ORIGINAL ARTICLE

Outcome-Relevant Effects of Shared Decision Making

A Systematic Review

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SUMMARY

Background: Shared decision making (SDM) is considered a gold standard for the cooperation of doctor and patient. SDM improves patients' overall satisfaction and their confidence in decisions that have been taken. The extent to which it might also positively affect patient-relevant, disease-related endpoints is a matter of debate.

Methods: We systematically searched the PubMed database and the Cochrane Library for publications on controlled intervention studies of SDM. The quality of the intervention and the risk of bias in each publication were assessed on the basis of pre-defined inclusion and exclusion criteria. The effects of SDM on patient-relevant, disease-related endpoints were compared, and effect sizes were calculated.

Results: We identified 22 trials that differed widely regarding the patient populations studied, the types of intervention performed, and the mode of implementation of SDM. In ten articles, 57% of the endpoints that were considered relevant were significantly improved by the SDM intervention compared to the control group. The median effect size (Cohen's d) was 0.53 (0.14–1.49). In 12 trials, outcomes did not differ between the two groups. In all 22 studies identified, 39% of the relevant outcomes were significantly improved compared with the control groups.

Conclusion: The trials performed to date to addressing the effect of SDM on patient-relevant, disease-related endpoints are insufficient in both quantity and quality. Although just under half of the trials reviewed here indicated a positive effect, no final conclusion can be drawn. A consensus-based standardization of both SDM-promoting measures and appropriate clinical studies are needed.

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The relationship between doctor and patient is continually changing under the influence of social and societal changes, among others (1). During the 20th century, improved access to information and patients' desire for more autonomy contributed to a change in the relationship between doctor and patient from a mainly disease- and/or physician-orientated one towards dialogue and partnership. The bilateral exchange of information is now emphasized, and the patient plays a more active role in the treatment process. In Germany, this development is also reflected at the health political and legal levels—for example, in the so-called Patients' Rights Act of 2013 (§ 630 of Germany's civil code) and in the Medical Association's Professional Code for Physicians in Germany. The latter states that patients' consent to treatment should be obtained after patients were first given information on the treatment's nature, importance, and consequences, including alternative treatments and associated risks. Increasingly, patients' participation in decisions is also finding its way into treatment guidelines, for example in terms of recommendations on shared decision making (SDM) (2).

Active participation of patients in their treatment process can enhance clinical and psychosocial patient-related outcomes. Among others, a willingness and readiness to undertake initial treatment steps, trust in the medical decision, perception of risk, and realistic expectations can be fostered (3). Further relevant effects include increased satisfaction of patients and better adherence to treatment (4).

SDM is a crucial method in implementing patients' education and participation. On the background of a partnership between doctor and patient, this is an interaction between both parties with the objective to use communication tools to reach a decision on an appropriate approach—for example, relating to treatment. Imparting current scientific evidence is a crucial component in this setting. The aim is to reach the best possible decision according to the clinical requirements and the patient's preferences (3, 5). It needs to be borne in mind that the approach of patient participation is continually evolving. Depending on the respective perceptions of shared decision making, but also on the context, the implementation may differ (6–8).

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BOX

Four criteria for shared decision making (14)

- At least two parties (patient and doctor) are involved in the process.
- They share information.
- Both parties undertake steps to achieve a consensus regarding treatment preferences.
- They agree on a form of treatment, which is then initiated.

Irrespective of this, SDM is a gold standard for the cooperation between doctor and patient (1). Studies have shown, however, that SDM has not yet comprehensively been adopted in clinical practice. Decisions about treatment are often still unilaterally made by doctors (9), although patients have a fundamental need to be involved in such decisions (10, 11).

Evidence for positive effects of increased patient participation in general has been delivered primarily for not directly disease-related outcomes (3, 4). The current state of research regarding the clinical relevance of SDM in particular is, however, not clear. A systematic review similar to our study investigated the effect on patient-relevant, disease-related outcomes, but did not focus on SDM as a form of patient participation and limited the number of studies included to merely seven, on the basis of very strict inclusion and exclusion criteria (12). A detailed study from the Cochrane Collaboration focused primarily on the implementation of SDM as the study endpoint, but did not consider many of the outcomes and studies addressed by our own review (13). In our systematic review, we included controlled studies that explicitly investigated the effect of patient participation in the form of SDM on patient-relevant, disease-related outcomes.

Methods

Search strategy

We conducted a literature search with a cut-off date of 30 June 2014 in PubMed and the Cochrane Library, using the search terms “patient participation” and “decision making” and limiting the search to “clinical trial” as the publication type. We did not search for “shared decision making” as a medical subject heading (MeSH) term, since in our experience, some interventions are consistent with shared decision making but are not explicitly named as such.

