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Effectiveness of a web-based treatment decision aid for men with lower urinary tract symptoms due to benign prostatic hyperplasia

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Objectives

To evaluate the effectiveness of a web-based decision aid (DA), with values clarification exercises compared with usual care, for men with lower urinary tract symptoms due to benign prostatic hyperplasia (LUTS/BPH).

Patients and Methods

Between July 2016 and January 2017, all new patients with LUTS/BPH who consulted the urologist were invited to use the DA and participate in this prospective questionnaire study. Patients who consulted the urologist between December 2015 and February 2016 served as controls. The DA was designed to support patients in making a well-informed treatment decision, corresponding with their personal preferences and values. Well-informed decision was measured by using a knowledge questionnaire. Value congruent decision was measured by the correspondence between responses on nine value statements and chosen treatment. The primary outcome, decision quality, was defined as the combination of well-informed decision and value congruent decision. Secondary outcomes were decisional conflict, involvement and received role in shared decision-making, decisional regret, and treatment choice.

Results

A total of 109 DA-users and 108 controls were included. DA-users were younger (68.4 vs 71.5 years; $P = 0.003$) and their education level was higher ($P = 0.047$) compared with the controls. Patients who used the DA made a well-informed and value congruent decision more often than the control group (43% vs 21%; $P = 0.028$). DA-users had less decisional conflict (score 33.2 vs 46.6; $P = 0.003$), experienced a less passive role in decision-making (22% vs 41%; $P = 0.038$), and reported less process regret (score 2.4 vs 2.8; $P = 0.034$). Furthermore, DA-users who had not used prior medication chose lifestyle advices more often than the control group (43% vs 11%; $P = 0.002$). Outcomes were adjusted for significantly different baseline characteristics.

Conclusion

The LUTS/BPH DA seems to improve the decision quality by supporting patients in making more well-informed and value congruent treatment decisions. Therefore, further implementation of this DA into routine care is suggested.

Keywords

benign prostatic hyperplasia, decision aid, shared decision-making, patient-centered care, #UroBPH, #LUTS

Introduction

Worldwide, LUTS due to BPH (LUTS/BPH) are common in ageing men. Prevalence ranges from 50% to 75% amongst men aged >50 years and increases with age [1]. Symptoms can have a major impact on quality of life (QoL) and, therefore, LUTS/BPH represents a substantial disease burden [2,3].

For men with LUTS/BPH with mild symptoms lifestyle advices are usually offered first, prior to medication or surgery [4]. When conservative or pharmacological treatments do not result in adequate symptom relief, surgery is indicated. According to international guidelines, only a minority of patients with severe BPH complications are eligible for surgery [4,5]. The treatment decision should not solely depend on the combination of diagnostic

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findings and the ability of treatments to reduce symptoms [4], but also on treatment preferences and expectations of individual patients. Therefore, trade-offs between treatment effects and impact on QoL have to be considered. Given the preference-sensitive elements of this treatment decision and common misconceptions about preferences and expectations about LUTS/BPH treatment [6,7], integrating patient preferences may improve and support shared decision-making (SDM).

To overcome barriers experienced with implementation of SDM in clinical practice, decision aids (DAs) have been developed to provide standardised information about available treatment options, to make decisions explicit, to support patients in exploring their preferences and values, and to engage patients and their clinicians into SDM [8]. Previous studies showed positive effects of DA use on different outcome measures for decision-making [9,10]. Some studies even showed that DA use lowered elective surgical rates, although these results showed to be inconsistent regarding the effect of LUTS/BPH DAs [9–13]. Compared to evidence on treatment DAs for prostate cancer, evidence on treatment DAs for men with LUTS/BPH is limited and outdated [11,14–20]. In addition, consensus is lacking on the best outcome measure to evaluate the effectiveness of DA implementation [21–23]. In many randomised controlled trials (RCTs) reduction of decisional conflict was considered as a positive outcome because it captures the uncertainty involved in the decision-making process. Contrarily, Vickers [21] argued that high decisional conflict scores could indicate that patients become aware of the difficulty of the decision after involvement in the decision-making process and after absorbing all available information. Furthermore, Kennedy [23] argued that knowledge improvement alone should not be the primary aim of DA use, as knowledge is not always used effectively and does not guarantee a good decision.

Therefore, in the present study, we chose decision quality as the primary outcome measure to evaluate the impact of the implementation of a previously developed DA for patients who face treatment decisions for LUTS/BPH [24]. Decision quality is one of the most important aspects of patient-centred care and is defined as the extent to which treatments reflect the considered preferences of well-informed patients, measured by knowledge scores combined with scores on value statements [25]. We hypothesised that DA use would improve decision quality by supporting patients in making more well-informed treatment decisions that reflect their personal preferences (value congruence), as compared to control patients who received usual care. Furthermore, we hypothesised that patients using the DA would experience less decisional conflict and regret, would be more involved in decision-making, and patients would choose conservative treatments more often.

