

# Training patients with schizophrenia to share decisions with their psychiatrists: a randomized-controlled trial

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## Abstract

**Purpose** Many patients with schizophrenia have a desire for shared decision-making (SDM). However, in clinical practice SDM often does not take place. One cause might be that many patients behave passively in the medical encounter, therefore not facilitating SDM. It was the aim of the study to evaluate the effects of a patient directed SDM-training on patients' communicative behavior in the consultation, their attitudes towards decision-making and their long-term adherence.

**Methods** Randomized-controlled trial comparing a five-session SDM-training for inpatients with schizophrenia with five sessions of non-specific group training. The SDM-training sessions included motivational (e.g. prospects of participation, patient rights) and behavioral aspects (e.g. role plays) and addressed important aspects of the patient–doctor interaction such as question asking or giving feedback.

**Results**  $N = 264$  patients were recruited in four psychiatric hospitals in Germany. The SDM-training yielded no group differences regarding the main outcome measure (treatment adherence) at 6 and 12 months after discharge. However, there were short-term effects on patients' par-

ticipation preferences, their wish to take over more responsibility for medical decisions and (according to their psychiatrists' estimate) their behavior in psychiatric consultations.

**Conclusions** While there was no effect regarding treatment adherence, the shared decision-making training for inpatients with schizophrenia has been shown to increase patients' active behavior in psychiatric consultations during their inpatient treatment. When implemented it should be combined with complementary SDM interventions (decision support tools and communication training for professionals) to yield maximum effects.

**Keywords** Shared decision-making · Schizophrenia · Adherence

## Background

The model of shared decision-making (SDM) has attracted much attention in recent years, also in mental health [1, 2]. Many patients desire to participate in decision-making [3] and also professionals exhibit positive attitudes toward this model [4, 5]. Moreover, the general feasibility of implementing SDM by using decision support tools or by training professionals has been shown (e.g. [6]). However, when observing communication between patients and doctors in mental health care, it becomes apparent that SDM does not take place routinely [7, 8], which might—among others—be rooted in patients' passiveness in psychiatric encounters [9]. In addition, the impact of existing SDM-interventions on long-term outcomes such as adherence has been poor [10, 11].

There has been little research in mental health with regard to interventions targeting patients' competencies to

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facilitate SDM and their active behavior in the consultation. There are, however, promising results from interventions in somatic medicine and mental health that generally aim at improving doctor-patient communication. Here it is discussed that improved patient communication skills such as question asking and information provision are relevant to treatment adherence [12] and might therefore explain beneficial effects of patient communication trainings on health outcomes (e.g. [13, 14]).

### Aims of the study

With regard to the promising results from existing research it was the aim of the present trial to test the hypothesis that an SDM-training for inpatients suffering from schizophrenia would improve their long-term adherence. Secondary outcomes were patients' attitudes towards decision-making and their communicative behavior in the consultation.

### Methods

We performed a randomized-controlled trial comparing a behavioral SDM intervention for inpatients with schizophrenia with an unspecific intervention (cognitive training).

### Participants

The trial took place in acute wards of four participating psychiatric hospitals in the greater Munich area, Germany. Broad inclusion criteria were used. Patients were eligible if they were inpatients of these hospitals, had a diagnosis of schizophrenia or schizoaffective disorder, and were aged 18–65 years. Exclusion criteria were lack of German language proficiency and mental retardation (diagnosed according to ICD10 criteria). Patients were recruited on the wards as soon as they were able to tolerate a 60 min behavioral intervention according to their psychiatrists estimate and consented to participate.

### Intervention and control condition

The intervention was a 5-session training (60 min/session) addressing patient competencies for SDM. The group was led by a psychiatrist (J.H. or A.P.), who was not involved in the patients' treatment, and another mental health professional (e.g. nurse, psychologist) and comprised 5–8 patients. The content of the group builds upon conceptual and empirical research on patient competences in the medical encounter (e.g. [15, 16]) and had been subject to extensive pilot testing [17]. The intervention follows a

structured manual which is available on request from the authors.

