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Original Article

Shared decision making with breast cancer patients – does it work? Results of the cluster-randomized, multicenter DBCG RT SDM trial

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A B S T R A C T

Background and purpose: Shared decision making (SDM) is a patient engaging process advocated especially for preference-sensitive decisions, such as adjuvant treatment after breast cancer. An increasing call for patient engagement in decision making highlights the need for a systematic SDM approach. The objective of this trial was to investigate whether the Decision Helper (DH), an in-consultation patient decision aid, increases patient engagement in decisions regarding adjuvant whole breast irradiation.

Material and methods: Oncologists at four radiotherapy units were randomized to practice SDM using the DH versus usual practice. Patient candidates for adjuvant whole breast irradiation after breast conserving surgery for node-negative breast cancer were eligible. The primary endpoint was patient-reported engagement in the decision process assessed with the Shared Decision Making Questionnaire (SDM-Q-9) (range 0–100, 4 points difference considered clinical relevant). Other endpoints included oncologist-reported patient engagement, decisional conflict, fear of cancer recurrence, and decision regret after 6 months.

Results: Of the 674 included patients, 635 (94.2%) completed the SDM-Q-9. Patients in the intervention group reported higher level of engagement (median 80; IQR 68.9 to 94.4) than the control group (71.1; IQR 55.6 to 82.2; $p < 0.0001$). Oncologist-reported patient engagement was higher in the invention group (93.3; IQR 82.2 to 100) compared to control group (73.3; IQR 60.0 to 84.4) ($p < 0.0001$).

Conclusion: Patient engagement in medical decision making was significantly improved with the use of an in-consultation patient decision aid compared to standard. The DH on adjuvant whole breast irradiation is now recommended as standard of care in the Danish guideline.

Introduction

Patient engagement in decision making is indispensably on the international healthcare agenda [1–7] with shared decision making (SDM) as a widely recognized patient engaging process especially advocated for preference-sensitive decisions [8–10]. Taking patient preferences into account is salient in transforming modern medicine into meaningful care [11,12], However, SDM has proven difficult to implement in daily clinic [13], which has encouraged its inclusion as a fundamental patient right in national health care standards and legislation [14–17]. For example, the 2016 National Cancer Action Plan in Denmark stipulated that SDM should be standard in oncology care [3], but actually incorporating SDM in clinical cancer care remains a work in progress.

Breast cancer is the leading malignancy in women [18]. Due to improved imaging, surgery, pathology and adjuvant treatment, the survival rates of breast cancer patients continue to increase [18,19]. Adjuvant treatment lowers the risk of recurrence but also holds the risk of side effects, some long lasting [20–22]. Adjuvant whole breast

