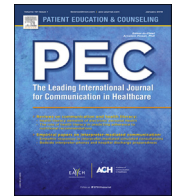




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Correlates of preferring a passive role in decision-making among patients with schizophrenia or bipolar disorder

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ABSTRACT

Objective: To assess the factors associated with the persistence of clinician-led style in the therapeutic relationship in cases of serious mental illness, and the conditioning factors that the patients identify as determinants of their health.

Method: Assessment of preferences in the decision-making process and health-related control locus of 107 outpatients with DSM-5 diagnosis of schizophrenia or bipolar disorder. Demographic and clinical information was also obtained through review of available records and using several scales.

Results: 64.4 % patients preferred to adopt a passive role in the therapeutic relationship. In the multivariate analysis, the preference of playing a passive role in the decision-making process was significantly associated with the elderly, being disabled, or the view that one's health depends on doctors (AUC ROC value: 0.80).

Conclusions: Patients with severe mental illness more frequently preferred a passive role in the decision-making process. We found several factors associated with a preference for the "expert role" model.

Practice implications: The identified factors may permit care to be tailored to the most probable expectations as regard decision-making. Since the populations concerned may be vulnerable and suffer inequalities in the provision of health services, promoting participation in the care process could help improve clinical parameters ethically.

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1. Introduction

Shared Decision Making (SDM) has been suggested as the optimal model of patient participation in decision-making process, based on the paradigm of patient-centred care [1]. SDM model is a new way of understanding the relationship between patients and physicians and its key steps, according to Charles et al. are the following: a) bidirectional information exchange; b) deliberation (e.g. expressing and discussing preferences and treatment options); and c) selection of treatment that is consistent with patients' values and preferences [2]. Previous research with patients with Serious Mental Illness (SMI) reported that applying SDM may reduce coercive interventions, symptoms and rehospitalisation, increase the likelihood that treatment is delivered in accordance with guidelines and improve service and treatment satisfaction as well as therapeutic alliance and self-rated

medication compliance [3–8]. SDM is recommended when a number of treatment alternatives are available and their effects are insufficiently documented [9], as may occur in some decisions in SMI [10]. Patients may have to take decisions about treatments involving high risks (e.g., side effects such as tardive dyskinesia), two or more possible alternatives (e.g., lithium vs. valproate), or low certainty [11–13].

The changes in healthcare policy both in Spain and other countries over the last two decades are aimed at converting the traditional therapeutic relationship model into a more collaborative one in which doctor and patient take joint responsibility in the decision-making process [14–17]. Thus, the inclusion of patient preferences in decision-making is now considered an essential requirement [18].

In addition to these regulatory constraints, the available literature recommends replacing the clinician-led model since patients who participate more actively in their medical care generally experience better health outcomes and their care is more cost-efficient [19–21]. For example in a randomized case-control study with patients with chronic conditions who faced treatment decisions, those who received enhanced decision-making support

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generated medical costs that were 5.3 % lower than patients receiving decision-making support as usual [19]. Several studies with people with SMI conclude that enhanced SDM may improve treatment adherence and treatment adherence may reduce overall healthcare costs [22–24].

According to previous research, the potential link between patient involvement in decision-making and outcomes strongly suggests that bipolar patients should participate in their medical encounters [25]. Patient satisfaction with their medical care and achievement of preferred participation levels also appear to be associated with improved medication adherence in bipolar patients [26]. Despite these findings, the development of the SDM model in psychiatric care seems to be more problematic than in other medical specialties [10] and it is rarely implemented in daily practice; nor are psychiatrists trained to be more power-sharing in their medical encounters [27,28]. Specific conditions in psychiatry, such as being one of the few specialties where patients may be treated against their will, can influence the model of therapeutic relationship and preferences concerning it [29]. People diagnosed with schizophrenia or bipolar disorder may experience coercive measures more often than people with other psychiatric diagnoses [5]. In addition, not all patients are able or want to be involved in healthcare process in the same way, due to fluctuations in their capacity level, with the subsequent difficulty in making some autonomous decisions [30]. Several studies have assessed the decision-making preferences of patients with SMI [25,31–33]. In a previous paper, we compared preferences of patients with schizophrenia or bipolar disorder with non-psychiatric subjects, finding that most patients preferred a passive role in decision-making [32]. A recent study compared European and Chinese patients with several psychiatric diagnoses and found that approximately a quarter of participants preferred passive involvement [31].

