

Agnes J Smink, Cornelia HM van den Ende, Thea PM Vliet Vlieland, Johannes WJ Bijlsma, Bart A Swierstra, Joke H Kortland, Theo B Voorn, Steven Teerenstra, Henk J Schers, Joost Dekker, Sita MA Bierma-Zeinstra

## Effect of stepped care on health outcomes in patients with osteoarthritis:

an observational study in Dutch general practice

### Abstract

#### Background

A stepped care strategy (SCS) to improve adequate healthcare use in patients with osteoarthritis was developed and implemented in a primary care region in the Netherlands.

#### Aim

To assess the association between care that is in line with the SCS recommendations and health outcomes.

#### Design and setting

Data were used from a 2-year observational study of 313 patients who had consulted their GP because of osteoarthritis.

#### Method

Care was considered 'SCS-consistent' if all advised modalities of the previous steps of the SCS were offered before more advanced modalities of subsequent steps. Pain and physical function were measured with the Western Ontario and McMaster Universities Osteoarthritis Index (range 0–100); active pain coping with the Pain Coping Inventory (range 10–40); and self-efficacy with the Dutch General Self-Efficacy Scale (range 12–48). Crude and adjusted associations between SCS-consistent care and outcomes were estimated with generalised estimating equations.

#### Results

No statistically significant differences were found in changes over a 2-year period in pain and physical function between patients who received SCS-inconsistent care ( $n = 163$ ) and patients who received SCS-consistent care ( $n = 117$ ). This was also the case after adjusting for possible confounders, that is,  $-4.3$  [95% confidence interval (CI) =  $-10.3$  to  $1.7$ ] and  $-1.9$  [95% CI =  $-7.0$  to  $3.1$ ], respectively. Furthermore, no differences were found in changes over time between groups in self-efficacy and pain coping.

#### Conclusion

The results raised several important issues that need to be considered regarding the value of the SCS, such as the reasons that GPs provide SCS-inconsistent care, the long-term effects of the SCS, and the effects on costs and side effects.

#### Keywords

general practice; osteoarthritis; outcome of care; stepped care strategy.

### INTRODUCTION

A multidisciplinary stepped care strategy (SCS), named Beating osteoARthritis, was developed to improve the non-surgical care of patients with hip or knee osteoarthritis (OA).<sup>1</sup> This strategy aims to support GPs and patients to achieve high-quality care by presenting the optimal sequence for care in three steps. In each step, it provides recommendations about diagnostic procedures, non-surgical treatment modalities, and length of treatment before evaluation. The SCS considers care as 'optimal' if all modalities of the previous steps have been offered to the patient before the more advanced modalities of the subsequent steps. The first step includes modalities (such as education, lifestyle advice, and paracetamol) that should be offered to all patients or can be provided through self-care. The second and third steps include more advanced modalities (such as, physical therapy, dietary therapy, and intra-articular injections) that can be provided if the previous options have failed.

A regional 2-year observational study was conducted to evaluate the implementation on a limited scale in primary care. Until now, little evidence exists that a SCS approach in OA results in improved health outcomes.

Porcheret *et al*<sup>2</sup> developed a similar stepped care model for older adults with knee pain, but the added value of this model has not been evaluated yet in primary care. However, the added value of a stepped care approach has been demonstrated in other fields, such as in the prevention of depression and anxiety.<sup>3,4</sup> Also, a stepped care intervention programme showed positive effects on the outcome of care in depressed older people, which were better physical function and enhanced quality of life,<sup>5</sup> and the cost-effectiveness of a stepped care programme has been established in people with a depressive disorder in primary care.<sup>6,7</sup>

In line with those findings, it was assumed that implementation of the SCS in primary care would improve adequate healthcare use and, ultimately, health outcomes. SCS-consistent care would be expected to be associated with less pain and better physical function over time. The SCS explicitly recommends the use of treatment strategies that improve self-management, thus it was also expected that SCS-consistent care would be related to more adequate self-efficacy and development of a more active coping style. This study examined the association between SCS-

**AJ Smink**, MSc, PhD; **CHM van den Ende**, PhD, Department of Rheumatology; **BA Swierstra**, PhD, MD, Department of Orthopaedics, Sint Maartenskliniek, Nijmegen, the Netherlands. **TPM Vliet Vlieland**, professor, Departments of Rheumatology and Orthopaedics, Leiden University Medical Center, Leiden, the Netherlands. **JWJ Bijlsma**, MD, professor, Department of Rheumatology and Clinical Immunology, University Medical Center, Utrecht, the Netherlands. **JH Kortland**, MSc, Dutch Patient Organization for Rheumatic Diseases, Amersfoort, the Netherlands. **TB Voorn**, MD, professor; **HJ Schers**, PhD, MD, Department of Primary and Community Care; **S Teerenstra**, PhD, Department for Health Evidence, Radboud University Nijmegen Medical Center, Nijmegen, the Netherlands. **J Dekker**, professor, Department of Rehabilitation

