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Effect of Pharmacist Intervention on Quality of Life of Patients with Major Depressive Disorder in Distressed North East Nigeria

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

Abstract

Background: Quality of life is considered as an integral component and outcome indicator of mental illness and while pharmacist interventions have been proven to be effective in improving quality of life, no attention has been given to patients with depression in distressed North East Nigeria.

Objectives: To explore the effect of pharmacist intervention on quality of life of patients with major depressive disorder.

Materials and Methods: A longitudinal prospective randomized controlled trial approved by Ahmadu Bello University Ethics Committee on use of Human Subjects for Research (approval number: ABUCUHSR/2020/018) was conducted on 101 patients with major depressive disorder between April 2019 and March 2020 at a tertiary Neuro-Psychiatric Hospital in Maiduguri, Nigeria. Consenting patients were randomized into Usual Care or Intervention groups using a computer-generated list. The intervention consisted of pharmacist-delivered educational counseling sessions of between 15-30 minutes. Data were collected at baseline, 3 months and 6 months using the World Health Organization Quality of life Bref scale.

Results: After the intervention, significant improvements ($p < 0.001$) in mean scores of participants in the intervention group were observed in all of the quality-of-life domains including; physical health [42.49 (SD=11.48) vs 72.25 (SD=15.82], psychological health [45.15 (SD=15.24) vs 85.57 (SD=12.95)], social relationship [40.47 (SD=21.24) vs 78.20 (SD=18.23)] and environment [40.94 (SD=14.09) vs 87.74 (SD=9.78)].Significant improvements ($p < 0.001$) were also observed in the general health [38.77 (SD=27.51) vs 86.53 (SD=21.27)] and overall quality of life [52.55 (SD=19.26) vs 76.92 (SD=25.16)] in the intervention group.

Conclusion: Pharmacist's intervention significantly improved quality of life in patients with major depressive disorder in this study.

Keywords: Quality of life, Pharmacist intervention, Major depressive disorder, Distressed North East Nigeria.

INTRODUCTION

In recent times, quality of life is considered as an integral component and outcome indicator of mental illness and is recommended to be integrated into the clinical evaluation and interventions of people with severe mental illness (Shumye *et al*., 2019). Quality of life is defined as an individual's perception of his or her position in life in the context of the culture and value systems in which he or she lives, and in relation to his or her goals, expectations, standards, and concerns (WHO, 1997_a).

Most standardized measures of quality of life utilize multidimensional constructs that usually include physical, emotional, and social domains (Vilhauer *et al*., 2013). Studies using quality of life measures have shown that the quality of life of depressed patients is significantly lower than that of the healthy population or those of individuals with chronic medical disorders, such as hypertension, cancer, or chronic pain (Vilhauer *et al*., 2013; Saragoussi *et al*., 2018; Shumye *et al*., 2019;). This implies that the symptoms of depression which include loss of interest, depressed mood, low self-esteem, psychomotor retardation, occupational and cognitive impairment play a significant role in the quality of life of people with depression (UlHaq *et al*., 2016).

Major depressive disorder (MDD) affects more than 300 million people worldwide and has been considered the leading cause of disability (WHO, 2017). Prevalence of depression or depressive symptoms within Nigeria ranges from 4-22% (Yusuf *et al*., 2019) and it has been estimated that over 7 million people living in the country are depressed (WHO, 2017). Borno State; located in the North-East region of Nigeria has been faced with Boko Haram insurgency which has resulted into over 20,000 deaths and the displacement of over 1.8 million people (Luana, 2017). One of the long-term effects of insurgency among people is the manifestation of depressive symptoms as a result of witnessing the killing of family members, separation from family and displacement, terror attacks, kidnapping and sexual harassment, participation in violent acts, bombardment, physical injuries and extreme poverty (Luana, 2017).

