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Shared decision making with schizophrenic patients: a randomized controlled clinical trial with booster sessions (DECIDE Study)☆

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ABSTRACT

Background: The treatment of schizophrenia requires a prolonged, multidimensional intervention that includes antipsychotic drugs. Treatment adherence is essential to effectively control the disorder. Shared decision-making (SDM) is a strategy, supported by numerous practical and ethical arguments, that seeks to involve patients in the therapeutic process to improve treatment adherence and satisfaction. The use of this model in mental health has been limited for many intrinsic and extrinsic reasons. The results of clinical trials conducted to date have largely been disappointing, potential due to study design-related limitations.

Aim/Question: To evaluate the efficacy, in terms of treatment adherence and improvement in clinical variables, such as severity of symptoms, days of hospitalization or insight, of a carefully timed SDM model initiated immediately prior to hospital discharge in patients with schizophrenia.

Methods: Single-blind, randomized clinical trial in an acute psychiatric care unit within the Andalusian Health Department to compare SDM (experimental group) to treatment as usual (TAU; control group) in a sample of patients hospitalized for an acute episode of schizophrenia or schizoaffective disorder. The study was performed between January 2014 and June 2017. The experimental group participated in SDM sessions prior to discharge with regular booster sessions over the one-year follow-up. The health care team responsible for SDM was predisposed to concordance (LatCon II scale) and received specific training in SDM. A hierarchical multiple linear regression analysis was performed to evaluate the factors independently associated with adherence, controlling for sociodemographic, clinical, and admission-related variables. Variables were assessed at admission, discharge and at 3, 6 and 12 months after discharge during the one year follow up. BARS, DAI, WAI-S, COMRADE and

☆ Relevance statement = Tweetable abstract. DECIDE study: Shared decision making with a reinforcement schedule improves adherence in schizophrenia.

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PANSS were used to evaluate adherence, attitude to treatment, therapeutic alliance, satisfaction and confidence with decision and clinical status, respectively.
Results: A total of 227 schizophrenic patients hospitalized with acute decompensation were evaluated; of these, 102 met all inclusion criteria and were included in the study. Most patients (95%) had prior experience with antipsychotics and most (82%) had experienced related side effects. Despite randomization, psychopathologic severity was greater in the experimental group, with a mean (SD) PANSS score of 104.08 (80) vs. 93.45 (20.30) ($p < 0.05$). The final regression model to explain adherence was significant (adjusted $R2 = 0.384$; $F [df= 6] = 4.386$; $p < 0.001$), with a direct, significant and independent association with SDM mediated by the number of booster sessions.
Discussion: Shared decision making with booster sessions appears to increase treatment adherence in patients with severe mental disorders.
Implication on practice: Ethical, practical, and clinical reasons support the use of strategies designed promote the use of long-term, shared decision-making in psychiatric patients, especially in schizophrenia spectrum disorder.

What is already known about the topic?

- Adherence to treatment plays an important role in the prognosis and course of schizophrenia spectrum disorder. Several factors have been associated with the degree of adherence, including satisfaction and confidence in the therapeutic process.
- Shared decision-making strategies promote patient involvement in the therapeutic process and may improve adherence. However, implementation of this strategy in severe mental disorders is limited.

What this paper adds

- This study overcomes the key limitations associated with previous attempts to apply a shared decision-making model. The study was performed in a single center, with two teams of professionals, and regular booster sessions for an extended time period (one year).
- In this study population of patients with schizophrenia, the longitudinal application of a shared decision-making strategy improved clinical outcomes and significantly improves satisfaction and confidence in the therapeutic process.

What are the implications for practice?

- Measures that promote the application of shared decision-making with booster sessions are likely to improve patients' subjective perception of the treatment and could have a clinically relevant impact mediated by greater adherence. This approach increases patient involvement in treatment decisions, thereby providing an ethical basis for its use.

1. Introduction

Schizophrenia is a serious mental disorder with a high global burden that requires a prolonged, multidimensional intervention [1,2]. Although antipsychotics have been shown to modify the natural course of the disorder, numerous factors influence the relative efficacy of these drugs [3–5]. As in other chronic conditions, treatment adherence in schizophrenia spectrum disorders is essential to ensure effectiveness, with poor adherence associated with worse symptomatology and prognosis [6–8]. Numerous factors influence adherence to antipsychotics, ranging from medication-related factors (experienced side effects, route of administration, dosing, polypharmacy) [9] to subjective patient-related factors such as attitude toward medication and confidence and satisfaction with the antipsychotic [10,11], all of which are influenced by the therapeutic model. Many patients with severe mental disorders do not feel involved in the therapeutic process [12]. In this context, shared decision making (SDM) could play an important role in improving adherence to antipsychotic treatment [13,14]. However, involving patients in the choice of therapy is not sufficient to increase adherence if, at the same time, there is no constant work of comparison and communication with the reference psychiatric team [15].

SDM is an interactive treatment selection process involving patients, physicians, and others to collaboratively select the optimal therapeutic approach, pharmacological and non-pharmacological, through a cooperative exchange [16,17] of relevant information [18–20]. Many authors argue that, for both ethical and practical reasons, SDM is a promising approach in mental health [21–25]. Importantly, some clinical guidelines recommend its use in patient-centered care [26,27]. This collaborative treatment selection process is based on patient-provider relationship at the time it likely increases patient involvement and satisfaction with treatment and help patients to better understand the therapeutic process and the available options [17,28,29].