Patients and Methods

Study Population

A prospective observational questionnaire study was conducted in five Dutch hospitals (one academic and four non-academic) between July 2016 and January 2017. New patients who consulted the urologist in the outpatient clinic of all hospitals because of LUTS suggestive of BPH were invited by their treating urologist to use the DA and to participate in this study. Results were compared with control patients who had consulted the urologist between December 2015 and February 2016. Control patients were identified from 'diagnosis-treatment-combination'-register databases from all hospitals and were invited by their urologist by letter. Patients who were eligible for two treatments (lifestyle advices, medication and/or surgery) were included. Furthermore, patients had to have access to the Internet. Patients with an absolute medical indication for surgery [4], prior prostate surgery, prostate cancer, cognitive impairment or insufficient Dutch language comprehension were excluded. For both patients and physicians, study participation was voluntary without remuneration.

The Intervention

The web-based DA was previously developed according to the International Patient Decision Aids Standards (IPDAS) [8,24]. The DA contains the following two decisions for patients with LUTS/BPH: the decision between lifestyle advices or medication (*decision A*) and to continue medication or undergo surgery (*decision B*). Based on clinical factors urologists need to indicate on a handout which treatment decision applies to the patients' individual situation. Subsequently, patients can log in and access the DA at https://bph.keuzehulp.nl/. The DA contains general information about LUTS/BPH based on current guidelines [4] and values clarification exercises to gain insight in to patients' preferences [24].

In order to fit clinical practice, the pragmatic approach of this study allowed hospitals to integrate the introduction of the DA with their own standard information provision routines. Therefore, the time points of offering the DA differed between hospitals. To enable comparison with controls, patients were only included for analyses when the DA was offered before or after the first or second consultation, and when patients had not visited a urologist in the past year for LUTS.

Outcome Measures

The primary outcome measure was decision quality, defined as the combination of a well-informed decision and value congruent decision. A disease-specific knowledge

questionnaire, adapted from previous studies, was used to assess well-informed decision [12,26]. Value congruent decision was measured by matching responses on nine value statements to the chosen treatment. The nine value statements were based on the values clarification exercises in the DA. Patients were asked to rate to what extent each statement was important for their decision, ranging from zero to 10. Each statement differentiates between one particular treatment and two alternative treatments (Table S1).

The decision-making process and decisional outcomes were secondary outcome measures in this study. The Decisional Conflict Scale (DCS) was used to measure patients' perceptions at time of treatment decision [27]. Scores were converted to an equivalent 0–100 scale, with higher scores indicating more conflict. To evaluate the level of patient involvement in the decision-making process the Shared Decision Making Questionnaire (SDM-Q-9) was used. All items were scored on a 6-point Likert scale and a mean score between zero and 5 was calculated, with higher mean scores indicating higher levels of involvement in SDM [28]. Patients' perceived role in decision-making was measured by the Control Preference Scale (CPS) [29]. Scores were summarised into provider-led, shared, and patient-led. One item was added to assess satisfaction with participation in decision-making. Decisional regret was measured using the Brehaut Regret Scale and a new regret scale, which measures three different aspects of decisional regret: process, option, and outcome regret [30,31].

Furthermore, to evaluate effectiveness of the DA on decisional outcomes, data on received treatment after the first visit to the urologist and performed diagnostics were collected from patient records. To investigate if DA use influenced surgical rate, decision for surgery within 3 months after the first visit to the urologist was reported. Clinical characteristics were also assessed. To standardise co-morbidity the Charlson Co-morbidity Index (CCI) was used. The IPSS was used to report patients' urinary symptoms [32].

Patients completed the first (online or paper) questionnaire directly after written informed consent was obtained (T1). Three months later, after treatment was chosen and received, patients completed the second questionnaire (T2). Data from the questionnaires were linked to patients' DA data. A complete overview of outcome measures including instruments and time points is presented in Table 1. Patients of whom informed consent was not obtained were still able to use the DA without study participation.

Statistical Analysis

The study was designed to enroll 99 patients per group to provide 80% power to detect effect sizes of 0.4 with an α of 0.05. Expecting a high attrition rate and non-responders in

Table 1 Overview of all outcome measures including instruments used with time points.

