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CHAPTER 8

GENERAL DISCUSSION



This thesis focused on the development and implementation of a stepped care strategy (SCS), named Beating osteoARthritis (i.e. BART), into clinical practice. The studies described in this thesis were designed to give recommendations for an implementation of this SCS on a larger scale, with the overarching aim to improve non-surgical health care use in patients with symptomatic hip or knee osteoarthritis (OA). We hypothesized that implementation of the SCS would improve health care use, in particular the sequence for care of non-surgical treatment options. Ultimately, we expected that patients who received care that is in line with the SCS-recommendations would perceive better health outcomes. Therefore, we described health care use in patients with hip or knee OA after implementation of the SCS in clinical practice. We identified starting points to further improve and tailor implementation activities at different levels. In this chapter, I discuss the results of our studies focusing on the limitations, the implications for clinical practice, and the future directions for research.

1. Development and content of the SCS

We used an extensive consensus procedure that warrants the quality of the content of the proposed SCS (Chapter 2). Our procedure resembles the nominal group technique and included important characteristics of good consensus methods such as face-to-face meetings, balanced group composition, feedback, iteration and involvement of experts.¹ All differences in opinions and raised concerns were resolved by discussion in multiple rounds and after multiple consultations of experts and patient representatives. In our opinion, the proposed SCS presents the optimal sequence for OA management. The content of the SCS was mainly based on existing national and international guidelines and systematic reviews regarding the management of hip or knee OA. Meanwhile there are new insights in the efficacy of several treatment modalities and, thus, updates of guideline recommendations.²⁻⁵ For example, one of the draft recommendations of the NICE guideline update is that glucosamine and chondroitin products should not be offered to manage OA, as the evidence on their clinical effectiveness is very limited and uncertain.⁵ Therefore, conform to regular updates of guidelines we suggest a regular SCS update based on new insights.

2. Implementation of the SCS

We used a multilevel and multifaceted intervention to implement the SCS in clinical practice. This intervention included implementation activities that were aligned to both patients and health care providers. We used the theoretical framework of Grol and colleagues to select implementation activities for each target group.^{6,7} A regional expert panel selected those activities that were also considered suitable to integrate in existing routines of the Dutch health care system. As there is no “gold standard”, we tried to find a combination of implementation activities that was not only focused on the education of patients and health care providers regarding the SCS, but was also focused on how to trigger the sense

of urgency, interest, attitude, and motivation to change of these target groups. Our study design did not allow inferences about the effectiveness of our implementation activities on clinical practice (i.e. compliance with the SCS). However, we did assess the extent to which the interventions were appreciated by the target group (e.g. participation rates). In this paragraph we will describe in more detail our experiences with these implementation activities for the different target groups.

Implementation activities aligned to patients

Based on the SCS-recommendations, a patient-friendly self-management booklet “Care for Osteoarthritis” (in Dutch: “Zorgwijzer Artrose[®]”) ⁸ was developed that provides information concerning OA, the non-surgical treatment modalities, and the recommended sequence for and duration of treatment. In addition, it aims to enhance the patient’s active role in the treatment of OA as well as the communication with health care providers by offering several patient-oriented tools. This booklet was provided by the general practitioner (GP) during a consultation or by mail after a recent consultation. After 6 months, still 39% of the patients reported that they did not read or had not used the booklet yet.

Besides the uptake, we also assessed patients’ perception regarding the usefulness of the booklet. The booklet consists of three sections. The first section provides information about OA in general, risk factors, symptoms, diagnostic procedures, and gives an overview of the health care providers. The second section provides information about the non-surgical treatment modalities as recommended in the SCS. Finally, the third section contains tools to monitor symptoms, to evaluate the effect of the treatment, to prepare consultations with health care providers, and to formulate a comprehensive overview of their own provided care. Only few ‘users’ reported to find the three sections useless, 2%, 2%, and 7% respectively. About half of the ‘users’ reported to find each section useful (53%, 48%, 34% respectively). Thus, the third section was reported least frequently as useful. The remaining ‘users’ reported to find the sections neither useful nor useless or had no opinion regarding the usefulness.

Based on these results, we considered it necessary to further explore the factors that influenced patients to use this booklet (this will be discussed in the paragraph “Barriers and facilitators of implementation”). This insight could be used to improve the uptake and usefulness of the booklet, or to develop possible other patient-oriented tools to implement the SCS.

