Effects of two guideline implementation strategies on patient outcomes in primary care – a cluster randomized controlled trial

Annette Becker, MD, MPH[1], Corinna Leonhardt[2], Michael M Kochen, MD, MPH, PhD, FRCGP [3], Stefan Keller, PhD[4], Karl Wegscheider, PhD[5], Erika Baum, MD, PhD [1], Norbert Donner-Banzhoff, MD, MHSc, PhD [1], Michael Pfingsten, PhD[6], Jan Hildebrandt, MD, PhD[6], Heinz-Dieter Basler, PhD[2], Jean-F Chenot, MD, MPH [3]

[1]Department of General Practice, Preventive and Rehabilitation Medicine, University of Marburg, Marburg, Germany
[2]Institute for Medical Psychology, University of Marburg, Marburg, Germany
[3]Department of General Practice, University of Göttingen, Göttingen, Germany
[4]Department of Public Health Sciences, University of Hawaii at Manoa, Hawaii, USA
[5]Institute of Statistics and Econometrics, University of Hamburg, Hamburg, Germany
[6]Department of Anaesthesiology, Pain Clinic, University of Göttingen, Göttingen, Germany

Correspondence:
Prof. Dr. med. Annette Becker, MPH
Philipps-University Marburg
Department of General Practice, Preventive and Rehabilitation Medicine
Robert-Koch-Straße 5
35032 Marburg
Germany
Tel: +49-6421-28 65125
Fax: +49-6421-28 65121
Annette.Becker@med.uni-marburg.de

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Abstract

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 to 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 one of three 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 six 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 – 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 to controls.

Conclusion: Active implementation of the German LBP guideline results in better outcomes during six months follow-up than its postal dissemination. Training of practice nurses in motivational counseling had no additional benefit.

Key words: guideline, implementation, low back pain, primary care, motivational counseling, effectiveness study, functional capacity

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 to its postal dissemination.
- Patients of the guideline intervention groups showed significant improvement with respect to functional capacity and days in pain compared to controls.
- Training of practice nurses in motivational counseling showed no additional benefit.

Mini abstract

A RCT on 1387 patients with low back pain was performed to study the effectiveness of a guideline implementation strategy alone or in combination with motivational counseling by practice nurses. Both interventions lead to better functional capacity and less days in pain during six months follow-up compared to controls.

Introduction

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 two 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 chronification. Success in this context usually implies 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[14,15,16]. 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 management programs because of physicians' limited work capacity.

We designed a randomized controlled trial on the effectiveness of two 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)[19]. 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 (ÄZQ). Based on the diagnostic triage, the guideline recommends early activation, symptomatic pain relief and manual therapy (optionally) for unspecific acute LBP. Patients with subacute and chronic pain should receive a multiprofessional 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 Method

Design

Within the German back pain research network (GBPRN) we designed a cluster randomized trial in two semi rural German regions with two intervention arms and

one 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 six 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.

Recruitment of practices and patients

We invited all 883 family physicians in two German regions to participate. Inclusion criteria for practices were the willingness to participate of at least one doctor 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 three 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 four basic modules (a detailed version and a pocket card for doctors, 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 doctors of the intervention groups received information about relevant local facilities for pain patients (self-help groups, fitness clubs, teaching sessions organised by health insurers, specialists etc.). Individual educational visits by study nurses ("academic detailing") were used twice to hand over the guideline and after three to six months to discuss individual problems with guideline implementation.

During the third educational session, GPs of the MC group were introduced to motivational counseling strategies. Two nurses per practice received a 20-hour training (two 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 three counseling sessions (max. 10-15min each), the first session within one to three 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.

The control group received the guideline via mail which has been shown to have no effect on patient outcome[20].

Effect measures

At the index visit, patients were asked to fill out two 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 two 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 (HFAQ) at baseline (questionnaire) and at 6 months (interview). The HFAQ 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)[21,22]. Normal function shows scores of 80%-100%, scores around 70% equal a moderately, scores below 60% a severely limited function.

Secondary outcomes were physical activity during one week prior to the interview, days in pain and days of sick leave during six months follow-up, quality of life measured with the EuroQol[23,24], and fear avoidance beliefs (FABQ)[25,26].

