Evaluating the impact of a quality of life assessment with feedback to clinicians in patients with schizophrenia: randomised controlled trial

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Background

Quality of life (QoL) measurements are increasingly considered to be an important evaluation of the treatment and care provided to patients with schizophrenia. However, there is little evidence that assessing QoL improves patient outcomes in clinical practice.

Aims

To investigate the impact of a QoL assessment with feedback for clinicians regarding satisfaction and other health outcomes in patients with schizophrenia.

Method

We conducted a 6-month, prospective, randomised and controlled open-label study. Patients with schizophrenia were assigned to one of three groups: standard psychiatric assessment; QoL assessment with standard psychiatric assessment; and QoL feedback with standard psychiatric assessment. The primary outcome was patient satisfaction at 6 months. The local ethics committee (Comité de Protection des Personnes Sud-Méditerranéee V, France, trial number 07 067) and the French drug and device regulation agency (Agence Française de Sécurité Sanitaire des Produits de Santé, France, trial number A01033-50) approved this study.

Results

We randomly assigned 124 patients into groups. Quality of life feedback significantly affected patient satisfaction. Global satisfaction was significantly higher in the QoL feedback group (72.5% of patients had a high level of satisfaction) compared with the standard psychiatric assessment (67.5%) and QoL assessment groups (45.2%). Despite trends towards decreased severity for all clinical outcomes and increased changes to medication in the QoL feedback group at 6-month follow-up, these effects were not significant.

Conclusions

Quality of life feedback positively influences patient satisfaction, which confirms the relevance of measuring QoL in clinical practice. The absence of a significant effect of QoL feedback on clinical outcomes also suggests that clinicians did not use these data optimally. Our findings suggest a nocebo effect of QoL assessment without feedback that should be considered by researchers and clinicians.

Declaration of interest

None.

Regulatory agencies such as the National Cancer Institute and the National Authority for Health in France recommend assessing quality of life (QoL) in daily clinical practice in patients with chronic illnesses. In particular, QoL measurements are increasingly considered to be an important way of evaluating the treatments and care provided to patients with schizophrenia.[1,2] Using QoL measures may provide clinicians with information regarding the general health statuses of their patients that might otherwise go unrecognised,[3,4] thereby improving patient satisfaction and health outcomes.[5] Thus, clinicians should consider QoL measures in the same way as routine objective measures such as symptomatic evaluation scales, laboratory tests and radiographs to manage the care of patients.[6]

Despite the acknowledged need to consider QoL issues in clinical practice, its measurement has not been routinely implemented,[7] especially in psychiatry.[5,8,9] Practical and attitudinal barriers have been described.[10] Obtaining QoL data in an efficient real-time manner is difficult because of feasibility issues (i.e. the lack of computer stations, hand-held devices[6]). Moreover, physicians often overlook QoL assessment as a result of time pressures and clinical constraints as well as a lack of training and interest.[11] Therefore, more work must be undertaken to increase the use of QoL instruments in clinical practice. In particular, trials are necessary to build a satisfactory evidence base for the routine clinical use of QoL in psychiatry[12,13] as has already been accomplished in oncology.[14–17] To our knowledge, and based on an extensive review,[18] only one previous randomised study in mental health has reported on the effectiveness of feedback of a standardised outcome assessment including QoL.[19] This found no difference in the mean follow-up QoL between a treatment as usual group and a feedback group. However, the specifics of this study should be mentioned: it was performed on a heterogeneous sample with different mental health illnesses and a short follow-up time. Moreover, it lacked a third control group, including assessment without feedback, that allowed for the isolation of the effect of a single assessment. These limitations prompted us to design a prospective and randomised trial to investigate the impact of QoL assessment with feedback for clinicians regarding satisfaction and other health outcomes in patients with schizophrenia.

Method

Study site and patient eligibility

This study was conducted at the Sainte-Marguerite University Hospital, a specialised psychiatric treatment centre in Marseille, France. The sample consisted of patients who attended the day hospital over a 6-month period. All consecutive attendees who came to the day hospital were approached to participate. The inclusion criteria were: age over 18 years, diagnosis of schizophrenia according to the DSM-IV-TR criteria,[20] stable

disease status (no need for a hospital admission at inclusion and no major change in patient condition for 2 months prior to inclusion) and native French speaking. The exclusion criteria were: reduced capacity to consent,[21] an Axis I diagnosis on the DSM-IV other than schizophrenia, acute decompensation of organic disease or mental retardation. The patients were provided with both oral and written information regarding the study prior to obtaining their informed consent. The local ethics committee (Comité de Protection des Personnes Sud-Méditerranée V, France, trial number 07 067) and the French drug and device regulation agency (Agence Française de Sécurité Sanitaire des Produits de Santé, France, trial number A01033-50) approved this study.