Group sessions took place twice a week and addressed the following topics:

- Patient rights.
- Prospects of SDM (better health).
- Communication skills (asking questions, information provision, being assertive).
- Preparing for ward rounds and consultations.

The skills were introduced and rehearsed using role plays and homework (e.g. pose a question to the doctor in charge, prepare oneself for the next ward round).

Patients in the control condition received a 5-session cognitive training (finding differences, completing lists etc) including also elements of euthymic therapy (e.g. “using all five senses”) [18] but with no reference to doctor-patient communication.

### Data obtained

Before the intervention, patients' socio-demographics, participation preferences (Autonomy Preference Index, [19]), insight (insight scale [20]), and satisfaction with treatment (ZUF8-questionnaire [21]) were obtained. Treating psychiatrists (>than 30 different psychiatrists working on the participating wards) provided the patients' diagnosis, duration of illness, Clinical Global Impression (CGI [22]) and Global Assessment of Functioning scores (GAF [23]).

Outcomes were obtained immediately after the intervention and 6 and 12 months after discharge from hospital. The main outcome parameter was predefined as adherence after 12 months, because there were positive results with regard to adherence in previous studies addressing patient activation.

In order to rate adherence with medication the following four measures were obtained:

1. MAQ (Medication Adherence Questionnaire), a four-item self-report questionnaire addressing patients' adherence to oral medication [24].
2. Physicians' rating of patients' adherence with medication (treating psychiatrists at 12 months who were different from the hospital psychiatrists) on a 5-point scale ranging from “poor adherence” to “very good adherence”.
3. Patients self-reported adherence with outpatient visits (patients were asked whether or not they were still visiting a psychiatrist 12 months after discharge, yes or no).
4. Physicians rating of patients' adherence with outpatient visits. Treating psychiatrists at 12 months after discharge, who were different from the hospital psychiatrists, were asked whether the patient had shown up at all 12 months after discharge (yes or no).

For the analysis of the primary outcome, data from these four measures were combined and dichotomized into “good” and “poor” adherence as follows:

- “Good adherence”: MAQ ratings  $\leq 1$  AND doctors’ ratings of 1 and 2 (very good and good adherence) AND patient still in treatment.
- “Poor adherence”: incongruence of ratings OR any rating suggesting poor adherence (e.g. MAQ ratings  $> 1$ , doctors adherence rating 3–5, patient has not shown up at outpatient psychiatrist).

For patients with missing data, the data available were used to determine adherence.

Secondary outcomes were:

- Patients’ participation preferences measured with the Autonomy Preference Index [19], a four-item instrument to measure patients’ desire for autonomy.
- Patients’ wish to take over responsibility in decision-making. Here, patients answered 15 questions on different aspects of the treatment process (e.g. “Who is responsible that there is a discussion about your treatment if you are suffering from side-effects?”). Since internal consistency was high (Cronbachs  $\alpha = 0.80$ ) we used the sum score of all 15 items for further analyses.
- Drug attitudes (Beliefs in Medication Questionnaire [25]).
- Satisfaction with treatment (Satisfaction with Treatment Scale [21]).
- Trust in physician scale [26].
- Rating of perceived profit from visiting intervention/control group sessions
- Medication adherence rating scale (MARS) [27], which includes the four items of the MAQ (Medication Adherence Questionnaire).
- Doctors’ rating of patient behavior in the consultation. Here the treating psychiatrists in charge were requested to give an overall rating of the patients’ behavior in ward rounds and consultations, i.e. to rate 8 possible behavior patterns of patients that were part of the intervention sessions (see Table 4) as present or not present.
- Difficult Doctor-Patient-Relationship Questionnaire [28].
- Information on readmissions was provided by the psychiatrists in charge for patients 12 months after discharge.

### Sample size

We estimated that a total sample of  $n = 186$  patients would be sufficient to detect a 20% difference in patients being

non-adherent (overall adherence, power: 80%, two-sided test,  $\alpha = 0.05$ ). To account for drop outs we aimed at recruiting 120 patients per group.

