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# Factors Associated with Changes in Quality of Life in Patients with Schizophrenia Using Atypical Antipsychotics

## *Fatores Associados às Mudanças em Qualidade de Vida em Pacientes com Esquizofrenia em Uso de Antipsicóticos Atípicos*

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**ABSTRACT**

**Introduction:** Schizophrenia is a mental disorder that affects the perception and thinking of individuals. It is known that the disease involves not only life expectancy, but also the health-related quality of life (HRQoL) of the affected individuals. Studies have investigated the relationship between HRQoL and schizophrenia, but few validate the dynamics of the variations in HRQoL over time. **Objective:** to evaluate factors related to changes in HRQoL in patients with schizophrenia using atypical antipsychotics in the Unified Health System (SUS). **Methods**: The prospective open cohort research followed 152 patients for 12 months in the scope of the SCHEEA (Schizophrenia Economics and Effectiveness Assessment) project, collecting data on HRQoL, psychological symptoms, social functioning and other relevant aspects. Linear regression models were used to identify the factors associated with changes in HRQoL. **Results**: there was an increase of 0.049 in the participants' average HRQoL. It was identified that worsening or instability in areas such as mobility, personal care, usual activities, pain, discomfort, anxiety, and depression were associated with lower HRQoL. It is suggested that the early identification and treatment of physical and psychological symptoms, along with the promotion of autonomy and functionality, are essential to improve the HRQoL of patients with schizophrenia in the SUS. **Conclusion**: This study contributes to the management of care for this population, highlighting the importance of multidimensional approaches that consider different aspects of the disease.

**Keywords:** Schizophrenia; Quality of Life; Antipsychotic Agents; Cohort Studies.

**RESUMO**

**Introdução:** A esquizofrenia é um transtorno mental que afeta a percepção e o pensamento dos indivíduos. Sabe-se que a doença compromete não somente a expectativa de vida, mas também a qualidade de vida relacionada à saúde (QVRS) dos indivíduos acometidos. Estudos têm investigado a relação entre QVRS e esquizofrenia, mas poucos avaliam a dinâmica das variações em QVRS ao longo do tempo**. Objetivo**: Avaliar os fatores associados às mudanças em QVRS em pacientes com esquizofrenia em uso de antipsicóticos atípicos no Sistema Único de Saúde (SUS). **Métodos**: A coorte aberta prospectiva acompanhou 152 pacientes durante 12 meses no escopo do Projeto SCHEEA (Schizophrenia Economics and Effectiveness Assessment) que coletou dados de QVRS, sintomas psicológicos, funcionamento social e outros aspectos relevantes. Um modelo de regressão linear foi utilizado para identificar os fatores relacionados às mudanças em QVRS. **Resultados**: Houve um aumento de 0,049 na média de QVRS dos pacientes. Foi identificado que piora ou instabilidade em áreas como mobilidade, cuidados pessoais, atividades habituais, dor, desconforto, ansiedade e depressão estavam associadas a uma menor QVRS. Sugere-se que a identificação e tratamento precoce de sintomas físicos e psicológicos, além da promoção da autonomia e funcionalidade, são essenciais para melhorar a QRVS de pacientes com esquizofrenia no SUS. **Conclusão**: Este estudo contribui para a gestão do cuidado dessa população, destacando a importância de abordagens multidimensionais que considerem diversos aspectos da doença.

**Palavras-chave:** Esquizofrenia; Qualidade de vida; Antipsicóticos; Estudos de Coorte

## Introduction

Mental disorders are characterized by clinically significant disturbances affecting cognition, emotional regulation, and behavior of the afflicted individual. In 2019, it was estimated that one in eight people worldwide lived with a mental disorder such as depression, anxiety, bipolar disorder, post-traumatic stress disorder, and schizophrenia.[1]

Schizophrenia affects about 1% of the global population[2] and significantly reduces the life expectancy of affected individuals.[3] The disease impacts thoughts and perception,[4] characterized by symptoms such as delusions, hallucinations, anhedonia, and social withdrawal.[2] The pharmacological treatment for this disorder involves antipsychotics.[5]

The symptoms of the disease and its treatment compromise the health-related quality of life (HRQoL) of patients, which is lower compared to the general population.[7] HRQoL has presented different concepts over time,[8] with the most widely used concept established by the World Health Organization (WHO), defining quality of life as the individual's perception in relation to aspects such as values, position in life and goals.[9]

Published studies have identified predictors of HRQoL in patients with schizophrenia.[6,10] These studies developed statistical models that evaluated the association between clinical, social aspects, and HRQoL. Such studies are important as they highlight characteristics and factors that can be targeted for interventions to improve HRQoL in patients with schizophrenia.[6] However, few studies have evaluated HRQoL using a longitudinal approach, observing the HRQoL variation over time. Thus, the aim of this study was to evaluate the characteristics related to the variation of HRQoL in a cohort of patients with schizophrenia in the Unified Health System (SUS).