	Instrument/measures	Subscales	Number of items	T1	T2	Medical record	DA
Patient characteristics	Age	–	–	–	–	X	–
	Sociodemographic items	–	–	*	X	–	–
	Duration of urinary symptoms	–	–	–	X	–	–
	CCI and LUTS-related variables	–	–	–	–	X	X
DA usability items†	SCIP-B	–	7	X	–	–	–
	Preparation for decision-making scale	–	10	X	–	–	–
Decision quality	Knowledge questions	–	7	–	X	–	
	Value statements	–	9	–	X	–	
Decision process	DCS	1 = Informed subscale 2 = Values clarity subscale 3 = Support subscale 4 = Uncertainty subscale 5 = Effective decision subscale	16	–	X	–	–
	SDM-Q-9	–	9	–	X	–	–
	CPS	–	1	–	X	–	–
	Satisfaction with perceived role in decision-making (study-specific)	–	1	–	X	–	–
Decision outcomes	First treatment choice after consultation	–	–	–	–	X	–
	Surgical rate	–	–	–	–	X	–
	New regret scales	1 = Process regret 2 = Option regret 3 = Outcome regret	18	–	X	–	–
	Brehaut regret	–	5	–	X	–	–

*T1 = directly after written informed consent was obtained and after DA use (DA group only). T2 = 3 months after first questionnaire was sent: after treatment was chosen and received (for the control group: 3–6 months after the first consultation with the urologist). *Sociodemographic data of DA-users were obtained from questionnaires at T1. †DA usability items were not described in this study. SCIP-B, Satisfaction with Cancer Information Profile B.*

both groups, we aimed to invite 200 patients for the DA group and 300 patients for the control group.

To compare baseline patient and clinical characteristics between groups, chi-squared tests for categorical variables and *t*-tests for continuous variables were used.

First, unadjusted regression models (linear, logistic, and multinomial) were used to compare all outcome measures between groups. Secondly, multivariable multilevel regression models were used in order to adjust for group differences, including all baseline characteristics with $P < 0.05$ as fixed factors and a random effect for hospital to account for between-hospital heterogeneity. Intention-to-treat analysis was performed. Questionnaire responses were included if <25% of the data were missing. For calculating informed and value congruent decision no missing data were allowed. Detailed information on primary outcome analyses can be found in Appendix S1.

All analyses were conducted using the IBM Statistical Package for the Social Sciences (SPSS®), version 24.0 (SPSS Inc., Chicago, IL, USA), with a $P < 0.05$ considered statistically significant.

Results

A flow chart of the study, with enrolment numbers, is shown in Fig. 1. In total, 109 DA patients and 108 control patients were included for analyses based on eligibility criteria. In all, 11 of those 109 DA patients (10%) appeared not to have used the DA, resulting in a viewing rate of 90%. Nonetheless, these patients were included for analyses according to the intention-to-treat principle. The response rate for questionnaires was 60% (100/165) in the DA group and 36% (108/303) in the control group.

Marital status, work status, co-morbidity, and LUTS/BPH-related characteristics were comparable between groups. DA-users were younger (mean age 68.4 vs 71.5 years; $P = 0.003$) and their education level was higher (42% vs 26%; $P = 0.047$) compared with the controls. Furthermore, there was less time between the first consultation with the urologist and questionnaire completion amongst DA-users, at a mean (SD) of 5.3 (1.7) vs 7.0 (1.4) months ($P < 0.001$; Table 2).

DA-users had higher knowledge scores than the controls (mean score 3.1 vs 2.1; $P = 0.009$; Table S2). The proportion of patients who made a well-informed decision was higher in DA-users than in controls (62% vs 36%; $P = 0.040$). Overall, value statements discriminated well between treatments, and better amongst DA-users than controls (Table 3). Value congruence scores (congruence between value statements and chosen treatment) were higher in DA-users than in controls for patients who chose medication after consulting the urologist (mean score 5.6 vs 4.8; $P = 0.012$; Table 4). There were no differences in value congruence scores between groups for patients who chose surgery or lifestyle advices. There were no differences in value congruent decision between groups (64% vs 55%; $P = 0.165$). To investigate decision quality, scores of well-informed decision and value congruent decision were combined, resulting in a higher proportion of decision quality in patients in the DA group than in the control group (43% vs 21%; $P = 0.028$; Table 4).

Overall, decisional conflict was lower in the DA patients than in controls (mean score 33.2 vs 46.6; $P = 0.003$), in particular in the informed (mean score 37.3 vs 57.9; $P < 0.001$) and value clarity (mean score 36.9 vs 58.2; $P = 0.001$) subscales. DA-users experienced marginally more involvement in the SDM process (SDM-Q-9 mean score 3.3 vs 2.9; $P = 0.049$) and perceived a less passive role (CPS) than controls (22% vs 41%; $P = 0.038$). Satisfaction with perceived role in decision-making was similar between groups (Table 4).