Physical activity was measured by the Freiburg Questionnaire on Physical Activity (FQPA)[27]. The questionnaire usually consists of 12 items. We omitted items 9-12 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= .46 (total physical activity).

Pain chronicity was measured by von Korff´s severity of chronic pain scale based on pain intensity, disability and duration of pain during 3 months[28].

Statistics

Expecting small effects (f=0.1) and a drop out rate of 25% we aimed for 1874 patients (α=0.05, power 1-β=80%, intracluster correlation ρ=0.03, expected cluster size n=16).

We used chi-square tests (categorical data), and t-tests or Mann-Whitney U tests (quantitative data) for comparison of baseline characteristics between groups and drop out analyses. Data on overall activity were outlier-corrected by “winsorizing” (values of the 98th percentile and above were set to this value).

Confirmatory testing of the primary and secondary outcome measures was based on multilevel mixed effects modeling accounting for clustering of data on practice level. Wald chi-square tests (α=5%) were used to determine whether differences in patient outcomes between the two intervention groups and between the intervention groups and the control group showed statistical significance. For sensitivity analysis, missing data for the primary outcome measure (at 6 and 12 months follow-up) were replaced according to the "last observation carried forward" procedure. To identify potential confounders or factors affecting improvements in functional capacity we selected sex, age, fear avoidance believes, physical activity and the number of days in pain during the previous six months (hypothesis driven) which were added to the model and we applied a stepwise backward procedure. Effect modification was considered by adding the corresponding interaction terms to the model if factors showed to be significant. Statistical analysis was performed with SPSS 12.0 (SPSS , Inc., Chicago. Illiniois).

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 I.

Patient inclusion, baseline characteristics and treatment

Based on the written documentation of 76 practices in which practice nurses recorded the numbers of all patients invited to participate, we found a mean patient participation rate of 44%. We had to exclude 209 patients, because they did not sign the informed consent or because they denied suffering from LBP on day of recruitment. Finally, 1378 patients (1-20 per practice, 11.8 on average, SD +/- 5.8) were included in the study. Baseline and socio-demographic characteristics are shown in table 2 and 3.

Most patients of the MC group (n=489, 80%) received motivational counseling sessions which were administered by 70 practice nurses in 39 practices (1 session/patient on average). The overall drop out rate during 12 months was 12.1% (n=167, figure 1). Drop outs showed no relevant differences to study remainers besides for a lower percentage belonging to chronification grade IV (high disability / severely limiting) and a significant less amount of energy expenditure per week for drop outs compared to participants (table 2).

Effectiveness of guideline implementation strategies after six 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. 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 4 shows the results of mixed modeling.

At the six 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 six months than controls at the six month follow-up assessment (table 4). 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 4).

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 to the control group (table 4). Patients of the MC group showed significant improvement in quality of life, but not in overall activity or days of sick leave.

Von Korff chronification grades were analyzed in those patients who suffered from pain during the previous three months at the one year follow-up (n=354, 25%). There

were 45.2% of patients who showed an improvement of the chronification grade, 32.5% remained stable and 22.3% showed a higher chronification 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 5 shows that intervention effects differed with gender. None of the other factors (age, physical activity or fear avoidance believes) 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 significantly improved patient outcomes with respect to functional capacity and days in pain. Motivational counseling by practice nurses had no additional benefit.

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 patients in our study is still below the mean 41.49 MET-hours per week reported in a population survey from Germany (West)[29]. Overall activity in our study increased with time, but independent of study arm. A similar phenomenon has

been observed by van Sluijs et al.[30] who stated that measurement of physical activity alone already affects participant's physical activity behavior. Keeping in mind recruitment of patients during an acute phase of disease, the observed improvement in outcomes in all three 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 was 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 six months – seem more sensitive to minor changes.