Study selection and data extraction

KH and JM each applied the inclusion and exclusion criteria listed below to the search results. The inclusion criteria were:

- A controlled study design
- The explicit use of the terms “shared decision making” (SDM) or “participatory decision making” in the description of the intervention or information indicating that patients were involved in making a decision about treatment according to the first criterion of Charles et al. (*Box*) (14)
- Fulfillment of at least one additional SDM criterion according to Charles et al. (14)
- Assessment of patient-relevant, disease-related outcomes.

The Charles criteria were applied in accordance with Joosten et al., among others (4). As patient-relevant, disease-related outcomes we considered parameters that were directly related to disease-dependent wellbeing or to a patient’s prognosis (*Tables 1* and *2*, *eTables 1* and *2*). We did not consider outcomes that related explicitly to the communication between doctor and patient—for example, the degree of informedness or satisfaction with the information—the doctor–patient relationship in general—such as the satisfaction of a patient with his/her doctor—or patient participation itself—for example, the number of questions asked by patients.

Our exclusion criteria were:

- Use of a decision aid as the only difference between control group and intervention group.
- Intended implementation of SDM in the control group too.
- Lacking statistical data supporting the reported results.

After we had finished identifying suitable studies as described above, KH extracted the data. Only patient-relevant, disease-related outcomes were considered, as described in our inclusion criteria (15, e1).

Quality of publications and interventions

The methodological quality of the studies and the implementation of SDM interventions were assessed according to Joosten and colleagues (4). KH and JM individually evaluated the methodological quality of the included publications regarding the risk of bias. To this end, we adapted the Cochrane Back Review Group’s recommendations for systematic reviews (16) (*eBox*). Furthermore, we assessed the extent of SDM implementation on the basis of the number of identifiably applied key aspects according to Charles et al. as indicators of intervention quality (14) (*Box*). Since the literature does not provide a single definition of SDM, we adopted for our review the four Charles criteria—in accordance with Joosten et al.—which, in our view, can be considered a common denominator in interpretations of SDM (4, 8, 14).

Effect sizes

Where the publications provided sufficient data, we calculated the corresponding effect sizes as Cohen’s *d*,

TABLE 1

Studies in which the interventions improved patient-relevant outcomes compared with control groups

Underlying (main) diagnosis	Patient-relevant outcomes (measurement instruments)*
Status post acute coronary syndrome (23)	Proportion of patients with ≥ 3 risk factors; total cholesterol ; LDL cholesterol ; triglycerides ; HDL cholesterol; systolic blood pressure , diastolic blood pressure ; body mass index ; Proportion of patients who started treatment with statins during the study period; quality of life (SF-36)
Diabetes mellitus (24)	HbA_{1c} ; physical functioning (self-assessment) ; psychological functioning (self-assessment)
Diabetes mellitus (19)	HbA_{1c} ; physical limitations (RAND Medical History Index) ; intensity of therapeutic regimen ; days of sickness absence from workplace
Ulceration (20)	Proportion of patients with role limitations ; extent of role limitations ; Proportion of patients with physical limitations ; Extent of physical limitations ; ulceration-related pain (9 questions)
Increased risk of breast cancer (BRCA1/2 mutation) (25)	Health status (self-assessment using 11-point scale) ; depression (CES-D); state anxiety (Spielberger STAI)
Breast cancer (17)	Generalized depression, specific depression (Leeds Anxiety and Depression Scale)
Substance-related addiction (21)	Severity of disorder (EuropASI) ; drug consumption, mental state ; burden owing to addiction disorder (EuropASI) relating to alcohol consumption; physical status; legal problems; work and livelihood issues; proportion of abstinent patients; proportion of dependent patients; quality of life (EQ-5D)
Schizophrenia (22)	Reduction in social invalidity (GAF/WHO-DAS) ; Severity of symptoms, severity of illness (GAF/BPRS); inpatient stays (number and duration); psychotic episodes (number and duration); homelessness
Bronchial asthma (26)	Adherence (proportion of collected prescriptions) ; lung function (FEV₁) ; use of medication as required ; asthma control (ATAQ score) ; Quality of life (Mini AQLQ questionnaire)
Arterial hypertension (18)	Blood pressure lowering (systolic) in patients with a great need to participate ; Adherence (number of medications taken)

* **bold**: effects that reached significance in favor of the intervention compared with the control group.

AQLQ, Asthma Quality of Life Questionnaire; ATAQ, Asthma Therapy Assessment Questionnaire; BPRS, Brief Psychiatric Rating Scale; CES-D, Center for Epidemiologic Studies Depression Scale; EuropASI, European Addiction Severity Index; FEV₁, forced expiratory volume in 1 second; GAF, Global Assessment of Functioning; STAI, State-Trait Anxiety Inventory; WHO-DAS, World Health Organization Disability Assessment Schedule

a measure of the relevance of statistically significant effects on patient-relevant, disease-related outcomes (*eTable 3*) (e2–e5).