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Figure 1: Patient flow

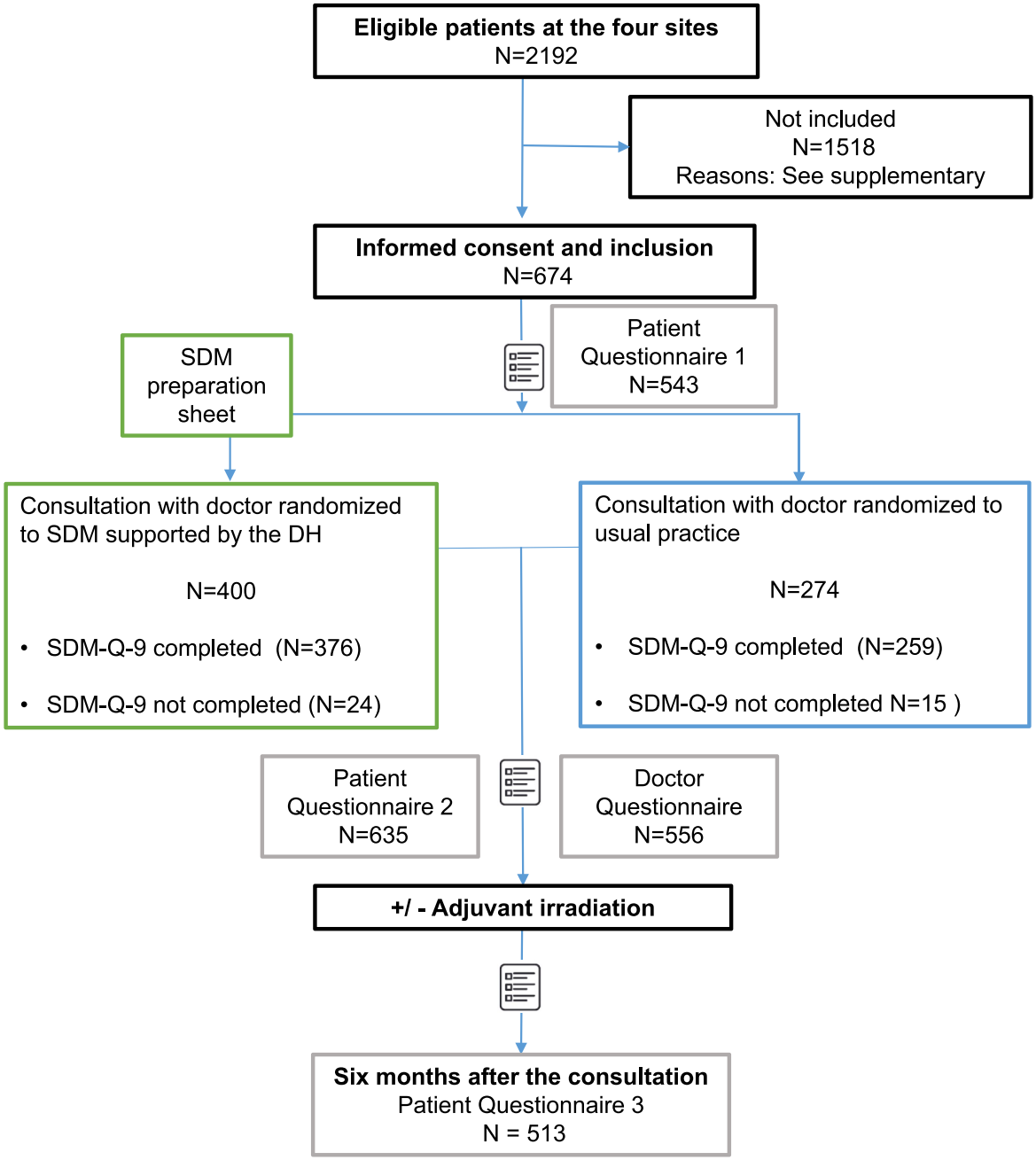

Fig. 1. Patient flow. Abbreviations: SDM: Shared Decision Making. DH: Decision Helper.

irradiation has been standard in node-negative breast cancer care for decades [23–25].Its benefit, however, is often limited to a decrease in risk of local recurrence from around 4 to 1.3 of 100 women [26]. In many patients, adjuvant irradiation lowers the risk of local recurrence but has no impact on overall survival or risk of distant recurrence [26,27]. For patients with comorbidity, especially ischemic heart disease, and smokers during the past 10 years, the side effects of irradiation may be considerable [28]. Considerations of trade-offs between benefits and harms have led to evidence-based reductions in the use of adjuvant irradiation in breast cancer care [26,29]. Current recommendations are described in international guidelines on breast cancer care such as provided by the American Society for Radiation Oncology [30]. For the individual patient, the decision on adjuvant whole breast irradiation after node-negative breast cancer is a trade-off between lowering the risk of local recurrence and suffering possible side effects, which makes it a preference-sensitive decision suitable for SDM [10,31–33].

Patient decision aids (PtDA) are tools designed to support SDM in healthcare decisions [34,35]. Overall, these tools come in 1 of 2 forms: as a pre-consultation PtDA providing the patient with an overview of an upcoming medical decision before the consultation or as a tool integrated into the consultation to facilitate SDM between patient and clinician [36–38]. A Decision Helper™ (DH), a generic, in-consultation PtDA template, is presently used in hospitals across Denmark [39,40]. Recent studies have shown the feasibility and efficacy of the DH in daily clinical work [41–45]. Likewise, the benefit of PtDAs on the cancer related decision making process is well-established [35]. However, implementation of SDM in breast cancer care is lacking, likely due to a lack of strong evidence.

