: guideline, implementation, low back pain, primary care, motivational counseling, effectiveness study, functional capacity. Spine 2008;33:473–480

Low back pain (LBP) is one of the leading causes of consultations in general practice.¹ Long-term sick leave and early retirement impose a major health burden for industrialized countries.² The evidence of extensive research has been summarized in international guidelines. All of them discourage diagnostic tests in unspecific LBP and emphasize patients’ self-responsibility by promoting increased physical activity.³

Until now, there is no agreement on the best guideline implementation strategy. Recent reviews have shown that postal dissemination of guidelines alone or didactic educational meetings, such as lectures, are not effective.⁴ To achieve changes in practice, multifaceted interventions combining 2 or more components, such as information material and workshops, and an active approach, e.g., educational outreach visits, reminders, and interactive educational meetings are necessary.⁵,⁶ So far, results are inconsistent and mostly affect single aspects of patient management.⁷,⁸ Only few guideline implementation studies report on patient outcomes.⁹,¹⁰ However, the aim of any implementation is to improve patients’ pain and function and to prevent patients from developing chronic pain. Success in this context usually requires changes in patients’ health behavior, like an increased physical activity. Stage-based interventions and motivational counseling have been promising, but they imply patient counseling and communication skills.¹¹,¹²

Implementation in general practice is difficult given the fact that time constraints determine physician behavior to a great extent.¹³ Internationally, there have been efforts to delegate parts of the health-promotion to practice nurses.¹⁴–¹⁶ In Germany, trained practice nurses are successfully integrated in the care of patients with diabetes or depression. The assignment in the context of other diseases is currently under evaluation.¹⁷,¹⁸ New models of nurses’ involvement are necessary especially with regard to disease man-
agement programs because of physicians’ limited work capacity.

We designed a randomized controlled trial on the effectiveness of 2 guideline implementation strategies. A central part of the trial is the guideline on the management of acute and chronic LBP issued by the German College of General Practitioners and Family Physicians (DEGAM). This is an evidence-based guideline of high quality. It was developed and tested in a 10-step program including panel and practice tests and was approved by the German Agency for Quality in Medicine (AZQ). Based on the diagnostic triage, the guideline recommends early activation, symptomatic pain relief, and manual therapy (optionally) for unspecified acute LBP. Patients with subacute and chronic pain should receive a multi-professional therapy or—if this is not available—its components physiotherapy, psychotherapy, back schools, or massage. Effects on patient outcomes will be addressed in this article.

Materials and Methods

Design

Within the German back pain research network, we designed a cluster randomized trial in 2 semi rural German regions with 2 intervention arms and 1 control group. The intervention arms received a multifaceted general practitioner education (guideline implementation group, GI) or the same education combined with a training of practice nurses in motivational counseling (motivational counseling group, MC). General practitioners (GPs) of the control group (controls, C) received the guideline via post. Follow-up assessments were performed at 6 and 12 months after baseline.

All participating GPs, nurses, and patients provided their written informed consent. The study was approved by the local institutional review boards (universities of Göttingen and Marburg, Germany).

Recruitment of Practices and Patients

We invited all 883 family physicians in 2 German regions to participate. Inclusion criteria for practices were the willingness to participate of at least one physician and one practice nurse.

GPs were asked to consecutively recruit all patients who presented for LBP. Inclusion criteria for patients were LBP as presenting symptom on the day of recruitment, written consent to participate in the study, and age above 19 years. Exclusion criteria were insufficient German language skills, pregnancy, and isolated thoracic pain.

Intervention

Practices were assigned to the 3 study arms by central permuted block randomization with allocation concealment.

GPs in both intervention groups (GI and MC) were trained in using the LBP guideline of the DEGAM: The guideline consists of 4 basic modules (a detailed version and a pocket card for physicians, a prescription-like short form information and a more detailed flyer for patients to be handed out during and after consultation). Three interactive seminars were held, including information on performance of the diagnostic triage and identification of red flags (first session), early identification of yellow flags, including general behavioral principles on management of chronic pain patients (second session), and informing and advising patients (third session). The third session gave room for discussion of implementation barriers and individual experiences. All physicians of the intervention groups received information about relevant local facilities for pain patients (self-help groups, fitness clubs, teaching sessions organized by health insurers, specialists, etc.). Both, physicians of the GI and the MC group, received 2 individual educational visits by study nurses (“academic detailing”), first to present the guideline and second after 3 to 6 months to discuss individual problems with the guideline implementation.

