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## Randomized Controlled Trial

## Decision aids can decrease decisional conflict in patients with hip or knee osteoarthritis: Randomized controlled trial

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## Abstract

### BACKGROUND

The interest in shared decision making has increased considerably over the last couple of decades. Decision aids (DAs) can help in shared decision making. Especially when there is more than one reasonable option and outcomes between treatments are comparable.

### AIM

To investigate if the use of DAs decreases decisional conflict in patients when choosing treatment for knee or hip osteoarthritis (OA).

### METHODS

In this multi-center unblinded randomized controlled trial of patients with knee or hip OA were included from four secondary and tertiary referral centers. One-hundred-thirty-one patients who consulted an orthopedic surgeon for the first time with knee or hip OA were included between December 2014 and January 2016. After the first consultation, patients were randomly assigned by a computer to the control group which was treated according to standard care, or to the intervention group which was treated with standard care and provided with a DA. After the first consultation, patients were asked to complete questionnaires about decisional conflict (DCS), satisfaction, anxiety (PASS-20), gained knowledge, stage of decision making and preferred treatment. Follow-up was

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carried out after 26 wk and evaluated decisional conflict, satisfaction, anxiety, health outcomes (HOOS/KOOS), quality of life (EQ5D) and chosen treatment.

**RESULTS**

After the first consultation, patients in the intervention group (mean DCS: 25 out of 100, SD: 13) had significantly ( $P$  value: 0.00) less decisional conflict compared to patients in the control group (mean DCS: 39 out of 100, SD 11). The mean satisfaction score for the given information (7.6 out of 10, SD: 1.8 *vs* 8.6 out of 10, SD: 1.1) ( $P$  value: 0.00), mean satisfaction score with the physician (8.3 out of 10, SD: 1.7 *vs* 8.9 out of 10, SD: 0.9) ( $P$  value: 0.01) and the mean knowledge score (3.3 out of 4, SD: 0.9 *vs* 3.7 out of, SD: 0.6) ( $P$  value: 0.01) were all significantly higher in the intervention group. At 26-wk follow-up, only 75 of 131 patients (57%) were available for analysis. This sample is too small for meaningful analysis.

**CONCLUSION**

Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

**Key Words:** Decision aid; Decisional conflict; Shared decision making; Anxiety; Hip osteoarthritis; Knee osteoarthritis

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**Core Tip:** Patients with knee or hip osteoarthritis provided with an additional decision aid appear to have less decisional conflict, more knowledge about their treatment, more satisfaction with the given information by their physician and therefore more satisfaction with their physician after their first consultation with the physician.

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**INTRODUCTION**

For patients with knee or hip osteoarthritis (OA) there are multiple treatment options. These treatment options vary from lifestyle adjustments to surgery. When a patient has radiographically end-stage OA combined with a lot of pain, other forms of treatment including physical therapy and corticosteroid injections have been unsuccessful, the choice for a knee or hip arthroplasty seems obvious. However, surgery comes with multiple risks and a period of rehabilitation, which are important factors for patients considering total joint arthroplasty. In the stages before end-stage OA, the choice of treatment is demanding because the results of conservative and operative treatment are comparable[1]. Therefore, in the treatment of OA it is preferable to use shared decision making. Physicians need to give complete, correct and neutral information about the possible treatments to aid the patient in making a shared decision[2]. Furthermore, it is necessary that patients share their own values about the benefits, risks and side effects of a treatment. Due to limited time during clinical visits and the complexity of the information, in many cases it is difficult to establish clear communication between the physician and the patient to make a shared decision. Therefore, it is difficult for the patient to define their values, and this can lead to worse outcomes of the surgery, followed by disappointment, and sometimes regret [3]. Decision aids (DAs) have been developed to support the decision-making process and provide evidence-based information to the patient[4,5]. A DA should be used as an addition to the information explained by the physician, not as a substitution for medical consultation[6]. On top of that with a DA the patient can reread the given information at home.