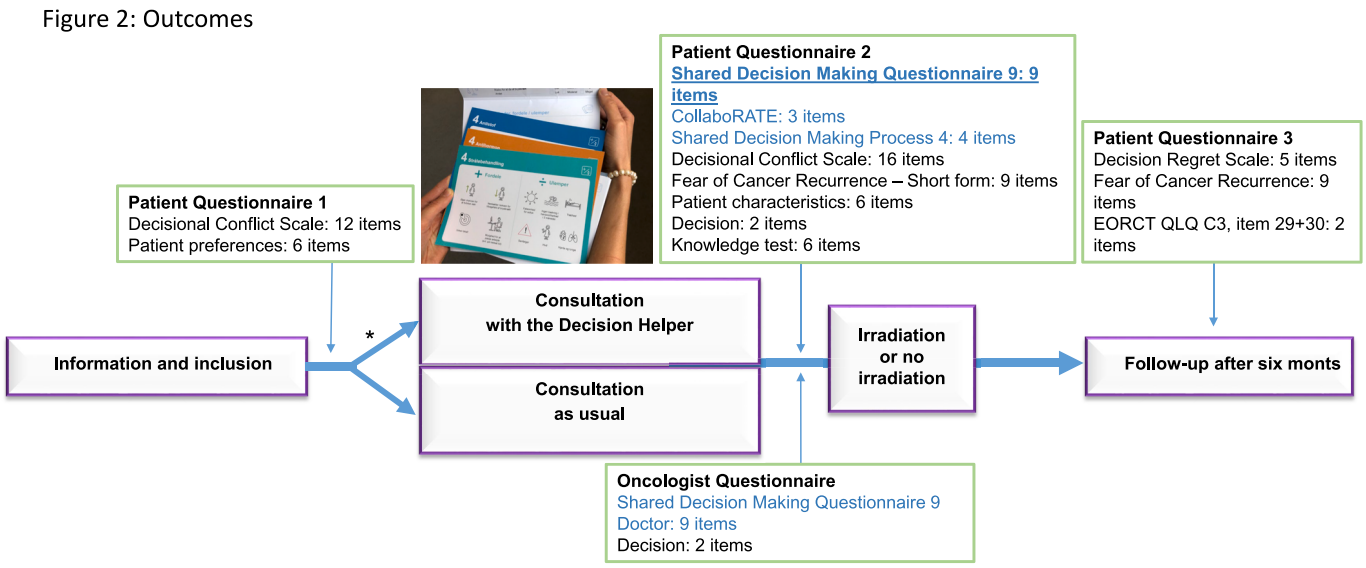

Fig. 2. Outcomes. Blue endpoints measure patient engagement. Primary endpoint is underlined. *A two-page preparation sheet for the SDM cohort. Abbreviation: EORCT: European Organization for Research and Treatment. QLQ: Quality of Life Questionnaire. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

To our knowledge, the first PtDA study on adjuvant irradiation in node-negative breast cancer care was an in-consultation, paper-based Decision Board developed in Canada in 1995 and evaluated in a pre- and post-intervention study with 82 patients [46]. The Decision Board increased patients' understanding of radiotherapy and the opportunity to make a choice. More recently, a Dutch online pre-consultation PtDA was evaluated in a multi-center pre- and post-intervention study with 403 patients recruited from 13 radiation oncology centers. The study showed improvement of informed choices but no change in decisional conflict or perceived level of SDM [33].

Here, we describe the results of a cluster-randomized controlled trial from the Danish Breast Cancer Group (DBCG) Radiotherapy Committee [47]. The trial was initiated to verify whether SDM and the use of an in-consultation DH adapted to decision making on adjuvant whole breast irradiation following surgery should be recommended as standard of care as advocated in the Danish National Cancer Action Plan. Based on our pilot study, an increase of 4 points on the 9-item Shared Decision Making Questionnaire (SDM-Q-9) scale was considered clinically relevant [31]. The hypothesis was that SDM supported by an in-consultation DH would increase patient-reported engagement in decision making on adjuvant irradiation by 4 points on the SDM-Q-9 scale. The primary objective of the present trial was to investigate whether an in-consultation patient decision aid (the DH) affects patient-reported engagement in the decision process on adjuvant irradiation after surgery for early-stage breast cancer [31].

Methods

Study design

The DBCG RT SDM trial (NCT04177628) was a multicenter, randomized, open-label, phase III study in patients with early-stage breast cancer. It is reported in accordance with international guidelines [48,49]. The study protocol was published prior to completion of the data collection [31]. Oncologists at four Danish departments of radiotherapy were randomized (stratified by department) to either use the DH in consultations with patients eligible for adjuvant whole breast irradiation (SDM arm) or continue usual practice without the DH (control arm). The four departments had different levels of experience with SDM; one had worked with SDM and a DH in other consultations for years, the other three were either in an early stage of integrating SDM or had not started yet. Neither oncologists nor patients were blinded to the study conditions due to the nature of the trial. The principal investigator explained the purpose of SDM to the oncologists in the SDM arm and prepared them for the use of the DH during a 30-minute training course before their participation in the trial.

Participants

Eligible patients had undergone breast-conserving surgery for ductal carcinoma in situ or node-negative invasive breast cancer and were eligible for adjuvant whole breast irradiation according to the DBCG national guidelines. Exclusion criteria were previous thoracic irradiation, bilateral breast cancer, suspicion of disseminated disease or any social or psychological condition hampering the patient's cognitive abilities. A nurse informed the patients of the study. Patients gave written and orally informed consent before learning about the randomization status of their oncologist. Fig. 1 summarizes the patient flow.

