SPINE Volume 30, Number 6, pp 595–600
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Implementation of the Dutch Low Back Pain Guideline for General Practitioners

A Cluster Randomized Controlled Trial

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Study Design. Cluster randomized controlled trial for a multifaceted implementation strategy.

Objectives. To assess the effectiveness of tailored interventions (multifaceted implementation strategy) to implement the Dutch low back pain guideline for general practitioners with regard to adherence to guideline recommendations.

Summary of Background Data. Guidelines for the management of low back pain in primary care have been developed in various countries, but little is known about the optimal implementation strategy. A multifaceted implementation strategy was developed to overcome identified barriers to the implementation of the Dutch low back pain guideline for general practitioners.

Methods. General practitioners were randomized to an intervention or a control group. The general practitioners in the intervention group ($n = 21$) received tailored interventions consisting of the Dutch low back pain guideline for general practitioners, a 2-hour educational and clinical practice workshop; two scientific articles on low back pain management; the guideline for occupational physicians; a tool for patient education; and a tool for reaching agreement on low back care with physical, exercise, and manual therapists. The control group ($n = 20$) received no intervention. The participating general practitioners were asked to recruit consecutive patients with a new episode of low back pain as the main reason for consultation. General practitioners completed registration forms of each individual consultation with regard to the main outcome measures: advice and information, referral to other health-care providers, and prescription of medication.

Results. Forty-one of the 67 randomized general practitioners reported on a total of 616 consultations for 531 patients with nonspecific low back pain. The advice and explanation provided by the general practitioners, the prescription of paracetamol or nonsteroidal anti-inflammatory drugs, and prescription of pain medication on a time contingent or a pain contingent basis showed no statistically significant differences between the intervention and control groups. There were also no differences in overall referral rate. However, in follow-up consultations fewer patients were referred to a physical or exercise therapist by the general practitioners in the intervention group than in the control group.

Conclusions. The multifaceted intervention strategy modestly improved implementation (for parts of the recommendations in) the Dutch low back pain guideline by general practitioners and produced small concomitant changes in patient management. The implementation strategy produced fewer referrals to therapists during follow-up consultations.

Key words: low back pain, guidelines, implementation, cluster randomized controlled trial, general practitioners, patient education. **Spine 2005;30:595–600**

Guidelines for the management of low back pain in primary care have been developed in various countries.[1–3] The content of the guidelines is very similar across countries.[4,5] The Dutch College of general practitioners (GPs) (NHG) published a low back pain guideline in 1996.[3] A recent study found that Dutch GPs adhere to most but not all of the recommendations to a fair extent.[6] Nonadherence has been found for type of pain medication prescribed; prescription of pain medication on a time-contingent basis; and appropriate referral to a physical, exercise, or manual therapist. Pain medication was prescribed in 53% of the cases, with 41% involving nonsteroidal anti-inflammatory drugs (NSAIDs) and the other 12% involving paracetamol.[6] The Dutch guideline recommends paracetamol as the medication of first choice and NSAIDs as second together with use on a time-contingent basis. In 62% of the cases in which pain medication was prescribed, it was indeed prescribed on a time-contingent basis.[6] Some 22% of patients with acute low back pain (<6 weeks) were referred to a therapist during the first consultation and 50% during follow-up consultation (still in the acute stage) while the Dutch guideline did not recommend referral for such therapy during the acute stage. Reasons for nonadherence to this aspect of the guideline included patients' former experiences and the GP's interpretation of patient preferences.[6] For example, GPs experience greater pressure from patients for referrals during follow-up consultations than during initial consultations. When GPs are asked about why they depart from evidence-based practice, the most

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Supported by the Ministry of Health, The Netherlands.
Acknowledgment date: June 23, 2003. First revision date: February 12, 2004. Acceptance date: April 15, 2004.
The manuscript submitted does not contain information about medical device(s)/drug(s).
No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.
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common reason reported is a reluctance to jeopardize their relationship with the patient.[7]