Medicine, VU University Medical Center, Amsterdam, the Netherlands. **SMA Bierma-Zeinstra**, professor, Departments of General Practice and Orthopaedics, Erasmus University Medical Center, Rotterdam, the Netherlands.

#### Address for correspondence

Agnes J Smink, Department of Rheumatology, Sint Maartenskliniek, PO Box 9011, 6500 GM Nijmegen, the Netherlands.

**E-mail:** a.j.smink@gmail.com

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## How this fits in

A stepped care strategy (SCS) was developed to improve the management of hip and knee osteoarthritis. It was assumed that implementation of this strategy in primary care would ultimately improve patients' health outcomes. This study describes the changes in different health outcomes in patients with hip or knee osteoarthritis after its implementation in clinical practice. Although the study could not demonstrate that SCS-consistent care results are associated with better health outcomes at 2 years after implementation, the results raise several important issues that need to be considered when implementing the SCS in clinical practice, and further research is advised regarding the additional value of the SCS.

consistent care in primary care and health outcomes in the treatment of hip or knee OA, that is, pain, physical function, self-efficacy, and active pain coping.

## METHOD

### Design and setting

Data were used from a 2-year observational prospective cohort study that was carried out from August 2010 to March 2013 in the region of Nijmegen in the Netherlands. In this cohort study, GPs recruited consecutive patients during a consultation or sent a letter after a recent consultation. After giving informed consent, patients received five questionnaires over a 2-year period. Several activities were developed and carried out that were directed at different healthcare providers and patients to implement the SCS. Patients received educational materials and tools to enhance self-management in the form of a booklet (*Care for Osteoarthritis*, in Dutch)<sup>8</sup>, were instructed about the use of this booklet, and received reminder materials. GPs received educational outreach visits, education and reminder materials, and were invited for a multidisciplinary seminar. The implementation strategy was described in a previous manuscript in more detail.<sup>9</sup>

### Study population

GPs of the Nijmegen University Network of General Practitioners were invited to participate in this study, which meant a total of 157 GPs working in 70 general practices. In addition, six practices outside this network were also approached. Patients were eligible if they visited their GP for a new episode of hip or knee complaints caused by symptomatic hip or knee OA, had

not visited their GP for the same episode during the preceding 3 months, and were aged  $\geq 18$  years. Exclusion criteria were a joint replacement of the hip or knee, being on the waiting list for a joint replacement, or an inability to complete the questionnaire because of a language barrier or terminal illness.

### Outcomes

Pain and physical function were assessed at baseline, after 6 ( $T_6$ ), 12 ( $T_{12}$ ), 18 ( $T_{18}$ ), and 24 months ( $T_{24}$ ) with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>10</sup> Standardised scores, ranging from 0 to 100, were used, where higher scores reflect better health status. Self-efficacy and active pain coping were assessed at baseline,  $T_{12}$ , and  $T_{24}$  with the Dutch General Self-Efficacy Scale<sup>11</sup> and Pain Coping Inventory,<sup>12</sup> respectively. Higher scores on the Dutch General Self-Efficacy Scale, ranging from 10 to 40, reflect higher self-efficacy. Higher scores on the subscales for active coping, ranging from 12 to 48, indicate greater use of an active coping style.

Healthcare use was assessed at baseline,  $T_6$ ,  $T_{12}$ ,  $T_{18}$ , and  $T_{24}$  by asking the patient which treatment modalities they had used in the preceding 6-month period related to their hip or knee symptoms. The list of modalities was based on the recommended modalities of the SCS. For each modality, the cumulative percentage 'users' was calculated. The patient was considered as a user if he or she reported having used that particular modality in one of the preceding time periods. If more than 30% of the items (that is, values on two or more time periods) were missing, the scores were treated as missing. Furthermore, referral to a dietician was only considered applicable in overweight patients (that is, if their body mass index was above 25 kg/m<sup>2</sup>).