Design

The present study was a 6-month, prospective, randomised, controlled, open-label and single-centre study. Figure 1 displays a flow chart of the study. A computer-generated, randomised list was created using a permuted block design. The participants were randomly assigned to one of the three groups (random assignment 1:1:1). These were (a) a standard psychiatric assessment group: patients completed the standard psychiatric assessment; (b) a QoL assessment group: patients completed a QoL questionnaire in addition to the standard psychiatric assessment; and (c) a QoL feedback group: feedback regarding the QoL scores was presented to clinicians in addition to the standard psychiatric assessment. The purpose of the QoL assessment group was to isolate the effect of a single assessment (i.e. without feedback) in the clinical use of QoL. Evaluations were performed at three different time points: (a) at randomisation (baseline; T_0) as well as 3 months (T_1) and 6 months (T_2) after randomisation.

Groups

Standard psychiatric assessment group

In this group each patient received a standard psychiatric assessment performed by a multidisciplinary team that included a psychiatrist, a clinical psychologist, a nurse and a social worker when appropriate. The standard psychiatric assessment was based on a face-to-face interview, clinical examination and standardised tools (i.e. Positive and Negative Syndrome Scale (PANSS),[22,23] Calgary Depression Scale for Schizophrenia (CDSS),[24,25] Extrapyramidal Symptoms Rating Scale (ESRS)[26] and Global Assessment of Functioning (GAF)[27]). Special attention was given to psychotic and depressive symptoms, drug-induced movement disorders and global functioning. This assessment may therefore play a role in the: (a) assessment of the clinical stability of the patient (for example symptomatic and functional remission); (b) detection and prevention of comorbid somatic and psychiatric disorders; (c) initiation or adaptation of specific pharmacological treatments; (d) evaluation of drug-induced disorders; (e) initiation of psychosocial therapy such as cognitive remediation and psychosocial rehabilitation; and (f) addressing of the administrative and financial issues (e.g. health insurance, free state aid).

QoL assessment group

In this group patients received a self-administered QoL questionnaire at each evaluation. Patients completed and returned
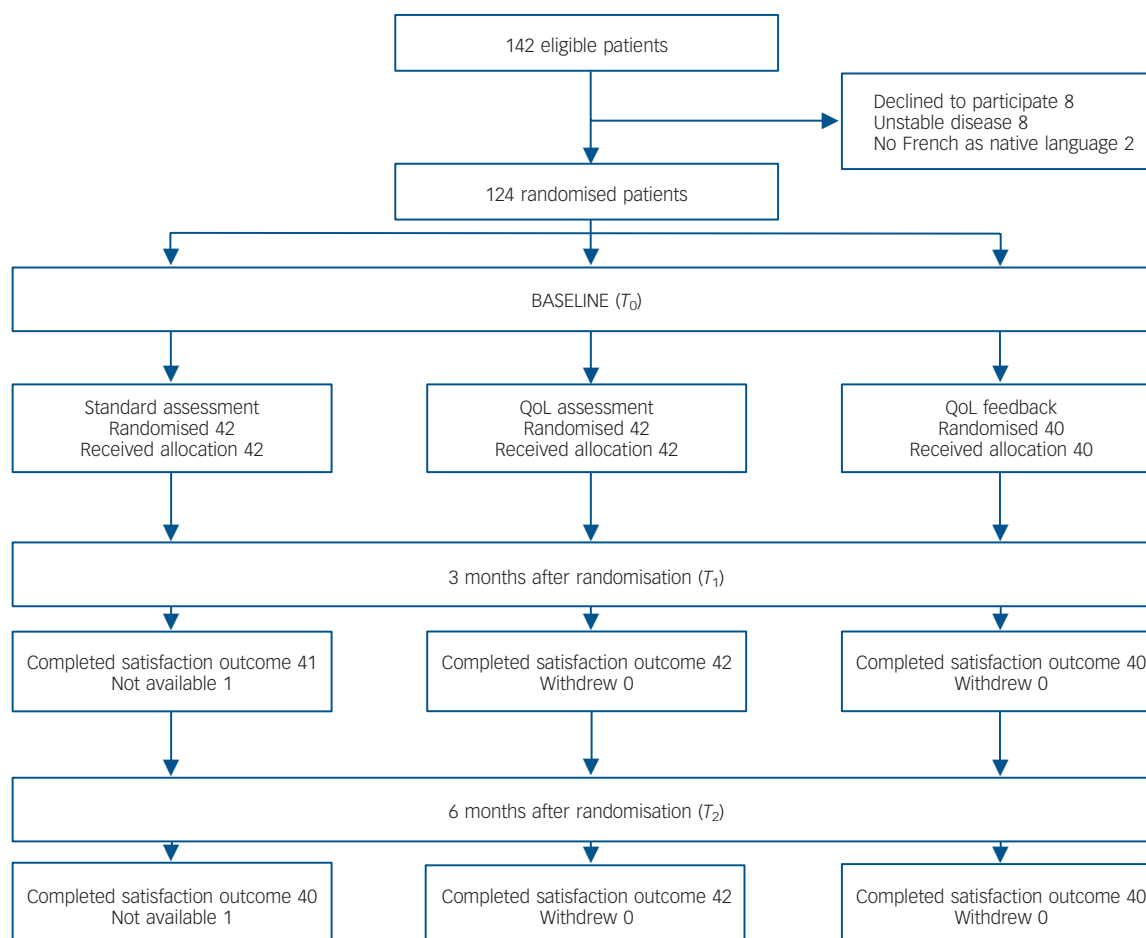