Adequate patient education is crucial for the management of low back pain.[8] Patients have specific views or beliefs about the cause of their back pain and thus the prognosis for cure and most effective course of treatment. These views and beliefs, however, may not correspond to the care proposed in the guideline. Patients sometimes have a strong preference for a specific intervention with no proven efficacy, for example, which means that GPs must have excellent patient-education skills to convince such patients that the course of treatment recommended in the guideline is indeed most appropriate. Patients expect a specific diagnosis and most of them are therefore not satisfied with the term "nonspecific" low back pain.[9–11] In addition, many patients think that their pain is not being taken seriously when they are simply prescribed paracetamol.[12] Many patients believe that a serious medical condition is causing the pain or that any movement or activity could cause further injury or long-term disability. The provision of adequate information and explicitly addressing patients' concerns therefore constitute a very real challenge for GPs.[12,13]

To address patient-related obstacles to guideline adherence, a multifaceted implementation strategy was developed with specific attention to the following: enhanced patient education skills; improved referral practices for manual, exercise, or physical therapy; increased use of written patient information (pamphlets); and increased knowledge of the Dutch guideline for GPs, other Dutch low back guidelines, and relevant scientific evidence. Because physical therapy is seen as a common therapy for low back pain, attention was paid also to cooperation between the GP and manual, exercise, or physical therapists. The aim of the present study was then to evaluate the effectiveness of this intervention in terms of GPs' prescription of pain medication; referral for manual, exercise, or physical therapy; and adequate provision of information for patients with low back pain.

■ Subjects and Methods

Design. We performed a cluster randomized controlled trial. The ethics committee from the University Medical Center Nijmegen approved the study protocol, and all of the patients and GPs provided their written informed consent.

Participants. A total of 67 GPs expressed their willingness to participate in the study. Before randomization, retrospective data were collected for stratification purposes. The GPs were asked to complete a self-registration form with respect to six patients recently treated in practice for low back pain. The retrospective data were used to stratify the GPs on the basis of the number of referrals to physical therapy within the first 6 weeks of an episode of nonspecific low back pain (high *vs.* low referral rate). Blind treatment allocation was conducted by an independent researcher with no information on the GPs, using a computer-generated random list of numbers: 34 GPs were allocated to the intervention group and 33 to the control group. Our sample size calculation was based on a power of 0.8 to detect a 15% difference (35%–20%) in the primary outcome, which is referral to a physical, exercise or to a manual therapist for patients with acute low back pain ($\alpha = 0.05$, intra cluster correlation = 0.05). This required 10 patients per GP.

The participating GPs were asked to recruit consecutive patients with a new episode of low back pain as the main reason for consultation. Low back pain was defined as pain, discomfort, stiffness, or fatigue between the lower edge of the shoulder blades and the gluteal fold either with or without radiation to the legs. Patients who were pregnant, younger than 16 years of age, or not familiar with the Dutch language were excluded. Only patients who were diagnosed with "nonspecific low back pain" and no "red flags" present were included in the analyses.

Data Collection. The data were collected from August 2000 through April 2001. The GPs were asked to prospectively complete self-registration forms shortly after the first consultations for all patients presenting with a new episode of low back pain during the study period. When the same patient returned for a follow-up consultation with regard to the same episode of low back pain within the period of study, the GP was asked to complete an additional form. Information was collected on the following: diagnosis, prescription or advice with regard to medication, recommendation of bed rest or exercise, ordering of additional imaging tests, and referral to other health-care providers. The information on patient characteristics was collected by giving the patient a questionnaire to be completed immediately after the consultation and was returned directly to the researchers. The relevant patient characteristics were pain duration, number of recurrences in the past year, severity of the back and/or leg pain (rated along a 5-point Likert scale ranging from "no trouble" to "very much trouble"), absence from work during the previous 4 weeks (number of days), and functional disability (Roland Morris Disability Questionnaire).[14]

Intervention. The intervention was designed to overcome certain barriers to adherence to the guidelines. Given that multifaceted interventions have been shown to be more effective than single interventions,[15–18] the intervention included the following facets: a two-hour workshop; distribution of a half-page patient-education card; distribution of the guideline for occupational physicians[19]; distribution of two scientific articles concerning GP management of nonspecific low back pain[6,20]; and distribution of a tool to facilitate greater agreement with physical, exercise, and manual therapists on the management of nonspecific low back pain (*i.e.*, "collaboration tool").