## Methods

This study is part of the SCHEEA project (Schizophrenia Economics and Effectiveness Assessment). It is a prospective open cohort study with patients with schizophrenia using atypical antipsychotics in SUS in the metropolitan region of Belo Horizonte, in Brazil. In the interviews of the cohort were evaluated sociodemographic, clinical, and behavioral aspects of participants, besides HRQoL, using the EQ-5D instrument (European Quality of Life-5 Dimensions).[10]

Two interviews were selected to evaluate the change in HRQoL over time, the baseline interview and the second interview. Baseline interview was conducted in person from September 2017 to March 2018. Between April 2018 and May 2019, the second interview was conducted by telephone, with an average follow-up time of 20 months.

Participants were diagnosed with schizophrenia, aged 18 years or older, and used atypical antipsychotics provided by the Specialized Component of Pharmaceutical Assistance of Minas Gerais. Participants who did not respond to any EQ-5D domain in any interview were excluded. The study recruited 448 patients in the baseline interview, of which 207 responded to the second interview. All of them agreed to the terms of the study by signing the Informed Consent Form. Among participants who responded to both interviews, 154, 152 completed all EQ-5D domains and were considered in the final analysis.

Utility values for the health states of each participant were assigned based on the EQ-5D responses in each interview, according to the population of Minas Gerais, as defined in a study published by Andrade et al.[11] HRQoL utility ranges from -0.223 (lowest HRQoL) to 1 (highest HRQoL). The dependent variable, a numerical variable, was defined as the difference in HRQoL utility between the two interviews (second minus baseline).

Independent variables investigated, collected at the baseline interview, were gender (female; male), age (20 to 39 years; 40 to 59 years; 60 years or older), skin color (non-white; white), marital status (without partner; with partner), education level (up to complete elementary school; complete high school; complete higher education), employment status (no; yes), income (up to 1 minimum wage; more than 1 and up to 4 minimum wages; more than 4 minimum wages), having children (yes; no), practice of physical activity (no; yes), family support feeling (none/never/rarely; most of the time/always), type of antipsychotic used (atypical;

atypical associated with typical), presence of other diseases (yes; no), and use of cigarettes or alcohol (yes; no). Additionally, changes (improvement; stability; worsening) between the two interviews in the individual responses to the five EQ-5D dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) were considered. These changes, as independent and categorical variables, do not refer to changes in HRQoL more broadly, but refer to the progressive nature of the level of problems (or symptoms) in the response options of each EQ-5D domain (no problems, some problems, extreme problems). Stability was assigned to the same response in a particular domain in both interviews. If the participant selected a more severe option in the second interview compared to the baseline, worsening was assigned for that domain. If a less severe option was selected, improvement was assigned. It is noteworthy that the present study investigated signs rather than diagnoses of anxiety and depression.

Given the ability of the linear regression model to establish relationships between independent and dependent variables, a model was used to evaluate the relationship between utility change and sociodemographic and clinical variables. The theory is that these independent variables, encompassing various aspects of patients' lives, may relate to HRQoL, given the broad sense of quality of life. The linear regression model was adjusted for the difference in utility in function of each independent variable separately, adjusted by the utility value in the baseline interview. Variables with a p-value $<0.10$ were included in an initial model, remaining in the final multiple linear regression model those with a p-value $<0.05$. The adjustment of utility difference was made due to its negative correlation with baseline utility. The utility value range is limited, and the higher the baseline utility, the lower the "gain" in utility in the second interview.

Statistical analyses were performed using IBM SPSS (Statistical Package for the Social Sciences) Statistics® version 20. The project was reviewed and approved by the Research Ethics Committee (COEP) of the Federal University of Minas Gerais (UFMG), with opinion number 1.691.265 (CAAE number 57420616.9.0000.5149), on August 23, 2016.