During the third seminar, GPs of the MC group were introduced to motivational counseling strategies. Two nurses per practice received a 20-hour training (2 full-day workshops and 1–3 supervision sessions) designed to increase the nurses’ skills to motivate LBP patients for regular physical activity. Practice nurses were asked to invite all identified patients for up to 3 counseling sessions (max 10–15 minutes each), the first session within 1 to 3 weeks after inclusion in the study. They were encouraged to use specifically designed brochures on motivational and behavior change and posters to communicate the key messages. Study coordinators contacted the practice nurses regularly to identify barriers and problems with regard to the implementation of this new counseling strategy. There was no such motivational intervention on patient level via practice nurses in the GI group.

The control group received the guideline via mail, which has been shown to have no effect on patient outcome.

Effect Measures

At the index visit, patients were asked to fill out 2 sets of questionnaires, one while waiting and another one at home (for postal return in a prepaid envelope). One baseline telephone interview (within 4 weeks) and 2 follow-up interviews (after 6 and 12 months) were performed by specially trained clinical nurses.

GPs evaluated each patient regarding the presence of complicating factors (red flags) on a one-page questionnaire.

The main outcome to assess the implementation effectiveness was functional capacity measured with the Hannover Functional Ability Questionnaire for Measuring Back Pain-Related Functional Limitations at baseline (questionnaire) and at 6 months (interview). The Hannover Functional Ability Questionnaire is a 12-item self-administered questionnaire for the assessment of functional limitations in activities of daily living (internal consistency reliability α = 0.90, retest reliability r = 0.75). Normal function scores scores of 80% to 100%, scores around 70% equal a moderately, scores below 60% a severely limited function.

Secondary outcomes were physical activity during 1 week before the interview, days in pain and days of sick leave during 6 months follow-up, quality of life measured with the EuroQol, and Fear Avoidance Beliefs Questionnaire. Physical activity was measured by the Freiburg Questionnaire on Physical Activity (FQPA). The questionnaire usually consists of 12 items. We omitted items 9 to 12 on sleep behavior, recreation time, and self-evaluation to shorten the interviews. The FQPA has satisfactory psychometrical properties and allows a calculation of weighted MET hours per week. Tests with our own sample show a retest-reliability from the second to the third interview (to account for intervention bias) within 6 months of r = 0.46 (total physical activity).
Functional capacity 67.52/H11006
Pain intensity (NRS 0–10) 5.32

Because they denied suffering from LBP on day of recruitment, we had to exclude 209 patients, because they did not sign the informed consent or because they refused participation. Overall, 118 practices (126 GPs) were randomized into either the GI group (37 practices), the MC group (38 practices), or the control group (C, 43 practices). One practice withdrew after randomization and one practice had to be excluded because no patient was recruited. GP characteristics are shown in Table 1.