The focus of the workshop was on the building of the necessary skills for effective communication with patients including clear acknowledgment of their feelings, cognitions, and expectations. The workshop also addressed the skills needed for successful negotiation under situations of marked disagreement (*e.g.*, when the patient requests a referral or medication that the GP considers inappropriate). In addition, information on the content of the Dutch guideline for low back pain for GPs (*NHG standaard lage rugpijn*)[3] and information on the need to prescribe pain medication on a time-contingent basis was provided. Finally, the skills needed to stimulate activity on the part of the patient and address those feelings and cognitions that may keep them from undertaking such activity were considered in the training session. A trained psychologist-physiotherapist (A. E.) with extensive experience in the domain of managing lower back pain patients within a variety of settings provided

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the training. An actor played the role of a patient with low back pain in three different situations of increasing physician-patient interaction difficulty. The workshops were conducted with groups of three to eight GPs and undertaken before the start of prospective measurement.

The GPs were also stimulated to use the written pamphlets and patient letters developed by the Dutch College of GPs for the education of patients with low back pain. Furthermore, the GPs were encouraged to use a half-page laminated card with a drawing of the muscles of the back on one side and an abstract from the guideline for the treatment of low back pain on the other side during consultations to facilitate the provision of information and advice. This "muscle card" was developed to illustrate the large number of muscles in the back and emphasize the importance of becoming and staying active as the best treatment for back pain. The card also briefly summarizes the main topics of the guideline and can therefore serve as a reminder.

To facilitate GPs to come to agreements on low back management with physical, manual, or exercise therapists, a tool was designed. This collaboration-tool was a step by step instruction and a checklist concerning potential agreements and disagreements concerning statements of the Dutch guideline for general practitioners to come to agreements on low back management.

The two articles[6,20] and the low back pain guideline for occupational physicians[19] were sent by mail 4 weeks after the training session to provide more background information and to remind participants of the topics addressed in the workshop.

The control group received no intervention, and the patients were therefore labeled as "usual care." Both the intervention and control groups had the Dutch low back pain guideline for GPs at their disposal because the guideline was published and circulated to the members of the Dutch College of GPs in 1996.

Effect Measures. The outcome measures used to assess adherence with the guideline recommendations were 1) number of referrals to a therapist (physical, exercise, or manual therapist); 2) prescription of pain medication on a time-contingent basis; 3) prescription of paracetamol *versus* NSAIDs; and 4) adequacy of patient education. The intervention was expected to foster a lower number of referrals to a physical, exercise, or manual therapist; greater prescription of pain medication on a time-contingent basis (when prescribed); increased prescription of paracetamol and decreased prescription of NSAIDs; and provision of more adequate patient information.

Data Analysis. Data were analyzed on an intention-to-treat basis. To detect any significant differences between the GPs and the patients in the two groups, χ^2 tests ($\alpha = 0{,}05$) were applied. Outcome measures were compared along with a number of other variables including age, sex, duration of the current episode (<12 weeks or $\geq$ 12 weeks), and first *versus* follow-up consultation. The duration of the current episode was defined as the number of weeks from self-reported onset until the moment of consultation. The effect of the intervention was evaluated on the basis of the between group difference for the postintervention scores corrected for the baseline scores and the clustering within practices in multilevel logistic regression analyses for the binary variables and multilevel linear regression analyses for the continuous variables.

Given that previous research showed a steep increase in the number of referrals to a physical, exercise, or manual therapist at follow-up consultation when compared with the number of such referrals during initial consultation for lower back pain, subgroup analyses for the follow-up consultations were planned.

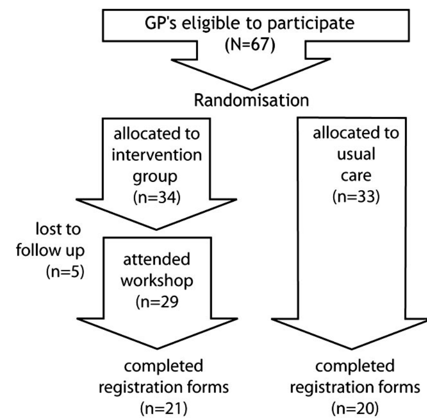

Figure 1. GPs who returned postconsultation forms.