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Positive effects of DAs related to decisional conflict and knowledge are reflected in previous studies[7,8]. Achaval *et al*[7] investigated the effect of an education booklet, video booklet and decision tool on the decisional conflict among patients with knee OA. It showed a significant overall reduction in decisional conflict. A recent systematic review by Riddle *et al*[8] looked primarily at the effect of DAs on patients' knowledge considering total knee arthroplasty. They found a positive effect on the knowledge of patients, but no effect on patients' anxiety, satisfaction or decisional conflict.

The primary objective of this study is to investigate if a DA reduces decisional conflict in patients choosing treatment for knee and hip OA after the first consultation with their physician. The secondary objective is to investigate if providing patients with a DA increases satisfaction, gained knowledge, influenced stage of decision making, preferred treatment or decreased anxiety after the first consultation and if it reduces decisional conflict, decreases anxiety, increases knowledge, satisfaction, quality of life or physical function and changes preferred treatment at enrollment after 26 wk of follow-up.

## MATERIALS AND METHODS

### Study design and participants

A multicenter unblinded randomized controlled trial (RCT) was carried out at four secondary and tertiary referral centers in the Netherlands after approval of the Institutional Research Board. Patients were included when they met the following inclusion criteria: Adult patients (18 years or older), newly diagnosed with OA of the knee or hip, Dutch fluency and literacy, and first consultation by an orthopedic surgeon for the complaint.

### Study setting

Patients received the diagnosis OA of the knee or hip at one of the participating centers. After the first consultation, patients were asked if they wanted to participate in this trial. When this was the case, the patients were randomized by a computer-generated randomization sequence by one of the research fellows into the control group or intervention group. The control group was treated with standard care. This consists of a thorough case history, physical examination, an X-ray of knee or hip followed by explanation about treatment options for OA. The intervention group was also treated with standard care and received an online DA for their specific diagnosis (knee or hip OA) after the first consultation.

An implementation workshop was conducted prior to the start of this trial to support the treating physicians in using the DAs. In total 14 physicians received the implementation workshop and the included patients. The online DAs were developed by patients and physicians according to the International Patient Decision Aids Standards and based on a previous study, carried out by this research group, assessing patients and physicians needs when deciding about the optimal treatment[3,9]. The DA consists of 5 steps comparing operative treatment, defined as total joint prosthesis, with non-operative treatment, defined as lifestyle advice, painkillers and corticosteroid injections ([Supplementary material](#)).

### Outcome measures

Our primary outcome was the difference in decisional conflict after the first consultation (mean: 11 d, range: 5-11) measured through the Decisional Conflict Scale (DCS)[10]. The DCS is a validated and reliable questionnaire that consists of 16 questions, divided into 3 categories: a) the level of uncertainty, b) factors contributing to uncertainty such as feeling uninformed, unclear about personal values, or unsupported in decision-making and c) effective decision making such as feeling the choice is informed, values-based, likely to be implemented, and expressing satisfaction with the choice. The total score ranges from 0 (no decisional conflict) to 100 (highest level of decisional conflict).

Our secondary outcomes were satisfaction, anxiety, gained knowledge, stage of decision making, preferred treatment options and if a final choice was made after the first consultation. At 26 wk (mean: 50 wk, range: 26-91) we evaluated differences in decisional conflict, satisfaction, anxiety, final choice, health outcomes and quality of life. The satisfaction questionnaire consisted of three questions to measure patients' satisfaction with the given information, the clinic and the physician. Patients could score each question from 0 (no satisfaction) to 10 (complete satisfaction). As outcome measurement for anxiety, we used the short Pain Anxiety Symptoms Scale (PASS-20)

questionnaire to measure patients' pain-related anxiety and fear. It consisted of 20 questions with a score ranging from 0 (no anxiety and fear) to 100 (extreme anxiety and fear)[11]. The knowledge questionnaire consisted of 4 questions and was used to measure the patients' knowledge of treatment options and risks. The score ranged from 0 (no correct answers) to 4 (all correct answers). The decision questionnaires contained 2 separate questionnaires. One questionnaire inquired what phase of decision making patients were in and which treatment they preferred. The second questionnaire was to determine whether patients had made their definitive decision. Health outcomes measured by the Hip Disability and Osteoarthritis Outcome Score (HOOS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS)[12,13]. Both questionnaires include questions about patients' symptoms, pain, activity limitations in daily life, sport, recreation and quality of life. The EuroQol 5 Dimensions (EQ-5D) questionnaire was used to measure health-related quality of life[14]. It consisted of 5 questions concerning mobility, self-care, usual activities, pain /discomfort and anxiety/depression.