Intervention

The intervention was the use of a PtDA developed from the generic DH template, which is available to all clinicians in Denmark and modifiable to fit any clinical decision-making situation [39]. The acceptability of the DH template design, such as space for data entry, icons, length, and font has been tested previously and found suitable for clinical use [40]. The template consists of a folding frame with a number of cards to be placed within it.

The DH version for the present trial clarifies patient preferences as to adjuvant whole breast irradiation and describes two options; receiving adjuvant whole breast irradiation or deselection it. The DBCG RT Committee and the principal investigator adapted the DH template to this trial based on input at a workshop with 4 patient representatives and 5 clinicians. Ten patients and 4 oncologists from other oncology subspecialties with DH template experience reviewed the adapted DH [31]. Their feedback led to the final version of the DH before trial initiation. The adapted DH is available online in English [50]. Patients who were to see an oncologist randomized to the SDM arm received a sheet introducing SDM and the concept of the DH at least 10 min before the consultation and the oncologist used the DH during the consultation.

Table 1
Patient baseline characteristics.

		SDM group	Control group	All
Patients, N		400	274	674
Age, Mean (SD)		59.7 (10)	60 (9.9)	59.86 (10.1)
Mariatal status, N (%)				
	Single	63 (16)	44 (16)	107 (16)
	In a relationship	312 (78)	220 (80)	532 (79)
	Other/missing	25 (6)	10 (4)	35 (5)
Children, N (%)				
	No	33 (8)	25 (9)	58 (9)
	Yes	346 (87)	242 (88)	588 (87)
	Missing	21 (5)	7 (3)	28 (4)
Education, N (%)				
	Public School	24 (6)	23 (8)	47 (7)
	High School	5 (1)	3 (1)	8 (1)
	Skilled worker	58 (15)	40 (15)	98 (15)
	Lower sec. Education	104 (26)	59 (21)	163 (24)
	Upper sec. Education	128 (32)	95 (35)	223 (33)
	Academic education	36 (9)	32 (12)	68 (10)
	Other	23 (6)	14 (5)	37 (6)
	Missing	22 (5)	8 (3)	30 (4)
Work, N (%)				
	Full time	120 (30)	92 (34)	212 (32)
	Part time	62 (15)	32 (12)	94 (14)
	Retired	134 (34)	96 (35)	230 (34)
	Absent owing to illness	46 (12)	31 (11)	77 (11)
	Unemployed	5 (1)	4 (1)	9 (1)
	Other/missing	33 (8)	19 (7)	52 (8)
Site of participation, N (%)				
	Site 1	44 (11)	22 (8)	66 (10)
	Site 2	138 (35)	103 (38)	241 (36)
	Site 3	177 (44)	110 (40)	287 (42)
	Site 4	41 (10)	39 (14)	80 (12)
Radiotherapy, N (%)				
	No	11 (3)	4 (2)	15 (2)
	Yes	389 (97)	269 (98)	658 (98)
Chemotherapy and/or HER2 targeted treatment, N (%)				
	No	252 (63)	191 (70)	443 (66)
	Yes	148 (37)	83 (30)	231 (34)
Endocrine treatment, N (%)				
	No	134 (34)	110 (40)	244 (36)
	Yes	266 (67)	164 (60)	430 (64)
Treatment prior to inclusion in the present trial				
	Lumpectomy, invasive tumor	263 (66)	168 (61)	431 (64)
	Lumpectomy, neoadjuvant	72 (18)	43 (16)	115 (17)
	Lumpectomy, DCIS	65 (16)	63 (23)	128 (19)

NOTE. No significant differences in patient baseline characteristics were found. "Neoadjuvant" refers to neoadjuvant chemotherapy and/or HER2 targeted treatment (s). Abbreviations: DCIS: ductal carcinoma in situ.

Outcome measures and data collection

The primary outcome measure was patient-reported engagement in the decision making process according to SDM-Q-9 [51]. The CollaboRATE [52] and Shared Decision Making Process 4 (SDMP_4) questionnaires [53] were also used to measure this parameter. The oncologists evaluated patient engagement by the 9-item Shared Decision Making Doctor questionnaire (SDM-Q-DOC) [51]. The Decisional Conflict Scale (DCS) [54], the Fear of Cancer Recurrence Inventory Short-Form (FCRI-SF) [55] and the Decision Regret Scale (DRS) [56] (Fig. 2) were used to detect any adverse events. Before the consultation, we asked patients about their preferences regarding decision making on radiotherapy. After the consultation, we asked them five questions about irradiation eliciting their knowledge on the benefit and harms of receiving irradiation and one question on whether they felt well informed.