Fig. 1 Flow diagram of participant progress through the phases of the study.

the questionnaire to a research assistant before the standard psychiatric assessment. The research assistant was independent of the care team, and the QoL scores were not returned to the clinicians. Quality of life was assessed using the S-QoL questionnaire, which is a self-administered questionnaire designed for people with schizophrenia.[28] The S-QoL is a multidimensional, 41-item instrument that was developed based on patient views, and assesses eight dimensions: psychological well-being, self-esteem, family relationships, relationships with friends, resilience, physical well-being, autonomy, and sentimental life; and a total score. Dimension and index scores range from 0 (low QoL) to 100 (high QoL).

QoL feedback group

In this group the patient completed and returned the S-QoL questionnaire to the research assistant at each evaluation. The assistant entered the item scores on a computer. A specific algorithm program calculated QoL scores. These scores and the scores of previous evaluations were provided to the care team before the standard psychiatric assessment. In addition, population norms[28,29] were provided to help clinicians interpret QoL scores. No other advice or guidelines regarding data interpretation and use were provided to clinicians. Patient management was entirely at the discretion of the treating physician.

Evaluation criteria

Primary criterion

The primary evaluation criterion was patient satisfaction, which was assessed using three items relating to different satisfaction domains including: global satisfaction; satisfaction/trust with the staff/care; and satisfaction/trust with the care structure. Because no valid French satisfaction questionnaire for out-patients with schizophrenia is available, 'ad hoc' questions were elaborated/created according to the items of the QSH-45, which is a well-validated French in-patient satisfaction questionnaire,[30] and from our own experience.[31] Three questions were developed by the steering committee project: (a) What is your degree of satisfaction regarding your global care management?; (b) What is your degree of satisfaction regarding the care structure?; and (c) What is your degree of satisfaction regarding the care staff? The primary criterion was global satisfaction at T_2, and the other items were considered as secondary criteria. All items were worded positively and assessed using a four-point Likert scale from 1 (very unsatisfied) to 4 (very satisfied). Satisfaction was assessed at T_1 and T_2.