In addition to decision-making involvement preferences, beliefs about who or what health depends on, may be related to whether patients adopt more active problem-solving strategies such as seeking information or discussing treatment decisions with their doctor [34]. If people think that their health depends on what they do, it may be more likely they take a more active role in their own care than someone who perceives his/her health is an effect of luck. To the best of our knowledge, except for the Spanish validation of measurement tools, no previous study has evaluated health-related control locus in adult Spanish psychiatric populations. For all these reasons, it is important to understand the health-related control locus and preferences in decision-making of people with schizophrenia or bipolar disorder. This study was conducted to assess the factors that are associated with the preference of patients with SMI for a passive role in decision-making, and which factors patients identify as determinants of their health. We also planned to develop a multivariate model of

factors associated with the passive role to understand which ones appear to be most relevant.

2. Methods

2.1. Type of study

A cross-sectional study was conducted and approved by the Research Ethics Committee of our referral hospital.

2.2. Participants

This study was conducted in an urban-located Mental Health Centre in south-eastern Spain from November 2018 to February 2019. All consecutive patients who attended the centre during the study period were invited to participate. The inclusion criteria were: (a) DSM-5 diagnosis of bipolar disorder or schizophrenia [35] (b) at least 18 years old, (c) fluency in Spanish (d) scoring at least 20 points on the Mini-Mental State Examination (MMSE) scale [36] and (e) to sign the voluntary informed consent to participate in the study.

2.3. Measures

DSM-5 diagnoses were made by the physician treating the patients, using all available sources of information, including the Structured Clinical Interview for DSM-5 [37], family informants and medical records.

The cognitive state was evaluated using the MMSE scale and patients with advanced cognitive impairment were excluded. For this, a cut-off score in the MMSE scale higher than 20 points was selected, as other authors have done previously [38–40].

Information was collected for each patient by means of a questionnaire designed to ascertain the clinical and socio-demographic variables that may influence any preference in decision-making according to previous research [18,34,41]. Clinical severity was assessed using Brief Psychiatric Rating Scale (BPRS) [42]. The Spanish version of the BPRS instrument showed good internal consistency (Cronbach's alpha = 0.79). The coefficients corresponding to inter-rater and test-retest reliability were 0.94 and 0.82, respectively [43].

What individuals believed concerning who or what was the agent that determined their state of health was assessed with the most widely used instrument for this purpose: the Multidimensional Health Locus of Control Scale form C (MHLC) [44]. This scale consists of 18 questions and has four subscales: a) MHLC-C Internal, which assesses the belief that one's own behaviour affects one's health status; b) MHLC-C Chance, which assesses the belief that health is a matter of luck, chance or fate, c) MHLC-C Doctors, which assesses the belief that doctors determine health outcomes;

Table 1
 Patients' preferences about decision-making and health-related control locus.

Category	CPS statement	n	%
Preferred Role	Active	5	4.7
		11	10.3
	Collaborative	22	20.6
	Passive	28	26.2
	"I prefer my doctor to make the decision alone"	41	38.6
Form C MHLC scales		Mean (SD)	
Internal (range 0–36 points)		22.82 (5.89)	
Chance (range 0–36 points)		18.67 (7.50)	
Doctors (range 0–18 points)		15.07 (3.43)	
Other people (range 0–18 points)		12.41 (3.43)	

CPS: Control Preference Scale; MHLC: multidimensional health locus of control; SD: standard deviation.

and d) MHLC-C Others, which assesses the belief that other people, such as family or friends, are responsible for the individual's health status. The Internal and Chance MHLC-C subscales are composed of six questions, while the Doctors and Others MHLC-C subscales are composed of three questions. Patients mark the degree to which they agree or disagree with each item on a six-point Likert scale, the higher the score on each subscale, the stronger the belief in that type of control. The study used the validated Spanish version of the scale, which has been shown to have moderate levels of internal consistency (Cronbach's alpha: internal = 0.74; chance = 0.65; doctors = 0.54; other people = 0.48) [45].

The degree of control that patients want to assume in their medical treatment was assessed using the Control Preference Scale (CPS) developed by Degner et al. [46]. Patients may choose their preferred style of decision-making from five categories in the encounters with their psychiatrists (see Table 1). Preference orders were reclassified, according to their response to the self-reporting version of the CPS scale as other authors have done [18,46,47]; as a result, the participants were categorized as preferring a passive, collaborative, or active role. A Cronbach's alpha of 0.72 was attained, pointing to a moderate degree of internal consistency and a good convergent validity of the Spanish version of the CPS instrument [47].