**Table 1. Characteristics of Participating GP (n = 126)**

| Variable                              | GI Guideline Implementation (n = 479) | MC GI + Motivational Counseling (n = 489) | Control Group C (n = 410) |
|---------------------------------------|--------------------------------------|------------------------------------------|--------------------------|
| Functional capacity                   | 67.52 ± 21.42                        | 68.74 ± 20.99                            | 65.81 ± 21.90            |
| Pain intensity (NRS 0–10)             | 5.32 ± 2.18                          | 5.0 ± 2.05                               | 5.27 ± 2.12              |
| Days of pain in the previous year     | 101 ± 123.02                         | 103 ± 123.91                             | 112 ± 130.96             |
| Chronic Pain Grade* (n (%))           |                                      |                                          |                          |
| Low disability/low intensity          | 101 (21.1)                           | 118 (24.1)                               | 84 (20.5)                |
| Low disability/high intensity         | 97 (20.3)                            | 87 (17.8)                                | 74 (18.0)                |
| High disability/moderately limiting  | 90 (18.8)                            | 95 (19.4)                                | 75 (18.3)                |
| High disability/severely limiting     | 51 (10.6)                            | 56 (11.5)                                | 57 (13.9)                |
| Activity (METHours/wk)†               | 25.65 ± 20.29                        | 26.97 ± 19.64                            | 27 ± 20.22               |
| Job satisfaction (NRS 0–10)           | 6.18 ± 2.33                          | 6.23 ± 2.54                              | 5.85 ± 2.50              |
| Depression score                      | 15.02 ± 9.34                         | 15.82 ± 9.50                             | 15.20 ± 9.30             |
| Fear avoidance beliefs score          |                                      |                                          |                          |
| Score II (physical activity = cause for pain) | 17.45 ± 6.83 | 16.76 ± 6.69 | 18.76 ± 6.77 |
| Score III (work = cause for pain)     | 13.10 ± 8.81                         | 12.91 ± 8.23                             | 14.57 ± 8.72             |
| Score IV (prognostic job)             | 8.77 ± 8.36                          | 8.16 ± 8.05                              | 10.02 ± 8.70             |
| Quality of life (VAS 0–100)           | 57.19 ± 19.9                         | 58.21 ± 18.87                            | 55.51 ± 18.92            |
| Days of sick leave (in 6 mo)          | 6.08 ± 18.0                          | 8.10 ± 26.39                             | 10.83 ± 31.63            |

Values are means ± SD, unless otherwise indicated.
*More than 20% missing.
†Outlier corrected by “winsorizing”: values >98th percentile were equated to this value.
‡Significant differences between groups p = 0.05.

Results

**General Practitioners and Practices**

We invited 883 GPs to participate: 52% did not respond and 34% GPs refused participation, because practice nurses were not interested. Overall, 118 practices (126 GPs) were randomized into either the GI group (37 practices), the MC group (38 practices), or the control group (C, 43 practices). One practice withdrew after randomization and one practice had to be excluded because no patient was recruited. GP characteristics are shown in Table 1.

**Table 2. Baseline Characteristics of Patients by Study Groups (n = 1378)**

| Variable                                    | GI Guideline Implementation (n = 479) | MC GI + Motivational Counseling (n = 489) | Control Group C (n = 410) |
|---------------------------------------------|--------------------------------------|------------------------------------------|--------------------------|
| Functional capacity                         | 67.52 ± 21.42                        | 68.74 ± 20.99                            | 65.81 ± 21.90            |
| Pain intensity (NRS 0–10)                   | 5.32 ± 2.18                          | 5.0 ± 2.05                               | 5.27 ± 2.12              |
| Days of pain in the previous year           | 101 ± 123.02                         | 103 ± 123.91                             | 112 ± 130.96             |
| Chronic Pain Grade* (n (%))                 |                                      |                                          |                          |
| Low disability/low intensity                | 101 (21.1)                           | 118 (24.1)                               | 84 (20.5)                |
| Low disability/high intensity               | 97 (20.3)                            | 87 (17.8)                                | 74 (18.0)                |
| High disability/moderately limiting        | 90 (18.8)                            | 95 (19.4)                                | 75 (18.3)                |
| High disability/severely limiting          | 51 (10.6)                            | 56 (11.5)                                | 57 (13.9)                |
| Activity (METHours/wk)†                    | 25.65 ± 20.29                        | 26.97 ± 19.64                            | 27 ± 20.22               |
| Job satisfaction (NRS 0–10)                 | 6.18 ± 2.33                          | 6.23 ± 2.54                              | 5.85 ± 2.50              |
| Depression score                            | 15.02 ± 9.34                         | 15.82 ± 9.50                             | 15.20 ± 9.30             |
| Fear avoidance beliefs score                |                                      |                                          |                          |
| Score II (physical activity = cause for pain) | 17.45 ± 6.83 | 16.76 ± 6.69 | 18.76 ± 6.77 |
| Score III (work = cause for pain)           | 13.10 ± 8.81                         | 12.91 ± 8.23                             | 14.57 ± 8.72             |
| Score IV (prognostic job)                   | 8.77 ± 8.36                          | 8.16 ± 8.05                              | 10.02 ± 8.70             |
| Quality of life (VAS 0–100)                 | 57.19 ± 19.9                         | 58.21 ± 18.87                            | 55.51 ± 18.92            |
| Days of sick leave (in 6 mo)                | 6.08 ± 18.0                          | 8.10 ± 26.39                             | 10.83 ± 31.63            |