Over the years, evidence has shown that patients with complex health needs require a multidisciplinary team to address issues relating to their health (Yusuf *et al*., 2019). An important aspect in the provision of clinical pharmacy practice is the provision of pharmaceutical care (Yusuf *et al*., 2017). Pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes and improvement in patient's quality-of-life (Hepler and Strand 1990)**.** It has been established that pharmacists have positive attitudes towards providing care to mentally ill patients (Watkins *et al*., 2017; Yusuf *et al*., 2018). It has also been discovered that Pharmacists can play an essential role in the primary care of patients with depression by giving advice, recommendations, counseling about medicines, following up the patients for drug-related problems, and assessing patients' adherence on the basis of their skills and knowledge about the medicines (Kamusheva *et al*., 2020; Candida *et al*., 2015). Pharmacist-provided patient care services have been proven to be hugely beneficial to patient health outcomes (Kamusheva *et al*., 2020).

Rubio-Valera and colleagues demonstrated that a brief intervention in pharmacies can help to improve quality of life of patients with depression (Rubio-Valera *et al*., 2013), Another study conducted by Gomes and co workers on the effectiveness of pharmaceutical care services and their influence on quality-of-life in patients with depression also demonstrated an improvement in quality of life and increasing level of compliance as a result of an educational program (Candida *et al*., 2015). However, to the best of our knowledge, no study has evaluated the effect of pharmacist intervention in improving quality of life in patients with depressive disorder in Nigeria; particularly in the distressed North East region. Therefore, this study aimed at exploring the effect of a pharmacist intervention on quality of life in patients with major depressive disorder.

METHODOLOGY

Study Design and Clinical Setting

The study was a longitudinal prospective randomized controlled trial conducted between April 2019 and March 2020 at Federal Neuro-Psychiatric Hospital Maiduguri, Nigeria. It was a single center multiphase study with 6-months follow-up and data were collected at base line, 3 months and 6 months. Federal Neuro-Psychiatric Hospital (FNPH) Maiduguri, is a regional Psychiatric Hospital that serves the North-east region of Nigeria (Yusuf *et al*., 2018). Patients from the neighboring countries of Chad, Cameroon, and Niger Republic also receive clinical care from the hospital (Yusuf *et al*., 2018). Eligible for the study were patients aged 18 years or older, who had been diagnosed with major depressive disorder using International Classification of Diseases (ICD)-10 criteria and who had received pharmacological treatment for at least six weeks. They also had no history of; bipolar disorder, drug abuse or dependency, cognitive impairment or other

conditions that could make it difficult to collect data from them. Primary study endpoints were differences in quality of life.

Sample Size Estimation and Sampling Technique

The sample size used for this study was calculated using a formula described by Chan (2003) with the following assumptions: c is a constant taken as 7.9 for 80% power, the means difference between the intervention and usual care group was taken as 0.3 units and standard common deviation taken as 0.5. Total participants needed for the intervention and usual care groups were calculated to be 90. Due to anticipated loss to follow up as noticed in a previous study (Rubio-Valera *et al*., 2013) and the humanitarian crisis in the study area; which could contribute to loss to follow up, 33% of the calculated sample size was added and a total of 120 participants were recruited for the study. Systematic random sampling with sampling interval of two was used to select depressed patients attending FNPH Maiduguri's depression clinic on clinic days (Mondays, Tuesdays, Thursdays and Fridays). They were approached verbally by the principal investigator to ascertain their eligibility to participate in the study. Patients who met the eligibility criteria were then informed about the study objectives, and their voluntary written consent was sought. Patients who consented to participate were randomized into a usual-care group (60) or intervention group (60) using computer-generated random numbers. Patients that completed the study were included in the final data analysis (fifty-two patients from the Intervention group and 49 patients from the Usual-care group).

Study Instrument

Quality of life of the patients was assessed using a translated version of World Health Organization quality of life BREF (WHOQOL-BREF) scale that had been earlier translated, validated and used in the same region by Wakawa and colleagues (2014). The WHOQOL-BREF is a shorter version of the original WHOQOL-100 and consists of 26- items of which 24 are divided into four major domains, namely: physical, psychological, social relationships and environment. The remaining two questions ascertain patients' perceptions of their general health and overall quality of life and are analyzed separately (Veeri *et al*., 2019). The responses of the WHOQOL-BREF are scored in a Likert Scale fashion ranging from 1 to 5 (very poor - very good, not at all - an extreme amount, not at all - completely, very dissatisfied - very satisfied, never – always), with higher scores indicating higher Quality of Life and vice versa (Ibrahim *et al*., 2013). The generated raw scores are then converted to their actual values using transformation equations (WHO, 1997_b). The instrument contains domains of life function that are critical to health-related quality of life (HRQOL), and being a generic scale, provides information that is comparable across patient populations with different cultural background (Wakawa *et al*., 2014).

