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CHAPTER 7

THE EFFECT OF STEPPED CARE ON HEALTH OUTCOMES IN PATIENTS WITH OSTEOARTHRITIS: AN OBSERVATIONAL STUDY

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Background

We developed the stepped care strategy (SCS) to improve adequate health care use in patients with osteoarthritis (OA) and implemented it 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

We used data from the 2-year observational study with 313 patients who had consulted their general practitioner (GP) due to OA.

Method

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

Results

We found no statistically significant differences 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 ($n=117$), also after adjusting for possible confounders, i.e. -4.3 (-10.3 to 1.7) and -1.9 (-7.0 to 3.1) respectively. Furthermore, we found no differences in changes over time between groups in self-efficacy and pain coping.

Conclusion

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

How this fits in

We developed a stepped care strategy (SCS) to improve the management of hip and knee osteoarthritis (OA). We assumed that 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 OA after its implementation in clinical practice. Although, we could not demonstrate that SCS-consistent care results is associated with better health outcomes at two years after implementation, our results raise several important issues that need to be considered when bringing the SCS in clinical practice and in further research regarding the additional value of the SCS.

Introduction

We developed the multidisciplinary stepped care strategy (SCS), named BART (i.e. Beating osteoARthritis), in order to improve the non-surgical care for patients with hip or knee osteoarthritis (OA).¹ This strategy aims to support general practitioners (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 (e.g. education, lifestyle advice, and acetaminophen) that should be offered to all patients or can be provided through self care. The second and third step include more advanced modalities (e.g. physical therapy, dietary therapy, and intra-articular injections) that can be provided if the prior options failed. We conducted a regional two-year observational study to evaluate the implementation on a limited scale in primary care. Until now, little evidence exists that a stepped care approach in OA results in improved health outcomes.

Porcheret and colleagues 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.² However, the added value of a stepped-care approach has been demonstrated in other fields, such as the prevention of depression and anxiety.^{3,4} Also, a stepped-care intervention program showed positive effects on the outcome of care in depressed elderly, i.e. better physical function and enhanced quality of life,⁵ and the cost-effectiveness of a stepped-care program has been established in people with a depressive disorder in primary care.^{6,7}

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

Methods

Setting

We used data from a 2-year observational prospective cohort study that was executed from August 2010 to March 2013 in the region Nijmegen, 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. We developed and executed several activities directed at different health care providers and patients in order 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: “Zorgwijzer Artrose[®]”)⁸, 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. We described the implementation strategy in a previous manuscript in more detail.⁹ The study was approved by the Medical Ethics Committee on Research Involving Human Subjects Regio Arnhem-Nijmegen (approval number: CMO 2009/246).

Study population

We invited GPs of the Nijmegen University Network of General Practitioners to participate in this study that consisted of 157 GPs working in 70 general practices. In addition, we approached six practices outside this network. Patients were eligible if they visited their GP for a new episode of hip or knee complaints due to symptomatic hip or knee OA, and had not visited their GP for the same episode during the preceding three months, and were aged 18 years or older. Exclusion criteria were a joint replacement of the hip or knee, on the waiting list for it, or the inability to complete the questionnaire, i.e. language barrier or terminal illness.

Outcomes

Pain and physical function were assessed at baseline, after 6 (T₆), 12 (T₁₂), 18 (T₁₈), and 24 months (T₂₄) with the Western Ontario McMaster University Index of osteoarthritis (WOMAC).¹⁰ Standardized 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, T₁₂, and T₂₄ with the Dutch General Self Efficacy Scale (DGSS)¹¹ and Pain Coping Inventory List (PCI)¹² respectively. Higher scores on the DGSS, ranging from 10 to 40, reflect higher self-efficacy. Higher scores on the subscales for active coping, ranging from 12 to 48, indicate more use of an active coping style.