2.4. Procedures

A researcher explained the study to the potential participants. Both researcher and patient then carefully reviewed the study information together and an informed consent form was signed.

Patients approached by their own psychiatrists were told that they could refuse to participate in the study without any consequences for their medical attention. MMSE and BPRS scales were administered and clinical and socio-demographic information was collected through the questionnaire designed *ad hoc*. Participants completed CPS and MHLC-C scales in the waiting room in the absence of their doctors.

2.5. Statistical analysis

The statistical analysis was conducted using the software program Stata©. Normality and homogeneity of variance were tested prior to analysis. Differences between groups concerning ordinal or continuous data were analysed with the Mann-Whitney U test Pearson's χ^2 or Fisher's exact test were used to examine differences in categorical variables between groups.

To characterize factors associated with preferring a passive role in decision-making, a binary logistic regression analysis was performed, calculating the Odds Ratios (ORs) at a 95 % Confidence Interval (CI). The binary response variable was defined as 1 if the patient preferred a passive role, and 0 otherwise. As a measure of clinical effect, we also reported the rate difference with a 95 % CI.

As there was only one dependent variable and the sample size was insufficient for structural equation modeling [48], multivariate analyses were carried out with variables related to decision-making according to previous research and with the variables that showed a significant relation with preferring a passive role in the univariate analysis. Because of the number of independent variables and the moderate sample size, a hierarchical "forward"

Table 2
Socio-demographic and clinical characteristics of patients according to the preferred role in decision-making.

	Passive preferred role (n = 69)	Active/collaborative preferred role (n = 38)	p
Age, mean (SD)	51.0 (11.9)	42.7 (12.5)	.002 ^a
Women (%)	52.2	52.6	.964 ^b
Marital status (%)	26.1	28.9	.838 ^b
Married/cohabiting	26.1	21.1	
Never married	47.8	50	
Previously married			
Living status (%)	44.9	36.8	.705 ^b
Alone	26.1	31.6	
With family	29.0	31.6	
With parents/institution			
Education level (%)	50.7	28.9	.088 ^b
Primary/no studies	29.0	44.7	
Secondary	20.3	26.3	
University degree			
Employment status (%)	21.7	18.4	.001 ^b
Employed	18.8	52.6	
Unemployed	59.4	28.9	
Retired due to psychiatric illness			
Diagnosis (%)	82.6	65.8	.049 ^b
Schizophrenia	17.4	34.2	
Bipolar disorder			
Compulsory admissions (%)	63.8	42.1	.031 ^b
No	36.2	57.9	
Sí			
Duration of illness, mean (SD)	15.8 (9.3)	12.6 (9.4)	.074 ^a
Psychiatric admissions, mean (SD)	2.0 (1.7)	2.8 (2.5)	.193 ^a
MMSE score (range, 0–30), mean (SD)	27.3 (2.2)	28.3 (1.6)	.020 ^a
BPRS global score (range, 18–126), mean (SD)	50.1 (17.6)	46 (17.7)	.242 ^a
Form-C MHCL score, mean (SD)	22.55 (5.62)	22.32 (6.39)	.727 ^a 584
Internal (range 0–36 points)	18.29 (6.96)	19.37 (8.44)	.049 ^a
Chance (range 0–36 points)	15.72 (2.69)	13.89 (4.27)	.974 ^a
Doctors (range 0–36 points)	12.43 (3.49)	12.37 (3.56)	^a
Other people (range 0–36 points)			

MMSE: Mini-Mental State Examination, BPRS: Brief Psychiatric Rating Scale.
SD: standard deviation, MHLC: multidimensional health locus of control, SD: standard deviation.

^a Pearson χ^2 .

^b Mann-Whitney U.

Table 3
 Factors associated with the presence of a passive role in decision-making.

Associated factors	Univariate analysis Raw OR CI 95 %	<i>p</i>	Multivariate analysis* Adjusted OR CI 95 %	<i>p</i>
Age	1.06 (1–02–1.10)	0.002	1.04 (1.00–1.09)	0.034
Employment status	0.57 (0.19–1.76)0.17 (0.07–0.46)	0.331	Ref.	0.037
Working	Ref.	< 0.001	2.97 (1.07–8.26)	
Not working	Ref.			
Retired due to psychiatric illness	Ref.			
Diagnosis	0.41 (0.16–1.01)	0.053	–	
Bipolar disorder	Ref.			
Schizophrenia	Ref.			
Compulsory admissions	2.42 (1.08–5.44)	0.032	–	
No	Ref.			
Sí				
MMSE score	0.76 (0.61–0.95)	0.018	–	
MHCL Doctor score	1.17 (1.03–1.33)	0.014	1.18 (1.02–1.36)	0.022

OR: Odds Ratio; CI: Confidence interval; MMSE: minimental examination; MHCL: Multidimensional Health Locus of Control.