### Randomization and blinding

Separate randomization lists for every study center (block size = 4) and numbered closed allocation concealment envelopes were generated prior to the study by our statistical department. Patients were recruited until group size was reached, then randomized to the intervention/control condition.

As to the nature of our intervention patients were not blinded. Psychiatrists in charge who also did the ratings were neither informed about allocation of their patients nor intentionally blinded.

### Statistical methods

Group differences regarding the main outcome parameter (adherence) were analyzed using a Chi<sup>2</sup>-test. Categorical secondary outcomes are described with absolute and relative frequencies, quantitative outcomes with means and standard deviations. For group comparisons Chi<sup>2</sup>-tests and *t*-tests were used, respectively. A two-sided level of significance ( $p < 0.05$ ) was used for all tests.

### Review board approval and study registration

The study was approved by the institutional review board of the Technische Universität München. The study was registered at clinicaltrials.gov (NCT02349880).

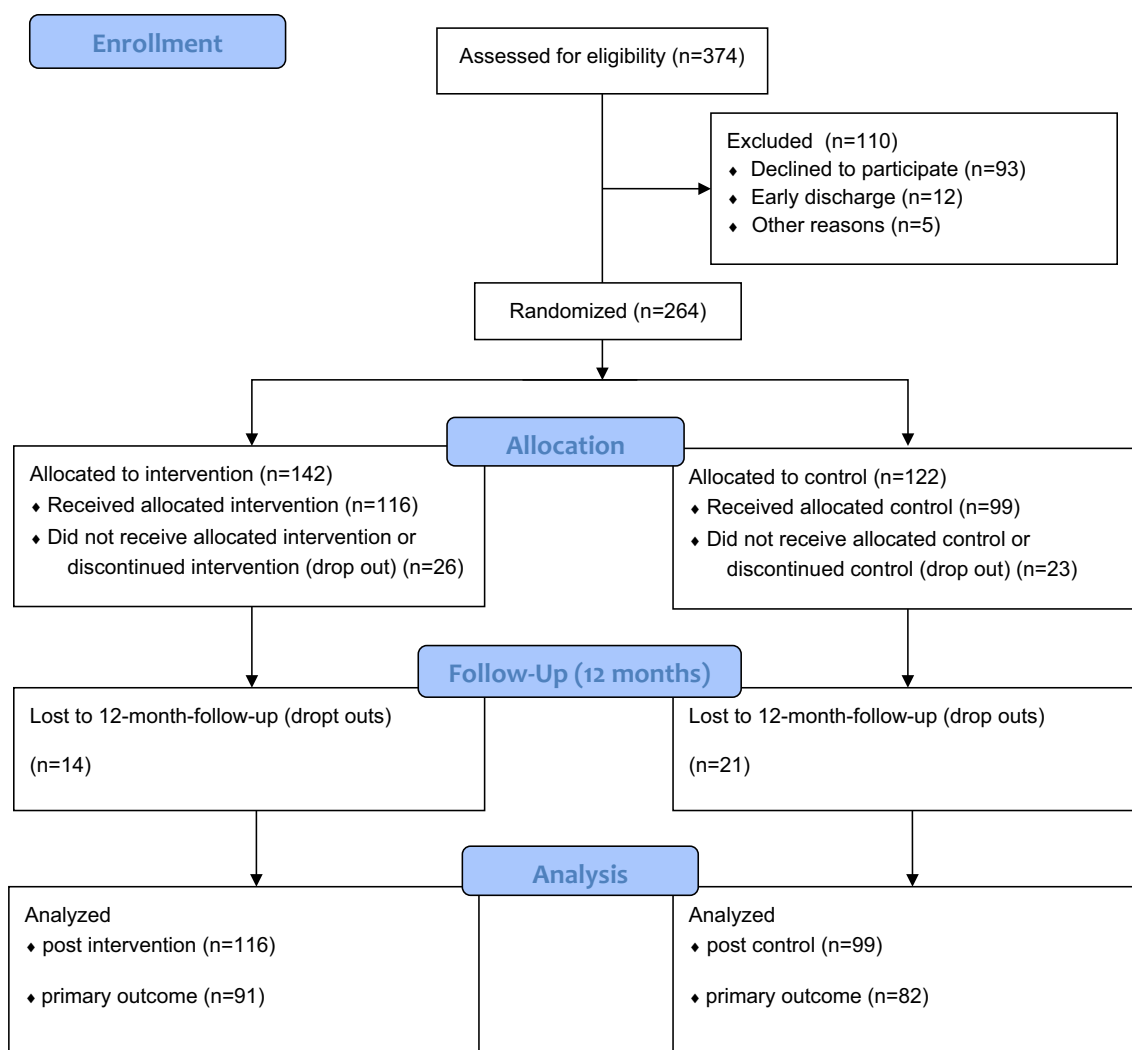
### Results

From October 2011 to April 2013  $N = 374$  patients in four psychiatric hospitals were approached for the study and  $N = 264$  patients consented to participate. Of those  $N = 142$  were allocated to the intervention group and  $N = 122$  to the control group (Fig. 1).

49 patients dropped out of the trial during the inpatient and intervention phase, most of them because they were suddenly discharged or left the hospital against their doctor’s advice, and were therefore excluded from the analysis. The remaining 215 patients received the full intervention/control condition and serve as the basis for the further analyses (Fig. 1).

### Baseline data

Apart from duration of illness there were no significant differences between the intervention and the control group with regard to socio-demographic or clinical variables at



**Fig. 1** CONSORT 2010 flow diagram

baseline. There was, however, a trend that patients in the intervention group were hospitalized involuntarily more often and more often had a legal guardianship (Table 1).