Overall, the effects in our study were rather small. In general, guideline implementation studies show inconsistent effects with respect to patient outcomes: A systematic review by Worrell et al.[31] showed little evidence that clinical practice guidelines in primary care (addressing different conditions like hypertension, asthma or cigarette smoking) actually improved patient outcomes. Only 38% of all studies showed statistically significant effects. As for LBP, Cherkin et al. presented a physician education intervention which, despite apparent benefits to physicians, did neither lead to improvements in patients' symptoms, disability nor satisfaction[32]. Very small or even no effects were also reported by Bekkering[9] or McGuirk[33]. On the other

hand, a recent study by Feuerstein et al.[34] revealed a positive association of physicians´ guideline adherence with function (odds ratio=1.45, 95% CI=1.31-1.60), patient satisfaction and general health (odds ratio=1.44, 95% CI=1.29-1.60).

The analysis of our data regarding the process of care[35] 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.[12] showed a significant dose-effect relationship with higher doses (higher duration and number of sessions) resulting in better study outcomes. Taking the frequency of counseling sessions as indicator of intervention intensity Hillsdon and colleagues[36] defined a cut off point for effectiveness at four 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 to the GI group or to controls. This may reflect local implementation barriers, since 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[37]. Similar to our trial, Witt et al.[38] 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[39] 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 shows 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. Its intervention effects are small, but promising regarding the challenge of transferring research results on LBP management into practice as recently outlined by Macfarlane et al.[40]. Future research should focus on an improved tailoring of guideline recommendations and on local strategies to overcome implementation barriers like e.g. organizational tasks.

References

1. Croft PR, Macfarlane GJ, Papageorgiou AC et al. Outcome of low back pain in general practice: a prospective study. BMJ 1998;316:1356-9
2. Raspe HH, Kohlmann T. The current backache epidemic. [German] Ther Umsch 1994;51:367-74
3. Koes BW, van Tulder MW, Ostelo R et al. Clinical guidelines for the management of low back pain in primary care. An international comparison. Spine 2001;26:2504-14
4. Grimshaw JM, Thomas RE, MacLennan G et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess 2004; 8,1-72
5. Bero LA, Grilli R, Grimshaw JM et al. Closing the gap betwwen research and practice: an overview of systematic reviews of interventions to promote the implementation of research findings. BMJ 1998;317:465-8
6. O`Brien MA, Oxman AD, Davis DA et al. Educational outreach visits: effects on professional practice and health care outcomes. The Cochrane Database of Systematic Reviews 1997, Issue 4. Art. No.: CD000409. DOI: 10.1002/14651858.CD000409
7. Dey P, Simpson CW, Collins SI et al. Implementation of RCGP guidelines for acute low back pain: a cluster randomised controlled trial. Br J Gen Pract 2004;54:33-7
8. Engers AJ, Wensing M, Van Tulder MW et al. Implementation of the Dutch low back pain guideline for general practitioners: a cluster randomized controlled trial. Spine 2005;30:559-600
9. Bekkering GE, van Tulder MW, Hendriks EJM et al. Implementation of clinical guidelines on physical therapy for patients with low back pain: Randomized trial comparing patient outcomes after a standard and active implementation strategy. Phys Ther 2005;85:544-55
10. Worrall G, Chaulk P, Freake D. The effects of clinical practice guidelines on patient outcomes in primary care: a systematic review. CMAJ 1997;156:1705-12
11. van Sluijs EM, van Poppel MN, van Mechelen W. Stage-based lifestyle interventions in primary care: are they effective? Am J Prev Med. 2004;26:330-43
12. Burke BL, Arkowitz H, Menchola M. The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials. J Consult Clin Psaychol. 2003;71:843-61
13. Shye D, Freeborn DK, Romeo J, Eraker S. Understanding physicians´ imaging test use in low back pain care: the role of focus groups. Int J Qual Health Care 1998;10:83-91
14. Streptoe A, Doherty S, Kendrick T et al. Attitudes to cardiovascular health promotion among GPs and practice nurses. Fam Pract 1999;16:158-63