*Only factors with *p* < 0.05 are shown.

selection method was used to obtain a model with the variables that played a relevant role in explaining the dependent variable. The sample size was the maximum that could be achieved within the recruitment period without incurring a selection bias. We assessed the validity of the predictive model with the area under the ROC curve and the Hosmer-Lemeshow test. For all the contrasts carried out, a significance level of 0.05 was considered.

3. Results

3.1. Demographic and clinical characteristics

There was a high response rate of 78 %. Of the 138 eligible participants for this research, 26 were unavailable to participate or excluded because they did not meet the inclusion criteria (61 %) or refused to participate (39 %). In total, 112 participants signed the informed consent, five withdrew, and 107 participants completed the study. The mean age of participants was 48.04 (Standard Deviation, SD = 12.71 years). The following diagnoses were made: 76.6 % had a psychotic disorder and 23.4 % a bipolar disorder. Of the group, 52.3 % were women, many of whom lived alone (42.1 %), while 48.6 % had previously been married and were retired.

3.2. Patients' preferences concerning the decision-making process

Patients' preferences concerning the decision-making process and health-related control locus are shown in Table 1. As can be seen, 64.5 % of patients preferred a passive role. Regarding to the health-related control locus, the MHCL Internal subscale score was 22.82 (SD = 5.89) points and among the external health-related control locus, the highest score was the MHCL Doctors subscale with 15.07 (SD = 3.43) points.

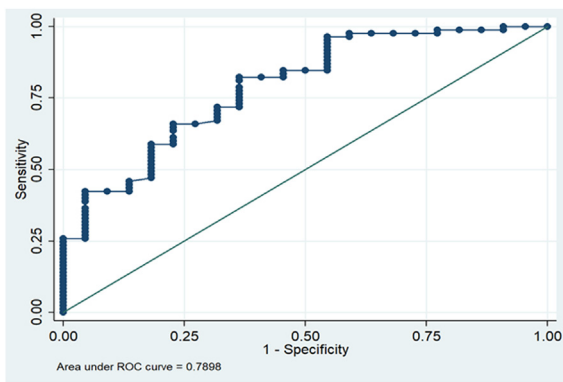
The socio-demographic and clinical characteristics of patients according to the role they preferred to adopt in decision-making process are described in Table 2. Patients who preferred a passive role were significantly older, 51 (SD = 11.9) vs. 42.7 (SD = 12.5) years; $Z = -3.06, p = 0.002$; most of them were retired because of their psychiatric illness (59.4 % vs. 28.9 %; $\chi^2(2, N = 107) = 13.89, p < 0.001$); diagnosed with schizophrenia (82.6 % vs. 17.4 %; $\chi^2(2, N = 107) = 3.87, p = 0.049$); without involuntary admissions (63.8 % vs. 36.2 %; $\chi^2(2, N = 107) = 4.67, p = 0.031$) and with a lower cognitive level, 27.3 (SD = 2.19) vs. 28.3 (SD = 1.6) points; $Z = -2.32, p = 0.020$. According to the health-related control locus, patients who preferred a passive role in decision-making thought that their

health mostly depended on doctors, 15.7 (SD = 2.69) vs. 13.9 (SD = 4.27) points; $Z = -1.97, p = 0.049$. No statistically significant differences were found in the remaining variables studied.