### **Statistical analysis**

We calculated a sample size of 128 patients to identify an effect size of 0.5 SD on the decisional conflict scale with a type 1 error (0.05) and type 2 error (0.20) based on a two-tailed prediction. To report continuous data, we used mean and SD when the group was normally distributed. To compare the control and intervention group we used the Student t-test for continuous dependent variables and dichotomous independent variables when normally distributed. In the case of skewed data, we used the Mann-Whitney U-test. For ordinal data the Kruskal Wallis test was used. We investigated the association between continuous dependent and continuous independent variables in bivariate analysis using Spearman correlation. Associations with a *P* value less than 0.05 were considered statistically significant

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## **RESULTS**

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### **Participants**

Between December 2014 and January 2016, 145 patients were eligible to participate in this study. Sixty-nine patients were assigned to the control group and 76 patients to the intervention group. Of these 145 patients, 4 patients in the control group and 10 patients in the intervention group did not complete the first questionnaires resulting in a total of 131 participants. Fifty-six patients, 29 in the control group and 27 in the intervention group, did not respond at follow-up (Figure 1).

The control group comprised of 30 men and 35 women, who were on average 66-years-old (SD: 10). The intervention group comprised 33 men and 33 women, who were on average 68-years-old (SD: 11). The baseline demographics are shown in Table 1.

### **After first consultation**

When we compared the total DCS after the first consultation, the total DCS of the intervention group (mean: 25) was significantly ( $P = 0.00$ ) lower than the total DCS in the control group (mean: 39). This means there was significantly less decisional conflict in the intervention group. The intervention group had significantly lower DCS-subscores (information, values clarity, support, uncertainty, and effective decision making) than the control group (Table 2).

Patients in the intervention group scored significantly higher on the knowledge scale than the patients in the control group ( $P < 0.01$ ), they were significantly more satisfied with the given information (mean: 8.6 *vs* mean: 7.6;  $P < 0.001$ ) and their physician (mean: 8.9 *vs* mean: 8.3;  $P = 0.01$ ) compared to the patients in the control group. There was no significant difference in satisfaction with the visit to the outpatient clinic ( $P = 0.30$ ) and anxiety ( $P = 0.29$ ).

### **Follow-up at 26 wk**

Only 75 of 131 patients (57%) were available for analysis at this follow-up point. This sample was too small for meaningful analysis.

**Table 1** Baseline characteristics of the patients, *n* (%)

	Without DA	With DA
Sex		
Male	30 (46)	33 (50)
Female	35 (54)	33 (50)
Age (yr; mean $\pm$ SD)	66 $\pm$ 10	68 $\pm$ 11
Level of education		
Pre-vocational secondary or secondary vocational education	15 (23)	22 (33)
Senior general secondary education	10 (16)	8 (12)
Pre-university education	30 (46)	24 (37)
Higher professional education or university	8 (12)	10 (15)
Unknown	2 (3)	2 (3)
Duration of pain in d (mean $\pm$ SD)	47 $\pm$ 75	55 $\pm$ 76
Marital status		
Single	13 (20)	16 (24)
Unmarried	8 (12)	8 (12)
Married	37 (57)	30 (45)
Divorced	2 (3)	1 (2)
Widowed	4 (6)	9 (14)
Unknown	1 (2)	2 (3)
Working status		
Working, full time	8 (12)	16 (24)
Working, part time	12 (18)	7 (10)
Sickleave	2 (3)	1 (2)
Retired	36 (55)	34 (51)
Unemployed, able to work	3 (5)	1 (2)
Unemployed, unable to work	3 (5)	3 (5)
Unknown	1 (2)	4 (6)
Location		
Left hip	10 (15)	9 (14)
Right hip	24 (37)	15 (23)
Both hips	6 (9)	3 (5)
Left knee	13 (20)	13 (20)
Right knee	9 (14)	18 (26)
Both knees	3 (5)	6 (9)
Unknown	0 (0)	2 (3)
Had non-operative treatment before		
Yes	18 (28)	25 (38)
No	47 (72)	39 (59)
Unknown	0 (0)	2 (3)
Hospital		
Hospital 1	2 (3)	9 (14)
Hospital 2	23 (35)	21 (32)