Pharmacist's Intervention

The pharmacist intervention was provided by a pharmacist who had Master of Science in Clinical Pharmacy and an experienced psychiatric pharmacist with research interest in mental health. The intervention included a pharmacist delivered educational counseling sessions of between 15-30 minutes, through one-on-one discussions with individual patients (once) after baseline and at 3 months. The intervention also included contacting patients once in every month within the 6 months' period through mobile-phone calls; to ascertain how they were faring with their medications, augment information given during the educational counseling sessions, provide answers to their questions if any and remind them of their appointment days. Patient counseling involved making patients understand the importance of antidepressant medication adherence, how to deal with possible medication side effects, the purpose of their medication, how and when to take medication and the reason for long-term use. Other content of these sessions involved identifying strategies to cope with medication forgetfulness which included; improving knowledge on what to do when a dose was forgotten, developing habit-based strategies for medication use and/or involvement of family members. Counseling to cope with lack of motivation was done by reducing the patients' concerns about the potential side effects of their medications and improving medication necessity beliefs. Other drug-related problems were resolved by providing solutions/alternatives when possible.

Data Collection Procedure

Data were collected at baseline, at 3 months and 6 months, by interviewing patients using the data collection instrument in a consulting room at the hospital. Patients in the Usual-care group received the usual care provided by the hospital, which included hospital visits on appointments or on sick days, consultations with physicians, review of medications and refilling of prescriptions by pharmacists. The usual-care was provided without any additional pharmacist interference. Patients in the intervention group received usual care plus the intervention for 6 months.

Data Analysis

Data analysis was done using Statistical Package for Social Science (SPSS) version 20 software (SPSS Inc, Chicago, Illinois, USA). Two-sample comparisons were computed using Student's t tests. A Repeated Measures ANOVA test was employed to quantify changes over time. Comparisons of proportions were carried out using chi-square test or fisher's exact test where applicable. The differences in mean quality of life scores of different domains in the intervention group and usual-care group were assessed at baseline, 3 months, and 6 months. Significance level of $p< 0.05$ was used throughout.

Ethical Approval

This study was approved by the Research Ethics Committee of Federal Neuro-Psychiatric Hospital Maiduguri (Approval number: FNPH/012019/REC002) and Ahmadu Bello University Ethics Committee on use of Human Subjects for Research (approval number: ABUCUHSR/2020/018). Written consent from study participants was also obtained prior to the commencement of the study.

RESULTS

Flow of Participants through the Study

During this study period, out of 140 eligible patients, 120 agreed to participate and 20 were excluded (5 were in critical condition and 15 refused to participate). A total of 49 (81.6%) and 52 (86.6%) participants completed the six months follow-up in the usual care and intervention groups, respectively. Reason for loss to follow-up of 19 participants was not known because connection to participants or their care givers was lost (Figure. 1).