## Results

The majority of the 152 study participants were male (55.9%), aged 40 to 59 years (43.7%), non-white (62.3%), without partner (74.8%), with complete high school education (35.8%), unemployed (82.7%), earning more than one and up to four minimum wages (49.2%), and without children (52.0%). Most were sedentary (52.6%), did not consume alcohol or smoke cigarettes in the last six months (67.3%), and felt supported by family most of the time or always (81.5%). Clinically, 55.1% reported other chronic diseases, and 83.6% were using only atypical antipsychotics **(Table 1)**.

In both interviews, most participants did not report mobility problems (73.7% and 81.6%), self-care issues (86.2% and 88.2%), or issues with usual activities (52.0% and 78.3%), nor did they report pain or discomfort (61.2% and 55.9%). However, 40.1% and 36.8% showed moderate signs of anxiety and depression in baseline and second interview, respectively. Improvement was observed in the ability to perform usual activities (37.5%) and in anxiety/depression (25.0%), the latter also showing the highest percentage of worsening (27.6%), along with the domain related to pain or discomfort (24.3%). The highest percentages of stability occurred in the self-care (84.2%) and mobility (73.7%) domains **(Table 2)**.

At the baseline interview, HRQoL utility attributed by patients had an average of 0.739 and a median of 0.789. In the second interview, these values increased to 0.788 and 0.832, respectively. The average difference between the two collections was 0.049, showing a statistically significant increase ($p=0.003$) (data not tabulated).

No statistically significant difference was observed in baseline utility values between the group of patients who remained in the study and the group who did not participate in the second interview (mean difference = 0.025; $p = 0.311$). The two groups don't showed diferences in the characteristics collected at the baseline interview.

**Table 1**. Sociodemographic characteristics, lifestyle habits, and clinical data of 152 patients with schizophrenia using antipsychotic medications from the Specialized Component of Pharmaceutical Assistance, in BH/MG, 2017-2019, at the baseline interview

| Characteristic | Category | n (%) |
|---|---|---|
| **Sex** | Female | 67 (44.1) |
| | Male | 85 (55.9) |
| **Age group (years)** | 20 to 40 | 46 (30.5) |
| | 41 to 59 | 66 (43.7) |
| | 60 to 95 | 39 (25.8) |
| | Don't know/no response | 1 |
| **Skin color/race** | Non-white | 91 (62.3) |
| | White | 55 (37.7) |
| | Don't know/no response | 6 |
| **Marital status** | Without partner | 113 (74.8) |
| | With partner | 38 (24.2) |
| | Don't know/no response | 1 |
| **Education level** | Up to complete elementary school | 53 (35.1) |
| | Complete high school | 54 (35.8) |
| | Complete higher education | 44 (29.1) |
| | Don't know/no response | 1 |
| **Employment** | No | 124 (82.7) |
| | Yes | 26 (17.3) |
| | Don't know/no response | 2 |
| **Income (in minimum wages of R$ 937.00)** | Up to 1 | 33 (26.6) |
| | More than 1 and up to 4 | 61 (49.2) |
| | More than 4 | 30 (24.2) |
| | Don't know/no response | 28 |
| **Children** | No | 79 (52.3) |
| | Yes | 72 (47.7) |
| | Don't know/no response | 1 |
| **Physical activity** | No | 80 (52.6) |
| | Yes | 72 (47.4) |
| **Alcohol and/or cigarette use in recent months** | No | 101 (67.3) |
| | Yes | 49 (32.7) |
| | Don't know/no response | 2 |
| **Feeling of family support** | No/rarely/sometimes | 28 (18.5) |
| | Most of the time/always | 123 (81.5) |
| | Don't know/no response | 1 |
| **Other diseases** | No | 66 (44.9) |
| | Yes | 81 (55.1) |
| | Don't know/no response | 5 |
| **Antipsychotic in use** | Atypical | 127 (83.6) |
| | Atypical and typical | 25 (16.4) |