3.3. Factors associated with the preference for a passive role

Table 2 summarizes the relationship between different clinical and socio-demographic variables and the preference for a passive role in decision-making process. In the univariate analysis, the variables age, MMSE and MHCL Doctors scores, employment status and compulsory admissions were significantly associated with the preference for a passive role in decision-making process. The logistic regression model included clinically relevant variables and those significantly associated with the preference for a passive role in decision-making process in the univariate analysis. Five variables out of 13 remained in the multivariate model and only three attained statistical significance: age, MHCL Doctors score and employment status (Table 3). The OR for age was calculated: each extra year increased the chance of preferring to adopt a passive role in decision-making by approximately 10 % ($p = 0.034$). The age rate-difference can be expressed as follows: the preference for a passive role in decision-making in 78 year-old patients was more than 45 percentage points higher than that of 18-years-old patients. (45.44 (7.58–83.29) 95 % CI). Regarding the score on the MHCL Doctors subscale, for each additional point, the odds of preferring a passive role in decision-making increased by approximately 11 % ($p = 0.022$). The preference for a passive role rate in people with an MHCL Doctors subscale score of 18 points, exceeded that of people with a score of 14 points by 11.45 (2.16–20.73) 95 % CI percentage points. People retired due to psychiatric illness were three times more likely to prefer a passive role in decision-making process than those who were employed or were not working ($p = 0.037$). The preference for a passive role rate in people retired due to psychiatric illness is by 19.74 (1.51–37.97) 95 % CI percentage points greater than the rest of the participant's rate.

The Hosmer-Lemeshow test obtained a high *p* value, indicating that the difference between observed and predicted values was small, $\chi^2(8, N = 107) = 7.20, p = 0.515$. The model showed good ability to discriminate, with a value of the area under the ROC curve of 0.80 95 % CI (0.72–0.88) (Fig. 1). The model correctly classified 72 % of cases and can therefore be considered acceptable. In addition, positive and negative predictive values were 76 % and 62.5 %, respectively. As the three significant predictors may be correlated, we adjusted the model with the possible interactions and none of



$\chi^2(5) = 28.53, p < .001, N = 107$; pseudo $R^2 = 0.21$. ROC: Receiver operating characteristic; CDM: Clinical decision-making

Fig. 1. ROC curve of the of the passive preference in decision-making predictive model.

them was significant ($p = 0.85$; 0.64 and 0.97 respectively). Similar results were obtained for the adjusted model (AUC ROC value = 0.8002 and $R^2 = 0.2059$).

4. Discussion and conclusion

4.1. Discussion

We believe this study is important because is the first to specifically evaluate factors that can be worked on to improve the implementation of the SDM model in our setting with people diagnosed with schizophrenia or bipolar disorder and the conditions on which they believe their health depends. We purposely chose this patient population because some patients are treated in an involuntary way and, therefore, any generic findings about the process of decision-making would not necessarily be applicable. Most of our patients expressed a preference for an expert-role approach, as they thought that doctors were the most important condition determining their health status.

Previous studies about health-related control locus have demonstrated that this approach constitutes a strategy that can help ascertain the usefulness of health promotion programmes in people with mental illness [34]. Previous authors found similar results to ours - patients with schizophrenia and bipolar disorder thought that their health depended on doctors. In a specialty where the therapeutic relationship is crucial, these findings may have important implications for clinical practice and the design of treatment adherence programmes and health promotion [34].

Some authors who evaluated preferences in decision-making in a general population found that most participants preferred to adopt a passive role [49], although the findings differ considerably as to the extent to which subjects prefer to participate in any decisions taken [14,34,50,51]. Most of our patients preferred to remain passively involved in decision-making, which may reflect the strong clinician-led tradition in psychiatry in our setting [41,52]. This finding is consistent with the results of a study analysing decision-making in European-wide psychiatric population, which concluded that in Spain patients with SMI showed less desire to participate in decision-making than patients from other European countries [53].

In general, our findings are in line with those of Cuevas, who stated that SDM takes place very sporadically in the Spanish National Health System [54], although in a previous study using the same scale, they found a greater desire for SDM than we did [18]. This may be because

their sampling was consecutive and included patients with mixed diagnoses, which perhaps biased the results. In another study by Cuevas et al. with 172 outpatients diagnosed with affective disorders, more than 90 % preferred to play a passive role in medical encounters [47]. Other authors who studied the same phenomenon concluded that the desire for information in the healthcare process is greater in patients with bipolar disorders than in those suffering schizophrenia [31,51,55]. Our study found no differences between the disorders in this respect, although there was a non-significant trend for more patients with schizophrenia to prefer the passive role. This tendency should be looked at in greater depth in studies with larger sample sizes. We believe that in SMI, patients' preferences for a more active role in decision-making process may be higher, but cultural barriers and social desirability may have prevented some participants from expressing a desire for this more active role [41,52]. On the other hand, patients may expect a passive role in medical encounters because is the only one they have always experienced [53].

Our response rate was similar to that of other studies of people with SMI [56]. In other studies of patients with mixed diagnoses the loss rates were slightly higher than in our [18,34]. Most of our patients had a previous therapeutic relationship with the psychiatrist who interviewed them and so may have been biased by social desirability or role expectations [57]. Our relatively high participation rate may have also been influenced by this relationship.