### SCS-consistent care regarding the sequence for non-surgical treatment

The recommended treatment modalities of the steps of the SCS are as follows:

- Step 1: education, lifestyle advice, paracetamol, and glucosamine sulphate.
- Step 2: physical therapy, dietary therapy (if overweight), non-steroidal anti-inflammatory drugs, and tramadol.
- Step 3: optional modalities such as multidisciplinary care, intra-articular injections, and transcutaneous electrical nerve stimulation.

The SCS recommends that the more advanced treatment modalities should only

be advised and/or provided if the modalities of the previous steps have failed to produce satisfactory results. In other words, patients should first have received all advised step-1 modalities before receiving any step-2 modality. Likewise, the patient should have received all advised step-2 modalities before receiving any step-3 modality. Even more, the SCS recommends that education and lifestyle advice are given to every patient with hip or knee OA. Based on these SCS recommendations, the variable 'SCS-consistent care' (yes/no) was constructed. Care was considered 'consistent with the SCS' if the patient received:

- at least education and lifestyle advice during the study period; AND
- all advised step-1 modalities prior to any step-2 modality, if applicable; AND
- all advised step-1 and step-2 modalities prior to any step 3 modality, if applicable.

#### Potential confounders

In the authors' previous study,<sup>9</sup> determinants of SCS-consistent care were identified that

were selected for this study as potential confounding variables. These were the number of comorbidities, having additional insurance coverage, the number of painful joints, GP's sex, and GP's attitude regarding the effectiveness of non-recommended non-surgical treatment modalities. In addition, variables were considered with statistical differences at baseline between patients who received SCS-consistent care (SCS-consistent group) and patients who received SCS-inconsistent care (SCS-inconsistent group) as potential confounding variables.

#### Statistical analysis

This study was originally powered to estimate the prevalence of patients who were provided SCS-consistent care with a maximal error margin of 6%. Allowing 10% loss to follow-up, a minimal sample of 297 patients was necessary. Differences between groups were analysed using the  $\chi^2$  test and the *t*-test or Mann-Whitney U test when appropriate. Changes over time in the four outcome measures were assessed with paired *t*-tests. To determine the association between SCS-consistent care and the health outcome measures, crude and adjusted models were estimated with generalised estimating equations analysis. This analysis enables correction for within-group correlations. For this analysis, missing data were imputed using switching regression, which is an iterative multivariable regression technique, to preserve power and obtain less biased results.<sup>13</sup> The reasons for missing data were unknown. The results are presented in beta-estimates and 95% confidence intervals (CI), which can be interpreted as the absolute difference between the SCS-consistent group and the SCS-inconsistent group. Statistical analyses were executed using STATA/IC software (version 10.1).

## RESULTS

### Study population

Seventy GPs from 38 different general practices agreed to participate. The participating GPs selected 528 patients eligible for the study. Of these patients, 83 patients (16%) were excluded by one of the researchers because they did not meet the eligibility criteria. Another 132 patients (25%) did not participate because they were not interested ( $n = 76$ ), reported another reason not to participate ( $n = 8$ ), or gave no reason ( $n = 48$ ). Finally, 313 patients were included, of whom 29 (9%) were lost to follow-up, leaving a total of 284 patients. Of these, in 280 patients it could be determined whether they received SCS consistent care or not.

**Table 1. Baseline characteristics of patients with hip or knee osteoarthritis**

Baseline characteristics	SCS-inconsistent (n = 163)	SCS-consistent (n = 117)	P-value
<b>Predisposing factors</b>			
Age, years, mean (SD)	65 (10)	62 (10)	0.05 <sup>a</sup>
Sex, male, n (%)	62 (38)	43 (37)	0.83
Overweight, BMI > 25 kg/m <sup>2</sup> , n (%)	117 (73)	75 (65)	0.19
Number of comorbidities (range 0–15), median (IQR)	1.2 (1.0–1.7)	1.0 (0.0–1.4)	0.04 <sup>a</sup>
Education, higher education, n (%)	22 (19)	15 (22)	0.65
Employed, paid work, n (%)	45 (28)	40 (34)	0.25
Self-efficacy (range 10–40), <sup>b</sup> mean (SD)	31 (5)	31 (6)	0.69
Active pain coping (range 0–48), <sup>c</sup> mean (SD)	26 (6)	26 (6)	0.61
<b>Enabling factors</b>			
Health insurance, with additional coverage, n (%)	143 (88)	109 (95)	0.05 <sup>a</sup>
Household composition, with partner, n (%)	118 (72)	94 (80)	0.08
Residence, rural, n (%)	104 (64)	76 (65)	0.90
<b>Disease-related factors</b>			
Location, n (%)			
Hip	80 (49)	63 (54)	0.43
Knee	130 (80)	87 (74)	0.29
Number of painful joints (range 0–9), median (IQR)	1.3 (1.0–1.7)	1.1 (1.0–1.4)	0.02 <sup>a</sup>
Duration of symptoms > 1 year, n (%)	131 (80)	88 (76)	0.37
WOMAC pain (range 0–100), <sup>d</sup> mean (SD)	61 (23)	63 (22)	0.42
WOMAC physical function (range 0–100), <sup>d</sup> mean (SD)	63 (22)	66 (20)	0.30