However, there is strong evidence showing that this model is less used in mental health than in other areas of medicine [30], and only a limited number of clinical trials have been conducted to evaluate the effectiveness of SDM in mental health [17,28,31]. Although no significant improvements in health outcomes (e.g., rehospitalization rates, treatment adherence, functional improvement, etc.) have been found in the trials conducted to date, SDM does appear to improve several subjective variables [32] such as satisfaction, confidence, and attitude to treatment. Despite, SDM-models quite consistently share some components [33], the wide variability among the different SDM models [34] and decision support tools [35,36], together with the variability of creating an experimental design that incorporates all the main elements of SDM [30,37], may explain this scant empirical evidence [17,38,39].

Hamann et al. [40] conducted the first multicenter RCT in schizophrenia, using a cluster randomized study design (psychiatric units) in schizophrenic patients hospitalized after an acute episode. In this study, SDM was implemented once for the antipsychotic selection started during the hospitalization. Although no significant improvements in health-related variables were obtained [41], several subjective variables improved significantly in the experimental group. However, as the authors acknowledged, that trial had several important limitations [40,41], including the very early application of SDM (a single session administered during admission, without subsequent booster sessions), which may explain the absence of effect in long-term compliance. This importance of the timing of the intervention was later emphasized by several authors [42–44]. Other aspects, such as cluster randomization and fidelity to the intervention, have also been discussed [45–47]. Since then, only a few clinical trials have been performed, with disappointing results [17,45,48–50].

To our knowledge, the efficacy of SDM with booster sessions to increase adherence to antipsychotic treatment in patients with schizophrenia has not been previously evaluated. The objective of the present single-center study, conducted in schizophrenic patients hospitalized following an acute episode, was to determine whether a traditional two-staged SDM model -information and deliberation, [18,19] complemented with a reinforcement stage (with three booster sessions at follow up), and a strict control of SDM timing— sessions administered immediately prior to hospital discharge with regular booster sessions at 3, 6 and 12 months during the follow-up—would be more effective than treatment-as-usual (TAU) in adherence or other health related variables

such as clinical status, days of hospitalization, insight, attitude to medication, satisfaction and confidence with the treatment decision and quality of therapeutic alliance.

2. Methodology

2.1. Study design and participants

We conducted a single-blind RCT at the Mental Health Unit (MHU) of the public university hospital of the Andalusian Health Department between January 2014 and June 2017. This hospital serves an approximate population of 455,000 inhabitants. Inclusion criteria were: (a) age ≥ 18 years; (b) fulfillment of ICD-10 and Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV-R criteria for schizophrenia or schizoaffective disorder (F20 and F25); (c) admission to the MHU with need for antipsychotic treatment at discharge; (d) signed informed consent by the patient or legal guardian (in case of legal incapacity). Exclusion criteria were: (a) inability to make decisions about treatment as measured by the Aid to Capacity Evaluation (ACE) [51]; b) Axis II comorbid diagnosis of moderate or severe intellectual disability, or (c) poor understanding of the Spanish language (the language of the assessment tools and intervention model). The flow of participants is shown in Fig. 1.

2.2. Outcomes measures

a) Data obtained.
At all points, (at baseline, at discharge, and at 3, 6 and 12 month after discharge), identical data were collected from the intervention and control groups. All instrument were used in their Spanish validated versions.

b) Baseline parameters
For all patients recruited, socio-demographics, diagnosis, clinical and data on anamnesis (previous hospitalisations, duration of illness, etc.) were recorded at baseline (at study entry). In addition, we administered the Insight Scale [52,53], and the Positive and Negative Syndrome Scale (PANSS) [54,55] and the Severity of Psychotic Symptoms specific scale included in DSM5 to evaluate level of insight and clinical status, respectively. We also measured the patients' attitude to be involved in a collaborative interaction to make decision about their medication by using the Leeds Attitude to Concordance (LATCon II) scale [56–58].

c) Primary outcome
The primary outcome was treatment compliance. Following recommendations from the Expert Consensus Guidelines [59], two complementary methods were used to evaluate compliance. The Brief Adherence Rating Scale (BARS) [60], a clinician-administered instrument including three questions and a visual analog scale, was administered at baseline (compliance the month prior to admission, in case the patient was already in antipsychotic medication), and at months 3, 6 and 12 after discharge and changes in its scoring was the primary outcome parameter in our study.

d) Secondary outcomes

Besides, attitude to medication, that is how participants view the use of antipsychotic medication and their experience with it, was evaluated with the Drug Attitude Inventory (DAI) [61,62], a self-administered instrument that was filled out by patients immediately prior to hospital discharge, and at months 3, 6 and 12.

Whether or not the intervention also had influence on the therapeutic alliance was evaluated by using the Working Alliance Inventory, Short version (WAI-S) [63–65], administered at discharge and at months 3, 6, and 12.

Satisfaction and confidence with the decision was measured by The Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness (COMRADE) [66,67]. This instrument