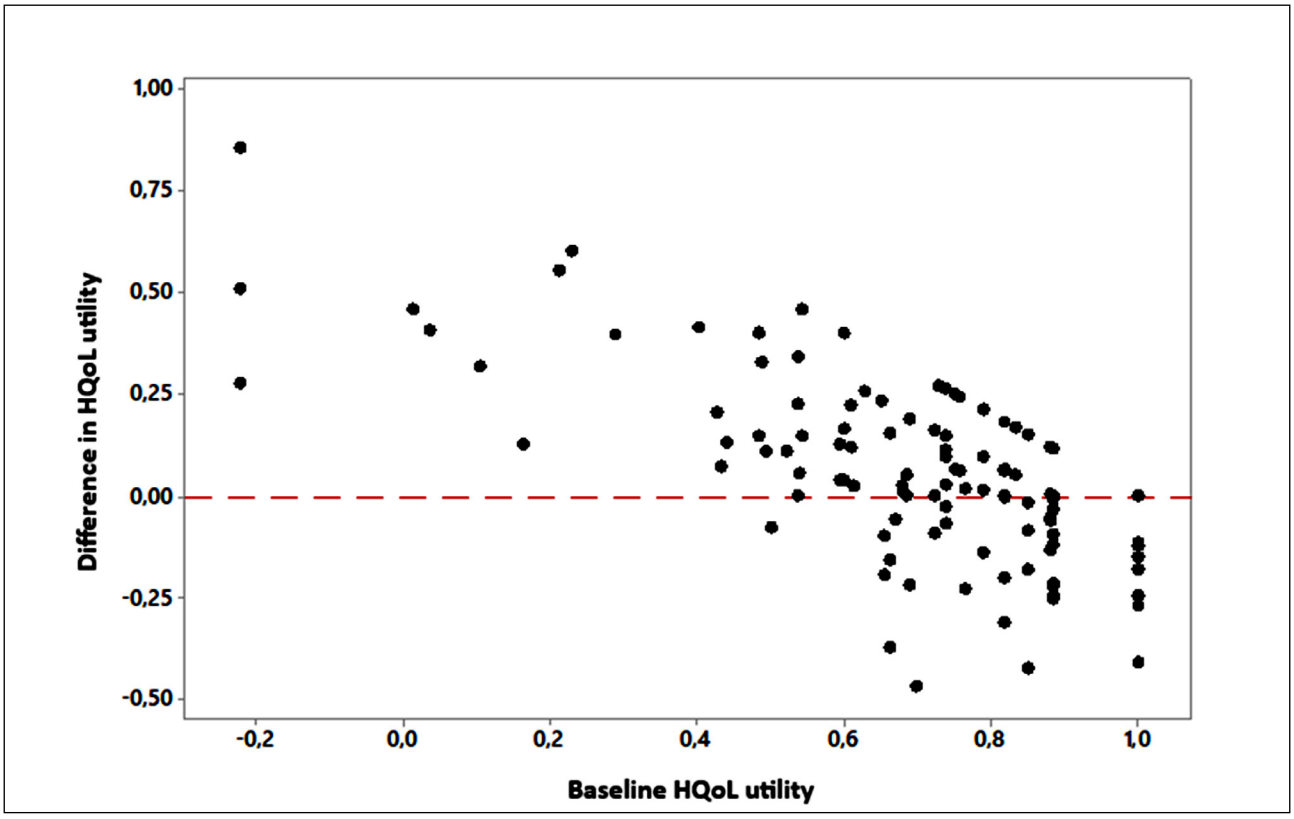
Source: the authors

**Table 2**. Responses to the EQ-5D dimensions between two interviews in a cohort of 152 patients with schizophrenia using antipsychotic medications from the Specialized Pharmaceutical Assistance Component, BH/MG, 2017-2019