Study data were collected and managed using the REDCap electronic data capture tools hosted by OPEN (Open Patient data Explorative Network, Odense University Hospital, Region of Southern Denmark) [57,58]. The first patient questionnaire (before the consultation) and the oncologist questionnaire (after the consultation) were paper based. The

Table 2
Effect of Shared Decision Making and the in-consultation Decision Helper.

Outcome	SDM group	Control group	*p*	Effects of SDM*
	Median (IQR)			(95% CI), *p*
SDM-Q-9	N = 376	N = 259	*<0.01*	9.54
Scale 0–100	80.0 (68.9 to 96.4)	71.1 (55.5 to 82.2)		(9.1 to 9.9), *<0.01*
SDM-Q-9-Doc	N = 331	N = 225	*<0.01*	17.6
Scale 0–100	93.3 (82.2 to 100)	73.3 (60 to 84.4)		(11.7 to 23.6), *<0.01*
SDMP_4	N = 376	N = 258	*<0.01*	0.49
Scale 0–4	3 (2 to 3)	2 (1 to 3)		(0.3 to 0.6), *<0.01*
CollaboRATE	N = 376	N = 259	*<0.01*	0.63
Scale 0–9	8.3 (7.3 to 9)	7.5 (6.3 to 8.3)		(0.4 to 0.9), *<0.01*
FCRI-SF	N = 374	N = 255	*0.51*	0.281
Scale 0–36	14 (9 to 20)	14 (10 to 19)		(−0.8 to 1.4), *0.62*
DCS before cons.	N = 327	N = 216	*0.51*	−1.96
Scale 0–100	27.1 (14.6 to 41.7)	29.2 (16.7 to 44.8)		(−5.5 to 1.5), *0.27*
DCS after cons.	N = 375	N = 257	*<0.01*	−2.95
Scale 0–100	10.9 (0 to 25)	15.6 (4.7 to 26.6)		(−5.1 to −0.8), *0.006*
Outcomes collected 6 months after the consultation				
FCRI-SF	N = 304	N = 203	*0.37*	0.98
Scale 0–36	14 (10 to 20)	13 (9 to 17)		(−0.6 to 2.6) *0.24*
Quality of Life	N = 304	N = 203	*0.99*	0.05
Scale 0–100	75 (58 to 83)	75 (58 to 83)		(−2.8 to 2.9) *0.97*
Decision Regret	N = 307	N = 206	*0.93*	0.21
Scale 0–100	10 (0 to 25)	10 (0 to 25)		(−2.1 to 2.5) *0.86*

NOTE. *Observed coefficient based on a population-average univariate GEE model with sites as proxy for clusters. Abbreviations: Ave: average. Marg: marginal. IQR: Interquartile range. DCS: Decisional Conflict Scale. SDMQ9: Shared Decision Making Questionnaire 9. DOC: Doctor. SDMP4: Shared Decision Making Process 4. DCS: Decisional Conflict Scale. Cons: consultation. FCRI-SF: Fear of Cancer Recurrence Short Form. DRS: Decision Regret Scale. QoL: Quality of Life.

second (after the consultation) and third (six months after the consultation) patient questionnaires were sent to the patients' electronic mailbox provided by the Danish State to all Danish citizens.

Study nurses collected the completed paper based questionnaires. They were typed into the REDCap database by two study nurses separately and then merged by the principal investigator based on comparison with the paper version. The Research Ethics Committee, University of Southern Denmark approved the trial (20/5350).

Power calculation and statistical analysis

The study was designed to assess the superiority of SDM supported by a DH over standard care in eliciting patient engagement in decision making on irradiation. The primary endpoint was patient-reported engagement in decision making measured by SDM-Q-9. The hypothesis was that SDM supported by a DH would increase the patient-reported engagement in this issue. The minimal clinically relevant difference on the SDM-Q-9 scale was considered to be 4 points based on data from our pilot study [31]. To detect a potential difference of 4 points, account for a 10% drop-out, and achieve 80% power and an alpha of 5%, a total of 662 patients were needed [31].

Continuous measures are presented as means with standard deviations (SD) or as medians with interquartile range (IQR). Means were compared using a 2-tailed *t*-test and medians using a non-parametric K-sample test on the equality of medians. A 2-sided p value of ≤ 0.05 was considered significant. Categorical measures were compared across groups using chi square tests. A generalized estimating equation (GEE) population averaged model was performed with the radiotherapy departments as clusters to analyze average marginal effects of the intervention using robust variance estimation. The GEE model was adjusted to detect potential differences in patient characteristics between the two groups. Data analysis was performed in STATA/IC 15 (StataCorp LLC, College Station, Texas, USA).