Results

The search in PubMed yielded 422 hits and that in the Cochrane Library 222 hits. After removal of duplicates, we verified the remaining 430 publications on the basis of their title and abstract with regard to the research question and the defined inclusion and exclusion criteria. Study protocols and designs without reporting concrete results were excluded. Of the 59 remaining articles, 37 were excluded after a review of their full text; ultimately, 22 controlled intervention studies were included in our review article (*eFigure, Tables 1 and 2, eTables 1 and 2*). We determined the risk for bias and found that the relevant information was often not fully reported. On average, 69% of the criteria were met. The proportion of lacking or unclear data relating to the criteria under study in the publications was 12%. It has to be kept in mind that we did not assess the quality of

particular studies but that of the respective publications.

In 10 of the 22 studies (45%), the intervention resulted in a significant improvement in at least one outcome compared with the control group (17–26) (*Table 1, eTable 1*). In 12 of the studies (55%) this was not the case (27–38) (*Table 2, eTable 2*). In the studies that showed benefits from the intervention, 57% of the relevant outcomes were significantly improved compared with the control group; this was the case for 39% when all 22 studies were considered. In studies that showed a benefit from SDM, the median effect size was 0.53 (range 0.14–1.49). Values were evenly distributed among ranges indicating small, moderate, and large effect sizes (*eTable 1*). We deemed individual outcomes in three studies not meaningful as significant differences existed between groups already at baseline. However, in one these three studies the positive effect on several other outcomes was greater than in the control group (23). In neither of the remaining two studies did any other relevant outcome show greater improvement

TABLE 2

Studies in which the interventions did not improve patient-relevant outcomes compared with control groups

Underlying (main) diagnosis	Patient-relevant outcomes (measurement instruments)
Diverse (members of AOK and LKK Baden-Württemberg insurance schemes, receiving outpatient treatment) (27)	Physical quality of life (SF-12); psychological quality of life (SF-12)
Increased cardiovascular risk (28)	Estimated cardiovascular risk (Framingham score)
Fibromyalgia syndrome (36)	Intensity of pain (VAS); Depression (CES-D); general health (SF-36)
Prostate cancer (37)	Trait anxiety (Spielberger STAI); depressiveness/depression (CES-D)
Arterial hypertension (35)	Systolic blood pressure; cardiovascular risk (estimated on the basis of blood pressure, cholesterol, and HbA _{1c} measurements); adherence (MARS-D)
Patients with increased cardiovascular risk (38)	Adherence (achieving self-defined targets for lifestyle modification); cholesterol concentrations
Antithrombotic treatment in atrial fibrillation (34)	Frequency of stroke or hemorrhagic events; proportion of patients taking warfarin; tendency to anxiety (Spielberger STAI)
Acute respiratory infection (32)	Adherence regarding original decisions in favor of or against antibiotic treatment; quality of life: physical and mental wellbeing (SF-12)
Depression (33)	Depressive symptoms (PHQ-D); adherence to treatment (self-assessment and doctor's assessment on a 5-point scale)
Schizophrenia (31)	Medication adherence (doctors' assessment, self-assessment); number of inpatient stays and admissions; proportion of patients who are still receiving psychiatric treatment
Schizophrenia (30)	Repeated inpatient admission within 8 months after discharge; medication adherence (MARS); global functioning (GAF); illness severity (CGI)
Atrial fibrillation, prostatic hyperplasia, menorrhagia, menopausal symptoms (29)	Illness-related tendency to anxiety and states of anxiety (Spielberger STAI); mental and psychological health (SF-12); adherence (yes/no-question)

AOK, a large German general statutory health insurance fund; CES-D, Center for Epidemiologic Studies Depression Scale; CGI, Clinical Global Impression; CME, continuing medical education; GAF, Global Assessment of Functioning; LKK, statutory health insurance for the agricultural sector; MARS, Medication Adherence Report Scale; PHQ, Patient Health Questionnaire; STAI, State-Trait Anxiety Inventory; VAS, visual analog scale

in the intervention group compared to the control group (37, 38).

The studies were quite heterogeneous regarding disorders, outcomes, and interventions (*Tables 1* and *2*, *eTables 1* and *2*). The studies showing favorable results for SDM, as well as those where the effects in the control and intervention groups did not differ, included, among others, patients with cardiovascular disorders, respiratory disorders, mental disorders, or tumor disease. Examples of patient-relevant, disease-related surrogate parameters—for example, blood pressure—or psychological constructs (data obtained using patient questionnaires), as in depression or schizophrenia. The studied interventions ranged from brief conversations with patients that immediately preceded doctor–patient contact to several hours of staff training delivered over several weeks (*eTables 1* and *2*). In the studies showing benefit from SDM, patients were more often directly targeted by the intervention.