Hospital 3	27 (42)	26 (39)
Hospital 4	13 (20)	10 (15)

DA: Decision aid.

## DISCUSSION

Our research shows that patients using a DA in making a shared decision had significantly less decisional conflict, increased satisfaction with the given information and the treating physician after their first consultation and more knowledge about their given treatment.

In previous studies, low decisional conflict was related to DCS scores of 25 or lower. Scores of 39 and higher were related to higher mental conflict which can result in delays in decision making[10,15]. The finding that patients provided with a DA experienced less decisional conflict after the first consultation compared to patients treated without a DA is in concordance with previous studies[6]. The systematic review by Stacey *et al*[16] included 105 studies comparing treatment with DAs to usual care. Sixty-three of the 105 studies used the DCS. A significant average decrease in the level of decisional conflict was observed in the DA group.

In the systematic review by Stacey *et al*[5], the level of satisfaction with the given information and the treating physician at enrollment seems to be positively influenced by DAs. Eleven studies measured satisfaction with the decision-making process, 4 measured satisfaction with the given information and 1 measured satisfaction with participating in the decision making. In these 16 studies, mixed outcomes were found for satisfaction, but none of the studies showed significantly less satisfaction in the DA group. A possible explanation for the positive effect of the DA on the level of satisfaction with the given information could be that patients were able to repeat the information that was given by the physician by reading the DA and have a better recollection. This could also make the patient feel more satisfied with the physician. A crucial factor in patients' satisfaction with their treating physician is how they communicate. An essential part of communication is how the physician provides information about treatments. If the patient is more satisfied with the information because of the DA, this could influence the satisfaction with the physician in a positive way[17-19].

The finding that DAs did not have an effect on the level of anxiety is also accordant with previous studies[5]. Thirty-one studies measured anxiety, and none of these studies showed differences in the effect on patients stated anxiety after one month, three months or one year. Our expectation was that if a patient knows more about potential risks then they might be more anxious. This was not seen in our results.

A well-designed DA should be substantiated by evidence-based research. This means that if one of the treatments has better results this will be seen in the DA. However, every treatment has disadvantages, which will also be reflected in the DA. It is then up to the patient to decide if the advantages are more important than the disadvantages. This means that after the implementation of a DA the preference for a certain treatment can change.

The positive effect of DAs in our results supports the use of DAs in clinical practice. It can help physicians to inform their patient in a better, easier and more complete way. For example, with knee OA, not many patients decide during the first consultation that they are ready for a total knee arthroplasty. In the majority of cases there will be a second and a third consultation. If the orthopedic surgeon provides the patient with a DA in the first consultation, the patient will return better informed. The orthopedic surgeon will have more time to personalize the consultation instead of giving only basic information about the treatments. The patient can ask more specific questions to support their decision. In this way, consultations can be more efficient, and this will be of benefit to the patient and the physician.

Further research is required to determine the positive effect on patients and physicians. In addition, the effect of individualized DAs and their cost-effectiveness should be investigated.

The strength of this study is that this RCT was performed in secondary as well as tertiary referral centers.

The first limitation of this study is the high loss to follow-up at 26 wk (Figure 1). After 26 wk, 56 patients (43%) did not respond during the follow-up period. Additionally, the initial follow-up period was set at 26 wk after the first consultation.