### Primary outcome

The numbers of patients judged as having “good adherence” at 12 months after discharge was not significantly different between the intervention group ( $n = 51$  of 91, 56%) and the control group ( $n = 49$  of 82, 60%,  $\chi^2 = 0.24$ ,  $p = 0.62$ ). When controlling for duration of illness there was still no significant group difference regarding adherence.

### Secondary outcomes: patient ratings

Overall patients enjoyed visiting both, the intervention and the control group. However, their ratings were more positive regarding the specific content of the intervention group

and more patients in the intervention group planned to play a more active role in future consultations compared with the control group (Table 2).

In addition, the intervention group had short-term (but no long term) effects regarding patients’ participation preferences and the wish to take over more responsibility in the doctor-patient relationship. Other parameters relating to satisfaction with treatment, trust in physician, drug attitudes or adherence were not influenced by the intervention (Table 3).

### Secondary outcomes: doctor ratings

There were significant group differences in the psychiatrists’ ratings regarding patient behavior in the consultation (for the time of the inpatient stay), for example a higher share of patients preparing for consultations or asking for treatment alternatives (Table 4).

**Table 1** Baseline data

	Intervention ( <i>N</i> = 116)	Control ( <i>N</i> = 99)	Comparison
Age (mean)	36.4 (12.6)	38.2 (12.2)	$T = -1.1, p = 0.29$
Gender (female, <i>N</i> )	47 (41%)	49 (49%)	$\chi^2 = 1.7, p = 0.19$
Diagnosis ( <i>N</i> )			
Schizophrenia (F20)	76 (69%)	68 (72%)	$\chi^2 = 1.0, p = 0.80$
Schizoaffective disorder (F25)	31 (26%)	25 (26%)	
Other	3 (3%)	2 (2%)	
Duration of illness in years (mean)	9.4 (8.9)	12.9 (9.8)	$T = -2.7, p = 0.008$
Involuntary admission ( <i>N</i> )	19 (17%)	8 (8%)	$\chi^2 = 3.5, p = 0.062$
Legal guardianship ( <i>N</i> )	41 (37%)	24 (25%)	$\chi^2 = 3.6, p = 0.059$
Number of hospitalizations ( <i>N</i> )	5.9 (6.9)	5.7 (4.6)	$T = 0.28, p = 0.78$
Clinical Global Impression, CGI (mean)	4.5 (1.1)	4.7 (1.0)	$T = -1.0, p = 0.32$
Global Assessment of Functioning, GAF (mean)	47.9 (16.0)	45.5 (14.5)	$T = 1.1, p = 0.28$
Autonomy Preference Index, API (mean)	10.3 (3.6)	9.8 (3.5)	$T = 1.0, p = 0.32$
Insight scale, (mean)	12.4 (2.5)	12.5 (2.5)	$T = -0.38, p = 0.70$
Treatment satisfaction (mean)	25.5 (4.6)	26.1 (4.1)	$T = -1.0, p = 0.32$