The extent to which SDM was implemented differed widely (*Box*). Twelve studies showed only one additional characteristic in addition to the participation of

doctor and patient (17, 22, 23, 25, 27, 29, 31, 33, 35–38), five studies showed two further characteristics (19, 20, 24, 32, 34). All four SDM criteria were realized in five studies (23%) (18, 21, 26, 28, 30). No association was seen between outcome effects and the degree of SDM implementation (data not shown). The degree of SDM implementation might have been underestimated, as not all criteria were verifiable on the basis of the publications.

Discussion

In 12 of the 22 studies, the outcomes in patients who had received an SDM intervention did not show any greater improvement than the outcomes in patients of the respective control groups. Ten studies showed an advantage for SDM for patient-relevant, disease-related outcomes compared with the control groups. The observed effect sizes were high to very high in some cases.

The heterogeneity of diseases in the included studies does not allow for identification of disorders with a higher probability of SDM being beneficial. Similarly, we did not observe any association between the extent

of SDM implementation and the outcome effect (data not shown). In the 10 studies that showed favorable results for SDM it is of note that most of the interventions (70%) directly aimed at the patient. In only three studies the intervention focused on doctors or nursing staff. Only 4 (33%) of the 12 studies in which the intervention showed no additional outcome benefit patients had been the primary target of the intervention. This finding suggests that an SDM intervention might improve patient-relevant, disease-related outcomes mainly if the intervention directly aims at the patient. Regarding SDM implementation as the outcome, Légaré et al. found that measures that involve doctors as well as patients are most effective (13).

Two studies in which treatment adherence was improved by the intervention to a greater extent than in the control groups showed an advantage for all outcomes that was deemed relevant for the present review (Table 1, eTable 1b). In 8 studies in which adherence was not improved as a result of the intervention, no significant outcome differences were seen (Table 2, eTable 2b). This finding suggests an association between adherence and improvements in patient-relevant, disease-related outcomes, similar to that we have recently found for antihypertensive treatment (5).

The fact that about half of the analyzed studies did not show any positive effects as a result of an SDM intervention may have different reasons. As the methodological quality of many studies was limited, effects may have remained hidden. Two other reviews that differed from our approach in terms of their search strategies also stated that conclusive results regarding the effects of improved patient participation in general (12) and SDM in particular (8) on patient-relevant, disease-related outcomes are lacking.

The quality of the implementation of SDM interventions was low to moderate in many studies. Twelve of the 22 studies included in our systematic review did not meet more than two Charles criteria. We did not find an association between the degree of SDM implementation and effects on the investigated outcomes (data not shown). However, considering the often insufficient information given in the publications, we cannot exclude that the aspects of SDM were not implemented intensely enough to reveal a corresponding effect. The problem of fitting the context—that is, the difficulty in finding the degree of SDM that meets the complex, context-specific needs of the individual patient—may also play a role (39).

It should also be considered that communication with and inclusion of patients in the control and intervention groups may not have differed sufficiently from one another. Thus, in studies where patients in the control group received so-called standard care, certain aspects of SDM may have been implemented more or less unintentionally. Of note, the literature does not provide an accepted consensus on the definition of SDM. Makoul and colleagues identified 31 different conceptual definitions (40). We and Josten et al. used SDM criteria originally defined by Charles et al. (4, 14),

KEY MESSAGES

- If treatment adherence is enhanced, clinical outcomes can be improved.
- Adherence to treatment can be optimized by patient participation in medical decision-making processes.
- Shared decision making (SDM) is considered a gold standard in patient participation.
- SDM can have a positive effect on patient-relevant, disease-related outcomes.
- The studies available so far indicate a need for minimum standards regarding the implementation and investigation of shared decision making.

representing only one SDM concept that has been modified by the same group later (6).

As suggested above, it is likely that perceptions of SDM and thus the tested interventions may have differed in the studies included in our review. Furthermore, the inclusion criteria we applied probably did not cover every concept of SDM. This may mean that potentially relevant studies might have been missed.

In sum, we wish to remind readers that we assumed a study to show benefits for SDM if at least one outcome in the intervention group was improved to a greater extent than in the control group. The number of outcomes addressed in a study increases the risk of a cumulative α error, and thus the proportion of SDM interventions considered outcome-relevant may have been subject to overestimation.