Values are means ± SD, unless otherwise indicated.
*More than 20% missing.
†Outlier corrected by “winsorizing”: values >98th percentile were equated to this value.
‡Significant differences between groups p = 0.05.
sion/patient on average, range 1–4 sessions). The overall drop out rate during 12 months was 12.1% (n = 11005, Figure 1). Drop outs showed no relevant differences to study remainers besides for a lower percentage belonging to Chronic Pain Grade IV (high disability/severely limiting) and a significant less amount of energy expenditure per week for drop outs compared with participants (Table 4).

Table 3. Sociodemographic Characteristics of Patients by Study Groups (n = 1378)

| Variables                        | GI Guideline Implementation (n = 479) | MC GI + Motivational Counseling (n = 489) | Control Group C (n = 410) |
|----------------------------------|--------------------------------------|-------------------------------------------|---------------------------|
| Age (mean ± SD, range)*          | 49.1 yr ± 13.3                       | 47.4 yr ± 13.5                            | 50.2 yr ± 14.3            |
| Gender (males)*                  | 195 (40.7)                           | 189 (39.0)                                | 193 (47.1)                |
| Marital status                   |                                       |                                           |                           |
| Single                           | 62 (12.9)                            | 81 (16.6)                                 | 56 (12.7)                 |
| Married                          | 280 (58.5)                           | 275 (56.2)                                | 250 (61.0)                |
| Widowed                          | 24 (5.0)                             | 26 (5.3)                                  | 20 (4.9)                  |
| Divorced                         | 52 (10.8)                            | 43 (9.8)                                  | 38 (9.3)                  |
| Living with partner              | 325 (67.9)                           | 317 (64.8)                                | 273 (66.6)                |
| Level and years of education     |                                       |                                           |                           |
| 13/12 yr                         | 60 (12.5)                            | 69 (14.1)                                 | 57 (13.9)                 |
| 10 yr                            | 132 (27.6)                           | 126 (25.8)                                | 104 (25.4)                |
| 9 yr                             | 174 (36.3)                           | 173 (35.4)                                | 159 (38.8)                |
| Other graduation                 | 47 (9.8)                             | 57 (11.7)                                 | 42 (10.2)                 |
| No qualification                 | 4 (0.8)                              | 2 (0.4)                                   | 1 (0.2)                   |
| Employment status                |                                       |                                           |                           |
| Working full or part-time        | 263 (54.9)                           | 279 (57.0)                                | 216 (52.7)                |
| Keeping house                    | 38 (7.9)                             | 47 (9.6)                                  | 35 (8.5)                  |
| Retired                          | 81 (16.9)                            | 68 (13.9)                                 | 79 (19.3)                 |
| Unemployed                       | 19 (4.0)                             | 19 (3.9)                                  | 17 (4.1)                  |
| Other                            | 14 (2.9)                             | 22 (4.5)                                  | 14 (3.4)                  |
| Applied for a pension*           | 37 (7.7)                             | 23 (4.7)                                  | 40 (9.8)                  |

Values are number (percentage), unless otherwise indicated.

*Significant differences between study groups p < 0.05.

Effectiveness of Guideline Implementation Strategies After 6 Months

The course of functional capacity is shown in Figure 2. In the primary analysis after 6 months, improvement of functional capacity was more pronounced in the intervention groups with statistically significant results for the adjusted difference between the MC group and controls.

Figure 1. Patient flow chart. Drop outs are given in italics. GI indicates Guideline implementation group; MC, Guideline implementation plus motivational counseling; C, controls (postal dissemination of the guideline).
The observed effects were robust in the sensitivity analyses for missing data [adjusted mean difference of 3.28 (95% CI 0.21–6.35) between MC group and controls (P = 0.04) and 2.52 (95% CI = −0.60–5.63) between GI group and controls (P = 0.11)]. Table 5 shows the results of mixed modeling.