**Table 2** Patients' evaluation of the group sessions

	Intervention	Control	Test
How did participation in the group change your attitudes towards psychiatric consultations? ( <i>N</i> )			
I will try to play a more active part	81 (80%)	49 (53%)	$\chi^2 = 18.7, p < 0.001$
There will be no change	18 (18%)	43 (46%)	
I will try to play a less active part	2 (2%)	1 (1%)	
How much will this group help you that future consultation will be running well? (mean, SD, <i>N</i> = 211)	4.1 (0.8)	2.9 (1.2)	$T = 8.6, p < 0.001$
How happy were you visiting the group? (mean, SD, <i>N</i> = 211)	4.3 (0.9)	3.9 (1.2)	$T = 2.6, p = 0.009$
How much did you profit from the experiences of the other group members? (mean, SD, <i>N</i> = 210)	3.8 (0.9)	3.2 (1.2)	$T = 4.4, p < 0.001$
How much did the group make you feel more comfortable when talking to doctors? (mean, SD, <i>N</i> = 211)	3.9 (0.9)	3.0 (1.2)	$T = 6.3, p < 0.001$
To what extent will you be able to use the content of the group in later life? (mean, SD, <i>N</i> = 209)	4.2 (0.8)	3.2 (1.2)	$T = 6.9, p < 0.001$
How much did you like the group overall? (mean, SD, <i>N</i> = 210)	4.5 (0.7)	4.3 (0.9)	$T = 2.0, p = 0.05$

All ratings (except when stated otherwise) range from 1 = not at all to 5 = very much

## Discussion

Our SDM-intervention addressing the patients' side of SDM has shown no effects regarding the main outcome measure (treatment adherence after 12 months). There were, however, short-term effects regarding patients' participation preferences, their attitudes on decision-making and on their actual behavior in doctor–patient contacts.

## Limitations

As only patients were recruited who were judged to tolerate a 60 min intervention we surely had a

recruitment bias towards less ill patients which results in a possible lack of generalizability of our data. On the other side, patients actually recruited were moderately to markedly ill according to CGI. Therefore cognitive limitations may have nonetheless hindered patients from profiting from the intervention. Psychiatrists were not blinded, so their ratings might be biased by expectation. Likewise the same researchers were involved in conducting the intervention sessions and in analyzing the data, which should have been avoided. Moreover there were some differences in patient characteristics at baseline between groups and centers that were not fully accounted for.