DA-users who had not used prior medication at the time of consulting their urologist, chose lifestyle advices more often than the controls who had not used prior medication (43% vs 11%; $P = 0.002$). However, no differences in treatment choices were found in patients who had used prior medication. The surgical rate did not differ between groups. DA-users had significantly less process regret than controls (mean score 2.4 vs 2.8; $P = 0.034$). Option, outcome, and overall regret (Brehaut Scale) did not differ between groups (Table 4).

Discussion

Implementation of the web-based DA in clinical practice improved decision quality for patients deciding on treatments for LUTS/BPH. Furthermore, overall decisional conflict was lower in DA-users. More specifically, they felt more informed and were clearer about their values. Involvement in the SDM process was slightly higher in the DA group than in the control group and DA-users experienced a less passive role. DA-users who had not used prior medication before consulting their urologist chose lifestyle advices more often than controls. Although DA-users had less process regret, the other aspects of regret did not differ between the groups. Additionally, the impact on surgical rate did not differ between DA-users and controls.

To the best of our knowledge, this is the first study to have investigated the effectiveness of a LUTS/BPH DA on improving decision quality by comparing DA patients with control patients. Investigating decision quality is challenging, as standardised quantification methods are lacking. In the present study, we attempted to quantify it by combining the two key elements of decision quality: well-informed decision and value congruent decision. Well-informed decision was assessed by using a disease-specific knowledge questionnaire. Similar to previous studies that measured LUTS/BPH

Fig. 1 Flow chart and enrolment numbers in the DA and the control groups.