15. Steptoe A, Rink E, Kerry S. Psychosocial predictors of changes in physical activity in overweight sedentary adults following counseling in primary care. Prev Med 2000;31:183-94
16. Little P, Dorward M, Gralton S et al. A randomised controlled trial of three pragmatic approaches to initiate increased physical activity in sedentary patients with risk factors for cardiovascular disease. Br J Gen Pract 2004;54:189-95
17. Gensichen J, Torge M, Peitz M et al. Case management for the treatment of patients with major depression in general practices--rationale, design and conduct of a cluster randomized controlled trial--PRoMPT (Primary care monitoring for depressive Patient's Trial) [ISRCTN66386086]--study protocol. BMC Public Health 2005;5:101
18. Rosemann T, Joest K, Körner T et al. How can the practice nurse be more involved in the care of the chronically ill? The perspectives of GPs, patients and practice nurses. BMC Fam Pract 2006;7:14
19. Becker A, Chenot JF, Niebling W et al. DEGAM Guideline Low Back Pain [German]. Düsseldorf: Omikron Publishing, 2003
20. Henrotin YE, Cedraschi C, Duplan B et al. Information and low back pain management: a systematic review. Spine 2006;31:E 326-34
21. Kohlmann T, Raspe H. Hannover Functional Questionnaire in ambulatory diagnosis of functional disability caused by backache. [German] Rehabilitation 1996;35:I-VIII
22. Roese I, Kohlmann T, Raspe H. Measuring functional capacity in backache patients in rehabilitation: a comparison of standardized questionnaires. Rehabilitation 1996;35:103-8
23. Brooks R and the EuroQol Group. EuroQol: the current state of play. Health Pol 1996;37:53-72
24. Schulenburg JM Graf v d, Claes C, Greiner W, Uber A. The German Version of the EuroQol Questionnaire. [German] Z Gesundheitswiss 1998;6:3-20
25. Waddell G, Newton M, Henderson I et al. A fear-avoidance beliefs questionnaire (FABQ) and the role of fear-avoidance beliefs in low back pain. Pain 1993;52:157-68
26. Pfingsten M. Fear avoidance beliefs in patients with back pain. Psychometric properties of the German version of the FABQ. Schmerz. 2004;18:17-27
27. Frey I, Berg A, Grathwohl D, Keul J. Freiburg Questionnaire of physical activity--development, evaluation and application. [German] Soz Praventiv Med 1999;44:55-64
28. Von Korff M, Ormel J, Keefe FJ et al. Grading the severity of chronic pain. Pain 1992;50:133-49
29. Rütten A, Abu-Omar K. Prevalence of physical activity in the European Union. Soz Praventivmed 2004;49:281-89

30. Van Sluijs JWR, van Poppel MNM, Twisk JWR et al. Physical activity measurements affected participants´ behavior in a randomised controlled trial. J Clin Epidemiol 2006;59:404-11
31. Worrall G, Chaulk P, Freake D. The effects of clinical practice guidelines on patient outcomes in primary care: a systematic review. CMAJ 1997;156:1705-12
32. Cherkin D, Deyo RA, Berg AO. Evaluation of a physician education intervention to improve primary care for low-back pain II. Impact on patients. Spine 1991;16:1173-8
33. McGuirk B, King W, Govind J et al. Safety, efficacy, and cost effectiveness of evidence-based guidelines for the management of acute low back pain in primary care. Spine. 2001;26:2615-22
34. Feuerstein M, Hartzell M, Rogers HL, Marcus SC. Evidence-based practice for acute low back pain in primary care: Patient outcomes and cost of care. Pain 2006;124:140-9
35. Becker A, Leonhardt C, Luckmann J et al. Effectiveness of two quality improvement strategies for management of low back pain in general practice: a randomised controlled trial. Z Allg Med 2006;82:V33 (Abstract)
36. Hillsdon M, Foster C, Thorogood M. Interventions for promoting physical activity. Cochrane Database of Systematic Reviews 2005, Issue 1. Art.No.:CD003180.DOI: 10.1002/14651858.CD003180.pub2
37. Thomas E, Silman AJ, Croft PR et al. Predicting who develops chronic low back pain in primary care : a prospective study. Br Med J 1999;318:1662-7
38. Witt CM, Jena S, Selim D et al. Pragmatic randomized trial evaluating the clinical and economic effectiveness of acupuncture for chronic low back pain. Am J Epidemiol. 2006;164:487-96
39. Clarke SA, Booth L, Velikova G et al. Social support: gender differences in cancer patients in the United Kingdom. Cancer Nurs 2006;29:66-72
40. Macfarlane GJ, Jones GT, Hannaford PC. Managing low back pain presenting to primary care: Where do we go from here? Pain 2006: 122: 219-22