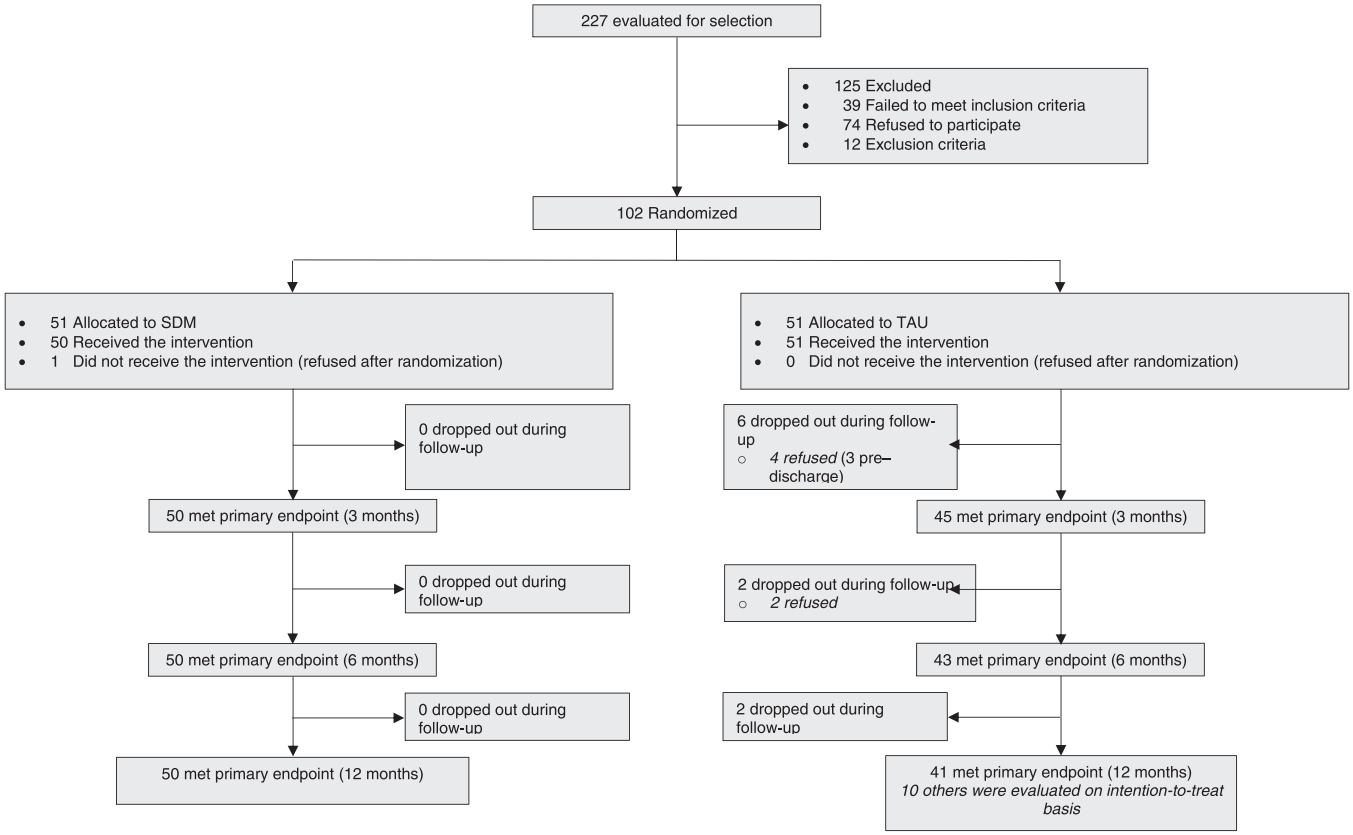

Fig. 1. Study flow diagram through this two-arm (shared decision making [SDM] vs. treatment-as-usual [TAU), parallel randomized clinical trial.

was designed to evaluate the results of the shared decision-making process and was administered prior to hospital discharge and at months 3, 6, and 12 after discharge.

In addition, we also evaluated readmissions (total number and total day of admission) one year prior to and one year after discharge as proxy variables of clinical instability, a consequence of noncompliance.

2.3. Procedure

All hospitalized patients were evaluated by their treating physician to determine if they were candidates for the study. Subsequently, the ACE scale was administered to all patients who met the study inclusion/exclusion criteria to confirm their capacity to participate. All study participants in both groups were evaluated in parallel for 12 months, with measurements performed at baseline, months 3 and 6, and at one year (final evaluation). Patients were randomly assigned to one of the two antipsychotic treatment decision strategies at discharge: 1) an experimental group assigned to the SDM model (experimental group) developed by Charles et al. [18,19] or TAU (control group).

Randomization was performed using a block procedure, applying a correspondence table created and custodied by a blinded researcher external to the clinical trial [68]. The evaluator was unaware of the entire process. This evaluator, a psychiatrist unaffiliated with the MHU, received specific training in the administration of the scales used in the study. The interventions were carried out by two different teams (one for SDM and one for TAU), each consisting of two psychiatrists and a nurse. The SDM team (experimental intervention) was comprised of professionals selected for their greater predisposition to concordance treatment with patients (LatCon II scale). This team received specific training in SDM (theoretical-practical workshops based on a slides presentation and written case vignettes for role plays) according to published recommendations [69]. The nurse on the SDM team was in charge of informing the patients about the procedures, providing help when necessary, exploring values, and clarifying any doubts. Weekly sessions of supervision of to what extent single elements of the intervention were implemented for patients were held with all personnel involved. In these sessions, a fidelity check list was used.

The experimental intervention was a three-stage process, involving two initial stages (see below) and a third stage comprised of decision reinforcement and follow-up. Decision to be shared was the type of antipsychotic medication and the route of administration, including an alternative option in case first choice was considered not to bet effective or caused important side effects. The intervention was initiated as soon as the treating physician determined that the patient was ready for discharge, based on the criteria established by Potkin et al. [70], starting from 5 to 7 days prior to discharge. The first stage consisted of three sessions (total duration = 150 min) carried out from 48 to 72 h before discharge. The treating nurse gave the patient an informational leaflet (adapted to the patient's cultural level) explaining the SDM model and briefly explained its purpose and stages. Then, the International *Patient Decision Aid Standards* for antipsychotic treatment, developed according to International Patient Decision Aid Standards (IPDAS) guidelines [71], was used to help the patient express his or her values and preferences using a treatment options worksheet. These patient decision aids included basic information of the treatment options, available antipsychotics, and side effects profiles. The second stage (deliberative) was carried out approximately 24–48 h before discharge and involved a single session in which the patient and treating psychiatrist agreed on an implementation plan after discharge based on the patients previously expressed options and preferences. After discharge, in the reinforcement stage, the treatment decision was reviewed and adjusted at months 3, 6, and 12. The plan was adapted as appropriate (Table 1).