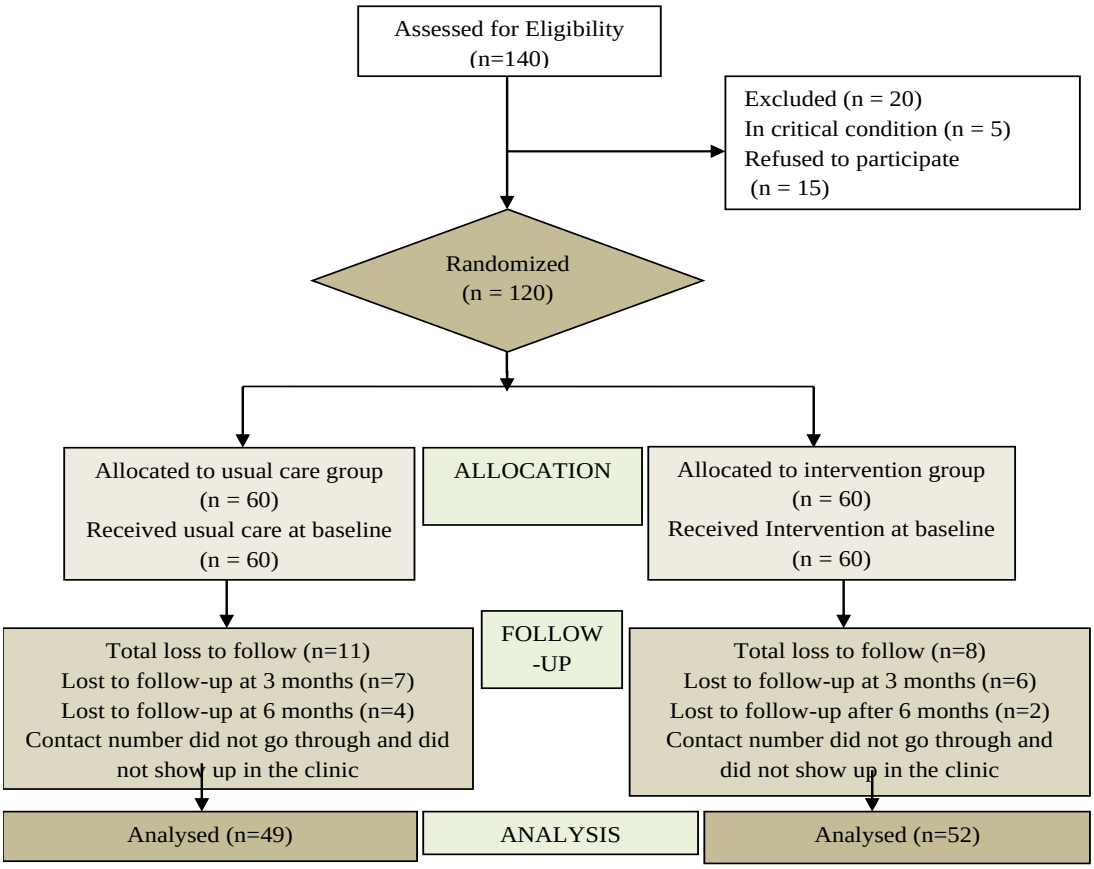

Fig.1 Flow of participants through the study

Socio-demographic Characteristics and Disease Severity of Study Participants

Majority of participants in both the usual-care (83.7%) and intervention (76.9%) groups were females. Most of them also fell within the 30–50-year age group (73.4% vs 61.5%), were married (57.1% vs 42.2%), had no formal education (44.9% vs 55.8%) and had moderate (55.1% vs 57.7%) to severe (40.8% vs 38.5%) depression in both the usual-care and intervention groups, respectively. No statistically significant differences existed between the groups in terms of their socio-demographic characteristics and disease severity at baseline.

Mean Quality of Life Scores in Various Domains at Baseline, 3 months and 6 months

Mean Quality of Life scores of study participants in various domains of the WHO Quality of Life Bref scale at baseline, 3 months and 6 months is presented in Table 1. At baseline, both the Usual-care and Intervention groups had low mean scores for Quality of Life in the physical health [44.09 (SD=12.53) vs 45.32 (SD=15.1)], psychological health [45.49 (SD=14.52) vs 45.19 (SD=13.39)], social relationship [37.39 (SD=18.40) vs 29.48 (SD=18.26)] and environment [38.58 (SD=12.87) vs 38.46 (SD=14.66)] domains. Also, there was no statistically significant difference between the mean quality of life scores in the physical health (p=0.662), psychological health (p=0.914) and environment (p=0.965) domains except for social relationship (p=0.023). After the intervention, significant improvements in mean quality of life scores of study participants in all of the domains in the intervention group were observed at 3 months (p <0.001) and 6 months (p <0.001) respectively (Table 1).

Table 1. Quality of Life of Study Participants in Various Domains at Baseline, 3 months and 6 Months at FNPH Maiduguri