Health care use was assessed at baseline, T₆, T₁₂, T₁₈, and T₂₄ by asking the patient which treatment modalities they had used in the preceding 6-months period related to their hip or knee symptoms. The list of modalities was based on the recommended modalities of the SCS. For each modality, we calculated the cumulative percentage “users”. We considered the patient as a user, if he reported having used that particular modality in one of the preceding time periods. If more than 30% of the items (i.e. values on two or more time periods) were missing, the scores were treated as missing. Furthermore, we considered referral to a dietician only applicable in overweight patients (if Body Mass Index > 25 kg/m²).

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, and acetaminophen.
- Step 2: physical therapy, dietary therapy (if overweight), Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and tramadol.
- Step 3: optional modalities like multidisciplinary care, intra-articular injections, and Transcutaneous Electrical Nerve Stimulation (TENS).

The SCS recommends that the more advanced treatment modalities should only be advised and/or provided if the modalities of the previous steps failed to produce satisfactory results. In other words, patients should first have received all advised step-1 modalities before receiving any step-2 modality and, thus, the patient should also have received all advised step-2 modalities before receiving any step-3 modality. Even more, the SCS recommends to provide education and lifestyle advice to every patient with hip or knee OA. Based on these SCS-recommendations, we constructed the variable “SCS-consistent care” (yes/no). We considered care “consistent with the SCS” if the patient received:

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

Potential confounders

In our previous study, we identified determinants of SCS-consistent care that were selected for this study as potential confounding variables, i.e. 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.⁹ In addition, we considered variables with statistically 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 analyzed using the chi-square 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 generalized estimating equations analysis. This analysis enables to correct 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.¹³ The reasons for missing data were unknown. The results are presented in beta-estimates and 95% confidence intervals

(95% 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 10.1-software.

Results

Study population

Seventy GPs from 38 different general practices agreed to participate. The participating GPs selected 528 patients eligible for the study. Out 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, we included 313 patients of whom 29 (9%) were lost to follow-up.

Baseline characteristics

The sequence of non-surgical treatment during the 24-months 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 less comorbidities and painful joints, and were more likely to have an additional health insurance ($P < 0.05$) (Table 1).

Health care use

SCS-recommended treatment modalities were frequently used in patients with hip or knee OA within two years after they consulted their GP with a new episode of complaints. (Table 2) Dietary therapy, multidisciplinary care, and TENS were used in less than 10% of the patients. Seventeen per cent of the patients received a surgical procedure within two years.

More patients in the SCS-consistent-group received education, lifestyle advice, acetaminophen, 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 (i.e. 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 two years (Table 3).

Changes in outcomes over time between patients who received SCS-consistent care and patients who received SCS-inconsistent care did not differ statistically significant, also after adjusting for possible confounders (Table 4). The adjusted differences (95% CI; P -value)

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

Baseline characteristics	SCS-inconsistent (n = 163)		SCS-consistent (n = 117)		P-value
Predisposing factors					
- Age, years; mean (SD)	65	(10)	62	(10)	0.05
- Sex, male; n (%)	62	(38)	43	(37)	0.83
- Overweight, BMI>25kg/m ² ; 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
- 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); mean (SD)	31	(5)	31	(6)	0.69
- Active pain coping (range 12-48); mean (SD)	26	(6)	26	(6)	0.61
Enabling factors					
- Health insurance, with additional coverage; n (%)	143	(88)	109	(95)	0.05
- Household composition, with partner; n (%)	118	(72)	94	(80)	0.08
- Residence, rural; n (%)	104	(64)	76	(65)	0.90
Disease-related factors					
- Location					
- Hip; n (%)	80	(49)	63	(54)	0.43
- Knee; n (%)	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
- Duration of symptoms, > 1 year; n (%)	131	(80)	88	(76)	0.37
- WOMAC pain (range 0-100) ‡; mean (SD)	61	(23)	63	(22)	0.42
- WOMAC physical function (range 0-100) ‡; mean (SD)	63	(22)	66	(20)	0.30

Baseline characteristics are divided in patients who received care consistent with the recommendations of the SCS (i.e. SCS-consistent care) and those who received inconsistent care (i.e. SCS-inconsistent care). Abbreviations: OA=Osteoarthritis, SCS=Stepped Care Strategy, SD=Standard Deviation, n=Number, BMI=Body Mass Index, IQR=Interquartile Range, WOMAC=Western Ontario McMaster University Index of osteoarthritis.