Conclusion

We conclude that to date, research on the effect of SDM on patient-relevant, disease-related outcomes is insufficient regarding the number of studies and the quality of relevant publications. Although nearly half of the identified studies indicated outcome-relevant effectiveness of SDM, the results so far do not allow for any conclusive assessment of the outcome relevance of SDM. A consensus-based standardization of SDM promoting measures and appropriate clinical studies are needed and desirable.

Conflict of interest statement

Professor Albus has received consultancy fees as an advisory board member from UCB Pharma and lecture honoraria from Berlin-Chemie and Actelion.

The other authors declare that no conflict of interest exists.

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Supplementary material

For eReferences please refer to:

www.aerzteblatt-international.de/ref4015

eBox, eFigure, eTables:

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Supplementary material to:

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eTABLE 1a

Studies in which interventions improved patient-relevant outcomes compared with control groups

Study	Underlying main disorder Case numbers = Intervention group vs. control group at start/end of study	Measures in intervention group and control group	Patient-relevant outcomes (measurement instruments)* ¹
(23)	Status post acute coronary syndrome n = 72/67 vs. 72/69	Intervention group: – Identification of risk factors – Selection of relevant risk factors that can be reduced by using targeted measures, by patients (with support) – Information on risk-reducing measures and patients' decision in favor of an option Control group: – Standard care All patients: – Cholesterol lowering measures (diet, pharmacotherapy)	After 12 months: – Proportion of patients with ≥ 3 fewer risk factors: n. a. – Total cholesterol: 1.2 ; LDL cholesterol: 0.69 ; Triglycerides: 0.52 – Systolic blood pressure: 1.02 ; Diastolic blood pressure: 0.63 – Body mass index: 0.56 – Proportion of patients who started taking statins on a regular basis during the study period: n. a. – Quality of life (SF-36): 0.3 – HDL cholesterol: 0
(24)	Diabetes mellitus n = 30/23 vs. 31/29	Intervention group: – Before discharge, chat (45 minutes) with nurse to obtain information, make decisions, and plan individual management of diabetes; concluding with formulating questions and intentions for the discharge discussion with the doctor – Information package for independent perusal after discharge, containing information on effective communication between doctor and patient, i.e. for example, formulating questions, place these, and defining them more precisely Control group: – Patient education (3 days) aiming to achieve better metabolic control	After 4 months: – Physical functioning (self assessment): 0.68 – Significant HbA _{1c} reduction in intervention group but not control group: 0.14 – Psychological functioning (self assessment): 0,17
(19)	Diabetes mellitus (n = 39/33 vs. 34/26)	Intervention group: – Preparatory talk (20 minutes) with study assistant, aiming to ensure effective participation of patient in the discussion between patient and doctor immediately afterwards – Support when individually relevant medical questions are identified on the basis of a patient's file – Explicit encouragement to negotiate medical decisions with the doctor Control group: – Preparatory talk (20 minutes) with study assistant, reading through information brochure together – Discussion of potential problems in implementing the treatment plan, especially regarding adherence	After 12 weeks: – Lowering of HbA _{1c} : 0.96 ^{*2} – Intensity of therapeutic regimen more often unchanged or reduced compared to control group: 0.65 – Quality of life (fewer physical limitations [RAND medical history index]): 1.01 ^{*2} – Illness-related days of absence from work: 1.49
(20)	Ulceration (n = 23/22 vs. 22/22)	Intervention group: – Intervention as in (19) Control group: – Preparatory talk (20 minutes) with study assistant, reading through information brochure together	After 6–8 weeks: – Health status (6 questions): Proportion of patients with role limitations: 0.65 ; Extent of role limitations: 0.9 ; Proportion of patients with physical limitations: 0.57 ; Extent of physical limitations: 0.85 – Ulceration-related pain (9 questions): 0.09
(25)	Increased risk for breast cancer (BRCA1/2 mutation) n = 44/42 vs. 44/40	Intervention group: – Exploration of how the patient evaluates individual treatment options in face-to-face interview; repeated over the telephone after a few weeks – Patient prioritizes one option Control group: – Standard care	After 9 months: – Health status in self-assessment (11-point scale): 0.4 ^{*2} – Depression (CES-D): 0.28 ^{*2} – State anxiety (Spielberger STAI): 0.19 ^{*2}