Implementation aligned to health care providers

Our main target group of the health care providers was the GP. However we also executed implementation activities aligned to exercise therapists, dieticians, practice nurses, rheumatologists, and orthopaedic surgeons. First, we used the top-down approach to achieve sufficient support from each discipline to implement the SCS. ⁹ We approached the national and regional professional associations before approaching the individual health

care providers. Our regional expert panel advised this approach in order to gain trust of the individual health care provider; e.g. it is easier to convince GPs to participate if the Dutch College of General Practitioners (i.e. the national professional association of GPs) already expressed his support.

Subsequently, we executed several GP-oriented activities including educational outreach visits to each of the participating practices, education material, reminder material, and a multidisciplinary seminar. The outreach visits (participation rate of GPs=54%) may not be feasible in this format for a nation-wide implementation considering the time and effort needed to visit each general practice. However, it could be possible to include the content of these outreach visits in existing education for GPs and the post-graduate training. Also, GPs with special interest in musculoskeletal disorders could play an important role in the regional implementation of the SCS, especially in the education of GPs and the dissemination of material. The seminar was poorly visited (participating rate of GPs=6%) and therefore is considered as the least effective activity regarding reaching the target group. In this project, we could only offer this seminar once. The participation rate might have been better if the seminar was offered recurrently. In the future, the possibility to integrate electronic reminders in the patient record systems could also be considered as they have the potential to improve primary care.^{10,11} Patients with OA often consult their GP for other reasons than their OA-related problems and therefore an electronic reminder can help GPs to monitor and evaluate the treatment with the patient.¹² However, this would be a costly procedure now as there are more than 15 different electronic record systems in general practice, but it does have potential for new systems or registers.

Regarding the self-management booklet “Care for Osteoarthritis” (in Dutch: “Zorgwijzer Artrose[®]”),⁸ almost all GPs reported to have read the booklet and would advise the booklet to their patients, 95% and 79% respectively. The first two sections were reported to be useful by most of the GPs, 90% and 77% respectively. The third section (with the self-management tools) was only reported to be useful by 19% of the GPs, 36% of the GPs reported to find this section useless, and 45% of the GPs reported to find this section neither useful nor useless or had no opinion regarding the usefulness. This finding is in concordance with the patients’ perception about the usefulness of the self-management tools and, thus, other tools to stimulate patients active pain coping and self-efficacy need to be considered that are adjusted to the patients’ needs.

3. Barriers and facilitators of implementation

The success of an implementation of a treatment strategy as the SCS can be influenced by factors at different levels, i.e. the level of the patient, the health care provider, and the organization.^{6,13,14} In this paragraph we will discuss the identified barriers and facilitators at each of these levels.

Identified factors at the level of the patient

The identified patient-related factors explained by far the most variance in health care use and, thus, our results suggest that the implementation activities should be mainly focused on these factors (Chapter 5). Recurrently, we found that having additional health insurance coverage, having an active coping style, and having less comorbidities or less painful joints had a positive influence on the management of hip or knee OA. Potential methods to address these factors are discussed below.

It is conceivable that health insurance companies want to play a role in optimizing the use of non-surgical treatment options. Currently, some of these modalities, like physical and dietary therapy, are not reimbursed by the basic insurance in patients with OA.¹⁵ Probably, patients will make more use of these modalities if they are reimbursed.

As mentioned before, the self-management booklet “Care for Osteoarthritis”⁸ was developed to stimulate an active pain coping style and enhance self-efficacy. Unfortunately, we did not find any changes in active pain coping and self-efficacy within the 2-year follow-up period after providing the patients this booklet (Chapter 7). Therefore, the effectiveness and the appropriateness of the booklet can be questioned. Maybe, it requires more advanced interventions such as cognitive-behavioral group interventions¹⁶, pain coping skill training^{17,18}, or self-management training¹⁹ to improve self-efficacy and an active pain coping style to achieve changes in these psychological outcomes. Or maybe, this booklet is just not the appropriate tool for every patient. In our qualitative study, we found that patients’ perception about the usefulness of the booklet was a barrier to use it (Chapter 4). The third section (with the self-management tools) was valued least useful and was used least frequent. For example, some patients reported that they prefer to leave control of their disease to powerful others such as GPs. These patients might benefit more from a direct approach such as verbal instruction. Without any doubt, GPs can not use a standard tool to improve pain coping style and self-efficacy in every patient. Therefore, we need more insight in the patients’ needs in order to adapt and/or develop the appropriate tools.