Results

Of the 67 GPs included in the study, a total of 41 returned one or more postconsultation forms (response rate of 61%). Of the 34 GPs allocated to the intervention group, 29 attended the workshop and 21 of these returned one or more postconsultation forms (see Figure 1). Of the 33 GPs allocated to the control group, 20 returned one or more postconsultation forms. The reason for drop-out was in all cases a "lack of time." There were no differences between the drop-outs and participants with respect to sex, age, number of years of education, number of years in practice, urbanization grade, practice setting (solo *vs.* group), or the number of patients in the practice.

There were no differences in baseline characteristics among GPs in the intervention and control group (see Table 1).

A total of 616 consultations for 531 patients with nonspecific low back pain were reported on by 41 GPs from 40 practices. Patient characteristics of the interven-

Table 1. Distribution of Characteristics of GPs

Characteristics	Intervention Group	Control Group
GPs	n = 21	n = 20
Men	71% (15)	75% (15)
Age (years):		
≥30–39	0% (0)	15% (3)
≥40–49	67% (14)	70% (14)
≥50	33% (7)	15% (3)
No. of doctors in clinic		
Solo	62% (13)	45% (9)
Duo	24% (5)	10% (2)
Group	14% (3)	45% (9)
Urbanization grade		
Small village	19% (4)	25% (5)
Large village	29% (6)	40% (8)
Small town	29% (6)	10% (2)
Large town	19% (4)	25% (5)

Note: Values are percentages (numbers) unless otherwise stated.

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Table 2. Distribution of Characteristics of Patients

Characteristics	Intervention Group	Control Group
Patients	n = 276	n = 255
Men	48% (131)	46% (115)
Age (years):		
≥16–29	16% (44)	22% (55)
≥30–39	22% (59)	23% (57)
≥40–49	25% (69)	25% (62)
≥50–59	21% (57)	19% (48)
≥60	16% (44)	12% (30)
Pain duration		
<12 wk	90% (247)	86% (220)
No. of recurrences in past 12 mo		
≤2	86% (238)	85% (216)
Severity of back pain * (mean; SD)	2.75 (0.91)	2.79 (0.87)
Severity of leg pain * (mean; SD)	1.30 (1.30)	1.32 (1.34)
Days absent from work in former 4 wk (mean; SD)	4.07 (7.42)	3.25 (4.55)
Days not functional in former 4 wk	4.24 (5.00)	3.69 (4.75)
Roland Disability Questionnaire score (mean; SD)	12.66 (5.32)	13.22 (5.23)

Note: Values are percentages (numbers) unless otherwise stated.
* 5-point Likert scale.

tion and the control group on inclusion were comparable (see Table 2). In sum, 18 (4%) of the patients had suffered more than two episodes of back pain during the past 12 months. Of the 616 consultations, 522 (85%) concerned acute low back pain (<12 weeks) and 40 (6%) concerned chronic low back pain (≥12 weeks), with 9% missing data. Of the 616 consultations, 531 (86%) concerned initial consultation for an episode and 85 (14%) concerned follow-up consultation.

The two distributed articles were read by 11 (52%) of the 21 GPs in the intervention group and rated as "informative" by 8 of them. Five (24%) of the GPs in the intervention group read the guideline for occupational physicians, and two rated it as informative; five (24%) read the collaboration tool and 2 rated it as informative; and eight (38%) of the GPs in the intervention group stated that they used the muscle card during consultations. Two GPs (10%), who were both from the intervention group, contacted physical, manual, or exercise therapists to agree on the management of low back pain.

The results concerning the management of low back pain for the intervention and control groups are presented in Table 3. The advice and explanation provided by the general practitioners, the prescription of paracetamol or NSAIDs, and the prescription of pain medication on a time contingent or a pain contingent basis showed no statistically significant differences between the intervention and control groups. The overall number of referrals to a physical, exercise, or manual therapist did not differ for the intervention *versus* control groups (20% *vs.* 21%, respectively). However, for the follow-up consultations, significantly fewer patients in the intervention group were referred to such a therapist than in the control group (36% *vs.* 76%, respectively; odds ratio of 0.2 (95% CI, 0.1–0.6)).

The results for the provision of information to the patient are presented in Table 4. Although the GPs in the intervention group tended to provide more adequate information and advice than the GPs in the control group, the differences between the groups did not prove statistically significant.