2.4. Statistical analyses

The main outcome measure was adherence to antipsychotic treatment, measured with the BARS scale. Data normality, linearity, homoscedasticity and multicollinearity were evaluated according to the criteria established by Tabachnick and Fidell [72]. All participants lost to follow-up were included in the analysis using intention-to-treat criteria, using either the last available measure or, in its absence, the best score of the control group or the worst score of the experimental group for that variable. To test for differences between groups at baseline, we applied Student's t-test for independent samples and the Chi-squared test. To check for changes of the primary and secondary outcomes in significance over time, Cohen's D statistic was used to measure effect size and was represented graphically. Finally, a hierarchical linear regression was run for the independently-associated to adherence 12 month later variables. We applied a conceptual approach, result of the evidence review, to select the model variables, which included the experimental intervention and the number of follow-up sessions completed by both groups, TAU and SDM. First, control variables were added to explore the proportion of variance explained by the model. Next, variables from previous and current clinical history that potentially modifiers of adherence were included. Then, the variable associated with the intervention itself were included, before the variable associated with the compliance degree of longitudinal follow-up in two different models. All tests were two-tailed, with the cut-off for statistical significance set at $p < 0.05$. All analyses were performed with the IBM SPSS software (PASW Statistics for Windows, v.18.0., SPSS Inc., Chicago, IL; USA).

3. Results

3.1. Participant demographic, clinical and admission data variables at baseline. Baseline comparison between groups of intervention.

Of 227 patients evaluated for possible study inclusion, 102 were finally included (51 per group). One patient in the experimental group revoked informed consent after randomization but prior to the intervention, thus leaving 101 participants (Fig. 1). Table 2 shows the differences between groups in baseline variables. The sample was comprised of schizophrenic patients with acute decompensation. Despite the randomization process used in this study, patients in the SDM group had more severe psychopathology, with a mean (standard deviation [SD]) PANSS score of 104.08 (80) versus 93.45 (20.30) in the TAU group (Student's $t = 2.434$, $p < 0.05$). Furthermore, mechanical restraint was indicated on eight occasions in the experimental group versus only one case in the controls. Although most patients in both groups have been on antipsychotics previously (100% in SDM group vs. 90,2 in TAU group), a higher proportion of patients in the SDM group had a prior history of adverse effects associated with antipsychotics (90% vs 74.5% in the TAU group, $p < 0.05$). There were no between-group differences in terms of insight (Markova-Berrios) and predisposition to concordance (LatCon II) before intervention.

3.2. Longitudinal comparison between groups of intervention: Adherence and secondary outcomes evolution

The longitudinal evolution and between-group differences for the outcome variables in the intermediate (months 3 and 6) and final evaluation (month 12) are shown in Fig. 2. Although a positive trend (higher mean adherence) was observed for the experimental group, the difference was not significant (Fig. 2). By contrast, the experimental intervention had an early, stable, large, and significant positive effect on (COMRADE) patient confidence and satisfaction with the treatment decision (Cohen's D, range: 0.68–0.70).

No between-group differences in PANSS scores were observed at 12 months (after correcting for the baseline differences in the SDM group). Psychotic symptom severity (DSM5 scale) decreased significantly from baseline to the final evaluation (12 months) in both groups, with a moderate effect size. The mean DSM5 score was lower at 12 months

Table 1
Description of SDM model used in the DECIDE Study.

SDM model	Personnel	Tools	Duration (minutes)	Objective
1. Informative stage			150	Exchange information
1.1 Introductory session	Nurse	Informative leaflets	30	Presenting SDM model to patient
1.2. Exploratory session	Nurse and psychiatrist	Patient decision aids	90	Bidirectional exchange of information about the disorder, treatments, and patient's personal experiences and preferences
1.3. Confirmatory session	Nurse	Personal Decision Guide	30	Completing the Personal Decision Guide
2. Deliberative stage			90	Expressing, discussing and getting to a consensus
2.1. Deliberation	Psychiatrist (and supportive relative if required)	Personal Decision guide	60	Constructing consensus on decision
2.2. Consensus decision	Psychiatrist (and supportive relative if required)	Implementation plan	30	Elaboration of implementation plan
3. Reinforcement stage			180	Reinforcement of consensus decision
3.1. 3 months booster session	Psychiatrist (and supportive relative if required)	Implementation plan	60	Monitoring and adjusting IP
3.2. 6 months booster session	Psychiatrist (and supportive relative if required)	Implementation plan	60	Monitoring and adjusting IP
3.3. 12 months booster session	Psychiatrist (and supportive relative if required)	Implementation plan	60	Monitoring and adjusting IP

Abbreviations: SDM: Shared decision making; IP: Implementation plan.

versus discharge in the experimental group, but not in the control group. No losses to follow-up were observed in the experimental group after the intervention versus 19.6% in the control group (relative risk [RR] = 0.80, 95% confidence interval [CI] = 0.70–0.92).

3.3. Conceptual theoretical model of adherence to antipsychotic treatment at one-year post-discharge explained by shared decision making and factors independently associated: Hierarchical multiple linear regression model

In this regression model, we included variables potentially explanatory of adherence, the experimental intervention and the number of follow-up sessions, called booster sessions for the SDM intervention. Table 3 shows the models and the variables considered independent predictors, taking into account the covariates. The variables finally included in the model were those found to be relevant in the evidence and a conceptul framework proposed, and those potential confounders found in the baseline bivariate analysis.