Study	Underlying main disorder Case numbers = Intervention group vs. control group at start/end of study	Measures in intervention group and control group	Patient-relevant outcomes (measurement instruments)* ¹
(17)	Breast cancer n = 36/13 vs. 35/10	Intervention group: – Discussion with psychologist regarding treatment preferences, fears, worries, attitudes to alternative surgical options, etc – Inviting patient to make a final decision Control group: – Clear recommendation by the surgeon for a particular surgical option All patients: – Discussion of surgical options with surgeon	After 15 months: – Depression scores (Leeds Anxiety and Depression Scale) for Generalized depression: 0,93 Specific depression: 0,98
(21)	Addiction n = 111/79 vs. 105/87	Intervention group: – SDM training for nursing staff (motivational interviewing/counseling) – In discussion with patient: identifying individual problem areas, setting out treatment objectives accordingly – Discussion format according to standardized SDM protocol Control group: – Doctors proceed as usual: patient participates in the decision in an unstructured conversation	After 3 months: – Illness severity (EuropASI) regarding drug consumption: 0.42 ; Psychological status: 0.38 – Burden owing to addiction disorder (EuropASI) Regarding alcohol consumption: 0.25; Physical condition: 0.15; Legal problems: 0.06; Work and livelihood issues: 0.05 – Proportion of abstinent patients: 0.04; Proportion of dependent patients: 0.1 – Quality of life(EQ-5D): 0.02
(22)	Schizophrenia n = 51/51 vs. 33/33	Intervention group: – Training in stress management, communication, and problem solving for patients in order to promote participation in treatment decisions – Cognitive behavioral therapy Control group: – Group therapy and awareness training for patients, support during professional rehabilitation All patients: – Combined treatment (antipsychotics, psychoeducation, living skill training) involving the family	After 24 months: – Decrease in social invalidity (GAF/WHO-DAS): 0.52/0.51 – Severity of symptoms, severity of illness (GAF/BPRS): 0.15/0.15 – Inpatient stays (number, duration): n. a. – Psychotic episodes (number, duration): n. a. – Homelessness: n. a.

Numbers in bold print: significant effect in favor of intervention group

*¹ Effect size as Cohen's d

*² Cohen's d calculated on the basis of the adjusted mean value

n/a., effect size not available; BPRS, Brief Psychiatric Rating Scale; CES-D, Center for Epidemiologic Studies Depression Scale; EuropASI, European Addiction Severity Index; GAF, Global Assessment of Functioning; HDL, high density lipoprotein; LDL, low density lipoprotein; SDM, shared decision making; STAI, State-Trait Anxiety Inventory; SF, short form; WHO-DAS, World Health Organization Disability Assessment Schedule

eTABLE 1b

Studies, in which interventions improved adherence and patient-relevant outcomes compared with control groups

Study	Underlying main disorder Case numbers = intervention group vs. control group at start/end of study	Measures in intervention group and control group	Patient-relevant outcomes (measurement instruments)*
(26)	Bronchial asthma n = 204/182 vs 204/189	Intervention group: – Training for non-medical healthcare professionals in implementing the SDM protocol – Conversation including SDM steps with patient as preparation for doctor–patient discussion of potential treatment optimization Control group: – Standard care according to recommendations of the National Asthma Education and Prevention Program	After 12 months: – Adherence, proportion of collected prescriptions: 0.41 – Lung function (FEV ₁): 0.28 – Use of medication as required: 0.32 – Asthma control (ATAQ score): 0.35 – Quality of life (mini AQLQ questionnaire): 0.38
(18)	Arterial hypertension n = n. a./39 vs n. a./38–45	Intervention group: – Communication training for doctors (16 hours minimum) regarding practical implementation strategies for SDM – Up to 6 SDM discussions between doctor and patient within 12 months Control group: – Patients participated in hypertension education previously – Care delivered by doctors who had not been trained in SDM but were informed about their patients' participation in the study	After 12 months, only in intervention group: – Correlation of blood pressure lowering (systolic) with increase in SDM in patients with a great need for participation: 0.49 – Increase in the number of medications taken after a year: 0.26

Numbers in bold print: significant effect in favor of intervention group

* Effect size as Cohen's d

AQLQ, Asthma Quality of Life Questionnaire; ATAQ, Asthma Therapy Assessment Questionnaire; FEV₁, forced expiratory volume after 1 second; SDM, shared decision making;

n. a., relevant data not available

eTABLE 2a

Studies in which interventions did not improve patient-relevant outcomes compared with control groups