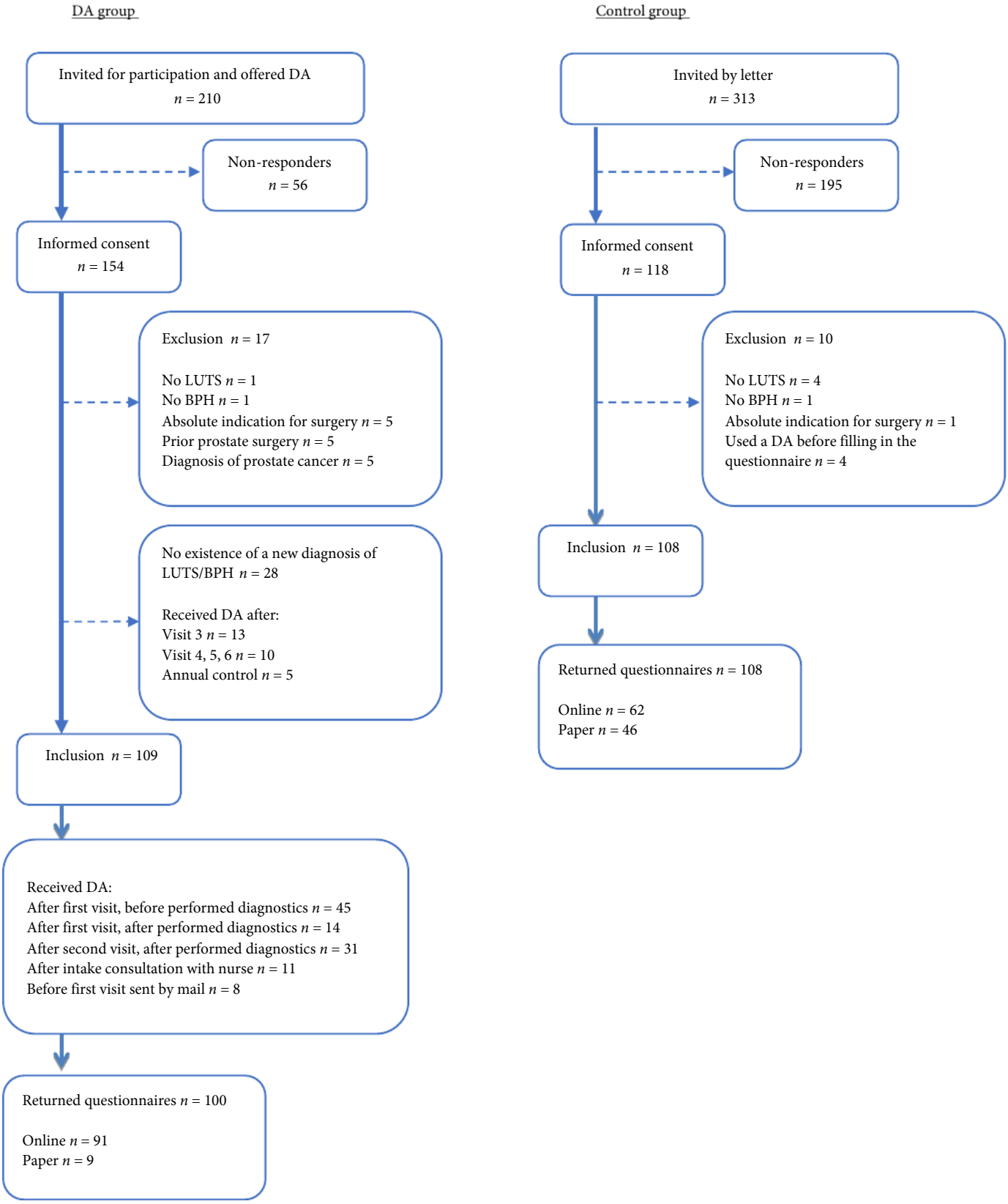

Table 2 Baseline characteristics of DA-users and controls (n = 217).

Variables	Categories/range	DA-users (n = 109)	Controls (n = 108)	P
Age, years, mean (SD)		68.4 (7.0)	71.5 (8.4)	0.003
Inclusion per hospital, % (n)	A	41 (45)	24 (26)	<0.001
	B	28 (31)	17 (18)	
	C	17 (18)	32 (35)	
	D	10 (11)	12 (13)	
	E	4 (4)	15 (16)	
Education, % (n)*	Low	34 (35)	41 (44)	0.047
	Medium	24 (24)	33 (35)	
	High	42 (43)	26 (28)	
Work status, % (n)	Employed/volunteer job	32 (33)	33 (35)	0.956
	Not employed/ retirement	68 (69)	67 (72)	
Marital status, % (n)	Married/living with partner	85 (88)	80 (86)	0.330
	Not married/living alone	15 (15)	20 (21)	
CCI, % (n)	0	57 (62)	50 (54)	0.509
	1–2	37 (40)	44 (48)	
	≥3	6 (7)	6 (6)	
Duration of urinary symptoms, months, % (n)	<6	3 (3)	5 (5)	0.369
	6–12	18 (18)	25 (27)	
	12–60	51 (51)	50 (54)	
	>60	28 (28)	20 (21)	
Use of medication before consultation, % (n)	No	43 (47)	51 (55)	0.249
	Yes	57 (62)	49 (53)	
IPSS, % (n)	Mild (score 0–7)	8 (5)	9 (6)	0.821
	Moderate (score 8–19)	55 (35)	49 (35)	
	Severe (score 20–35)	37 (24)	42 (30)	
QoL score, mean (SD); n	Range 0 (delighted) to 6 (terrible)	3.2 (1.2); 64	3.4 (1.3); 70	0.264
Prostate volume, % (n)†	Small <30 mL	17 (17)	21 (21)	0.614
	Medium 31–50 mL	46 (47)	48 (49)	
	Large >50 mL	37 (38)	31 (32)	
PSA level, ng/mL, mean (SD); n		4.2 (3.3); 90	3.9 (3.9); 85	0.576
Q_{max}, mL/s, mean (SD); n‡		12.3 (5.1); 61	11.3 (4.6); 55	0.286
Post-void residual urine, % (n)	0–50 mL	34 (21)	49 (26)	0.361
	51–100 mL	28 (17)	19 (10)	
	101–150 mL	15 (9)	10 (5)	
	151–200 mL	7 (4)	11 (6)	
	>200 mL	16 (10)	11 (6)	
Time to completion of questionnaire, months, mean (SD)		5.3 (1.7)	7.0 (1.4)	<0.001

*Q_{max}, maximum urinary flow rate. Percentages do not include missing data. QoL measured by a single item. *Education: low (no primary school, lower general secondary education or lower vocational training), medium (higher general secondary education, vocational training), high (high vocational training and university). †Prostate volume is measured by rectal examination or TRUS. ‡Voided volume was at least 150 mL.*

knowledge amongst patients in SDM programmes, DA-users had higher mean knowledge scores than patients who received usual care (3.1 vs 2.1; P = 0.012) [12,17]. Evaluation of value congruent decision is relatively new. Only one study has investigated the association between ratings of possible health outcomes and actual treatment decisions amongst patients with LUTS/BPH before [20]. A systematic review by Munro et al. [33] showed the supportive value of DAs in making value congruent decisions in different clinical settings. Although not significant, we did find relatively higher proportions of patients who made a value congruent decision, with higher proportions in the DA group than in the control group (64% vs 55%). Moreover, the proportion of patients who made both a well-informed and value congruent decision was significantly higher in the DA group than in the control group. Together with the reduction of decisional conflict, less passive role in decision-making, and less process regret, our present findings suggest that the LUTS/BPH DA facilitates an improvement in decision quality and the decision-making process.