Another possible reason why patients received SCS-inconsistent care is that many patients reported to have comorbidities that could have received co-treatment that interfered with one of the SCS-recommendations. Most prevalent comorbid diseases are cardiac diseases, diseases of the eye, ear, nose, throat and larynx, other urogenital diseases and endocrine/metabolic diseases.²⁰ However, little is known regarding the appropriate strategy in patients with relevant comorbid diseases and, thus, the SCS also gives no recommendations regarding this aspect. In the Netherlands, researchers are working on a protocol for comorbidity-associated adaptations for exercise therapy in patients with hip or knee OA, which could be included ultimately in the updated version of the SCS.²¹

As mentioned before, our results suggest that the variance in health care use is mainly at the patients’ level. However, we need to emphasize that these factors could only explain 10% of the variance in health care use. Therefore, there are still unidentified factors that can influence health care use.

Identified factors at the level of the health care provider

We found mixed results concerning GPs' attitude toward the SCS-recommendations. On the one hand, patients reported that they perceived no endorsement for non-surgical treatment modalities from their GPs (Chapter 4). On the other hand, however, the results of our survey among a sample of Dutch GPs suggest that GPs do find non-surgical treatment modalities effective in the treatment of OA (Chapter 3). This discrepancy between the perception of patients with OA and health care providers about the attitude of health care providers and the actual attitude of health care providers towards treatment options has also been described in another qualitative study.²² In the latter study, they found that patients have a negative perception of medication and a feeling of uncertainty regarding the progression of the disease, while practitioners do not. GPs could use this knowledge to improve the patient-doctor communication by taking efforts to identify and resolve these discrepancies.²³

Another important target to improve is the appropriate use of diagnostic procedures. This conclusion is based on the findings that a considerable number of GPs overuse X-rays (Chapter 3). GPs legitimize their use of X-ray by expressing the view that it aids the discussion of management with the OA patient, is required for specialist referral, and can be used to reduce referrals.²⁴ Also, GPs believe that X-rays provide reassurance to the patient which can outweigh the risks and, furthermore, denying X-rays could adversely affect the doctor-patient relationship.²⁵ It is conceivable that there are justified reasons for ordering X-ray in a relatively early stage of the disease, but it could be hypothesized that this also has a negative effect on the outcome of care considering the finding that patients with lower back pain who had X-ray reported more pain, lower overall health status and no difference in disability, and consult their doctor more frequently.²⁶ The latter findings warrant further research on the costs and benefits for ordering X-rays in the early stage of OA.

Finally, there are some practical tools that could support GPs to deliver care as recommended by the SCS. One of the tools suggested during one of the outreach visits was a pocket card with the SCS-recommendations. Other tools that could be considered are a practical guide with the SCS-recommendations or electronic reminder tools (that informs GPs when to evaluate treatment with the patient). The NICE in the UK has set up some tools like this for various kinds of disorders.²⁷

Another option is to delegate some tasks to practice nurses, like education, monitoring, and evaluating the treatment, as they seem highly suitable for these tasks. Patients perceive lack of consultation time as an explanation for the limited encouragement they received for GP (Chapter 4), which could probably also be provided by practice nurses. Also, only 18% of the GPs reported to have their practice nurse involved in OA management (Chapter 3), which indicates that practice nurses could be more involved. This could not only lead to better use of self-management support, but also to less health care costs.^{28,29}

Identified factors at the level of the organization

In the Netherlands, integrated care is advocated for different chronic conditions for which regional and national multidisciplinary networks are installed. Our results also show that having structural collaboration with any other health care provider regarding OA management and working in non-solo practices is associated with an higher agreement with the SCS-recommendations (Chapter 3).