Discussion

The multifaceted intervention designed to address certain barriers to the implementation of the Dutch guideline for low back pain for GPs was found to have minimal impact with regard to patient education, referral to a therapist, and prescription of pain medication. Although the GPs studied here were already found to adhere to the guidelines to a fair extent and thus confirm the results of previous research showing GPs in the Netherlands to act largely in accordance with the Dutch low back pain guideline,[6] we were able to further reduce the number of inappropriate referrals to physical, exercise or to manual therapy during follow-up consultations. The findings show the GPs in the intervention group to perform slightly better or, in other words, more in line with the recommendations provided by the guideline than the GPs in the control group.

All GPs in the intervention group read the guideline. However, only 24 to 52% also read the additional materials: the occupational guideline and two scientific ar-

Table 3. Effect of Intervention on Low Back Pain Management Behavior of GPs per Consultation

	All Consultations (n = 616)			Follow-up Consultations Only (n = 85)		
	Intervention group (n = 328)	Control group (n = 288)	Odds Ratios (95% CI)	Intervention group (n = 52)	Control group (n = 33)	Odds Ratios (95% CI)
Referral to a therapist	23% (75)	28% (79)	0.8 (0.5–1.4)	36% (19)	76% (25)*	0.2 (0.1–0.6)
Prescription of pain medication	60% (198)	65% (188)	0.9 (0.5–1.6)	60% (31)	42% (14)	2.0 (0.6–6.3)
Pain contingent	30% (59)	31% (58)		38% (12)	29% (4)	
Time contingent	70% (139)	69% (130)	1.0 (0.3–3.0)	62% (19)	71% (10)	0.7 (0.1–4.3)
Paracetamol	33% (65)	21% (39)	2.0 (0.8–5.5)	23% (7)	7% (1)	4.8 (0.1–181.2)
NSAIDs	54% (107)	62% (117)		61% (19)	71% (10)	
Something else	7% (14)	4% (8)		0%	21% (3)	
Not known/missing	6% (12)	13% (24)		16% (5)	0%	

Note: Values are percentages (no.).
* Significant difference between intervention and control groups, $P \leq 0.05$.

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Table 4. Information Provided to Patients by GPs per Consultation Based on Self-Reports by GPs

	All Consultations (n = 616)			Follow-up Consultations Only (n = 85)		
General information	Intervention Group (n = 328)	Control Group (n = 288)	OR (95%CI)	Intervention Group (n = 52)	Control Group (n = 33)	OR (95%CI)
Explained that no specific cause could be detected	74% (214)	83% (238)	0.6 (0.3–1.3)	64% (33)	67% (22)	0.9 (0.3–2.8)
Explained that back pain will ease by itself	84% (274)	86% (246)	1.1 (0.4–2.5)	69% (36)	70% (23)	0.9 (0.3–3.1)
Explained that there is no harm	83% (270)	74% (212)	1.5 (0.6–3.9)	85% (44)	61% (20)	3.0 (0.6–16.3)
Explained that it is better to accept the pain	64% (209)	63% (180)	1.1 (0.2–5.4)	56% (29)	52% (17)	1.7 (0.2–13.3)
Handed out an information pamphlet	37% (121)	38% (110)	0.9 (0.7–1.3)	21% (11)	12% (4)	1.6 (0.4–7.8)
Activating Information						
Advised to stay active	95% (312)	89% (257)	1.9 (0.7–5.0)	81% (42)	49% (16)	1.7 (0.3–9.0)
Advised to gradually increase activity	78% (256)	66% (188)	2.9 (0.8–10.9)	87% (45)	58% (19)	3.3 (0.7–17.0)
Advised which activities to increase at what moment	18% (58)	9% (26)	2.2 (0.7–6.4)	21% (11)	16% (5)	2.1 (0.7–11.5)
Advised to stop with activity when in pain	26% (86)	29% (83)	0.4 (0.1–1.5)	17% (9)	21% (7)	0.4 (0.0–4.0)

Note: Values are percentages (no.).

ticles on back pain. This additional material was used as background information to provide information on the evidence basis of the guideline and to stimulate collaboration with occupational physicians. The low adherence of the GPs to read this additional material will not have had a major impact on the results of this trial, because these aspects were also extensively discussed during the workshop. Future implementation strategies should include activities to improve adherence of additional materials, for example by providing feedback.