At the 6-month follow-up, 617 of 1259 patients (49%) indicated suffering from pain on the interview day (35% of the GI group, 31% of the MC group and 34% of controls). Regarding days in pain, patients of both intervention groups showed significantly less days in pain during the previous 6 months than controls at the 6-month follow-up assessment (Table 5). Less patients of the intervention groups indicated suffering from permanent pain than control patients (P = 0.02).

We found no significant intervention effects regarding other secondary outcomes: physical activity, quality of life, or days of sick leave (Table 5).

### Long-term Effects of the Implementation Strategies Over 12 Months

At the time of the 12-month follow-up, 573 of 1209 patients reported being in pain. Cluster-adjusted mixed model analysis showed no significant effects in functional capacity, but a more pronounced reduction of days in pain in both intervention groups compared with the control group (Table 5). Patients of the MC group showed significant improvement in quality of life, but not in overall activity or days of sick leave.

Only a minority of patients was able to answer the von Korff questionnaire referring to the last 3 months of follow up, since only 354 patients (25%) did suffer from pain during that time: There were 45.2% of patients who showed an improvement of the Chronic Pain Grade, 32.5% remained stable and 22.3% showed a higher grade than before. There was, however, no significant difference between the study arms (P = 0.81).

### Factors Affecting the Improvement of Functional Capacity or Pain Days

Table 6 shows that intervention effects differed with gender. None of the other factors (age, physical activity or fear avoidance beliefs) showed any relevant influence on treatment outcome.

### Discussion

Clinical guidelines for LBP are expected to improve patients’ long-term outcome. This study showed that a multifaceted physician education has only little effect on patient outcomes with respect to functional capacity and days in pain. Intervention effects are slightly more pronounced when practice nurses are trained in motivational counseling.

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**Table 4. Drop Outs—Selected Sociodemographic and Baseline Characteristics Compared With Total Participants With Completed Follow Up**

| Variable                              | Drop Outs (n = 167) | Participants With Completed Follow Up (n = 1211) |
|--------------------------------------|---------------------|-----------------------------------------------|
| Age (mean ± SD)                      | 48.39 yr ± 16.7     | 48.9 yr ± 13.34                               |
| Gender (males)                       | 68 (40.7)           | 509 (42.0)                                    |
| Functional capacity (mean ± SD)      | 66.30 ± 20.82       | 67.60 ± 21.52                                 |
| Days of pain in the previous 12 mo (mean ± SD) | 102.46 ± 128.1     | 105.18 ± 128.98                               |
| Chronic pain grade*                  |                     |                                               |
| Low disability/low intensity         | 31 (18.6)           | 272 (22.5)                                    |
| Low disability/high intensity        | 30 (18.0)           | 228 (18.6)                                    |
| High disability/moderately limiting  | 24 (14.4)           | 236 (19.5)                                    |
| High disability/severely limiting†   | 29 (17.4)           | 135 (11.1)                                    |
| Activity (METhours/vk)†‡             | 26.59 ± 30.93       | 36.09 ± 32.77                                 |
| Quality of life (VAS 0–100)†         | 54.49 ± 18.15       | 57.38 ± 19.39                                 |
| Days of sick leave (in 6 mo)*        | 9.53 ± 26.9         | 7.98 ± 25.3                                   |

Values are number (percentage), unless otherwise indicated.

*More than 20% missing.

†Significant differences between groups α = 0.05.

‡Outlier corrected by “winsorizing”: values ≥98th percentile were equated to this value.
There are limitations to this study: Efforts were made to ensure consecutive patient inclusion in the study, but the inclusion rate reached only 44% which might be due to selection bias. Patients who agreed to participate may have felt less disabled and handicapped by the pain, and may have had a higher level of physical activity and a higher readiness to change than LBP patients in general. This may reduce the external validity of the study. However, physical activity measured as energy expenditure of hours per week reported in a population survey from Germany (West). Overall activity in our study increases with time, but independent of study arm. A similar phenomenon has been observed by van Sluijs et al who stated that measurement of physical activity alone already affects participants’ physical activity behavior. Keeping in mind recruitment of patients during an acute phase of disease, the observed improvement in outcomes in all 3 study arms may as well be a sign of regression to the mean, or alternatively—for physical activity—of social desirability bias in patient answers that leads to an underestimation of intervention effects for this variable.