Probably community-based multidisciplinary OA care, including education, lifestyle advices, exercise therapy, and dietary therapy could also be developed. Community-based care covers services within the community that involves the coordination and provision of integrated care provided by a range of health care providers. Such a community-based program, named the BOA-intervention, has been introduced in Sweden and showed promising results.³⁰ About 1300 physiotherapists were educated to deliver and evaluate the BOA intervention. Data from 9.800 consecutive patients showed high participation and satisfaction rates (still after three years after the intervention) regarding the intervention. Also, initiatives can be made to install multidisciplinary networks in which patients with hip or knee OA receive a standard package of care with all recommended modalities and in which health care providers can collaborate and communicate about the management of these patients. To make such a network, it is necessary to start with a small number of motivated experts, improve their expertise in OA management, promote the visibility of the available expertise for patients and professionals, and show transparent results of this network. ParkinsonNet is a promising example of such a network in the Netherlands to deliver high quality care for patients with Parkinson's disease.³¹

Another promising development is installing national registers to obtain transparent data about health care use.³² With these registers, it is easier to implement guidelines and recommendations, such as the SCS. Even more, feedback can be given to health care providers by using equivalent data as health care use can be compared and evaluated. In the Netherlands, health care insurances³³ and the Netherlands institute for health services research³⁴ already use this kind of information to stimulate health care providers to provide most cost-effective care.

4. Effectiveness of the SCS

After implementation of the SCS, most recommended non-surgical health care use seemed to be well used (Chapter 5). However, some modalities were underused, especially dietary therapy in overweight patients. Even more, modalities lacking evidence for efficacy, such as massage and manual therapy, are still used in clinical practice to treat hip or knee OA. Providing GPs and patients the knowledge that modest changes in weight improve symptoms, could possibly enhance implementation of weight reduction efforts.

With the results in this thesis we could not confirm our hypothesis that receiving care that is in line with the SCS-recommendations has a positive impact on physical outcomes measures (i.e. pain and limitations in functioning) and psychological outcomes (i.e. self-

efficacy and active pain coping) over a period of two years after implementation of the SCS in clinical practice (Chapter 7). However, in reflecting on our results, several important issues were raised that need to be considered in further research regarding the value of the SCS.

First of all, the lack of effect does not suggest that we do not longer need to explore the effects of an optimal sequence for care on outcomes of care. Considering the chronicity of OA and its slow progression we probably need to explore these effects after a longer follow-up period. 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.³⁵ Thus the potential benefit of the SCS might pay off after a prolonged period of time.

Moreover, we may need to consider a range of other health outcomes. The aim of the SCS is to reduce inappropriate use of advanced treatment modalities and, thus, not only to improve the assessed physical and psychological outcomes. The number of side-effects and the cost-effectiveness were important drivers for the SCS-recommendations. Possibly, the added value of the SCS can only be appraised by including a range of outcome measures including side effects and costs-benefits among others.

Also, we did not assess the reasons why patients received SCS-inconsistent care. What we considered *SCS-inconsistent care* might be sometimes unavoidable or even preferable. For example, a regular exercise program might be not feasible in an OA patient with severe cardiovascular disease. The current SCS takes contextual factors only to a minor extent into account. We suggest further exploration of physicians' reasons to provide SCS-inconsistent care in order to gain insight and redefine SCS-consistent care in a more sophisticated way.

5. Methodological issues

In this paragraph, we discuss several issues that could have limited the validity of our results. These issues mainly consider our prospective observational cohort study.

Study design

An observational study is not the ideal design to find a potential association between SCS-consistent care and health outcomes as the most important limitation of such a design is the threat of potential confounding by indication (i.e. forgotten or unknown factors not included in the analysis or factors that interact complexly). Other study designs could counterbalance this potential bias, although each design has its limitations. A study with a randomized design to assess the long-term effects of a complex intervention program like a stepped care approach in a chronic condition like OA would have had some practical limitations.^{36,37} For example, it is not feasible to randomize at the level of the patient because of the risk for contamination (i.e. that members of the 'control'-group inadvertently are exposed to the intervention activities). Cluster randomization can be used to overcome this problem but is associated with a decrease of effective sample size due to the positive correlation between the subjects within the clusters (thus, the need for larger study samples) and the risk of slow or stagnating patient recruitment in the clusters that are going to

receive what the patients or recruiters consider to be the “less interesting” treatment (thus, a risk for recruitment bias).^{38,39} Another alternative is the propensity score technique (i.e. a statistical matching technique that attempts to mimic randomization by creating a sample of units that received the intervention that is comparable on all observed covariates to a sample of units that did not receive the intervention).⁴⁰ However this technique still does not guarantee comparability between the groups as it is impossible to know and measure all possible confounders.⁴¹ Thus, although experimental designs are preferred to observational designs to evaluate complex interventions such as the SCS, the trade-off between the costs to overcome the practical consequences of experimental designs and the value of the evidence that can be gathered given these constraints should be considered in further research.