Model 1 included the control variables that were significantly different between the groups at baseline. As theoretically expected, they did not explain a relevant percentage of variance (adjusted $R2 = 0.04$; $F(df = 4) = 1.98$; $p = 0.081$). Later models increased the percentage of explained variance. In model 2, sociodemographic and clinical variables conceptually related to adherence were added (adjusted $R2 = 0.25$; $F[df = 9] = 3.81$; $p < 0.001$); furthermore the duration of admission was significant predictors for this model and the next ($p = 0.048$; IC 95%: −0.01 to −0.001), in an inverse relation, and years since the initial diagnosis of the disorder ($p = 0.028$; IC95% 0.00 – 0.01). In model 3, experimental intervention was added (adjusted $R2 = 0.330$; $F(d.f = 12) = 4.74$; $p < 0.001$); and identified as significant predictor in this model in a direct relation ($p = 0.002$; IC 95% 0.07 – 0.30), also with prior history of antipsychotic treatment, duration of admission and years since the initial diagnosis. The final model included the degree of follow – up sessions completed (adjusted $R2 = 0.37$; $F[df = 13] = 5.09$, $p < 0.001$). In this final model, 3 variables remains as significant direct predictor, both variables related with the intervention and the model of longitudinal follow-up, in addition to the years since diagnosis.

4. Discussion

To our knowledge, this is the first study to use a shared decision-making intervention to help select antipsychotic treatment in patients with schizophrenia admitted to a single psychiatric inpatient unit. Although no significant between-group differences were observed in the main outcome variable (adherence at 12 months), SDM was associated with a positive influence on key health variables such as psychopathologic severity at 12 months. These findings provide evidence for the need to apply booster sessions of SDM during follow-up, as these sessions stabilized and improved the results, consistent with the early studies carried out by Hamman et al. [40,41] as well as with the results of their most recent study [48,80].

In our study, we initiated the experimental intervention when the patient was nearly ready for discharge, in contrast to the approach used by Hamann et al. [40], who initiated this process at the time of admission. Our aim was to avoid weakening the patient's involvement in planning their treatment after discharge [40,41]. Additionally, in contrast to other studies, we included a third stage of the intervention: booster sessions at months 3, 6, and 12 after discharge. The purpose of these sessions, as noted by Hamann et al. [40,41], was to strengthen the beneficial effect of SDM and make it more persistent and thus less likely to fade over time. Ishii et al. did note difficulties related to the loss of effect of SDM over time in their RCT [50]. Similarly, in their recent study [48], Hamann and colleagues found that the effect of SDM diminished in the transition from hospitalization to outpatient treatment.

Although we were unable to find a significant between-group difference in variables such as adherence or days of admission, a positive trend was observed in the experimental group (Fig. 2). Importantly, these differences, together with the differences observed in secondary variables (e.g., attitude to medication and therapeutic alliance), increased over the follow-up period, which raises the question of whether a longer follow-up period—such as 16 months as in the original study by Hamann et al. [40], together with booster sessions—would confirm these trends. This emphasizes the relevance of follow-up for feedback supported by Grim et al. [73]. However, due to the complexity of this intervention, it may be necessary to deliver it in stages, and thus the results may depend not only on patient-related variables, but also provider-related or even context-related variables [74]. In this regard, Fiorillo et al. [15] pointed out that SDM may not, by itself, be sufficient to improve treatment adherence, even though it could play a decisive role on the use of certain strategies, such as the use of long-acting injectable APS.

It is important to emphasize that all patients in both groups received their usual care in the community mental health center during the follow-up period, and this could have reduced the effects of the experimental intervention without modifying outcomes in the control group. Furthermore, despite randomization, there were significant baseline

Table 2
Participant characteristics at baseline (n = 101).

Variable	Total sample (n = 101)	SDM (n = 50)	TAU (n = 51)	Statistics	p-value
Demographics					
Age, M (SD)	42.24 (11.05)	40.22 (10.78)	44.23 (11.07)	t = –1.846	0.068
Sex, n (%)					
Female	27 (26.73)	11 (22)	16 (31.37)	$\chi^2 = 1.132$	0.287
Male	74 (73.27)	39 (78)	35 (68.63)		
Educational level, n (%)					
Primary education or less	76 (75.25)	34 (68)	42 (82.35)	$\chi^2 = 2.792$	0.095
Secondary or university education	25 (24.75)	16 (32)	9 (17.65)		
Living situation, n (%)					
Alone	20 (19.80)	10 (20)	10 (19.61)	$\chi^2 = 0.002$	0.961
With family	81 (80.20)	40 (80)	41 (80.39)		
Legal incapacity status, n (%)	14 (13.86)	5 (10)	9 (17.65)	$\chi^2 = 1.237$	0.266
Clinical					
Diagnosis, n (%)					
Schizophrenia (ICD F20)	69 (68.32)	32 (64)	37 (72.55)	$\chi^2 = 0.853$	0.356
Schizoaffective disorder (ICD F25)	32 (31.68)	18 (36)	14 (27.45)		
First psychotic episode, n (%)	7 (6.93)	2 (4)	5 (9.80)	$\chi^2 = 1.318$	0.251
Years since initial diagnosis, M (SD)	17.86 (11.83)	17.17 (11.97)	18.53 (11.77)	t = –0.576	0.566
Number of admissions on clinical records, M (SD)	4.85 (7.15)	4.64 (7.13)	5.06 (7.23)	t = –0.293	0.770
Number of admissions in last year, M (SD)	0.15 (0.36)	0.14 (0.35)	0.16 (0.37)	t = –0.236	0.814
Total days of admission in last year, M (SD)	4.85 (18.51)	3.7 (10.91)	5.98 (23.78)	t = –0.617	0.539
Prior use of antipsychotics, n (%)	96 (95.05)	50 (100)	46 (90.20)	$\chi^2 = 5.157$	0.023
History of adverse effect with APS, n (%)[a]	83 (82.18)	45 (90)	38 (74.51)	$\chi^2 = 4.136$	0.042
Number of APS prescribed, M (SD)[b]	1.41 (0.71)	1.44 (0.67)	1.37 (0.75)	t = 0.476	0.635
Prior adherence to APS according to BARS, M (SD)	0.47 (0.41)	0.47 (0.39)	0.46 (0.44)	t = 0.081	0.936
Smoker, n (%)	71 (70.30)	35 (70.0)	36 (70.59)	$\chi^2 = 0.004$	0.948
Use of substances of abuse, n (%)[c]					
Prior	65 (64.36)	33 (66)	32 (62.75)	$\chi^2 = 0.117$	0.733
Current	36 (35.64)	17 (34)	19 (37.25)	$\chi^2 = 0.117$	0.733
Involuntary admission, n (%)	46 (45.54)	24 (48)	22 (43.14)	$\chi^2 = 0.241$	0.624
Duration of admission, M (SD)	24.06 (14.03)	24.82 (13.21)	23.31 (14.87)	t = 0.538	0.592
Indication for MR during admission, n (%)	9 (8.91)	8 (16.0)	1 (1.96)	$\chi^2 = 6.131$	0.013
PANSS, M (SD)	98.71 (22.48)	104.08 (23.50)	93.45 (20.30)	t = 2.434	0.017
Psychotic symptom severity DSM5, M (SD)	15.41 (4.51)	15.94 (4.80)	14.88 (4.18)	t = 1.181	0.240
Insight (Markova–Berrios scale), M(SD)	16.29 (6.33)	16.35 (5.58)	16.22 (7.04)	t = –0.104	0.917
Attitude to Concordance (LATCon II), M (SD)	44.18 (9.0)	45.22 (8.51)	43.14 (9.38)	t = 1.151	0.253