Figure legends

Figure 1: Patient flowchart
Figure 2: Course of functional capacity according to study arm (n=1387 patients)

Table 1: Characteristics of participating GP (n=126)

	n (%)	Missings
Sex	53 (42%) females	0
Mean age: years (s)	48,73 (6,63)	2
Type of practice		1
single	69 (55%)	
Group practice	57 (45%)	
Mean duration of practice	12,4 (7,0)	
Mean number of patients per 3 months		3
Less than 500	5 (4%)	
500-1000	40 (36,3)	
1000-1500	46 (36,5)	
More than 1500	32 (25,4)	

Table 2: Baseline characteristics and drop out analysis (n=1387 patients)

Variables		Guideline implementation	Guideline implementation & motivational counseling	Control (Dissemination only)	Drop Out
Functional capacity	Mean (SD)	67,52 (21.42)	68,74 (20.99)	65,81 (21.90)	66.30 (20.82)
Pain intensity (NRS 0-10)	Mean (SD)	5.32 (2.18)	5.0 (2.05)	5.27 (2.12)	5.21 (2.35)
Acute pain (<=90 days/year)	n(%)	239 (62.3)	233 (59.3)	171 (53.9)	74 (60.7)
Persistent pain (>90 and <=182 days/year, one episode)	n(%)	7 (1.8)	12 (3.1)	9 (2.9)	3 (2.5)
Recurrent pain (>90 and <=182 days/year, more than one episode)	n(%)	28 (7.3)	30 (7.6)	3 (10.4)	6 (4.9)
Chronic pain (>182 days/year)	n(%)	110 (28.6)	118 (30.0)	104 (32.8)	39 (32.0)
Days of pain in the previous year	Mean (SD)	101 (132.02)	103 (123.91)	112 (130.96)	102.46 (128.118)
Chronification Grade[+] Low disability / low intensity	n(%)	101 (29.9)	118 (33.2)	84 (28.9)	31 (27.2)
Low disability / high intensity	n(%)	97 (28.6)	87 (24.4)	74 (25.5)	30 (26.3)
High disability / moderatly limiting	n(%)	90 (26.5)	95 (26.7)	75 (25.9)	24 (21.1)
High disability / severely limiting *	n(%)	51 (15.0)	56 (15.7)	57 (19.7)	29 (25.4) *
Activity (METhours/week) *, outlier corrected [a]	Mean (SD)	25.65 (20.29)	26.97 (19.64)	27.00 (20.22)	26.59 (30.93)
Job satisfaction (NRS 0-10)	Mean (SD)	6.18 (2.33)	6.23 (2.54)	5.85 (2.50)	5.66 (2.60)
Depression score	Mean (SD)	15.02 (9.34)	15.82 (9.50)	15.20 (9.30)	18.56 (10.0)
Fear avoidance believes score Score I * (physical activity = cause for pain)	Mean (SD)	17.45 (6.83)	16.76 (6.69)	18.76 (6.77)	18.17 (6.76)
Score II * (work = cause for pain)	Mean (SD)	13.10 (8.81)	12.91 (8.23)	14.57[+] (8.72)	14.65 (9.09)
Score III * (prognostic job)	Mean (SD)	8.77 (8.36)	8.16 (8.05)	10.02[+] (8.70)	9.19 (9.0)
Quality of life (VAS 0-100)	Mean (SD)	57.19 (19.9)	58.21 (18.87)	55.51 (18.92)	54.49 (18.15)
Days of sick leave	Mean (SD)	6.08 (18.0)	8.10 (26.39)	10.83 (31.63)	9.53 (26.92)