Baseline measurement

Before gathering any data for our observational prospective cohort study, we had to approach and inform the GPs about the SCS and the project. Thus, several implementation activities had already been executed prior to baseline assessments. This made it impossible to collect information about the situation before implementation and compare health outcomes before and after implementation of the SCS. Also, patients received the first questionnaire *after* they visited their GP with their symptoms and gave informed consent. This questionnaire included questions regarding their health care use in the preceding 6 months and, thus, their health care use in the period between the consultation and the moment that they filled in this first questionnaire was also taken into account in this baseline measurement. Therefore, we do not have insight in their health care use before the consultation and are, therefore, not able to give statements about the changes in health care use.

Method of inclusion

We recruited the patients in two different ways: 1) consecutive patients visiting their GP and 2) after extraction from GP-records based on the coded diagnoses of hip or knee OA (i.e. L89 or L90 according to the International Classification of Primary Care). Consecutive patients were informed and instructed by their GP, whereas the patients selected from the GP-records were informed and instructed by one of the researchers. For that matter, we corrected our analyses for the method of inclusion if necessary. One could argue that using two methods of inclusion could have created a heterogeneous study sample, as we did find differences in baseline characteristics (e.g. number of comorbidities and duration of symptoms) and health care use (e.g. education and GP consultations). However, our method reduced selection bias by inviting all eligible patients to participate in the study. Thus, our method probably increased the generalizability of our findings.

Patient reported outcome measures

We only used patient reported outcome measures (PROMs) in our observational cohort study. Although PROMs suffer from biases associated with subjective measures, they do measure the patients' perception and that is probably what matters most.⁴² There has been a growing interest in the patient experience of the disease and the need to appropriately capture it in assessments, especially in the chronic conditions where patients' satisfaction and shared decision-making are key elements in the treatment.⁴³

Most of the used outcome measures were assessed with validated questionnaires, however, some were not tested regarding all properties in the checklist of the COSMIN-group.⁴⁴ For example, some instruments have not been validated in our target population while others have not been assessed on responsiveness (and are therefore probably not appropriate to measure change scores). This could have resulted in some incorrect results.

6. Implications and recommendations

Improving non-surgical management in patient with hip or knee OA is an important area of research regarding the quality and cost-effectiveness of care. Based on the findings of this thesis the following implications for implementation on a larger scale and recommendations for future research can be made.

Implications for implementation

- The SCS can be used as a practical framework for patients and health care providers to manage hip and knee OA, however, an update of the SCS needs to be considered in which modalities like glucosamine could be excluded and advanced interventions to stimulate active pain coping styles (such as cognitive-behavioral group interventions, pain coping skill training, or self-management training) could be included. Also, recommendations regarding the treatment options in patients with comorbidities could add some additional value to the current SCS.
- Variance in health care use was mainly explained at the patient's level. Health care use can be further improved in particularly in patients with passive pain coping styles, comorbidities, and other painful joints by providing them all recommended non-surgical treatment modalities.
- GP-oriented targets such as having a positive attitude regarding non-surgical treatment options towards the patient and reducing X-ray overuse in the diagnosis for OA can be considered for the development of implementation activities for this target group.
- Organizational-oriented implementation activities such as community-based care for patients with OA and installing multidisciplinary (regional) networks can be considered to enhance implementation of the SCS at the organizational level.
- Probably, health insurance companies, practice nurses, and GPs with special interest in musculoskeletal disorders could play an important role in the implementation of the SCS and the improvement of non-surgical OA management.

Recommendations for further research

- Research is needed regarding GPs' reasons for providing care that is inconsistent with the SCS in order to determine if they are legitimate or not.
- More research is necessary to assess the long-term effects of the SCS on physical and psychological health outcomes of care, i.e. pain, functioning, self-efficacy, pain coping.
- The effects of SCS-consistent care on other health outcomes, such as the number of side effects and the cost-effectiveness, should be studied to comprehensively assess the success of the SCS implementation.
- In this thesis we mainly focused on the implementation in primary care. Also, barriers and facilitators of implementing the SCS in secondary care need to be identified in order to implement the SCS in all involved settings.

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