After completion of the follow-up assessment, a large proportion of patients in all study groups are pain free (49% in the intervention arms, 40% in the control arm). The validity of the FQPA might not be sufficient for a primary care sample with low disability, because its questions are tailored to pain-related functional limitations. This might limit its discriminative power due to ceiling effects. Outcomes reflecting time intervals—like days in pain during the previous 6 months—seem more sensitive to minor changes.

In general, guideline implementation studies show inconsistent effects with respect to patient outcomes: A systematic review by Worrell et al revealed little evidence that clinical practice guidelines in primary care (addressing different conditions like hypertension, asthma or cigarette smoking) actually improve patient outcomes. Only 38% of all studies presented statistically significant effects. As for LBP, Cherkin et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk. On the other hand, a recent study by Feuerstein et al developed a physician education intervention, which despite apparent benefits to physicians, did neither lead to improvements in patients’ symptoms, disability nor satisfaction. Very small or even no effects were also reported by Bekkering or McGuirk.

### Table 5. Effectiveness of the 2 Implementation Strategies

| Study Arm | 6 Months Compared With Controls | 12 Months Compared With Controls |
|-----------|--------------------------------|---------------------------------|
|            | Mean (95% CI) | Mean Difference (95% CI) | P | Mean (95% CI) | Mean Difference (95% CI) | P |
| Functional capacity | | | | | | |
| GI | 72.941 (70.609 to 75.273) | 2.652 (–0.704 to 6.007) | 0.120 | 72.956 (70.433 to 75.479) | 1.396 (–2.224 to 5.017) | 0.446 |
| MC | 73.940 (71.646 to 76.233) | 3.650 (0.320 to 6.979) | 0.032 | 74.637 (72.205 to 77.141) | 3.113 (–0.470 to 6.697) | 0.088 |
| C | 70.290 (68.877 to 72.702) | | | 71.559 (68.963 to 74.156) | | |
| Days in pain | | | | | | |
| GI | 63.345 (57.167 to 71.524) | –16.433 (–26.833 to –6.034) | 0.002 | 58.482 (51.217 to 65.748) | –12.833 (–23.382 to –2.296) | 0.018 |
| MC | 62.911 (55.855 to 69.963) | –17.868 (–28.183 to –7.553) | 0.001 | 61.567 (54.452 to 68.681) | –9.755 (–20.190 to –0.689) | 0.067 |
| C | 80.779 (72.252 to 88.306) | | | 71.321 (63.679 to 79.964) | | |
| Overall activity | | | | | | |
| GI | 36.471 (33.309 to 39.633) | 2.959 (1.628 to 4.291) | 0.203 | 46.429 (43.005 to 49.852) | 3.546 (1.452 to 5.643) | 0.002 |
| MC | 36.294 (33.160 to 39.428) | 2.781 (1.784 to 3.747) | 0.230 | 45.393 (41.985 to 48.801) | 2.516 (2.476 to 7.495) | 0.396 |
| C | 33.512 (30.192 to 36.832) | | | 42.883 (39.244 to 46.523) | | |
| Days of sick leave | | | | | | |
| GI | 12.998 (9.856 to 16.140) | –1.342 (–5.972 to 2.327) | 0.569 | 6.159 (2.453 to 9.865) | –3.112 (–8.582 to 2.358) | 0.256 |
| MC | 13.054 (9.928 to 16.179) | –1.287 (–5.905 to 3.331) | 0.584 | 6.458 (2.498 to 10.428) | –2.813 (–8.463 to 2.837) | 0.220 |
| C | 14.341 (10.949 to 17.733) | | | 9.271 (5.248 to 13.294) | | |
| Quality of life | | | | | | |
| GI | 66.592 (64.810 to 68.373) | –0.254 (–2.864 to 2.355) | 0.847 | 68.456 (66.724 to 70.189) | 0.804 (–1.736 to 3.344) | 0.535 |
| MC | 67.535 (65.751 to 69.318) | 0.689 (–1.924 to 3.302) | 0.602 | 70.375 (68.649 to 72.100) | 2.723 (0.185 to 5.260) | 0.036 |
| C | 66.846 (64.393 to 68.753) | | | 67.852 (65.794 to 69.910) | | |

Values shown in the table are adjusted for clustering of data. Results for primary analysis are shaded; significant results are given in bold numbers.