| Dimension | Category | Interview | | Variation between interviews | | |
|---|---|---|---|---|---|---|
| | | Baseline *n* (%) | Second *n* (%) | Better *n* (%) | Stable *n* (%) | Worse *n* (%) |
| **Mobility** | No problems | 112 (73.7) | 124 (81.6) | 29 (19.1) | 112 (73.7) | 11 (7.2) |
| | Some problems | 32 (21.1) | 28 (18.4) | | | |
| | Confined to bed | 8 (5.3) | 0 (0.0) | | | |
| **Self-care** | No problems | 131 (86.2) | 134 (88.2) | 14 (9.2) | 128 (84.2) | 10 (6.6) |
| | Some problems | 17 (11.2) | 16 (10.5) | | | |
| | Unable to Wash or dress | 4 (2.6) | 2 (1.3) | | | |
| **Usual activities** | No problems | 79 (52.0) | 119 (78.3) | 57 (37.5) | 80 (52.6) | 15 (9.9) |
| | Some problems | 54 (35.5) | 29 (19.1) | | | |
| | Unable to perform usual activities | 19 (12.5) | 4 (2.6) | | | |
| **Pain/ discomfort** | No pain or discomfort | 93 (61.2) | 85 (55.9) | 23 (15.1) | 92 (60.5) | 37 (24.3) |
| | Moderate pain or discomfort | 40 (26.3) | 40 (26.3) | | | |
| | Extreme pain or discomfort | 19 (12.5) | 27 (17.8) | | | |
| **Anxiety/ depression** | No anxiety or depression | 53 (34.9) | 54 (35.5) | 38 (25.0) | 72 (47.4) | 42 (27.6) |
| | Moderate anxiety or depression | 61 (40.1) | 56 (36.8) | | | |
| | Extreme anxiety or depression | 38 (25.0) | 42 (27.6) | | | |

Source: the authors

**Figure 1.** Scatter plot of the differences in HRQoL utility between the two interviews based on the baseline HRQoL utility in 152 patients with schizophrenia using antipsychotic medications from the Specialized Pharmaceutical Assistance Component, BH/MG, 2017-2019




Source: the authors

**Table 3**. Results of univariate linear regression and final multivariate models for the difference in HRQoL utility according to sociodemographic characteristics, lifestyle habits, and clinical conditions, adjusted for baseline utility, in 152 patients with schizophrenia using antipsychotic medications from the Specialized Pharmaceutical Assistance Component, BH/MG, 2017-2019

| Variable | | Univariate linear regression model | | Multivariate regression model | | |
|---|---|---|---|---|---|---|
| | | Coefficient | P-value | Coefficient | p-value | %SQR |
| Constant | | 0.4699 | - | 0.7286 | - | - |
| Basal HRQoL utility | | -0.5653 | **<0.001** | -0.1941 | **<0.001** | 2.36 |
| Sex | Female | - | - | - | - | - |
| | Male | 0.0098 | 0.704 | | | |
| Age group (years) | 20 to 40 | - | - | | | |
| | 41 to 59 | -0.0332 | 0.267 | - | - | - |
| | 60 to 95 | 0.0075 | 0.827 | | | |
| Skin color/race | Non-white | - | - | - | - | - |
| | White | -0.0027 | 0.916 | | | |
| Marital status | Without partner | - | - | - | - | - |
| | With partner | -0.0041 | 0.890 | | | |
| Education level | Up to elementary school | - | - | | | |
| | High school | 0.0074 | 0.815 | - | - | - |
| | Higher education | 0.0522 | 0.101 | | | |
| Employment | No | - | - | - | - | - |
| | Yes | 0.0549 | 0.108 | | | |
| Income (in minimum wages of R$937.00) | Up to 1 | - | - | | | |
| | More than 1 and up to 4 | 0.0436 | 0.194 | - | - | - |
| | More than 4 | 0.0713 | **0.073** | | | |
| Children | No | - | - | - | - | - |
| | Yes | 0.0068 | 0.790 | | | |
| Physical activity | No | - | - | - | - | - |
| | Yes | 0.0146 | 0.567 | | | |
| Alcohol and/or cigarette recent use | No | - | - | - | - | - |
| | Yes | -0.0250 | 0.365 | | | |
| Feeling of family support | No, never, rarely | - | - | - | - | - |
| | Mostly, always | 0.0693 | **0.033** | | | |
| Other diseases | No | - | - | - | - | - |
| | Yes | -0.0166 | 0.526 | | | |
| Antipsychotic in use | Atypical | - | - | - | - | - |
| | Atypical+typical | 0.0165 | 0.634 | | | |
| Mobility | Improved | ´- | - | - | - | |
| | Stable | -0.1180 | **0.003** | -0.1323 | **<0.001** | 5.9 |
| | Worsened | -0.2463 | **<0.001** | -0.2194 | **<0.001** | |
| Self-care | Improved | - | - | - | - | |
| | Stable | -0.1438 | **0.003** | -0.1410 | **<0.001** | 6.4 |
| | Worsened | -0.3090 | **<0.001** | -0.2792 | **<0.001** | |
| Usual activities | Improved | - | - | - | - | |
| | Stable | -0.0630 | **0.025** | -0.1020 | **<0.001** | 7.7 |
| | Worsened | -0.2626 | **<0.001** | -0.2219 | **<0.001** | |
| Pain/discomfort | Improved | - | - | - | - | |
| | Stable | -0.0878 | **0.005** | -0.1128 | **<0.001** | 11.8 |
| | Worsened | -0.2550 | **<0.001** | -0.2304 | **<0.001** | |
| Anxiety/ depression | Improved | - | - | - | - | |
| | Stable | -0.0862 | **0.002** | -0.0689 | **<0.001** | 8.0 |
| | Worsened | -0.2001 | **<0.001** | -0.1717 | **<0.001** | |