Results

From March 1, 2020 to December 31, 2022, 674 patients were enrolled in the study of which 635 (94%) completed the SDM-Q-9 questionnaire. No significant differences in patient characteristics were found between the two groups (Table 1). Adjustment of the GEE model for education, work status, children or marital status did not change the effects of the Decision Helper.

Patient engagement in decision making was significantly higher in the SDM group as measured with SDM-Q-9 with a median of 80.0 (IQR 68.9 to 94.4) and 71.1 (IQR 55.6 to 82.2) in the SDM and control group, respectively ($p < 0.0001$). The average marginal effect of the intervention was 9.54 (95% CI 9.1 to 9.9, $p < 0.0001$) on the SDM-Q-9. The three other outcome measures also showed significantly higher level of patient engagement in the SDM group (Table 2). The maximum of 100 on the SDM-Q-9 scale, reflecting the top level of self-reported patient engagement, was scored by 51 patients (14%) in the SDM group and 16 (6%) in the control group ($p = 0.003$). For the CollaboRATE questionnaire, 125 (33%) in the SDM group and 45 (17%) in the control group scored the maximum ($p < 0.0001$). For the SDMP_4 questionnaire, the maximum was scored by 71 (19%) and 29 (11%) in the SDM and control group, respectively ($p = 0.009$). Furthermore, 120 (36%) oncologists in the SDM group reported maximum patient engagement compared to only one oncologist (<1%) in the control group ($p < 0.0001$).

To detect the level of agreement between patient-reported and oncologist-reported patient engagement, the scores on the SDM-Q-9 and SDM-Q-DOC were compared. We found that the oncologists generally rated patient engagement higher than the patients themselves (Fig. 3). In the SDM group, the mean difference between the reported patient engagement by oncologists and patients (SDM-Q-DOC minus SDM-Q-9) was 13.2 (10.5 to 16.0). In the control group the difference was 5.96 (2.5 to 9.4), ($p = 0.0012$).

No between-group differences were found in decisional conflict before the consultation or in fear of cancer recurrence after the consultation (Table 2). After the consultation, the SDM group reported significantly less decisional conflict (10.9 (0 to 25)) compared to the control group (15.6 (4.7 to 26.6)), ($p = 0.006$). We found an explicit difference in two of the DCS subscores reported after the consultation, i.e. informed subscore and values clarity subscore, meaning that patients in the SDM group reported to be better informed and that their preferences had been clarified to a higher degree than preferences of patients in the control group (Table 3). No between-group differences were found