Secondary criteria

We used PANSS to assess psychotic symptomatology. This scale is composed of three subscales: positive, negative and general psychopathology.[22,23] Higher scores indicate more severe symptomatologies. We used the CDSS to examine depressive symptomatology; it uses a nine-item scale that evaluates depression independent of extrapyramidal and negative symptoms.[24,25] The CDSS is specifically designed for patients with schizophrenia. Higher scores indicate greater levels of depression. Drug-induced movement disorders (such as Parkinsonism, akathisia, dystonia and dyskinesia) were evaluated using the ESRS.[26] Higher scores indicate more severe disorders. Global functioning was assessed using GAF. The GAF considers psychological, social and occupational functioning, and scores range from 0 to 100. Higher scores indicate higher levels of

functioning.[27] Disease severity was assessed using the Clinical Global Impression (CGI) severity scale. The CGI classifies disease severity as mild, moderate or severe.[32] Psychotic symptomatology, depression, drug-induced movement disorders, global functioning and severity of disease were assessed at T_0, T_1 and T_2. The psychiatrist indicated any medication changes between T_0 and T_1 as well as between T_1 and T_2.

Additional data

The following parameters were recorded for each participant: gender, age, education level (<12 years/$\geqslant 12$ years), living arrangement (partner or parents/alone) and employment status (no/yes).

Statistical analyses

Baseline characteristics were compared across the three groups. Frequencies were compared using chi-squared tests, and quantitative variables were compared using the Kruskal–Wallis one-way analysis of variance on ranks with a *post hoc* Dunnett's test. The proportions of patient global satisfaction at T_2 (primary criterion) were compared across the three groups. Group comparisons with regard to the other scores (i.e. the PANSS positive, negative and general psychopathologies as well as CDSS, ESRS and GAF scores) were performed using analysis of variance. Statistical significance was defined as $P<0.05$. Statistical analyses were performed using SPSS Statistics for Windows, Version 17.0.

Results

Participants

Of the 142 patients who were eligible, 124 participants were enrolled: 42 were enrolled in the standard psychiatric assessment group, 42 in the QoL assessment group and 40 in the QoL feedback group. All but two patients in the standard psychiatric assessment group completed the 3- and 6-month assessments (Fig. 1). The mean age of participants was 41.1 years (s.d.=11.8); 67.7% were male, and 21.8% had at least 12 years of education. These patients were mildly ill, with a mean total PANSS score of 63.0 (s.d.=21.6) and positive, negative and general psychopathology subscale scores of 12.9 (s.d.=5.9), 15.6 (s.d.=6.3) and 34.6 (s.d.=11.5) respectively. Patient characteristics did not differ across the three groups at baseline (Table 1). The proportion of highly satisfied patients in the entire sample ranged from 64.2 to 68.3% at 3 months and from 61.5 to 65.6% at 6 months (Table 2).

The effects of QoL assessment and feedback on patient satisfaction

Global satisfaction and satisfaction/trust with the care structure significantly differed across the three groups at the 6-month follow-up (Table 2): a significantly larger percentage of patients reported high levels of satisfaction in the QoL feedback group compared with the standard psychiatric assessment and QoL assessment groups with regard to these domains. In particular, global satisfaction was significantly higher in the QoL feedback group (72.5% patients had high levels of satisfaction) compared with the standard psychiatric assessment (67.5%) and QoL assessment groups (45.2%; $P=0.025$). This trend towards higher satisfaction in the QoL feedback group was also found at the 3-month follow-up visit with regard to global satisfaction and satisfaction/trust with the staff/care. A total of 75%, 68.3% and 50.0% of patients in the QoL feedback, standard psychiatric

Table 1 Sociodemographic and clinical characteristics between the three groups at baseline (T_0)