<sup>a</sup>Statistically significant. Baseline characteristics are divided into patients who received care consistent with the recommendations of the SCS (that is, SCS-consistent care) and those who received inconsistent care (that is, SCS-inconsistent care). <sup>b</sup>Higher scores reflect higher self-efficacy. <sup>c</sup>Higher score indicates more use of an active coping style. <sup>d</sup>Standardised scores were used where higher scores reflect better health status. BMI = body mass index. IQR = interquartile range. OA = osteoarthritis. SCS = stepped care strategy. SD = standard deviation. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

**Table 2. Cumulative healthcare use by patients with hip or knee osteoarthritis who received SCS-inconsistent or SCS-consistent care in the 2 years after a new complaint**

Treatment modalities	SCS-inconsistent (n= 163) n(%)		SCS-consistent (n= 117) n(%)		P-value
<b>Non-surgical modalities</b>					
<b>Step-1 modalities, as recommended in the SCS</b>					
Education	113	(69)	117	(100)	<0.01 <sup>b</sup>
Lifestyle advice	84	(52)	117	(100)	<0.01 <sup>b</sup>
Paracetamol	126	(78)	102	(87)	0.05 <sup>b</sup>
Glucosamine sulphate	48	(30)	43	(38)	0.18
<b>Step-2 modalities, as recommended in the SCS</b>					
Exercise therapy	92	(56)	81	(70)	0.02 <sup>b</sup>
NSAIDs (oral or topical)	82	(50)	64	(55)	0.42
Tramadol	24	(15)	15	(13)	0.70
Dietary therapy <sup>a</sup>	10	(6)	17	(15)	0.02 <sup>b</sup>
<b>Step-3 modalities, as recommended in the SCS</b>					
Multidisciplinary care	16	(10)	6	(5)	0.16
Intra-articular injections	46	(28)	15	(13)	<0.01 <sup>b</sup>
TENS	5	(3)	1	(1)	0.22
Referral to rheumatologist	26	(16)	14	(12)	0.37
Referral to orthopaedic surgeon	71	(44)	53	(46)	0.79
<b>Surgical modalities</b>					
Surgical procedures	29	(18)	19	(17)	0.82

<sup>a</sup>Dietary therapy if overweight (body mass index>25kg/m<sup>2</sup>), which includes nutrition therapy and weight loss.

<sup>b</sup>Statistically significant. NSAIDs = non-steroidal anti-inflammatory drugs. OA = osteoarthritis. SCS = stepped care strategy. TENS = transcutaneous electrical nerve stimulation.

### Baseline characteristics

The sequence of non-surgical treatment during the 24-month follow-up was consistent with the SCS in 117 patients (42%) and inconsistent in 163 patients (58%). Patients in the SCS-consistent group were younger, had fewer comorbidities and less painful joints, and were more likely to have an additional health insurance ( $P<0.05$ ) (Table 1).

### Healthcare use

SCS-recommended treatment modalities were frequently used in patients with

hip or knee OA within 2 years after they consulted their GP with a new complaint (Table 2). Dietary therapy was used in 27 (<10%) of the patients, multidisciplinary care was used in 22 patients (8%), and transcutaneous electrical nerve stimulation was used in six patients (2%). Forty eight (17%) of the patients received a surgical procedure within 2 years.

More patients in the SCS-consistent group received education, lifestyle advice, paracetamol, exercise therapy, and dietary therapy than patients in the SCS-inconsistent group. Fewer patients in the SCS-consistent group received the step-3 treatment modality intra-articular injections. There were no differences in the use of secondary care options (that is, referral to an orthopaedic surgeon or a rheumatologist, multidisciplinary care, and surgical procedures) between both groups.

### Course of the outcome of care and the effect of receiving SCS-consistent care

Pain and physical function improved significantly after a 2-year follow-up period (7% and 6%, respectively), whereas the levels of self-efficacy and active pain coping did not differ after 2 years (Table 3).