**Table 3** Secondary outcomes: patient ratings

	Intervention (mean, SD)	Control (mean, SD)	Comparison
T1 (after the intervention/control groups)			
Participation preferences, Autonomy Preference Index (API), $n = 210$	11.6 (3.3)	10.3 (3.8)	$T = 2.50, p = 0.013$
Beliefs in Medication (necessity), $N = 205$	17.7 (4.5)	18.2 (4.9)	$T = -0.75, p = 0.45$
Beliefs in Medication (concerns), $N = 205$	14.5 (3.8)	14.0 (3.9)	$T = 0.85, p = 0.40$
Beliefs in Medication (general overuse), $N = 206$	11.2 (3.1)	11.4 (3.3)	$T = -0.41, p = 0.68$
Beliefs in Medication (general harm), $N = 204$	9.0 (2.7)	9.3 (3.1)	$T = -0.77, p = 0.44$
Satisfaction with treatment (ZUF8), $N = 206$	25.7 (4.2)	25.8 (5.2)	$T = -0.15, p = 0.88$
Responsibility for decision-making, $N = 192$	39.5 (6.2)	37.5 (6.5)	$T = 2.21, p = 0.029$
Trust in Physician, $N = 204$	40.3 (7.5)	41.4 (6.8)	$T = -1.15, p = 0.25$
“Who makes important decisions about your medical treatment?” $N = 211$	3.4 (0.8)	3.6 (0.7)	$T = -1.29, p = 0.20$
T2 (6 months after discharge)			
Participation preferences, $N = 121$	10.4 (3.7)	10.5 (3.6)	$T = -0.02, p = 0.98$
Responsibility for decision-making, $N = 118$	39.6 (6.7)	39.2 (5.5)	$T = 0.34, p = 0.73$
Medication Adherence Rating Scale, MARS, $N = 100$	2.6 (2.1)	2.5 (2.2)	$T = 0.36, p = 0.72$
T3 (12 months after discharge)			
Participation preferences, $n = 97$	10.6 (3.6)	9.8 (3.7)	$T = 1.16, p = 0.25$
Responsibility for decision-making, $N = 87$	40.8 (6.3)	40.0 (6.8)	$T = 0.57, p = 0.57$
Medication Adherence Rating Scale, MARS, $N = 85$	2.4 (2.1)	2.8 (2.3)	$T = -0.81, p = 0.42$

## Interpretation

Assuming SDM can be implemented through three potential access paths [2]: training of communication techniques to professionals, implementing decision support tools, training communication skills to patients, efforts in mental health have mostly focused on two of them, namely decision support tools and to a smaller extent on professionals' training [2]. Evidence on these two types of interventions is mixed with many positive short-term outcomes regarding patient satisfaction, treatment attitudes or improved perceived involvement in decision-making [6]. What had been missing were interventions directly addressing patients' active behavior in the psychiatric consultation. The present trial has now filled this gap. There are several lessons that can be learned from our results:

First, contrary to our expectations and previous research from somatic medicine [12] our intervention did not lead to an improvement of patients' adherence. Thus, the expected link between the observed effects on patient attitudes and behavior during inpatient treatment and changes in patients' long-term health behavior could not have been shown in our trial. Potential reasons for this finding are manifold and include the sample studied, the intervention applied and the outcome measure used. Regarding the patient sample we have included rather ill patients with a chronic course of illness. Therefore patients might have been limited in their ability or motivation to implement the content of the intervention into

their consultations with psychiatrist. Regarding the intervention, it might just not have been “powerful” enough to lead to long-term changes in patients' health behavior. Thus, our intervention was applied only during inpatient treatment and not further implemented in the outpatient setting. The effects of only five sessions might have therefore dissolved over time. In addition, we did not implement an intervention addressing patients *and* professionals, which might have been a way to have yielded more powerful effects [14]. Finally one might question whether treatment adherence is an adequate outcome measure for the success of SDM interventions addressing patient activation. Thus, our results are in line with studies using similar approaches but different outcome measures such as level of patient activation [29].

Second, we have, despite negative finding regarding our main outcome measure, shown, that an empowering intervention that aims at strengthening patients' abilities to demand participation in treatment decisions can be implemented even in very acute psychiatric settings. We think that this is one of the strengths of our study that we have included a rather non-selected sample. Therefore our results may be generalizable to most other mental health settings. This means that most mental health patients can tolerate and can be expected to be highly interested in a decision-making intervention and that empowering them does not lead a worsening of outcomes. Interestingly the more “provocative” strategies (e.g. objecting the physician) did not rise after the intervention. Accordingly,