We also hypothesised that by providing patients with the DA, patients would choose conservative treatments more often. Consistent with this hypothesis, previous studies already demonstrated increased preferences for more conservative LUTS/BPH treatments after DA use [18,19]. Some studies even showed that DA use may lower elective surgical rates [9–11]. Our present results only support less use of medication in the subgroup of DA-users who had not used prior medication before consultation, without an effect on surgical interventions. Thus, by improving patient knowledge, they were not only more empowered to choose the treatment that reflected their own values, but they also choose more conservative treatments if they had not used prior medication.

Table 3 Importance of individual value statements by treatment chosen.

Value statements, score	Lifestyle advices	Medication	Surgery	η^2	*P*
DA-users, *n*	**24**	**64**	**10**		
My urinary symptoms bothered me so much, that I wanted active treatment	4.3	6.6	7.7	0.158	<0.001
I wanted to avoid taking medication daily	5.3	3.2	7.1	0.160	<0.001
I wanted to avoid taking medication because of side effects	5.5	3.1	5.8	0.131	0.001
I wanted to postpone surgery as long as possible	7.3	7.5	4.7	0.078	0.021
I wanted to postpone surgery because of the risks	7.3	7.6	4.4	0.120	0.002
I wanted a one-time treatment for my urinary symptoms	5.0	3.9	8.1	0.158	<0.001
I wanted a treatment with the highest chance of permanent effect	7.5	7.0	8.5	0.031	0.227
I wanted a treatment with the highest chance of significant improvement of my urinary stream force	7.3	6.7	8.5	0.047	0.102
I wanted a treatment with the highest chance of significant improvement of my urinary symptoms	7.4	7.6	8.7	0.028	0.257
Controls, *n*	**17**	**77**	**13**		
My urinary symptoms bothered me so much, that I wanted active treatment	4.0	6.8	8.3	0.177	<0.001
I wanted to avoid taking medication daily	3.9	4.0	7.3	0.102	0.005
I wanted to avoid taking medication because of side effects	5.0	3.2	6.1	0.098	0.006
I wanted to postpone surgery as long as possible	5.3	6.6	4.8	0.041	0.121
I wanted to postpone surgery because of the risks	5.8	6.2	4.4	0.030	0.221
I wanted a one-time treatment for my urinary symptoms	4.4	5.7	7.2	0.038	0.143
I wanted a treatment with the highest chance of permanent effect	7.3	8.0	9.5	0.055	0.061
I wanted a treatment with the highest chance of significant improvement of my urinary stream force	6.2	7.3	8.3	0.036	0.161
I wanted a treatment with the highest chance of significant improvement of my urinary symptoms	7.3	8.4	8.7	0.029	0.232

Cell entry is the mean on value statement (0 = not important to me, 10 = very important to me) computed for those choosing a specific treatment. Eta-squared (η^2) and P value from one-way analysis of explained variance.

In contrast to a systematic review of RCTs for DAs [9], our present study was not a randomised comparison of the DA and control groups. Nonetheless, we reason that the present study's pragmatic approach is a strength. In order to fit clinical practice, we allowed participating hospitals to integrate DA introduction with their own standard information provision routines, resulting in a viewing rate of 90%. This is a high percentage compared to the 25% [34] and 37% [35] described in the literature, which may partly be explained by the mode of delivery [14]. In one study they used the automatic method of mailing the DA to men eligible for prostate cancer screening [34]. In the present study, most patients were directed to use the DA by either their urologist or the nurse. This approach may have promoted the viewing rate and successful DA implementation after the end of study. Furthermore, in order to respond to some barriers experienced by physicians with implementing DAs, such as lengthening consultation, patients were able to access the DA at home. The fact that the DA was developed using a Delphi study with urologists and patients with LUTS/BPH, and that five Dutch hospitals with different clinical practices participated in the present study, suggests that our results are generalisable and further disseminating of the DA is feasible [24].

There are several limitations of the present study. First, to enable comparison with patients who received usual care, a 'historical' control group was used. Besides our goal to achieve successful implementation of the DA, we chose this design to avoid potential contamination of controls that might have occurred if urologists were required to use the DA for some patients and not others. However, historical controls come with their own bias, explaining the low response rate on questionnaires of 36% amongst controls. The response rate might be extra low due to the benign nature of the disease. As urologists were aware that they participated in the present study, it is likely that they have encouraged patients more in decision-making than they usually would do. Furthermore, urologists could have applied their own selection criteria when offering the DA to patients resulting in selection bias. Significant differences in baseline characteristics between groups support this assumption. The mean age was lower in DA-users and education level was higher in the DA-users than in controls. In order to adjust for such group differences, we corrected outcomes for age, education level, and hospital. In addition, this non-randomised study design might have resulted in selection bias as variables, such as patient's personality, intelligence and mental health status, were not considered and adjusted for but which could have influenced the impact of the DA on the outcome measures.