Figure 3: Scatter plot

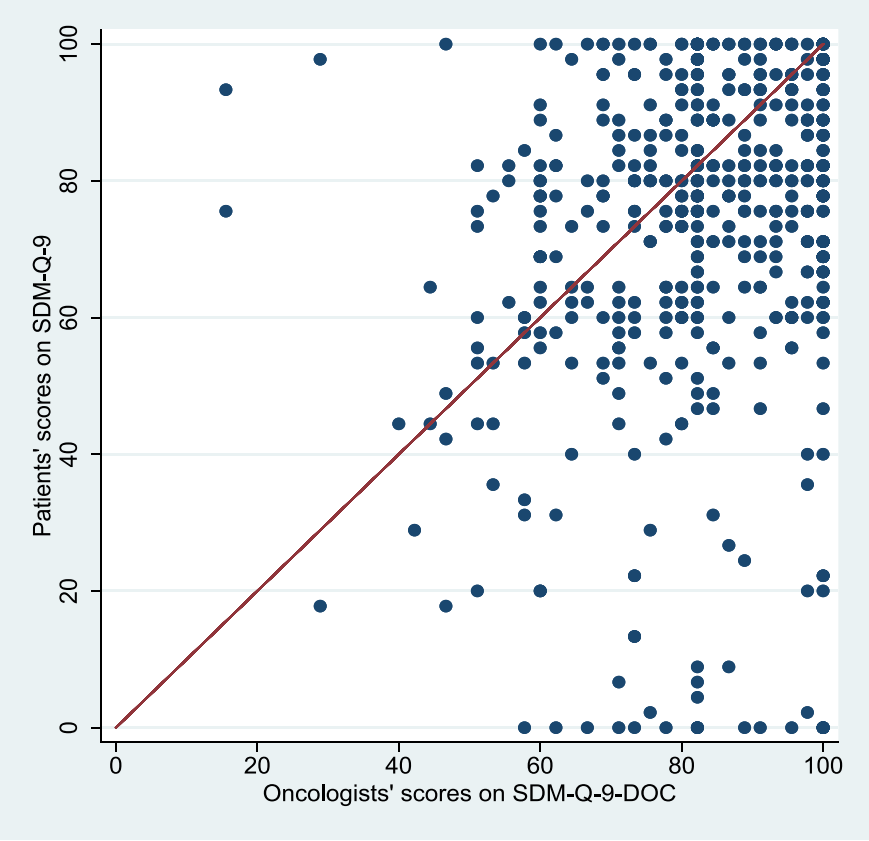

Fig. 3. Scatter plot of oncologist-reported patient engagement (x-axis) versus patient-reported patient engagement (y-axis). Both scores are reported on a 0 (no patient engagement) to 100 (maximum patient engagement) scale. The mean difference between the two scores was 10.27 with oncologists reporting higher patient engagement than the patients. Limits of agreement: −39.9:60.5. A Blandt-Altmann plot of the same data is available in the Supplementary material. The intra correlation coefficient (ICC) showed poor reliability between the patients' and the oncologists' rating on the SDM-Q-9 scales (0.32, 95% CI 0.19: 0.43).

for fear of cancer recurrence, quality of life, or decision regret, at the six-month follow-up (Table 2).

No between-group differences were found in patient preferences before the consultation. Of the 544 responses (SDM = 327, control = 217), 343 (63%) answered "a lot" and 128 (24%) answered "some" concerning the degree to which they would like to participate in the decision making process of whether or not to receive irradiation. The majority of the patients (457/544, 84%) reported before the consultation that they intended to agree to irradiation, 84 (16%) did not know or left the question unanswered. Of the 15 patients who did not receive irradiation, 5 (SDM = 3, control = 2) reported before the consultation an intent to receive irradiation. The remaining 11 were unsure or the question was left unanswered. Likewise, the majority of patients (465, 86%) stated that they would like as much information as possible about the proposed irradiation treatment. Regarding patient concerns, 233 (43%) stated they were very concerned about the risk of breast cancer recurrence and 173 (32%) that they were very concerned about side effects of irradiation.

After the consultation, we asked the patients five questions to evaluate their knowledge on irradiation. Patients answering at least four of the questions correctly were considered knowledgeable. In the SDM group, 152 patients (38%) scored a high knowledge on breast irradiation compared to 68 (25%) in the control group ($p < 0.0001$). Patients in the SDM group had significantly higher knowledge (54%) as to how much the risk of local recurrence is reduced by irradiation compared to the control group (31%), $p < 0.0001$). Likewise, the SDM group showed higher knowledge about the effect of not smoking during irradiation treatment (39% answered correctly in the SDM group and 32% in the control group, $p < 0.0001$). Three questions on expected symptoms during and after irradiation showed no difference between the groups. To our questions whether the patients felt well informed about radiotherapy 87.5% in the SDM group and 84% in the control group answered "yes" ($p = 0.47$).

Discussion

This trial demonstrated that SDM supported by a PtDA significantly increased patient engagement in decisions on adjuvant whole breast irradiation. At the same time, it lowered decisional conflict without increasing adverse effects such as fear of cancer recurrence and decision regret. The trial's power calculation was based on a minimum significant difference of 4 points on the SDM-Q-9 (primary endpoint). We found an even bigger difference of more than twice the a priori defined clinically significant difference, which emphasizes the use of SDM and a DH as instrumental in positively increasing patients' experience of being involved in decisions about their treatment.

The study's positive findings align with the literature on the benefit of PtDAs in cancer-related decision making [35] including that on adjuvant treatment for early breast cancer [59].Our SDM intervention led to patients experiencing less decisional conflict, in line with the findings of a systematic review subanalysis on SDM in oncology [35]. However, this finding is in contrary to the aforementioned Dutch non-randomized study, where patients did not experience that SDM led to decreased decisional conflict. In that study, clinicians were offered an e-learning opportunity and the PtDA was used before the consultation (as

Table 3
Decisional Conflict subscores.