[a] "Winsorizing": values >= 98th percentile were equated to this value

* significant difference between groups a = 0.05

[+] more than 20% missings

[#] significant differences between drop outs and total participants α = 0,05

Table 3: Sociodemographic Characteristics

Variables		Study Arm A (Guideline only)	Study Arm B (Guideline + MC)	Study Arm C (Control Group)	Drop Outs
N (=1378)		479	489	410	167
Age (in years) *	Mean SD Range	49,1 13,3 21 - 83	47,4 13,5 20 - 91	50,2 14,3 20 - 81	48.39 (16.67) 20-85
Gender (N, %) *	male	195 (41)	189 (39)	193 (47)	68 (41.0)
Marital status (N, %)	Single Married Widowed Divorced	62 (14,8) 280 (67,0) 24 (5,7) 52 (12,4)	81 (19,1) 275 (64,7) 26 (6,1) 43 (10,1)	56 (15,4) 250 (68,7) 20 (5,5) 38 (10,4)	38 (30.6)[#] 58 (46.8)[#] 17 (13.7) 11 (8.9)
Living with partner (N, %)	yes	325 (79,5)	317 (76,2)	273 (78,7)	77 (64.2)[#]
Level and years of Education (N, %)	13/12 years 10 years 9 years other graduation No qualification	60 (14,4) 132 (31,7) 174 (41,7) 47 (11,2) 4 (1,0)	69 (16,2) 126 (29,5) 173 (40,5) 57 (13,4) 2 (0,5)	57 (15,7) 104 (28,7) 159 (43,8) 42 (11,6) 1 (0,3)	22 (18.1) 40 (32.8) 57 (46.7) 2 (1.6) 1 (0.8)
Employment status (N, %)	Working full or part-time Keeping house Retired Unemployed Other	263 (63,4) 38 (9,2) 81 (19,5) 19 (4,6) 14 (3,4)	279 (63,4) 47 (11,0) 68 (15,9) 19 (4,5) 22 (5,1)	216 (59,8) 35 (9,7) 79 (21,9) 17 (4,7) 14 (3,8)	70 (41.92) 12 (9.8) 20 (16.4) 10 (8.2) 10 (8.2)
Applied for a pension * (N, %)		37 (9,2)	23 (5,7)	40 (11,8)	9 (8.2)