Changes in outcomes over time between patients who received SCS-consistent care and patients who received SCS-inconsistent care were not statistically significant. This was also the case after adjusting for possible confounders (Table 4). The adjusted differences ( $P$ -value) in improvement in pain and physical function scores were numerically in favour of patients who received SCS-inconsistent care, that is, -4.3 points (95% CI = -10.3 to 1.7;  $P = 0.21$ ) and -1.9 points (95% CI = -7.0 to 3.1;  $P = 0.45$ ), respectively. The adjusted differences in change in self-efficacy and active pain coping scores were numerically in favour of patients who received SCS-consistent

**Table 3. Course of pain, physical function, self-efficacy, and pain coping in patients with hip or knee osteoarthritis after implementation of the SCS**

Outcome measurements	Baseline		T <sub>6</sub>		T <sub>12</sub>		T <sub>18</sub>		T <sub>24</sub>		Total difference between baseline and 24 months <sup>b</sup>	
	Mean (SD)	mv	Mean (SD)	mv	Mean (SD)	mv	Mean (SD)	mv	Mean (SD)	mv	Δ (95%CI)	P-value
WOMAC pain <sup>a</sup>	62 (22)	8	68 (22)	19	67 (23)	34	71 (23)	54	70 (23)	64	7.0 (4.2 to 9.8)	0.00
WOMAC physical function <sup>a</sup>	64 (21)	12	68 (22)	20	68 (22)	38	70 (22)	54	70 (23)	57	5.6 (3.2 to 8.0)	0.00
Self-efficacy	31 (5)	8			31 (6)	36			31 (5)	55	0.0 (-0.6 to 0.6)	0.99
Active pain coping	54 (12)	8			53 (13)	36			52 (13)	59	-1.2 (-2.6 to 0.3)	0.12

<sup>a</sup>Standardised scores were used where higher scores reflect better health status (ranging from 0 to 100). <sup>b</sup>Positive values indicate improvement over time; that is, decrease in pain or physical function or increase of self-efficacy or active pain coping. mv = missing values. OA = osteoarthritis. SCS = stepped care strategy. SD = standard deviation.

T<sub>6</sub> = after 6 months. T<sub>12</sub> = after 12 months. T<sub>18</sub> = after 18 months. T<sub>24</sub> = after 24 months. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

**Table 4. Unadjusted and adjusted differences in outcome of care between baseline and 24 months in patients who received SCS-consistent care versus patients who received SCS-inconsistent care**

Outcome measurements	SCS-inconsistent (reference group)		SCS-consistent		Unadjusted difference			Adjusted difference <sup>a</sup>		
	Coefficient	95% CI	Coefficient	95% CI	Coefficient	95% CI	P-value	Coefficient	95% CI	P-value
WOMAC pain	8.8	4.9 to 12.7	3.6	-0.6 to 7.7	-5.2	-10.1 to 0.5	0.08	-4.3	-10.3 to 1.7	0.16
WOMAC physical function	7.4	4.0 to 10.8	4.3	0.42-8.1	-3.1	-8.1 to 1.9	0.22	-1.9	-7.0 to 3.1	0.45
Self-efficacy	-0.4	-1.2 to 0.4	0.6	-0.3 to 1.5	0.8	-0.5 to 2.2	0.23	0.6	-8.3 to 2.0	0.41
Active pain coping	-1.6	-3.6 to 0.4	-0.6	-2.8 to 1.6	1.1	-2.1 to 4.3	0.49	1.7	-1.5 to 4.9	0.30

<sup>a</sup>Adjusted for potential confounders; such as, age, number of comorbidities, having additional insurance coverage, number of painful joints, GPs' sex, and GPs' attitude regarding the effectiveness of non-recommended non-surgical treatment modalities. SCS = stepped care strategy. WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

care, that is, 0.6 points (95% CI = -8.3 to 2.0;  $P = 0.41$ ) and 1.7 points (95% CI = -1.5 to 4.9;  $P = 0.30$ ), respectively.

## DISCUSSION

### Summary

This is the first observational study regarding the effects of the SCS on outcomes of care, that is, the degree of pain, physical function, self-efficacy, and active pain coping, in patients with hip or knee OA over a period of 2 years after implementation of the SCS in primary care. Although more than half of the patients received health care that was considered inconsistent with the SCS recommendations, statistically significant differences were not identified in any of the outcomes of care between patients receiving care inconsistent with the SCS recommendations and patients receiving care consistent with the SCS recommendations.