### Table 6. Mean Differences of Functional Capacity and Days in Pain After 6 Months Between Intervention Groups and Controls, Adjusted for Clustering of Data and Gender

| Study Arm | Women Mean Difference (95% CI) | Men Mean Difference (95% CI) |
|-----------|--------------------------------|-----------------------------|
| Functional capacity | | | |
| GI | 2.952 (–1.088 to 6.992) | 3.038 (–1.384 to 7.460) |
| MC | 6.098 (2.088 to 10.109) | 1.213 (–2.350 to 5.765) |
| Days in pain | | | |
| GI | –13.467 (–26.505 to –0.430) | –20.205 (–33.867 to –6.543) |
| MC | –14.377 (–27.226 to –1.528) | –23.30 (–37.25 to –9.409) |

Significant results are given in bold letters.
The analysis of our data regarding the process of care showed a decrease in inadequate diagnostic imaging and physiotherapy, as well as less injection therapies for acute LBP without radiation to the leg or red flags. Patients of the MC group received one counseling session on average. A metaanalysis on the efficacy of motivational interviewing by Burke et al showed a significant dose-effect relationship with higher doses (higher duration and number of sessions) resulting in better study outcomes. Sample size of our patients receiving more than 2 sessions (n = 38 vs. 356 patients receiving one or 2 sessions) is too low to draw conclusions from the corresponding subgroup analysis. Taking the frequency of counseling sessions as indicator of intervention intensity, Hillsdon and colleagues defined a cut off point for effectiveness at 4 contacts. Furthermore, the single session in our study was not performed by experts, but by practice nurses who might not yet have been proficient in counseling. Therefore, the low number of actually delivered counseling sessions in our study is probably not enough to achieve additional effects in the MC group compared with the GI group or to controls. This may reflect local implementation barriers, because in Germany, practice nurses are usually restricted to performing administrative and organizational tasks.

The influence of gender on onset and prognosis of LBP has been described previously. Similar to our trial, Witt et al showed reduced back function loss in males and a more pronounced back pain reduction in females in a secondary analysis of a randomized controlled trial on the effectiveness of acupuncture. Ex post subgroup analyses showing small effects like ours have to be interpreted cautiously. However, they may help to clarify which interventions are best for which individuals. Support needs are different for women and men and may require different interventions to change health behavior. In this study, we tried to recruit a representative sample of primary care patients with LBP. Therefore, our sample presents a wide range of different pain quantities and qualities as well as different motivational stages for behavior change. This is in line with the target patient group of the guideline, but it minimizes study power and may mask individual differences in intervention effects. Motivational counseling is probably useful for some, but not for all primary care patients. The same applies for interventions like psychotherapy or multiprofessional rehabilitation as they are recommended in the guideline.

Our study is the largest guideline implementation study for LBP in German general practice. But, despite its multifaceted interventions, it shows very little impact on patient outcomes, reflecting the challenge of transferring research results on LBP management into practice as recently outlined by Macfarlane et al. Practice nurse involvement in LBP patient counseling seems to be promising, but has to be clarified in future studies ensuring a sufficient number of counseling sessions and adequate process of care. Future research should focus on an improved tailoring of guideline recommendations and local strategies to overcome implementation barriers like, e.g., organizational tasks.

**Key Points**

- Even though evidence-based guidelines on low back pain management are expected to improve patient care, studies on their effectiveness regarding patient outcomes are rare.
- This cluster randomized controlled trial studied the effect of a guideline implementation strategy alone or in combination with motivational counseling by study nurses compared with its postal dissemination.
- Patients of the guideline intervention groups show only little improvement with respect to functional capacity and days in pain compared to controls.
- Intervention effects are slightly more pronounced when practice nurses are trained in motivational counseling.

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