* significant difference between study arms α = 0,05

significant differences between drop outs and total participants α = 0,05

Figure 1: Patient flowchart

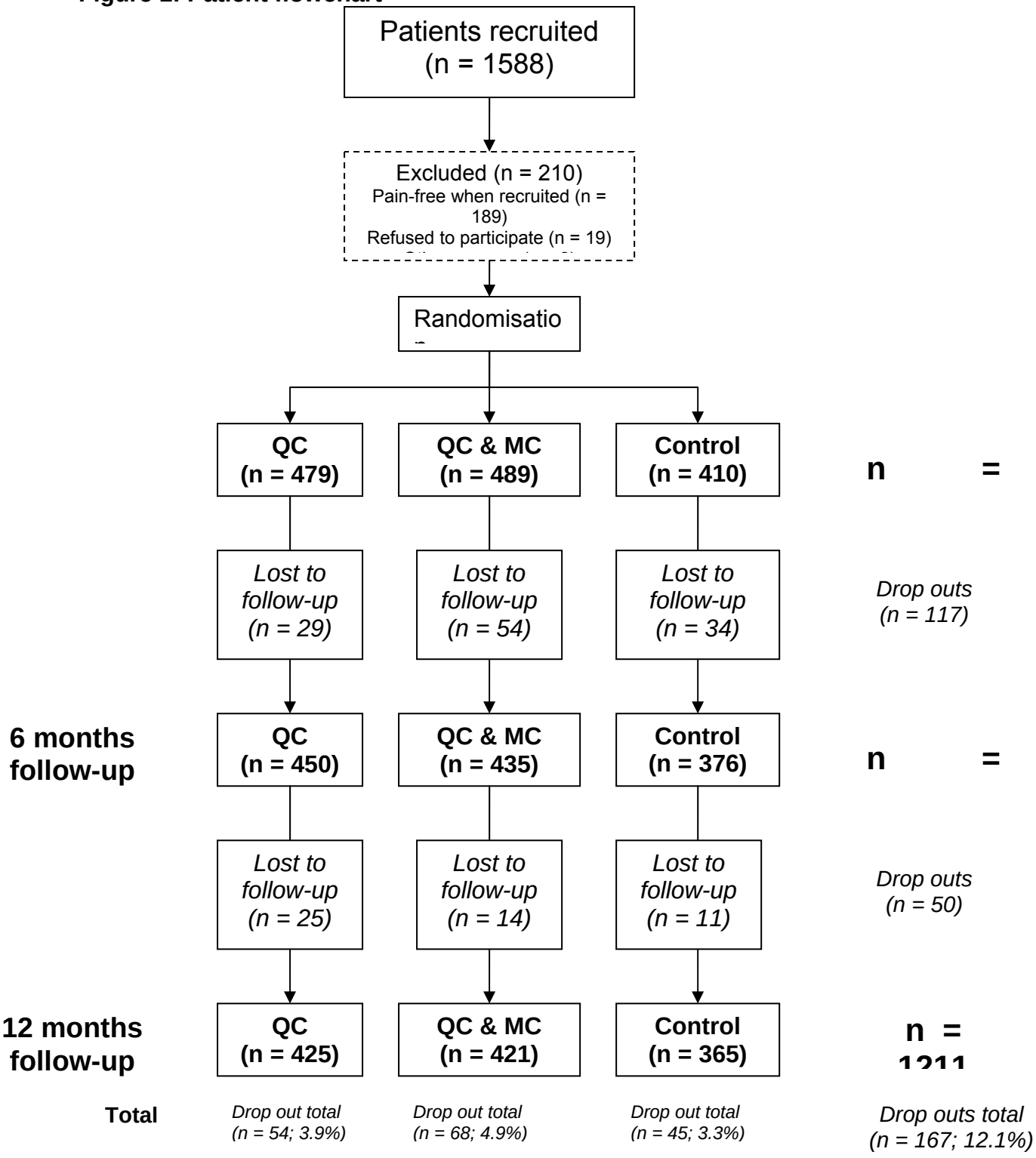

Figure 2: Course of functional capacity according to study arm (n=1387 patients)