Note: The italic and bold numbers are statistically significant.

in improvement in pain and physical function scores were numerically in favor of patients who received SCS-inconsistent care, i.e. -4.3 points (-10.3 to 1.7; $P=0.21$) and -1.9 points (-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 favor of patients who received SCS-consistent care, i.e. 0.6 points (-8.3 to 2.0; $P=0.41$) and 1.7 points (-1.5 to 4.9; $P=0.30$) respectively.

Table 2. Cumulative health care use of patients with hip or knee osteoarthritis who received SCS-inconsistent or SCS-consistent care in the 2 years after a new episode of complaints

Treatment modalities	SCS-inconsistent (n=163) n (%)	SCS-consistent (n=117) n (%)	P-value
Non-surgical modalities			
Step-1 modalities, as recommended in the SCS			
- Education	113 (69)	117 (100)	<0.01
- Lifestyle advice	84 (52)	117 (100)	<0.01
- Acetaminophen	126 (78)	102 (87)	0.05
- Glucosaminesulphate	48 (30)	43 (38)	0.18
Step-2 modalities, as recommended in the SCS			
- Exercise therapy	92 (56)	81 (70)	0.02
- NSAIDs (oral or topical)	82 (50)	64 (55)	0.42
- Tramadol	24 (15)	15 (13)	0.70
- Dietary therapy*	10 (6)	17 (15)	0.02
Step-3 modalities, as recommended in the SCS			
- Multidisciplinary care	16 (10)	6 (5)	0.16
- Intra-articular injections	46 (28)	15 (13)	<0.01
- 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
Surgical modalities			
- Surgical procedures	29 (18)	19 (17)	0.82

Abbreviations: OA=Osteoarthritis, SCS=Stepped Care Strategy, n=Number,

NSAIDs=Non-Steroidal Anti-Inflammatory Drugs, TENS=Transcutaneous Electrical Nerve Stimulation.

Note: The italic and bold numbers are statistically significant.

* Dietary therapy if overweight (Body Mass Index>25kg/m²), which includes nutrition therapy and weight loss.

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 ₆		T ₁₂		T ₁₈		T ₂₄		Total difference between baseline and 24 months†		
	mean (SD)	<i>mv</i>	mean (SD)	<i>mv</i>	mean (SD)	<i>mv</i>	mean (SD)	<i>mv</i>	mean (SD)	<i>mv</i>	Δ (95%CI)	P-value	<i>mv</i>
WOMAC pain*	62 (22)	8	68 (22)	19	67 (23)	34	71 (23)	54	70 (23)	64	7.0 (4.2 – 9.8)	0.00	70
WOMAC physical function*	64 (21)	12	68 (22)	20	68 (22)	38	70 (22)	54	70 (23)	57	5.6 (3.2 – 8.0)	0.00	62
Self-efficacy	31 (5)	8			31 (6)	36			31 (5)	55	0.0 (-0.6 – 0.6)	0.99	60
Active pain coping	54 (12)	8			53 (13)	36			52 (13)	59	-1.2 (-2.6 – 0.3)	0.12	64

Abbreviations: OA=Osteoarthritis, SCS=Stepped Care Strategy, T₆=after 6 months, T₁₂=after 12 months, T₁₈=after 18 months, T₂₄=after 24 months, SD=Standard Deviation, *mv*=Missing Values, 95% CI=95% Confidence Interval, WOMAC=Western Ontario McMaster University Index of osteoarthritis.

* Standardized scores were used where higher scores reflect better health status (ranging from 0 to 100).