**Table 4** Secondary outcomes: doctors' ratings

	Intervention	Control	Comparison
T1 (after the intervention/control groups)			
CGI, $n = 177$	4.6 (1.1)	4.4 (0.9)	$T = 0.87, p = 0.39$
“Who makes important decisions about the patient’s medical treatment?” (mean, SD, $N = 210$ )	3.5 (0.6)	3.4 (0.6)	$T = 1.30, p = 0.20$
Difficult doctor-Patient Relationship Questionnaire, DDPQRQ (mean, SD, $N = 208$ )	43.0 (8.1)	44.0 (7.4)	$T = -0.90, p = 0.37$
“Patient explicitly requested a talk with the doctor”, $n = 209$	107 (94%)	84 (88%)	$\chi^2 = 1.95, p = 0.16$
“Patient asked questions”, $n = 209$ ( $N$ )	113 (99%)	90 (95%)	$\chi^2 = 3.58, p = 0.06$
“Patient expressed an opinion”, $n = 209$ ( $N$ )	110 (96%)	89 (94%)	$\chi^2 = 0.90, p = 0.34$
“Patient prepared for the consultation (e.g. using a leaflet)”, $n = 208$ ( $N$ )	90 (79%)	41 (44%)	$\chi^2 = 27.6, p < 0.0001$
“Patient brought a relative to the consultation”, $n = 209$ ( $N$ )	47 (41%)	23 (24%)	$\chi^2 = 6.74, p = 0.009$
“Patient made treatment proposal”, $n = 209$ ( $N$ )	72 (63%)	51 (54%)	$\chi^2 = 1.92, p = 0.17$
“Patient asked for treatment alternatives”, $n = 209$ ( $N$ )	81 (71%)	53 (56%)	$\chi^2 = 5.25, p = 0.02$
“Patient objected the doctor’s recommendations”, $n = 208$ ( $N$ )	61 (54%)	50 (53%)	$\chi^2 = 0.04, p = 0.95$
Sum score, $n = 207$ ( $N$ )	6.0 (1.6)	5.1 (2.0)	$T = 3.69, p < 0.0001$
T2 (6 months after discharge)			
“Who makes important decisions about the patient’s medical treatment?” (mean, SD, $N = 136$ )	2.9 (0.6)	2.8 (0.7)	$T = 0.35, p = 0.73$
T3 (12 months after discharge)			
Hospitalized within 12 months, $n = 170$ ( $N$ )	29 (31%)	23 (31%)	$\chi^2 = 0.00, p = 0.98$
“Who makes important decisions about the patient’s medical treatment?” mean, SD, $N = 140$ )	3.0 (0.6)	3.0 (0.6)	$T = -0.28, p = 0.78$

patients in the intervention group showed no decline of trust in their physicians compared to the control group.

Third, the SDM-intervention actually affects patients' attitudes and behavior with regard to decision-making. Patients become more active in that they use some of the strategies taught in the SDM-intervention, which is in line with findings from other studies in (less acute) mental health settings [29]. However, this effect did not remain stable one year after discharge which may result from the low dose (5 sessions) of the intervention and the lack of reinforcement during the 12 months' follow-up. Another possible reason is the experience of decision-making processes after discharge, where the newly acquired SDM strategies could not be exercised and therefore may have dissolved over time.

Finally, our intervention obviously affected patients' attitudes and behavior very specifically as neither patient satisfaction nor any other outcome (e.g. trust, drug attitudes) were touched. This is a very different pattern compared to other SDM-interventions (e.g. decision aids) that often positively influence drug attitudes or consumer satisfaction [30]. One might speculate whether decision aids yielded these results because they increase professionals' devotion to patients which then results in better satisfaction. An intervention like ours, addressing only patients and not professionals seems to have only very limited effect on overall treatment parameters like adherence and treatment satisfaction. Seen the other way around, to affect

adherence, interventions may need to address patients and physicians to use the effect of the mediator satisfaction. In addition, if our intervention had been peer-led (such as e.g. [31].) the effects might also have been stronger.

## Conclusions

As our intervention resulted in short-term effects of patient behavior in the consultation (according to the psychiatrists' rating) but no effects on long-term outcomes such as adherence it is debatable whether or not it should be recommended for implementation. If one sees patient engagement in treatment decision-making as a value per se, the SDM-training might be a valuable treatment offer for any psychiatric in- or outpatient department. If one aims at changing long-term patterns of psychiatric care or even treatment outcomes, the SDM-training might yield beneficial effects only when administered with higher dose (i.e. more than 5 sessions), continuously during outpatient treatment or as part of a multi-faceted intervention that also incorporates the other implementation methods of SDM, i.e. decision aids and staff communication training [32].

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## Compliance with ethical standards

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