**Table 2 Outcomes after the first consultation, *n* (%)**

	Without DA	With DA	<i>P</i> value
Decisional conflict scale (mean, SD)			
Informed subscore	39 (20)	32 (20)	0.03
Values clarity subscore	50 (22)	25 (16)	0.00
Support subscore	45 (16)	27 (13)	0.00
Uncertainty subscore	35 (15)	23 (16)	0.00
Effective decision subscore	28 (13)	20 (15)	0.00
Total score	39 (11)	25 (12)	0.00
Satisfaction (mean, SD)			
Information	7.6 (1.8)	8.6 (1.1)	0.00
Visit outpatient clinic	8.0 (1.7)	8.3 (1.5)	0.30
Physician	8.3 (1.7)	8.9 (0.9)	0.01
Anxiety (mean, SD)	23 (19)	20 (17)	0.29
Knowledge (mean, SD)	3.3 (0.9)	3.7 (0.6)	0.01
Stage of decision making			0.11
Have not begun to think about the treatment options	2 (3)	1 (1.5)	
Have not begun to think about the treatment options, but I am interested to do so	6 (9)	0 (0)	
I am considering the treatment options now	9 (14)	10 (15)	
I am close to selecting an option	1 (2)	3 (4.5)	
I have already made a decision, but am still willing to reconsider	10 (15)	15 (23)	
I have already made a decision and I am unlikely to change my mind	37 (57)	37 (56)	
What treatment option do you prefer?			0.46
Watchful waiting	3 (5)	5 (8)	
Lifestyle changes	3 (5)	1 (2)	
Physiotherapy	13 (20)	22 (33)	
Painkillers	3 (5)	3 (5)	
Corticosteroid injection	12 (18)	7 (11)	
Prosthesis	27 (41)	26 (38)	
Other	4 (6)	2 (3)	
Did you make a final choice			0.84
Yes	51 (78)	50 (76)	
No	14 (22)	16 (24)	
If yes, what did you choose			0.26
Watchful waiting	2 (4)	4 (8)	
Lifestyle changes	3 (6)	1 (2)	
Physiotherapy	8 (16)	16 (32)	
Painkillers	2 (3)	1 (2)	
Corticosteroid injection	11 (22)	6 (12)	
Prosthesis	25 (49)	21 (42)	
Other	0 (0)	1 (2)	

DA: Decision aid.