† Positive values indicate improvement over time, i.e. decrease in pain or physical function or increase of self-efficacy or active pain coping.

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*	
	Coefficient	(95% CI)	Coefficient	(95% CI)	Coefficient	(95% CI)	P-value	Coefficient (95% CI)
WOMAC pain	8.8	(4.9 – 12.7)	3.6	(-0.6 – 7.7)	-5.2	(-10.1 – 0.5)	0.08	-4.3 (-10.3 – 1.7)
WOMAC physical function	7.4	(4.0 – 10.8)	4.3	(0.42 – 8.1)	-3.1	(-8.1 – 1.9)	0.22	-1.9 (-7.0 – 3.1)
Self-efficacy	-0.4	(-1.2 – 0.4)	0.6	(-0.3 – 1.5)	0.8	(-0.5 – 2.2)	0.23	0.6 (-8.3 – 2.0)
Active pain coping	-1.6	(-3.6 – 0.4)	-0.6	(-2.8 – 1.6)	1.1	(-2.1 – 4.3)	0.49	1.7 (-1.5 – 4.9)
								0.30

Abbreviations: SCS=Stepped Care Strategy, 95% CI=95% Confidence Interval, WOMAC=Western Ontario McMaster University Index of osteoarthritis.

* Adjusted for potential confounders, i.e. age, number of comorbidities, having an additional insurance coverage, number of painful joints, GPs' sex, and GPs' attitude regarding the effectiveness of non-recommended non-surgical treatment modalities.

Discussion

This is the first observational study regarding the effects of the SCS on outcomes of care, i.e. the degree of pain, physical function, self-efficacy, and active pain coping, in patients with hip or knee OA over a period of two 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, we did not identify statistically significant differences 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. Our 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. First, patients who received SCS-consistent care were younger, had less comorbidities and painful joints, and were more likely to have an additional health care insurance. The SCS takes contextual factors into account only to a minor extent. Therefore, SCS-inconsistent care might be sometimes unavoidable or even preferable. For example, a regular exercise program for OA is not feasible for patients with severe cardiovascular disease. Also, not having an additional health insurance might be an insurmountable barrier to use SCS-recommended modalities. Therefore, we need further exploration of GPs' reasons to provide SCS-inconsistent care in order to gain insight and redefine SCS-consistent care in a more sophisticated way. As we only included patients who were able to communicate in Dutch, we did not address any cultural factors. When exploring GPs' reasons, cultural factors should also be considered as they might influence the choice for treatment as well.

Second, it appeared that relevant differences existed in health care use between the two groups. For example, we found that patients in the SCS-consistent-group were 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 might be relatively small, whereas the effect of intra-articular injections might be relatively large.¹⁴ SCS-inconsistent care (e.g. 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 (e.g. arthroplasties) by making optimal use of the non-surgical treatment modalities as long as possible.¹ Therefore, side-effects and costs were important drivers for the SCS-recommendations. SCS-consistent care might in this sense lead to high quality care at the cost of pain and dysfunctioning. 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 costs-benefits and the number of side-effects should be included.¹⁵

Third, the time frame of our 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 might pay off only after a prolonged period of time.¹⁶⁻¹⁸ Also, the results suggest that we cannot exclude a relevant difference in change of pain scores in favor of

the patients who received SCS-inconsistent care, as the minimal important change of the WOMAC pain score¹⁹ lies within our 95% CI. Further, self-efficacy and active pain coping hardly changed during our 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 randomized controlled trial regarding the effect of a self-management intervention for long term chronic conditions in primary care, as they concluded that the intervention had no noticeable value to existing care.²⁰ It might require more advanced interventions such as cognitive-behavioral group interventions²¹, pain coping skill training^{22,23}, or self-management training²⁴ to effectively improve self-efficacy and an active coping style. Finally, an observational study might 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 we adjusted for baseline differences 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.²⁵ 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 conclude, SCS-consistent care showed no better health outcomes two years after implementation of the SCS in primary care. Our 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 operationalize 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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