Study	Underlying main disorder Case numbers = intervention group vs. control group at start/ end of study	Measures in intervention group and control group	Patient-relevant outcomes* ¹ (measurement instruments)* ²
(27)	Diverse (members of AOK and LKK Baden-Württemberg insurance funds, receiving outpatient treat- ment) n = 496/309 vs. 911/408	Intervention group: – Patient selects trusted doctor as primary contact and cross-sectoral coordinator for his/her care. – Patient receives written version of their information and participation rights (so-called charter of patients' rights). – Election of a patient advisory board as institutional representation of patients' interests – Commitment of doctors and psychotherapists in private practice to negotiate individual health objectives with patients – Three hours of training for doctors in private practice as regards greater involvement of patients in treatment decisions, and its implementation – Two further 3-hour training sessions for doctors on doctor–patient communications in the sense of salutogenesis Control group: – Parallel control group from comparable region	– Physical quality of life (SF-12): 0.05 (0.99) – Psychological quality of life (SF-12): 0.06 (0.08)
(28)	Cardiovascular risk n = 550/460 vs. 582/466	Intervention group: – Two 2-hour training sessions for doctors on risk assessment, ethical aspects of SDM, but especial- ly on practical aspects of communication and mat- terial for the doctor–patient conversation – Doctor–patient conversation using the “arriba” decision aid—which adopts crucial elements from SDM—aiming to agree together a strategy for lowering the cardiovascular risk. Control group: – In order to sustain motivation, doctors were offered to attend seminars on topics not related to SDM (placebo CME).	– Lowering of estimated cardiovascular risk (Framingham score): 0.07 (0.31)
(36)	Fibromyalgia syndrome n = 44/34 vs 41/33	Intervention group: – Twelve 90-minute training units for doctors on patient-centered communication, interaction, and implementation of SDM Control group: – Treatment by doctors from a specialist rheuma- tology hospital	– Intensity of pain (VAS): 0.21 (0.45) – Depression (CES-D): 0.27 (0.26) – General health status (SF-36): 0.08 (0.89)
(37)	Prostate cancer n = 30/n. a. vs 30/n. a.	Intervention group: – Before the consultation the patient is asked for specific information he/she requires in order to feel competent enough to participate in a decision about treatment. – Patient receives this information; a list with rele- vant questions for the conversation/discussion between doctor and patient is set out jointly. – Patients are encouraged to participate actively in the decision about subsequent treatment methods. Control group: – Patients receive an information brochure and are motivated to read this from cover to cover after their consultation with the doctor.	– Trait anxiety (Spielberger STAI): n. a. (n. a.) – Depressiveness/depression (CES-D): n. a. (n. a.)

*¹ The p value of the group comparison is shown in parentheses.

*² Effect size as Cohen's d

n. a., relevant data not available; AOK, a large German general statutory health insurance fund; CES-D, Center for Epidemiologic Studies Depression Scale; CME, continuing medical education; LKK, statutory health insurance for the agricultural sector; SDM, shared decision making; SF, short form; STAI, State-Trait Anxiety Inventory; VAS, visual analog scale

eTABLE 2b

Studies in which interventions did not improve adherence and patient-relevant outcomes compared with control groups

Study	Underlying main disorder Case numbers = intervention group vs. control group at start/end of study	Measures in intervention group and control group	Patient-relevant outcomes* ¹ (measurement instruments)* ²
(35)	Arterial hypertension n = 552/381 vs 568/357	Intervention group: – Six-hour training program for doctors on doctor–patient communication and risk communication, steps of SDM, motivational interviewing/counseling as an implementation form of SDM and on how to use decision aids – Info brochure for patients Control group: – Standard care	– Systolic blood pressure: n. a. (0.2) – Cardiovascular risk (estimated on the basis of blood pressure, cholesterol, and HbA _{1c} measurements): n. a. (0.31) – Adherence (MARS-D): n. a. (0.21)
(38)	Patients with increased cardiovascular risk n = 322/266 vs 293/254	Intervention group: – Management of cardiovascular risk factors by nursing staff – Training for nursing staff on risk evaluation, risk communication, motivational interviewing/counseling, and how to use decision aids – Initial conversation/discussion with patient (explanation of cardiovascular risk and measures to reduce this risk) – Second conversation/discussion with patient (intention: personal target setting regarding lifestyle modifications) – Motivational interviewing/counseling over the telephone to confirm and support the self-selected objectives/targets Control group: – Two-hour training session for nursing staff on risk evaluation – Standard care	– Adherence in terms of achieving self-selected targets for lifestyle modifications: 0.08 (0.33) – Cholesterol concentrations: 0 (0.77)
(34)	Antithrombotic treatment in atrial fibrillation n = 53/51 vs 56/54	Intervention group: – Joint development of a treatment decision according to SDM, using a computer-based decision aid and balancing expected benefits and individual risk Control group: – Information brochure for patients – Doctor's recommendation, based on the individual patient's risk profile as calculated on the computer	– Frequency of stroke or hemorrhagic events: n. a. (0.06) – Proportion of patients taking warfarin: n. a. (>0.05) – Tendency to anxiety (Spielberger STAI): 0 (0.98)
(32)	Acute respiratory infection n = 216/181 vs 213/178	Intervention group: – Two-hour online tutorial and two-hour workshop for doctors (topics: SDM, communicating risks/benefits, promoting patients' participation, diagnosis and antibiotic treatment for acute respiratory infections, use of a decision aid) Control group: – Standard care	– Adherence regarding original decision in favor of or against antibiotic treatment: 0.23 (n. a.) – Quality of life regarding physical and psychological wellbeing (SF-12): 0.16 (n. a.) and 0.05 (n. a.)
(33)	Depression n = 283/191 vs 142/96	Intervention group: – Training program for doctors including a maximum of 20 50-minute training sessions (lectures, discussion, exercises on how to communicate a diagnosis, patient information, suicidality, treating depression, conversational techniques, doctors' attitudes, and medical decision making) – Information brochures and decision aids for patients – Single contact between doctor and patient in the discussion about treatment prescription Control group: – Standard care	– Depressive symptoms (PHQ-D): 0.16 (0.61) – Therapy adherence (self-assessment and doctor's assessment on 5-point scale): 0.49 (0.73) and 0.6 (0.56)