Abbreviations: SDM: Shared decision making; TAU: Treatment as usual; APS, antipsychotics; M, mean; SD, standard deviation; MR, mechanical restraint; BARS, Brief Adherence Rating Scale; LATCon II, Leeds Attitude to Concordance; PANSS, positive and negative syndrome scale.
a Of the patients with a prior history of antipsychotic-related adverse effects (AE), 61.4% had abandoned treatment. In the experimental and control groups, 64% and 58.8%, respectively, had previously stopped taking antipsychotics due to AEs: $\chi^2 = 0.286$. p = 0.593.
b Number of active principles corresponding to antipsychotics prescribed to the patient in the last month. If the drug formulation was the same but in different dosages (oral, long acting injectable), they are counted as one drug.
c Current and previous substance abuse use are not mutually exclusive.

differences between the groups, with a higher proportion of patients in the SDM experiencing adverse effects with antipsychotic drugs (which were also more severe) and greater psychopathologic severity in the experimental group (PANSS). Although previous experience with antipsychotics side effects in the experimental group may have influenced results in a negative way, there were no differences with the control group in attitude towards medication at discharge and over the follow-up. Notably, this difference in psychopathologic severity had disappeared before discharge, after the intervention, with a positive trend at 12 months. This finding is further strengthened by the changes in symptom severity (DSM5 dimensional scale), which shows a similar trend over time: at baseline, there were no between-group differences in symptom severity, while the clinical status at one year in patients in the experimental group was significantly better, with a moderate effect size. This finding points to an association between the experimental intervention and psychopathologic recovery and stability during follow-up.

Losses to follow-up could be considered a secondary outcome measure. The lower loss rate in the experimental group (0% vs. 19.6%; Fig. 2) could be attributed to the intervention itself. Both groups received the same attention from the evaluator in charge of planning follow-up visits, who was blinded to the treatment allocation. We believe that the higher compliance rate in the experimental group may be attributable to two phenomena. First, patients who participated in the SDM model had greater therapeutic alliance and adherence, indicating that they felt more involved in their treatment process. Second, participants in the control group were unlikely to have perceived any specific benefit from the control intervention compared to their usual outpatient follow-up [30].

Thus, the lack of significant between-group differences in the main outcome measure at the final evaluation is likely due to various different factors, which is why the conventional clinical trial design may not be appropriate to evaluate this therapeutic approach [45,74–77]. Consequently, long-term studies with using different study designs may be necessary to better determine the true association between health outcomes and increased knowledge and transmission of information to the patient, greater participation and co-responsibility in the decision-making process, and a better doctor-patient relationship [78]. In these studies, the areas of intervention should be expanded at the community level. Similarly, we also need to structurally evaluated the complex interrelationships between the different variables that mediate adherence.

This study has several limitations, in addition to the suitability of RCTs methodology, already, mentioned. The complexity of the intervention makes it impossible to use a double-blind study design. Also, the clinical setting used in this study (psychiatric inpatient unit), which has more coercive characteristics, could negatively influence the model; although patients admitted involuntarily or subject to coercive measures can also benefit from SDM [79,80]. Nevertheless, our findings may be