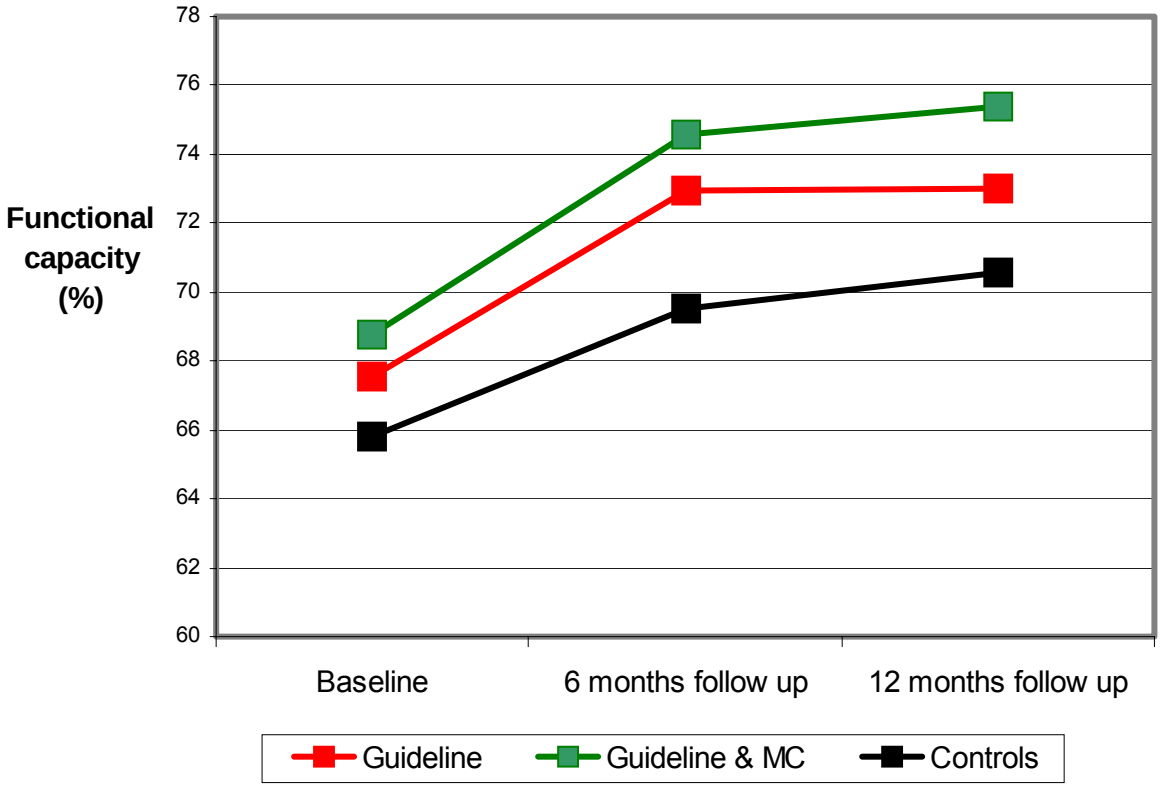

Table 4: Effectiveness of the two implementation strategies. Values shown in the table are adjusted for clustering of data.
Results for primary analysis are shaded.

		6 months			12 months		
			Compared to controls			Compared to controls	
	Study arm	**Mean (CI)**	**Mean difference (95%-CI)**	**p-Value**	**Mean (95%-CI)**	**Mean difference (95%-CI)**	**p-Value**
Functional capacity	GI	72.941 (70.609, 75.273)	2.652 (-0.704, 6.007)	0.120	72.956 (70.433, 75.479)	1.396 (-2.224, 5.017)	0.446
	MC	73.940 (71.646, 76.233)	**3.650 (0.320, 6.979)**	**0.032**	74.637 (72.205, 77.141)	3.113 (-0.470, 6.697)	0.088
	C	70.290 (68.877, 72.702)			71.559 (68.963, 74.156)		
Days in pain	GI	63.345 (57.167, 71.524)	**-16.433 (-26.833, -6.034)**	**0.002**	58.482 (51.217-65.748)	**-12.839 (-23.382, -2.296)**	**0.018**
	MC	62.911 (55.859, 69.963)	**-17.868 (-28.183, -7.553)**	**0.001**	61.567 (54.452, 68.681)	-9.755 (-20.198, -0.689)	0.067
	C	80.779 (73.252, 88.306)			71.321 (63.679, 78.964)		
Overall activity	GI	36.471 (33.309, 39.633)	2.959 (-1.628, 7.545)	0.203	46.429 (43.005, 49.852)	3.546 (-1.452, 8.543)	0.202
	MC	36.294 (33.160, 39.428)	2.781 (-1.784, 7.347)	0.230	45.393 (41.985, 48.801)	2.516 (-2.476, 7.495)	0.396
	C	33.512 (30.192, 36.832)			42.883 (39.244, 46.523)		
Days of sick leave	GI	12.998 (9.856, 16.140)	-1.342 (-5.972, 3.287)	0.569	6.159 (2.453, 9.865)	-3.112 (-8.582, 2.358)	0.256
	MC	13.054 (9.928, 16.179)	-1.287 (-5.905, 3.331)	0.584	6.458 (2.488, 10.428)	-2.813 (-8.463, 2.837)	0.320
	C	14.341 (10.949, 17.733)			9.271 (5.248, 13.294)		
Quality of life	GI	66.592 (64.810, 68.373)	-0.254 (-2.864, 2.355)	0.847	68.456 (66.724, 70.189)	0.804 (-1.736, 3.344)	0.535
	MC	67.535 (65.751, 69.318)	0.689 (-1.924, 3.302)	0.602	70.375 (68.649, 72.100)	**2.723 (0.185, 5.260)**	**0.036**
	C	66.846 (64.939, 68.753)			67.652 (65.794, 69.510)		

Table 5: Mean differences of functional capacity and days in pain after six months between intervention groups and controls, adjusted for clustering of data and gender.

		Women	Men
	Study arm	**Mean difference (95%-CI)**	**Mean difference (95%-CI)**
Functional capacity	GI	2.952 (-1.088, 6.992)	3.038 (-1.384, 7.460)
	MC	**6.098 (2.088, 10.109)**	1.213 (-3.250, 5.675)
Days in pain	GI	**-13.467 (-26.505, -0.430)**	**-20.205 (-33.867, -6.543)**
	MC	**-14.377 (-27.226, -1.528)**	**-23.30 (-37.25, -9.409)**