	Total (n = 124)	Standard assessment group (n = 42)	QoL assessment group (n = 42)	QoL feedback group (n = 40)	P^a
Sociodemographic					
Age, years: mean (s.d.)	41.08 (11.77)	41.95 (12.05)	41.76 (13.14)	39.45 (9.92)	0.582
Gender, n (%)					0.349
Men	84 (67.7)	32 (76.2)	27 (64.3)	25 (62.5)	
Women	40 (32.3)	10 (23.8)	15 (35.7)	15 (37.5)	
Educational level, n (%)					0.106
<12 years	97 (78.2)	37 (88.1)	29 (69.0)	31 (77.5)	
≥12 years	27 (21.8)	5 (11.9)	13 (31.0)	9 (22.5)	
Partnership status, n (%)					0.801
Not single	69 (55.6)	25 (59.5)	22 (52.4)	22 (55)	
Single	55 (44.4)	17 (40.5)	20 (47.6)	18 (45.0)	
Employment status, n (%)					0.788
No	107 (86.3)	37 (88.1)	35 (83.3)	35 (87.5)	
Yes	17 (13.7)	5 (11.9)	7 (16.7)	5 (12.5)	
Clinical					
Positive and Negative Syndrome Scale, mean (s.d.)					
Total	63.01 (21.59)	64.74 (19.24)	64.19 (23.58)	59.87 (21.96)	0.445
Positive	12.90 (5.92)	13.33 (5.72)	13.36 (6.81)	11.95 (5.09)	0.530
Negative	15.56 (6.27)	16.33 (6.22)	15.50 (6.67)	14.79 (5.92)	0.395
General psychopathology	34.55 (11.48)	35.07 (9.87)	35.33 (12.20)	33.13 (12.44)	0.445
Calgary Depression Scale for Schizophrenia, mean (s.d.)	4.47 (3.57)	4.90 (3.84)	4.4 (3.231)	4.05 (3.65)	0.604
Extrapyramidal Symptoms Rating Scale, mean (s.d.)					
Dyskinesia	0.09 (0.38)	0.19 (0.59)	0.05 (0.22)	0.03 (0.16)	0.183
Parkinsonism	0.12 (0.54)	0.21 (0.81)	0.10 (0.37)	0.05 (0.22)	0.495
Dystonia	0.06 (0.23)	0.07 (0.26)	0.07 (0.26)	0.03 (0.16)	0.580
Akathisia	0.07 (0.34)	0.14 (0.47)	0.07 (0.34)	0 (0)	0.135
Global Assessment of Functioning, mean (s.d.)	61.94 (13.18)	60.9 (13.67)	61.57 (12.36)	63.43 (13.66)	0.604
Clinical Global Impression of Severity, n (%)					0.678
Mild	39 (31.5)	12 (28.6)	12 (28.6)	15 (37.5)	
Moderate	68 (54.8)	23 (54.8)	26 (61.9)	19 (47.5)	
Severe	17 (13.7)	7 (16.7)	4 (9.5)	6 (15.0)	

QoL, quality of life.
a. P-value Kruskall–Wallis test or χ^2 test.

Table 2 Comparison of patients' satisfaction between the three groups at 3 and 6 months

	n (%)				
	Total (n = 124)	Standard assessment group	QoL assessment group (n = 42)	QoL feedback group (n = 40)	P^a
T_1 (3 months)					
n	123	41	42	40	
Global satisfaction					**0.049**
From unsatisfied to mild satisfied	44 (35.8)	13 (31.7)	21 (50.0)	10 (25.0)	
Very satisfied	79 (64.2)	28 (68.3)	21 (50.0)	30 (75.0)	
Satisfaction with staff/care					**0.029**
From unsatisfied to mild satisfied	41 (33.3)	13 (31.7)	20 (47.6)	8 (20.0)	
Very satisfied	82 (66.7)	28 (68.3)	22 (52.4)	32 (80.0)	
Satisfaction with the care structure					0.153
From unsatisfied to mild satisfied	39 (31.7)	10 (24.4)	18 (42.9)	11 (27.5)	
Very satisfied	84 (68.3)	31 (75.6)	24 (57.1)	29 (72.5)	
T_2 (6 months)					
n	122	40	42	40	
Global satisfaction					**0.025**
From unsatisfied to mild satisfied	47 (38.5)	13 (32.5)	23 (54.8)	11 (27.5)	
Very satisfied	75 (61.5)	27 (67.5)	19 (45.2)	29 (72.5)	
Satisfaction with staff/care					0.095
From unsatisfied to mild satisfied	42 (34.4)	14 (35.0)	19 (45.2)	9 (22.5)	
Very satisfied	80 (65.6)	26 (65.0)	23 (54.8)	31 (77.5)	
Satisfaction with the care structure					**0.025**
From unsatisfied to mild satisfied	42 (34.4)	12 (30.0)	21 (50.0)	9 (22.5)	
Very satisfied	80 (65.6)	28 (70.0)	21 (50.0)	31 (77.5)	

QoL, quality of life.
a. Bold values: $P < 0.05$.