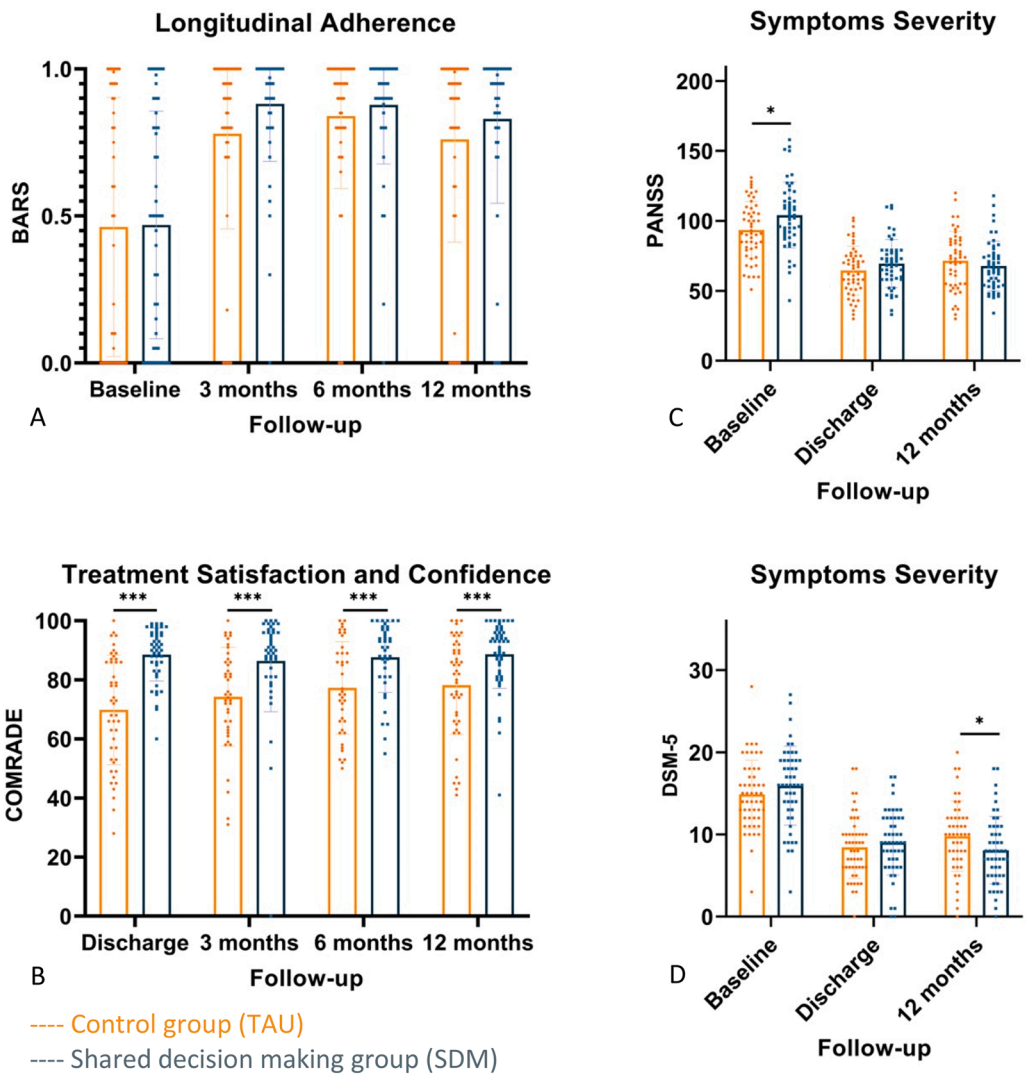

Fig. 2. Outcome variables comparison with significant differences over time by treatment condition. A) Adherence assessed by Brief Adherence Rating Scale (BARS). Sample siza 50 for SDM during the whole follow-up and 51 for TAU. In control group 10 values are obtained by intention to treat analysis (TAU sample size over time: 3 months, 45; 6 months, 43; 12 months, 41). B) Satisfaction and Confidence with antipsychotic treatment decision assessed by Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness (COMRADE). There are significant differences observed early after intervention, maintained over time. Effect size of the difference and sample sizes without data loss, after taking into account the specific missing data in each stage: Discharge, Coheńs D: 1.08, SDM n: 47, TAU n: 46; 3 months, Coheńs D: 0.68, SDM n: 43, TAU n: 42; 6 months Coheńs D: 0.70, SDM n: 40, TAU n: 40; 12 months, Coheńs D: 0.69, TAU n: 47. C and D) Psichopathological symptoms severety measure by (C) Positive and Negative Syndrome Scale (PANSS) and (D) DSM5 severity scale. There is an improvement in psychopatological state for experimental group over time, with significant difference observed when is measured with DSM5 scale. Sample size SDM 50, TAU 51 in different times except 12 months TAU, n:49. Effect size for DMS-5 at discharge Coheńs D: − 0.40. * $p < 0.05$; *** $p < 0.001$.

generalizable to similar treatment units, but perhaps not to other care settings (community care units, therapeutic communities, etc.). Another limitation is that the concomitant influence of routine outpatient follow-up could influence the differences between groups observed in this study. The size of the sample, although sufficient according to the previous estimation, could have limited the observation of more definitive results in relation to certain observed trends. Especially in the control group, due to follow-up. Finally, the intention-to-treat analytical approach used to address the issue of missing data, together with the relatively short follow-up period (12 months), may have minimized the observed effects and underestimated the relevance of losses to follow-up.

In conclusion, the present study represents an attempt to overcome the limitations of prior trials conducted to evaluate the role of SDM in mental health. Our findings confirm that SDM positively influence subjective variables (satisfaction and confidence in treatment) in patients with schizophrenia, but also demonstrate an impact on health-related outcomes. Despite the complexity of the concept of adherence, explanatory models that include variables related to clinical status, cohabitation, and prior history of the disease and treatments appear to have a moderate predictive capacity on adherence at one year. Consequently, the application of shared decision-making with regular booster sessions is likely to increase adherence, a finding that supports—for ethical, practical and clinical reasons—the use of this model in mental health, especially in patients with severe mental disorders.