A second limitation might be that results are influenced by the moment of completing the questionnaire. Although both groups were supposed to complete the questionnaire at the same time, there was significant difference in the time between first consultation with the urologist and completion

Table 4 Differences in all outcome measures between DA-users and controls (n = 217).

Variables	Categories/range	DA-users (n = 109)	Controls (n = 108)	Unadjusted		Adjusted*	
				β estimate/ OR(95% CI)	P	β estimate/ OR(95% CI)	P
Decision quality							
Informed choice	Total correctly answered questions, mean (SD); n	3.1 (1.8); 98	2.1 (1.7); 105	1.1 (0.6;1.6)	<0.001	0.6 (0.2;1.2)	0.009†
	Knowledge score >3/7, % (n/N)	62 (61/98)	36 (38/105)	2.9 (1.6;5.1)¶	<0.001	2.1 (1.0;4.1)¶	0.040†
Value congruent choice	Lifestyle advices, mean (SD); n	4.9 (1.5); 24	4.5 (1.6); 16	0.3 (0.7;1.3)	0.514	0.4 (0.7;1.4)	0.483
	Medication, mean (SD); n	5.6 (1.2); 63	4.8 (1.3); 72	0.8 (0.4;1.2)	<0.001	0.6 (0.1;1.1)	0.012†
	Surgery, mean (SD); n	7.3 (1.2); 10	7.3 (1.0); 12	0.0 (1.0;1.0)	0.948	0.5 (1.5;0.5)	0.336
	Mean value congruent score >5, % (n/N)	64 (62/97)	55 (55/100)	1.4 (0.8;2.5)¶	0.203	1.6 (0.8;3.2)¶	0.165
Informed and value congruent choice	Knowledge score >3/7 and mean value score >5, % (n/N)	43 (42/97)	21 (21/99)	2.8 (1.5;5.3)¶	0.001	2.3 (1.1;4.7)¶	0.028†
Decision process							
DCS	Total, mean (SD); n	33.2 (18.7); 95	46.6 (21.2); 92	13.4 (19.2; 7.6)	<0.001	9.8 (16.4; 3.3)	0.003†
	Informed subscale, mean (SD); n	37.3 (25.8); 96	57.9 (27.8); 106	20.6 (28.1; 13.2)	<0.001	16.3 (25.0; 7.7)	<0.001†
	Values clarity subscale, mean (SD); n	39.6 (25.1); 97	58.2 (28.1); 106	18.6 (26.0; 11.2)	<0.001	14.6 (23.2; 5.9)	0.001†
	Support subscale, mean (SD); n	28.7 (20.2); 97	42.3 (23.7); 105	13.6 (19.7; 7.5)	<0.001	9.1 (16.2; 2.0)	0.012†
	Uncertainty subscale, mean (SD); n	32.2 (23.2); 97	43.9 (29.8); 106	11.7 (19.1; 4.2)	0.002	6.8 (15.5;1.9)	0.124
	Effective decision subscale, mean (SD); n	30.3 (20.2); 97	37.6 (24.2); 105	7.3 (13.5; 1.1)	0.022	4.8 (12.1;2.4)	0.189
SDM-Q-9	mean (SD); n	3.3 (1.1); 96	2.9 (1.2); 96	0.5 (0.2;0.8)	0.004	0.4 (0.0;0.7)	0.049†
Perceived role in decision-making	Provider-led, % (n)	22 (21)	41 (40)	2.2 (1.1;4.5)¶	0.029	2.5 (1.0;5.8)¶	0.038†
	Shared, % (n)‡	38 (36)	31 (31)				
	Patient-led, % (n)	40 (38)	28 (27)	0.8 (0.4;1.6)¶	0.584	0.9 (0.4;2.1)¶	0.884
	Satisfied with participation, % (n)	89 (85)	79 (79)	–	–	–	–
	Would rather have a more active role, % (n)	11 (10)	21 (21)	0.4 (0.2;1.0)¶	0.049	0.5 (0.2;1.4)¶	0.161
	Would rather have a more passive role, % (n)	–	–		–		–
Decision outcomes							
First treatment choice after consultation the urologist	Patients who did not use medication before:						
	Lifestyle advices % (n)	43 (20)	11 (6)	0.2 (0.1;0.4)¶	<0.001	0.2 (0.0;0.6)¶	0.002†
	Medication, % (n)§	51 (24)	87 (48)	–	–	–	–
	Surgery, % (n)	6 (3)	2 (1)	0.2 (0.0;1.7)¶	0.129	0.2 (0.0;2.4)¶	0.206
	Patients who used medication before:						
	Lifestyle advices % (n)	3 (2)	2 (1)	0.5 (0.0;6.2)¶	0.623	0.9 (0.1;13.5)¶	0.945
	Medication, % (n)§	81 (50)	87 (46)	–	–	–	–
	Surgery, % (n)	16 (10)	11 (6)	0.7 (0.2;1.9)¶	0.441	0.6 (0.2;1.8)¶	0.393
Surgical rate	Decision for surgical treatment < 3 months (%)	12 (13)	11 (12)	0.8 (0.3;2.0)¶	0.851	0.8 (0.3;2.2)¶	0.945
New regret scales	Process regret, mean (SD); n	2.4 (0.7); 96	2.8 (0.7); 96	0.3 (0.6; 0.2)	<0.001	0.3 (0.5;0.2)	0.034†
	Option regret, mean (SD); n	2.1 (0.8); 96	2.3 (0.7); 96	0.2 (0.4;0.0)	0.116	0.0 (0.3;0.2)	0.727
	Outcome regret, mean (SD); n	2.1 (0.8); 95	2.3 (0.7); 96	0.1 (0.4;0.1)	0.181	0.0 (0.3;0.2)	0.904
Brehaut regret	mean (SD); n	2.1 (0.8); 95	30.3 (17.7); 96	0.1 (0.4;0.1)	0.117	0.6 (5.1;6.3)	0.844