Decisional Conflict subscore	SDM group	Control group	*p*	Effects of SDM
	Median (IQR)			(95% CI), *p*
Before the consultation	N = 327	N = 216		
Informed subscore				
(question 1, 2, 3)	33.3	33.3	*0.365*	−0.21
Scale 0–100	(25 to 50)	(25 to 50)		(−5.1 to 4.7), *0.93*
Values clarity subscore				
(question 4, 5, 6)	25	25	*0.858*	−2.9
Scale 0–100	(16.7 to 50)	(20.8 to 50)		(−6.1 to 0.3), *0.07*
Support subscore				
(question 7, 8, 9)	25	25	*0.657*	−1.82
Scale 0–100	(8.3 to 33.3)	(8.3 to 37.5)		(−3.9 to 0.2), *0.08*
Uncertainty subscore				
(question 10, 11, 12)	25	25	*0.465*	−2.59
Scale 0–100	(0 to 41.7)	(8.3 to 41.7)		(−5.1 to −0.1), *0.04*
After the consultation	N = 375	N = 256		
Informed subscore				
(question 1, 2, 3)	16.67	25	*<0.01*	−6.05
Scale 0–100	(0 to 25)	(0 to 25)		(−6.8 to −5.3), *<0.01*
Values clarity subscore				
(question 4, 5, 6)	8.3	25	*<0.01*	−5.22
Scale 0–100	(0 to 25)	(0 to 25)		(−6.2 to −4.3), *<0.01*
Support subscore				
(question 7, 8, 9)	8.3	16.67	*0.14*	−2.21
Scale 0–100	(0 to 25)	(0 to 25)		(−3.3 to −1.2), *<0.01*
Uncertainty subscore				
(question 10, 11, 12)	8.33	16.67	*0.13*	−0.87
Scale 0–100	(0 to 25)	(0 to 25)		(−3.3 to 1.6), *0.48*
Effective decision subscore				
(question 13, 14, 15, 16)	6.25	6.25	*0.31*	−0.91
Scale 0–100	(0 to 25)	(0 to 25)		(−1.9 to 0.1), *0.08*

NOTE. Effect of SDM and the in-consultation Decision Helper on decisional conflict subscores. The Effect of SDM is the population-average effect, an observed coefficient based on a population-average univariate GEE model with sites as proxy for clusters.

opposed to during a consultation together with the oncologist) [33]. Previous studies have found indications of a more positive impact from an in-consultation PtDA compared to a pre-consultation PtDA for both patient and clinician [36,60], although further research is needed on this matter [61]. Also, it is well established that the attitude of doctors is crucial, more than skills and tools, for SDM to take place [62]. The timing (in-consultation use) of the present intervention, the mandatory SDM training, and the oncologists' attitudes towards patient engagement are likely salient to our findings.

From the literature, it seems that for SDM to be implemented beyond clinical trials, PtDAs should be integrated in clinical guidelines and continuously updated by guideline committees [64]. A guideline providing insight into reasons and considerations behind a recommendation, allowing for alternatives and encouraging patient engagement in decision making, paves the way for patients to engage in SDM [63]. Based on the findings of this trial and recent findings on the benefit of SDM in relation to patient complaints and patient satisfaction [65,66], the DBCG Radiotherapy Committee now recommends SDM and use of the adapted DH as standard care in the national clinical guideline on adjuvant whole breast irradiation [67].

Among the strengths of this trial are the multicenter setting with different levels of experience in SDM and the randomized design. The participation of the national collaborate society, DBCG, enabled efficient data collection. Moreover, the DH was based on a well-established template previously proven feasible and efficient in oncology and beyond [40–42,68].

The limitations include the lack of an in-consultation observer objectively scoring the level of patient involvement and the use of the DH. Also, many patients declined to participate, mainly due to the questionnaires (reasons not collected systematically due to lack of consent). The trial patients may thus represent patients particularly interested in being involved in decision making. The findings of the trial could ideally have been supported by interviews with patients, oncologists and nurses, especially in the light of the differences between patients' and oncologists' reports of patient engagement.

An opportunity for future research is the implications of DH-supported SDM on patient inequality [69]. The high proportion of patients declining to participate in this trial reveals a risk of underserving certain groups of patients, e.g. those with low health literacy.

The study demonstrated significantly increased patient engagement as a result of standardized introduction of SDM and a DH at four Danish departments of radiotherapy with different levels of experience with SDM. This is a step forward in the process of fully implementing SDM with cancer patients, aided by the integration of SDM and the DH in the Danish national guideline on whole breast irradiation.

CRediT authorship contribution statement

Stine Rauff Søndergaard: Data curation, Formal analysis, Investigation, Writing – original draft. **Troels Bechmann:** Conceptualization, Methodology, Supervision, Writing – review & editing. **Else Maae:** Investigation, Supervision, Writing – review & editing. **Anders W. Mølby Nielsen:** Investigation, Project administration. **Mette Holck Nielsen:** Conceptualization, Data curation, Investigation, Writing – review & editing. **Mette Møller:** Conceptualization, Data curation, Investigation, Writing – review & editing. **Signe Timm:** Methodology, Supervision, Validation. **Ebbe Laugaard Lorenzen:** Data curation, Methodology, Supervision. **Leonard L. Berry:** Conceptualization, Supervision, Writing – review & editing. **Robert Zachariae:** Conceptualization, Writing – review & editing. **Birgitte Vrou Offersen:** Conceptualization, Investigation, Methodology, Project administration, Resources, Supervision, Writing – review & editing. **Karina Dahl Steffensen:** Conceptualization, Investigation, Methodology, Resources, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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