CRediT authorship contribution statement

Contributors JVM is the principal investigator for this research project. JVM and FGS specifically developed the design and methods for this study. JPR performed the statistical analyses and wrote the manuscript. JVM, JPP, JMS and CRG were the physicians in charge of the two treatment teams, and they developed the tools to aid in decision-making and helped to review and edit the content of the manuscript. JMM was the nurse in charge of the study, participating in the design of the decision aid tools and the implementation of the shared decision-making strategy. EBś experience was useful for the development of her supervision activities on the application of the protocol, the randomization process and the analyses performance. LMM participated in the collection and processing of the data. The clinical interviews were conducted by JPR. FGS and JVM revised the manuscript and contributed to writing it. All authors have approved the final manuscript.

Ethical statements

The study (registered in the clinical trials database ISRCTN36203678) was approved by the Research Ethics Committee of Cádiz, Andalusia, Spain (File: PI-0309–2013). Informed consent was obtained from all participants or the legal guardian in patients with legal incapacity.

Table 3
Linear regression of variables independently associated with adherence to treatment 12 months after hospital admission according to conceptual model.

	B	t	p	95% CI	
Model 1: Control variables shown statically different between groups at baseline					
(Constant)	1.10	5.92	< 0.001	0.73	1.47
Prior use of antipsychotics	0.05	0.32	0.747	-0.27	0.38
History of adverse effect with APS	-0.17	-1.72	0.089	-0.37	0.03
PANSS baseline	-0.00	-1.43	0.156	-0.00	0.00
Indication for MR during admission	-0.13	-1.14	0.254	-0.34	0.09
$R^2 = 0.08$; adjusted $R^2 = 0.04$; $F(d.f = 4) = 1.98$					
Model 2: Previous model + Variables from previous and current clinical history that potentially modifiers of adherence					
(Constant)	0.90	4.17	< 0.001	0.47	1.33
Prior use of antipsychotics	-0.25	-1.53	0.129	-0.58	0.08
History of adverse effect with APS	-0.04	-0.44	0.659	-0.23	0.15
PANSS baseline	-0.00	-0.33	0.740	-0.00	0.00
Indication for MR during admission	-0.10	-0.98	0.329	-0.29	0.10
Prior adherence to APS according to BARS	0.15	1.76	0.081	-0.02	0.33
Use of substances of abuse	-0.07	-1.03	0.307	-0.21	0.06
Insight (Markovà–Berrios) at discharge	0.01	1.56	0.123	-0.00	0.02
Duration of admission	-0.00	-2.00	0.048	-0.01	-0.00
Living with family	0.12	1.55	0.125	-0.03	0.27
Total days of admission in last year	-0.00	-1.13	0.261	-0.01	0.00
Years since initial diagnosis	0.01	1.63	0.107	-0.00	0.1
$R^2 = 0.34$; adjusted $R^2 = 0.25$; $F(d.f = 9) = 3.81$ * *					
Model 3: Previous models + Experimental intervention (SDM) application					
(Constant)	0.95	4.61	< 0.001	0.54	1.36
Prior use of antipsychotics	-0.35	-2.21	0.030	-0.67	-0.04
History of adverse effect with APS	-0.05	-0.63	0.528	-0.23	0.12
PANSS baseline	-0.00	-0.74	0.459	-0.00	0.00
Indication for MR during admission	-0.17	-1.71	0.091	-0.36	0.03
Prior adherence to APS according to BARS	0.16	1.91	0.059	-0.01	0.32
Use of substances of abuse	-0.06	-0.98	0.330	-0.18	0.06
Insight (Markovà–Berrios) at discharge	0.01	1.43	0.156	-0.00	0.02
Duration of admission	-0.00	-2.05	0.043	-0.01	-0.00
Living with family	0.13	1.71	0.092	-0.02	0.27
Total days of admission in last year	-0.00	-1.14	0.259	-0.01	0.00
Years since initial diagnosis	0.01	2.23	0.028	0.00	0.01
Experimental intervention (SDM)	0.19	3.19	0.002	0.07	0.30
$R^2 = 0.42$; adjusted $R^2 = 0.33$; $F(d.f = 12) = 4.74$ * *					
Model 4: Previous models + longitudinal monitoring degree compliance					
(Constant)	0.72	3.27	0.002	0.28	1.16
Prior use of antipsychotics	-0.26	-1.65	0.102	-0.58	0.05
History of adverse effect with APS	-0.10	-1.13	0.263	-0.28	0.08
PANSS baseline	-0.00	-0.99	0.325	-0.00	0.00
Indication for MR during admission	-0.14	-1.47	0.147	-0.33	0.05
Prior adherence to APS according to BARS	0.16	1.96	0.054	-0.00	0.32
Use of substances of abuse	-0.05	-0.91	0.367	-0.17	0.06
Insight (Markovà–Berrios) at discharge	0.01	1.26	0.212	-0.00	0.015
Duration of admission	-0.00	-1.87	0.066	-0.01	0.00
Living with family	0.07	0.94	0.352	-0.08	0.22
Total days of admission in last year	-0.00	-1.27	0.209	-0.01	0.00
Years since initial diagnosis	0.01	2.05	0.044	0.00	0.01
Experimental intervention (SDM)	0.16	2.78	0.007	0.05	0.28
Follow-up sessions completed	0.11	2.40	0.019	0.02	0.19
$R^2 = 0.46$; adjusted $R^2 = 0.37$; F(d.f = 13) = 5.09 **					

Abbreviations: SDM, Shared decision making; MR, mechanical restraint; BARS, Brief Adherence Rating Scale; CI, confidence interval; APS, antipsychotics. PANNS, positive and negative syndrome scale.
* p-value ≤ 0.05; ** p-value ≤ 0.01

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Conflict of interest

All authors declare no financial interests or potential conflicts of interest related directly to this work.

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