Table 3 Comparison of secondary criteria between the three groups at 6 months

	Total (n = 124)	Standard assessment group (n = 42)	QoL assessment group (n = 42)	QoL feedback group (n = 40)	Pa
Positive and Negative Syndrome Scale, mean (s.d.)					
Total	61.20 (20.53)	64.64 (20.20)	60.55 (20.58)	58.28 (20.81)	0.227
Positive	12.48 (5.48)	13.47 (5.79)	12.36 (5.64)	11.58 (4.91)	0.223
Negative	15.21 (5.94)	16.07 (5.94)	15.07 (5.88)	14.45 (6.03)	0.358
General psychopathology	33.51 (10.65)	35.10 (10.30)	33.12 (10.67)	32.25 (11.05)	0.312
Calgary Depression Scale for Schizophrenia, mean (s.d.)	3.63 (2.90)	4.19 (3.00)	3.5 (2.73)	3.18 (2.97)	0.229
Extrapyramidal Symptoms Rating Scale, mean (s.d.)					
Dyskinesia	0.07 (0.34)	0.14 (0.52)	0.05 (0.22)	0.03 (0.16)	0.364
Parkinsonism	0.13 (0.54)	0.24 (0.82)	0.1 (0.37)	0.05 (0.22)	0.299
Dystonia	0.05 (0.22)	0.07 (0.26)	0.05 (0.22)	0.03 (0.16)	0.621
Akathisia	0.08 (0.35)	0.14 (0.47)	0.07 (0.34)	0.03 (0.16)	0.364
Global Assessment of Functioning, mean (s.d.)	64.57 (12.97)	62.36 (13.33)	65.12 (12.12)	66.33 (13.43)	0.273
Clinical Global Impression of Severity, n (%)					0.938
Mild	36 (29.0)	11 (26.2)	12 (28.6)	13 (32.5)	
Moderate	74 (59.7)	25 (59.5)	26 (61.9)	23 (57.5)	
Severe	14 (11.3)	6 (14.3)	4 (9.5)	4 (10.0)	
Medication change, n (%)b					0.374
Yes	15 (12.4)	5 (11.9)	3 (7.5)	7 (17.9)	
No	106 (87.6)	37 (88.1)	37 (92.5)	32 (82.1)	

a. P-value Kruskall–Wallis test or χ^2 test.
b. The data for medication changes are based on: total n = 121, Standard assessment group n = 42, QoL assessment group n = 40, QoL feedback group n = 39.

assessment and QoL assessment groups, respectively, reported high levels of global satisfaction ($P = 0.049$).

No significant group effect was observed with regard to the different clinical outcomes and changes in medication at the 3-month (data not shown) and 6-month follow-up visits (Table 3). Importantly, there was a trend towards better clinical outcomes (PANSS, CDSS, ESRS, GAF and CGI scores) in the QoL feedback group that was present at 3 months and continued at 6 months. Although not significant, there were more changes made to medication in the QoL feedback group.

Discussion

This randomised study is the first to provide an evidence base for the routine clinical use of QoL assessment and feedback in the management of patients with schizophrenia. Of particular interest is the finding that patient satisfaction levels were higher when clinicians were provided with QoL assessments compared with that of patients whose clinicians did not have this information. This finding is consistent with previous oncology studies reporting that feedback of QoL scores to clinicians improves patient–physician communication.[14–17] Quality of life measures may help to understand the subjective experiences that are key in treating people with mental disorders[33] and improve patient–clinician communication. Moreover, better communication is related to decreases in the paternalistic view of care as well as increases in interactive approaches with patients and patient decision-making, all of which lead to increased patient satisfaction.[34,35] We thus hypothesise that QoL assessment with feedback may provide useful information to psychiatrists, which leads to better clinician–patient communication[17] and clinician awareness/detection of patients' social and psychological problems,[4] and that this plays a part in enhancing satisfaction. In addition, our findings provide strong support for integrating QoL assessment and feedback with standard psychiatric assessments. In fact, patient satisfaction predicts future behaviours including adherence with treatment, intent to return for care[36–38]

and final health outcomes.[39] Thus far, obtaining QoL data in an efficient, real-time manner was difficult and rare in clinical practice.[6,10] Priority should be given to strategies to implement QoL measurements in routine practice, including providing systematic feedback for clinicians. The logistics of obtaining patient QoL data should be the same as those for other clinical indicators.[6,40] Interestingly, recent technologies such as electronic medical records are being implemented in psychiatric settings;[41–43] these methods may efficiently and automatically collect QoL data.[10,44,45]