Study	Underlying main disorder Case numbers = intervention group vs. control group at start/end of study	Measures in intervention group and control group	Patient-relevant outcomes* ¹ (measurement instruments)* ²
(31)	Schizophrenia n = 32/32 vs 29/29	Intervention group: – Five 1-hour training sessions for groups of 5–8 patients – Motivation for greater participation in the psychiatric consultation and impulses for mutual support and a good therapeutic bond between doctor and patient – Practicing interactions in role plays with the doctor Control group: – Not reported	– Adherence to medication treatment (doctor's assessment/self-assessment): 0.07 (0.78)/n. a. (0.1) – Number of inpatient stays and admissions: n. a. (0.57) – Proportion of patients receiving ongoing psychiatric treatment: n. a. (0.22)
(30)	Schizophrenia n = 35/30 vs 47/40	Intervention group: – Working through information brochure on options for medication treatment for schizophrenia; patients together with trained nursing staff and considering patients' experiences and preferences – Subsequent planning discussion with a doctor, based on the preferences determined previously Control group: – Standard care	– Repeated inpatient admission within 18 months after discharge: 0.14 (>0.05) – Adherence to medication treatment (MARS): 0.05 (>0.05) – General level of functioning (GAF): 0.21 (>0.05) – Severity of illness (CGI): 0.07 (>0.05)
(29)	Atrial fibrillation, prostatic hyperplasia, menorrhagia, menopausal symptoms n = 152/136 vs 201/186	Intervention group: – Participation of doctors in workshops, where SDM skills are practiced using simulated patients Control group: – Participation of doctors in risk communication workshop	– Illness-related tendency to anxiety and anxiety states (Spielberger STAI): n. a. (>0.05) – Mental health (SF-12), n. a. (>0.05) – Adherence (yes/no question): n. a. (>0.05)

*¹ The p value of the group comparison is shown in parentheses.

*² Effect size as Cohen's d

SDM, shared decision making; n. a., relevant data not available; CGI, Clinical Global Impression; GAF, Global Assessment of Functioning; MARS, Medication Adherence Report Scale; PHQ, Patient Health Questionnaire; SF, short form; STAI, State-Trait Anxiety Inventory

eTABLE 3

Statistical procedures used to calculate effect size d

Available data	Mean, $\bar{x}$ standard deviation, s	t statistic, t or F statistic, F group or sample size, $n_1 + n_2 = N$	Significance level, p group or sample size, $n_1 + n_2 = N$	Chi square, χ^2 group or sample size, $n_1 + n_2 = N$
Formula	$d = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{s_{x1}^2 + s_{x2}^2}{2}}}$	$d = \frac{t(n_1 + n_2)}{\sqrt{df} \sqrt{n_1 n_2}}$ or $d = \frac{F(n_1 + n_2)}{\sqrt{df} \sqrt{n_1 n_2}}$	$t = \text{tinv}(p; df)$ (Microsoft Excel) with $df = n_1 + n_2 - 2$ Followed by calculation of d using t-statistic (see column 3)	$r = \sqrt{\frac{\chi^2}{N}}$ with $df = 1$ subsequently $d = \frac{2r}{\sqrt{1 - r^2}}$
Source	(e2)	(e2)	(e3)	(e4)
Resource	(e5)	(e5)	Microsoft Excel	(e5)

The statistical procedures used depended on the data available from the relevant publications

eBOX

Criteria for assessing methodological study quality according to Furlan et al. (16):

- Was the study randomized?
- Was the study adequately blinded?
- Was the dropout rate/the proportion of subjects lost to follow-up 20% at most?
- Were the outcomes in the groups under study measured at a comparable time?
- Were the groups under study comparable regarding demographic characteristics and outcome-relevant parameters at baseline?
- Were the results reported without bias and non-selectively?

eFIGURE

Systematic selection process of outcomes studies on shared decision making
SDM, shared decision making