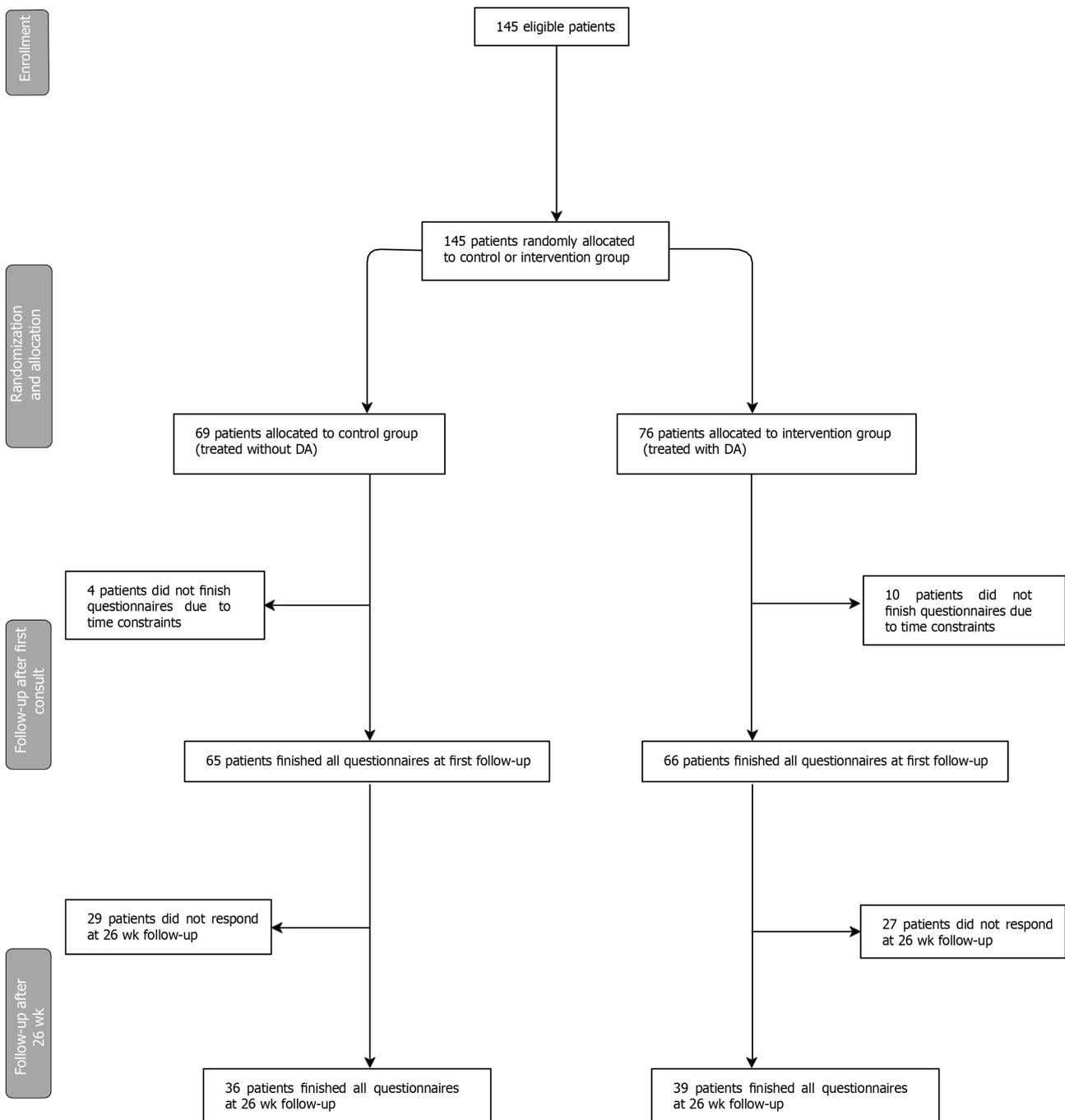


Figure 1 Flow of the patients in the study.

However, eventually, the mean follow-up period was 350 d, thus closer to 52 wk than the anticipated 26 wk. Although the loss to follow-up in both groups was approximately the same, no conclusion can be drawn from the follow-up results. The loss to follow-up was due to time constraints, even though great effort was made to try and contact these patients.

The second limitation was the exclusion of 14 patients, 4 patients in the control group and 10 patients in the intervention group, who did not complete the questionnaires after the first consultation due to time constraints at the outpatient clinic.

The third limitation was that knee or hip OA patients may experience different levels of decisional conflict related to their stage of the OA. We did not categorize patients into different stages of OA. However, due to randomization we expect that patients with varying stages of OA were equally divided over both groups.

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## CONCLUSION

Providing patients with an additional DA may have a positive effect on decisional conflict after the first consultation. Due to loss to follow-up we are unsure if this effect remains over time.

## ARTICLE HIGHLIGHTS

### **Research background**

Shared decision making has become more popular over the years. A decision aid (DA) can help the patient and the physician with the shared decision making process in case a diagnosis has multiple treatment options.

### **Research motivation**

To determine if DAs can help in optimizing orthopedic healthcare we provide to patients with hip or knee osteoarthritis (OA).

### **Research objectives**

The objective of this study was to determine the influence of a DA on decisional conflict in patients that require treatment for hip or knee OA.

### **Research methods**

A multi-center unblinded randomized controlled trial was conducted in which we compared decisional conflict in patients with hip or knee OA. The control group was treated with standard care, and the intervention group was treated with standard care and was provided with a DA.

### **Research results**

In the intervention group, we observed a significant decrease in decisional conflict after their first consultation with the physician. At 26 wk the sample was too small for analysis due to excessive loss to follow-up.

### **Research conclusions**

Patients with hip or knee OA choosing treatment seem to have less decisional conflict after their first consultation with their physician when treated with an additional DA.

### **Research perspectives**

In further research we should investigate the cost-effectiveness of decision aids and the satisfaction among physicians.

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