Despite the positive effect that QoL assessment with feedback had on patient satisfaction (i.e. there was a trend towards improved clinical outcomes in the QoL feedback group), there was no significant effect on other health outcomes (PANSS, CDSS, ESRS, GAF and CGI scores) or patient management (changes in medication). The failure to detect significant between-group differences may be because of the small sample size of each group. Alternatively, this failure might be because the disease severity of our sample tended to be mild, which left little room for health status improvements, especially given the relatively short 6-month follow-up period of our study.[46] However, these findings are consistent with previous studies that have failed to report any changes in clinical management or health outcomes.[13,47] Therefore, we cannot exclude the possibility that clinicians did not optimally use the QoL feedback. In particular, studies have suggested that clinicians did not feel comfortable interpreting QoL data to improve QoL of patients.[6,40] Strategies for the implementation of QoL measurements should include training sessions aimed at motivating professionals to use QoL data and provide norms, advice and guidelines regarding data interpretation and patient management.[13]

One last finding was particularly important in our study. Quality of life assessments without feedback for clinicians was associated with lower patient satisfaction levels compared with patients whose clinicians were provided with QoL feedback and those whose QoL was not assessed. This finding suggests a QoL-assessment nocebo effect (i.e. negative expectations that derived from the clinical encounter and led to poor therapy

adherence and health outcomes[48]). Measuring QoL may cause 'side-effects' through the exploration of sensitive subjects, thereby generating new expectations from clinicians on the part of the patients.[49] The absence of the appropriate clinical use of these QoL data (i.e. examine, interpret and act) might negatively affect patient satisfaction (i.e. create a match or mismatch between patient expectations and perceptions[24]). Thus, this finding has direct implications for both research and clinical practice. Clinicians should consider possible nocebo effects.

Limitations and perspectives

Certain limitations of this study must be considered carefully. First, the sample might not be representative of the entire population of patients with schizophrenia. The participants had paranoid schizophrenia, and were mostly male, middle aged, with mild disease severity and more than 5 years of illness duration. Likewise, the clinicians might not be representative of all of their colleagues in the mental healthcare system because the study was conducted at one university hospital. Therefore, replication is needed in other settings using more diverse and larger groups of patients and clinicians.

Second, clinicians treated patients from all three study groups; this design may have contaminated the results. Therefore, the differences between each group may be underestimated. Future studies should better control for contamination effects, especially by using a randomised cluster design.[13]

Third, a longer follow-up period is necessary to better explore the impact of QoL assessment and feedback on clinical outcomes and changes in patient management[13] as well as to confirm the trend towards improved clinical outcomes in the QoL feedback group. Studying the effect of measuring QoL on other relevant outcomes such as social variables (i.e. how patients live, function in society and perform various roles)[50] or recovery (i.e. subjective changes in how people appraise their lives and the extent to which they view themselves as meaningful agents in the world) would be necessary to evaluate long-term outcomes.[51,52]

Fourth, our approach for measuring satisfaction, which was not based on a validated questionnaire but rather on three *ad hoc* questions, is debatable. At the beginning of the project, no validated questionnaire assessing patient satisfaction in psychiatry was available in French. However, it can be assumed that the choice of the three questions was both reasonable and pragmatic. The three items were: (a) developed from a standardised and well-validated questionnaire of patients' satisfaction with care;[24,53,54] (b) identified as relevant both from an extensive review of the literature on this topic[25] and by the steering committee of this project; and (c) in accordance with current standards in terms of content and response modalities.[41,55] The measurement bias can be considered to be minimal.

Finally, our findings concern only patients with schizophrenia and might not be generalisable to all mental disorders and chronic diseases. The current findings need to be replicated in future studies that include other chronic diseases.

Implications

Our study indicates that QoL assessment with feedback for clinicians has a positive impact on patient's satisfaction. This finding confirms the relevance of including QoL in clinical practice. However, the absence of a significant effect of QoL assessment with feedback on clinical outcomes suggests that clinicians did not optimally use these data. In addition to feedback, providing advice and guidelines regarding data interpretation and use is necessary to ensure that QoL data have direct implications for clinical practice. Finally, our findings suggest a nocebo effect of QoL assessment without feedback that clinicians should consider.

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