**Adjusted P value is adjusted for age, level of education, time between first consultation and completion of questionnaire, and accounted for between-hospital heterogeneity with multivariate multilevel regression analyses. For linear regression analyses, the adjusted and unadjusted β coefficient with 95% CI are presented. For logistic and multinomial regression, the adjusted and unadjusted odds ratios (ORs) with 95% CIs are presented. The risk association with treatment arm is presented with the control group as reference. Percentages do not include missing cases. †Significant ($P < 0.05$). ‡The reference category is shared . §The reference category is medication . ¶OR.*

of the questionnaire between groups (mean 5.3 vs 7.0 months). As preferences can change over time, this difference may have influenced the responses of controls on value statements [36]. Furthermore, it may be possible that disease-specific knowledge about LUTS/BPH diminishes after a few months. This may explain the overall low knowledge scores amongst patients in both groups, with significantly lower knowledge scores in the control group. Ideally, it would have been more appropriate to ask for patients' preferences before the treatment decision was made and to assess knowledge directly after the decision was made [25]. Furthermore, adverse clinical outcomes or side-effects of treatments could have negatively influenced responses on decisional process measures. In order to adjust for group differences, we corrected outcomes for the time between the first consultation with the urologist and questionnaire completion, next to age, education level, and hospital.

Lastly, we were not able to demonstrate an effect of the DA on prostatic surgical rates. Results of previous RCTs for

LUTS/BPH DAs on this outcome varied between no difference to a lower surgical rate amongst DA-users [12,13]. The Cochrane review also describes that DA implementation does not result in a decrease in elective surgical rates in diseases where baseline surgical rates are already low (e.g., LUTS/BPH) [9]. Nevertheless, results on surgical rate in LUTS/BPH remain to be elucidated.

In conclusion, implementation of the web-based LUTS/BPH DA with standardised information based on current guidelines and assessment of personal preferences seems to improve well-informed and value congruent treatment decisions, and thereby decision quality. Furthermore, results on treatment choice indicate that patients, who are informed by the DA on the risks and benefits of treatments, choose lifestyle advices more often if they do not use prior medication. Our present findings are of importance in informing clinicians on how this LUTS/BPH DA can serve as a guide to support the SDM process by helping well-informed patients choose treatments that reflect their individual preferences.

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Con ict of Interest

None declared.

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Abbreviations: CCI, Charlson Co-morbidity Index; CPS, Control Preference Scale; DA, decision aid; DCS, Decisional Conflict Scale; QoL, quality of life; RCT, randomised controlled trial; SDM, shared decision-making; SDM-Q-9, Shared Decision Making Questionnaire.

Supporting Information

Additional Supporting Information may be found online in the Supporting Information section at the end of the article:

Table S1. Relation of scores on value statements and chosen treatment.
Table S2. Responses on knowledge items.
Appendix S1. Description of statistical analyses of primary outcome measure decision quality, defined as 'well-informed and value congruent' decision.