Domain	Usual care (n=49) Mean score (SD)	Intervention (n=52) Mean score (SD)	p value
Physical health			
Baseline	44.09 (12.53)	45.32 (15.51)	0.662
3 months	44.31 (12.02)	62.36 (16.53)	<0.001*
6 months	42.49 (11.48)	72.25 (15.82)	<0.001*
Psychological health			
Baseline	45.49 (14.52)	45.19 (13.39)	0.914
3 months	47.19 (14.31)	70.19 (13.18)	<0.001*
6 months	45.15 (15.24)	85.57 (12.95)	<0.001*
Social relationship			
Baseline	37.92 (18.40)	29.48 (18.26)	0.023*
3 months	32.31 (19.66)	58.97 (15.64)	<0.001*
6 months	40.47 (21.24)	78.20 (18.23)	<0.001*
Environment			
Baseline	38.58 (12.87)	38.46 (14.66)	0.965
3 months	39.60 (12.42)	66.82 (12.77)	<0.001*
6 months	40.94 (14.09)	87.74 (9.78)	<0.001*

Independent samples T Test: SD= Standard deviation; *= significant at p< 0.05

WHO Quality of life bref scale (0-100): the higher the score, the better the quality of life

General Health and Overall Quality of Life of Study Participants at Baseline, 3 months and 6 months

Two items (general health and overall quality of life) on the WHO Quality of Life Bref scale were analysed separately at baseline, 3 months and 6 months and the mean scores are presented in Table 2. At baseline, both the usual care and intervention groups had low mean scores for general health [38.26 (SD=28.45) vs 48.07 (SD=18.42)] and overall quality of life [48.46 (SD=19.37) vs 50.0 (SD=14.0)] respectively. In the general health domain, a statistically significant difference was observed between the usual care and intervention groups at baseline (p =0.041) while there was no statistically significant difference between the overall quality of life (p =0.649) of participants in the usual care and intervention groups at baseline. After the intervention, significant improvements in mean general health scores of study participants in the intervention group were observed at 3 months (p <0.001) and 6 months (p <0.001) respectively while a significant improvement in the overall quality of life score (p <0.033) was only observed in the same group at 6 months but not at 3 months (Table 2).

Table 2.General Health and Overall Quality of life of Study Participants at Baseline, 3 months and 6 Months

Variable	Usual care (n=49) Mean score (SD)	Intervention (n=52) Mean score (SD)	P value
General health			
Baseline	38.26 (28.45)	48.07 (18.42)	0.041*
3 months	46.42 (27.00)	65.38 (30.53)	<0.001*
6 months	38.77 (27.51)	86.53 (21.27)	<0.001*
Overall quality of life			
Baseline	48.46 (19.37)	50.00 (14.00)	0.649
3 months	54.59 (20.20)	61.53 (30.70)	0.185
6 months	52.55 (19.26)	76.92 (25.16)	<0.001*

Independent samples T Test: SD= Standard deviation; *= significant at p< 0.05
WHO Quality of life bref scale (0-100): the higher the score, the better the quality of life

Overall Quality of Life scores with Consideration of Time and Group

To further evaluate the impact of the intervention on overall Quality of Life, repeated measures ANOVA analyses with consideration for time and group was conducted. Significant improvements in overall quality of life with time and in groups was observed (Table 3). It was observed that the overall Quality of Life significantly changed with time (p< 0.001), and this accounted for 16.5% (Partial eta squared = 0.165) of the change depicted. However, the direction of this change depended on participant group (p<0.001) and 10.4% (Partial eta squared = 0.104) of this change could be explained by interactions between time and group.

Table 3. Overall quality of Life of Study Participants with Consideration of Time and Group

Source	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	p value	Partial eta Squared
Time	49.25 (16.75)	58.16 (26.24)	65.09 (25.51)	<0.001*	0.165
Time *Group					
Usual care	48.46 (19.37)	54.59 (20.20)	52.55(19.26)	<0.001*	0.104
Intervention	50.00 (14.00)	61.53 (30.70)	76.92 (25.16)		

Number of Study Participants Scoring above the Mean Score on the WHO Quality of Life Bref Scale

The number of study participants scoring above the mean score (>50) of the WHO quality of life bref scale (0-100) at baseline, 3 months and 6 months is presented in Table 4. At baseline, in both the usual care and intervention groups, only very few participants [13 (26.5%) vs 8 (15.4%)] scored above the mean score of the WHO quality of life bref scale (0-100) and no statistically significant difference was observed between the two groups (p=0.168). After the intervention, significant improvements (p< 0.001) in the number of study participants [17 (34.7%) vs 36 (69.2%)] that scored above the mean score (>50) of the WHO quality of life Bref scale (0-100) was observed in the intervention group at 6 months (table 4).