The results raise several important issues that need to be considered in further research regarding the additional value of a complex intervention such as the SCS.

### Strengths and limitations

First, patients who received SCS-consistent care were younger, had fewer comorbidities and painful joints, and were more likely to have additional healthcare insurance. The SCS takes contextual factors into account only to a minor extent. Therefore, SCS-inconsistent care may sometimes be unavoidable or even preferable. For example, a regular exercise programme for OA is not feasible for patients with severe cardiovascular disease. Also, not having additional health insurance may be an insurmountable barrier to use SCS-recommended modalities. Therefore, further exploration of GPs' reasons for providing SCS-inconsistent care is needed to gain insight and redefine SCS-consistent

care in a more sophisticated way. As patients were only included if they were able to communicate in Dutch, any cultural factors were not addressed. When exploring GPs' reasons, cultural factors should also be considered as they may influence the choice for treatment as well.

Second, it appeared that relevant differences existed in healthcare use between the two groups. For example, patients in the SCS-consistent group were found to be more likely to receive education and lifestyle advice, while patients in the SCS-inconsistent group were more likely to receive intra-articular injections. This may have influenced outcome differences, because the effect of education and lifestyle on pain may be relatively small, whereas the effect of intra-articular injections may be relatively large.<sup>14</sup> SCS-inconsistent care (for example, receiving injections before lifestyle advice) may thus show better outcomes. An important aim of the SCS is to reduce the inappropriate use of advanced treatment modalities, such as arthroplasties, by making optimal use of the non-surgical treatment modalities for as long as possible.<sup>1</sup> Therefore, side effects and costs were important drivers for the SCS recommendations. SCS-consistent care may in this sense lead to high-quality care at the cost of pain and dysfunction. The added value of the SCS can only be appraised by considering a range of outcome measures simultaneously over a prolonged period of time in which cost-benefits and the number of side effects should be included.<sup>15</sup>

Third, the time-frame of this study may have been too short to detect differences in these outcomes. Evidence shows that changes in pain and physical function within the first years of follow-up in patients with hip or knee OA are relatively small and, thus, the potential benefit of the SCS may

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### Ethical approval

The study was approved by the Medical Ethics Committee on Research Involving Human Subjects Region Arnhem-Nijmegen (approval number: CMO 2009/246).

### Provenance

Freely submitted; externally peer reviewed.

### Competing interests

The authors have declared no competing interests.

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only be seen after a prolonged period of time.<sup>16-18</sup> Also, the results suggest that a relevant difference in change of pain scores cannot be excluded in favour of the patients who received SCS-inconsistent care, as the minimal important change of the WOMAC pain score<sup>19</sup> lies within the 95% CI. Further, self-efficacy and active pain coping hardly changed during the follow-up period, whereas the self-management booklet was intended to strengthen patient empowerment on these issues. These findings were in line with a recent randomised controlled trial regarding the effect of a self-management intervention for long-term chronic conditions in primary care, which concluded that the intervention had no noticeable value to existing care.<sup>20</sup> It may require more advanced interventions such as cognitive-behavioural group interventions,<sup>21</sup> pain-coping skill training,<sup>22,23</sup> or self-management training<sup>24</sup> to effectively improve self-efficacy and an active coping style.

Finally, an observational study may not be the ideal design to find a potential association between SCS-consistent care and better health outcomes, as the most important limitation of such design is the threat of potential confounding by indication. Although baseline differences were adjusted for between the two groups, unknown and not measured differences cannot be adjusted for. Many will prefer the use of controlled designs over observational

designs to evaluate complex interventions such as the SCS, as those can potentially counterbalance this bias. However, these designs have their own limitations, such as the risk of contamination, recruitment bias, the need for larger study samples, or costs.<sup>25</sup> The external validity of controlled trial results can often be questioned in studies with complex interventions. Therefore, the trade-off between the costs to overcome the practical consequences of controlled designs and the value of the evidence that can be gathered given these constraints should be considered in further research.

To the authors' knowledge, this is the first study examining the association between care that is provided according to implemented guidelines and health outcomes.

#### **Implications for research and practice**

This study illustrates that evaluation of a complex intervention for OA such as the SCS is a challenge; it brings various problems in addition to the practical and methodological difficulties that any successful evaluation must overcome. Further research is necessary to operationalise SCS-consistent care by identifying GPs' reasons for providing SCS-inconsistent care. Long-term effects and the effects on other outcomes of care such as the number of side effects and costs need to be assessed to achieve a more comprehensive understanding of the value of SCS-consistent care.

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