Several clinical and socio-demographic variables, such as marital status, sex, years of education or treatment, or clinical severity did not play any significant role in decision-making preferences in our study. Our findings are in line with those of previous research [52,54], although other studies did find a relationship [41,49]. The absence of previous compulsory admissions was univariately associated with the preference of a passive role in medical encounters in our study. A possible explanation for this finding is that those who have been treated involuntarily may deny their condition and wish to make autonomous decisions. Previous research that analysed the relationship between decision-making preferences in people with SMI and coercive measures found similar results [41].

The employment status was also associated in our study with preferences in the degree of participation in the decision-making process. People who had been forced to retire due to psychiatric illness preferred to take a passive role in decision-making process. Previous studies that considered the employment situation in a dichotomous way (employed/non-employed), found no significant association with preferences in decision-making [53], while other authors did not consider this variable [58]. Given the connotations of disability and its possible influence on decision-making process, future studies in this respect would be valuable and would allow comparison with our results.

In the present study, age was also associated with the preferred role in the decision-making process, older patients expressing a preference for a passive role. The results of our study add to the existing literature that describes how younger participants often wish to be more involved in decision-making process [49,59].

Only three of the studied variables remained independently associated with the preference for a passive role in decision-making process in the multivariate analysis: employment status, age and MHCL Doctor score. Older people and disabled patients are often the most vulnerable population and prone to inequalities in health-care provision, and adapting health care to their preferences would seem a matter of justice and human rights.

Some authors suggest that SDM could prevent relapses, reduce coercion and improve adherence and therapeutic alliance [8] so it would be valuable to promote the participation of patients with SMI in decision-making process. However, we believe that such participation should be carried out after careful deliberation because, as our findings suggest, not all patients wish to be involved in the process in the same way. Coercing those

participants who are reluctant to take an active role in decision-making may be as threatening to their autonomy as excluding them without consultation. Some authors argue that crisis planning for future treatment may reduce the likelihood of compulsory treatment. In this sense, some early experiments on crisis planning in our setting were carried out by certain professional associations and user movements [15,16]. Although little progress has been made since the phenomenon of SDM was first studied in Spain [54], further studies would help clarify whether this model is appropriate to achieve the degree of participation in medical encounters desired by each participant. A case-control study targeting this phenomenon would clarify whether a training intervention to teach psychiatrists to be more power-sharing would help overcome barriers to achieve SDM, with a control group of psychiatrists providing medical treatment as usual. The primary outcome would hopefully be a reduction in coercive measures such as compulsory admissions.

4.2. Limitations of the study

Some limitations should be mentioned. First, the research was conducted in an urban setting with a relatively small number of outpatients, which may limit any generalization of the results. Further studies are needed to evaluate these results in other settings with other participants. Studies using a larger sample size would also allow multiple regression analyses with a larger number of variables to confirm all univariate associations. Second, we assessed decision-making preferences with a self-reporting questionnaire. Although self-reporting measures have been shown to be practical and entail a low participant burden, there may be several limitations in terms of recall bias and social desirability as mentioned above [57].

4.3. Conclusions

The present study shows that patients with SMI prefer a passive role in decision-making process, at least in our setting. Most patients thought that doctors were the most important determinants of their health. We found several factors associated with the persistence of the expert-role model, which may help tailor care according to the most probable expectations of patients in decision-making.

4.4. Practice implications

Several variables that influence SMI patients to prefer a clinician-led model have been identified, which may help in the design of adherence and health promotion programmes. Two of these variables can be identified easily by psychiatrists without the need to administer any additional scale and should help them choose the model most suited to the probable expectations in decision-making process. As another practical application of these results, psychiatrists should tailor patients' participatory approaches considering individual preferences, values and expectations about decision-making. Since SMI patients may be more vulnerable and suffer from an unequal provision of health services, promoting care process participation according to their preferences should improve some clinical parameters in an ethically acceptable manner.

Credits author statement

Inés Morán-Sánchez: Conception and design of study, Acquisition of data, Analysis and interpretation of data, Drafting the manuscript, Approval of the version of the manuscript to be published.

María Ángeles Bernal-López: Conception and design of study, Acquisition of data, Revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published.

Diego Salmerón: Conception and design of study, Analysis and interpretation of data, Approval of the version of the manuscript to be published.

María-Dolores Pérez-Cárceles: Conception and design of study, Revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published.

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Declaration of Competing Interest

None.

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