Table 4. Number of Study Participants Scoring above the Mean Score on the WHO Quality of Life Bref Scale

Time	Usual care (n=49) n (%)	Intervention (n=52) n (%)	P value
Baseline	**13 (26.5)**	**8 (15.4)**	**0.168**
3 months	**21 (42.9)**	**32 (61.5)**	**0.060**
6 months	**17 (34.7)**	**36 (69.2)**	**0.001***

Chi- Square test: *= significant at $p < 0.05$
WHO Quality of lifebref scale (0-100).

DISCUSSION

To the best of our knowledge, this is the first study that evaluates the effect of pharmacist intervention on quality of life of patients with major depressive disorder in Nigeria; particularly in the fragile North east region.

Mean Quality of Life scores in various domains of the WHO quality of life bref scale of study participants was obtained at baseline, 3 months and 6 months in both usual care and intervention groups. At baseline, both the usual care and intervention groups had low mean scores for quality of life in the physical health, psychological health, social relationship and environment domains. This finding is consistent with what was observed in a study conducted by Wakawa *et al* (2014) on the impact of comorbid clinical depression on the health-related quality of Life of adults on highly active antiretroviral therapy in Maiduguri, northeastern Nigeria, where it was discovered that depressed patients had low quality of life scores in all of the domains when compared to non-depressed patients. This finding is also similar to another study conducted by Ibrahim and colleagues (Veeri *et al*., 2019).

At baseline, there were no statistically significant differences between the mean quality of life scores in the physical health, psychological health and environment domains except for social relationship in both groups. This significant difference observed in the social relationship domain was in favor of the usual care group. At 3 months and 6 months after the intervention, a statistically significant difference was observed between the groups in all of the quality-of-life domains. This is an indication that pharmacist intervention can significantly improve various components of quality of life including; physical health, psychological health, environment and social relationship.

Two other components of the WHO quality of life-bref were analyzed separately. These includes; general health and overall quality of life. For the general health domain, even though a statistically significant difference was observed in the mean scores of the two groups at baseline; appreciable improvement was noticed in the mean scores of the intervention group at 3 months and 6 months when compared to that of the usual care group. A statistically significant difference was also observed between the mean general health scores of the two groups at 3 months and 6 months. On the other hand, no significant differences in mean overall quality of life scores were seen in this study's intervention group until after 6 months. This indicates that while pharmacist intervention can improve quality of life in patients with depression, a minimum of six months pharmacist intervention maybe required in producing a significant impact on the overall quality of life of these patients.

Changes in overall quality of life were significant over time; however, the effect size was very small. This also suggests that a longer duration (more than 6 months) may be required to achieve larger effect sizes. Similarly, a statistically significant difference was observed between the percentages of patients that scored above the mean score on the WHO quality of life bref in both groups only at 6 months. The result of this study are consistent with the findings of Rubio-Valera *et al* (2013) during their evaluation of a pharmacist intervention on patients initiating pharmacological treatment for depression conducted in Spain. They also observed a statistically significant difference in health-related quality of life between the intervention and control groups with a small to moderate effect size. Our results are also similar to the findings of Gomes *et al* (2015). The result of our study is contrary to what was observed in a study conducted by Aljumah and Hassali (2015) on the impact of pharmacist intervention on adherence and measurable patient outcomes among depressed patients in Saudi Arabia where there was no significant difference in health-related quality of life between groups. However, they reported that the lack of significant differences may be due to the fact that health related quality of life is influenced by various psychological co-morbidities and that the

instrument they used (EQ-5D) may not detect small changes as both groups reported moderate scores at baseline.

This study has some limitations. Firstly, the study was carried out in one facility (the only federal neuropsychiatric hospital in North-east region) in Nigeria which may limit the generalizability of the result. Secondly, subjective methods (self-report scales) were used to measure patient outcomes which may be subject to social desirability bias.

CONCLUSION

Pharmacist's intervention significantly improved quality of life in patients with major depressive disorder in this study and a minimum of six months intervention was required to produce a significant impact in the overall quality of life. To achieve a larger effect size, a longer duration (more than 6 months) may be required. Pharmacists should be encouraged and involved in the long-term management of these patients, especially with respect to the provision of interventions that will improve their quality of lives.

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