Another study reported a steep increase in the number of referrals to a physical, manual, or exercise therapist from the first consultation for an episode of low back pain (22%) to the second consultation for the same episode (50%).[6] We found an even larger increase in the control group in our study. The higher referral rate in follow-up consultations can be hypothesized to be attributable to a lack of appropriate patient education skills of GPs. The significant lower referral rate in follow-up consultations in our experimental group seems to support this hypothesis.

The type of pain medication prescribed by the GPs in the intervention *versus* control groups almost differed significantly. The GPs in the intervention group tended to prescribe paracetamol more often after intervention than the GPs in the control group and NSAIDs less often after intervention than the GPs in the control group. No difference was found for the prescription of medication on a time-contingent basis. Time contingency stands in contrast to pain contingency, which is associated with pain behavior and thereby chronicity. Along these lines, recommending that a patient *not* be guided by pain and *not* stop all activity when in pain appears to be critical.

The information and advice provided by the GPs in both the intervention and control groups was largely in keeping with the recommendations contained in the guideline. When compared with the control group, however, the GPs in the intervention group explained slightly more often that there was no harm in movement despite the back pain being experienced and that becoming more active and/or staying active on a time-contingent basis was highly recommended and effective. This advice is in line with current medical opinion and scientific research on how to prevent chronicity.[5,21] Explicit recommendation to gradually increase activity was generally provided more often by the intervention group than by the control group (78% *vs.* 66%) with the difference reaching significance for the follow-up consultations.

The present study also has some limitations. Those GPs who agreed to participate may be particularly responsible, interested, and dedicated, which means that the results for the control group reflect good as opposed to average usual care.

Although we asked the GPs to include all consecutive patients with a new episode of low back pain during the inclusion period of 9 months, there may have been a selection bias. Not all patients may have been included and those who were not included may have been the more "difficult" patients. We do not have any information on patients who were not included in the trial. However, if difficult patients were excluded, results would likely be more positive. We don't find a statistically significant effect in favor of the intervention group and consequently believe that selection bias did not play a major role. Also, another study on low back pain in general practice in the Netherlands showed inclusion of 15 patients in a period of 9 months compared with 13 in our trial.[22]

Yet another possible limitation is the use of a self-report measure. Although the physicians were assured of anonymity and asked to report their actual behavior regarding actual patients, their answers may nevertheless reflect an idealized version of their behavior. In other words, the results of the present study may underestimate the frequency of behavior that is not in keeping with the recommendations provided in the guideline.

Also there was a high drop-out rate among GPs in our study. Forty-one of the GPs who had agreed to partici-

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pate and were randomized to one of the two groups completed registration forms. All GPs reported lack of time as reason for dropping out. Although this low participation rate may have introduced a bias, we believe that this effect is limited because there were no differences in drop-out rates between groups, no differences in reason for drop-out, and no differences in baseline characteristics between GPs who participated and the drop-outs.

Despite these limitations, the present results show a brief, multifaceted intervention to slightly modify the management behavior of GPs and thereby medical consumption. It is possible that more intensive intervention repeated on several occasions may further reduce the number of referrals to physical therapy and improve patient education. However, the GPs in the control group also performed well, which raises the question whether further improvement should be called for. In other words, the effects of the use of a multifaceted strategy for the implementation of the Dutch low back pain guideline for GPs were probably small because the management behavior of the GPs studied here was already largely in keeping with the guideline. Perhaps in situations where adherence to the clinical guidelines is known to be limited, a multifaceted intervention will have a more pronounced effect.

■ Key Points

- Implementation of the Dutch low back pain guideline for general practitioners was evaluated in a randomized controlled trial.
- Forty-one general practitioners reported on a total of 616 consultations for 531 patients with nonspecific low back pain.
- Dutch general practitioners adhere to the low back pain guideline to a fair extent.
- The implementation strategy produced fewer referrals to therapists during follow-up consultations.
- The implementation strategy did not lead to more adequate provision of information to patients.

Acknowledgements

The authors thank the general practitioners who gave time to participate in this study. We also thank Reinier Ackermans for assistance with the multilevel analysis.

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