Note: %SQR: percentage contribution of the variable to the Sum of Adjusted Regression Squares.
Source: the authors

HRQoL utility difference was positively related to income and family support and negatively to stability or worsening in problems in the five EQ-5D domains, according to univariate regression models adjusted by baseline utility **(Table 3)**. However, income and family support lost statistical significance in the final multivariate model. This model showed an adjusted determination coefficient of 89.8%, with pain or discomfort (11.8%) and mobility (5.9%) being the domains with the highest and lowest impact on HRQoL utility, respectively (Table 3).

## Discussion

The profile of study participants was similar to other cohorts of patients with schizophrenia, with a higher prevalence of males[12-15] and a significant portion of persons without a partner.[15] The characteristics of the sample also resemble the profile of patients using atypical antipsychotics in Brazil, where between 2008 and 2017, the average age of the participants was 44 years.[17] It is noteworthy, as a finding of this study, that despite being a population of economically active age, there is low labor and relationship participation.

It was observed an average increase of 0.049 (6.6%) in HRQoL utility after an average follow-up of 453 days, representing a significant improvement in quality of life. Similar findings have been reported in other studies that evaluated changes in HRQoL in individuals with schizophrenia, whether using the EQ-5D[18] or other instruments[12,19]. The mean utility values observed among participants may be associated with the use of antipsychotic medications.

In the final regression model, a relationship between the worsening severity of anxiety and depression symptoms and the decline in HRQoL was identified, corroborating the findings of other studies.[5,14,20]

Signs of anxiety disorders were identified in more than 78% of a Polish sample of individuals with schizophrenia. The sample still had more than 50% of individuals with signs of depressive disorders. Another important finding of the study was the correlation between the severity of these disorders and lower levels of HRQoL.[21] A similar correlation involving anxiety and HRQoL was also observed in Thailand.[22]

Depression can influence the HRQoL of individuals with schizophrenia through low self-esteem and the negative view they may have of themselves.[22] The review by Temmingh and Stein[23] concluded that anxiety is related to increased severity of positive symptoms of schizophrenia and that anxiety symptoms serve as a predictor of suicide in patients with schizophrenia.

No studies were found that relate all the variables with statistical significance in the model to changes in HRQoL in longitudinal studies. Although no studies were identified in the literature indicating worsening in dimensions mobility, personal care, and usual activities, in addition to the increase in the severity of pain or discomfort symptoms, this study demonstrated a significant association between deterioration in these dimensions and a reduction in HRQoL.

Studies using other pharmacoepidemiological designs have already observed that impaired mobility in individuals with schizophrenia is associated with more negative symptoms, metabolic syndrome, cognitive impairments, and lower HRQoL.[24] Considered one of the diagnostic criteria for the disorder[25], impairment in personal care is characteristic of individuals with schizophrenia and is influenced by the symptoms of the disease.[26] It was identified that individuals with metabolic syndrome tend to have poorer levels of personal care.[27] Regarding the preservation of usual activities, a systematic review of Western, Japanese, and Chinese studies identified an uncertain yet positive relationship between employment and HRQoL. A Brazilian study that evaluated the relationship between HRQoL in individuals with schizophrenia who experienced pain and those who did not, using the WHOQOL-brief instrument, did not identify lower overall HRQoL in the first group but did verify that individuals with pain had physical impairments.[29]

A limitation of this study is the sample size, which may have hindered the inclusion of more independent variables with statistical significance in the final regression model. Despite this, the study presents real-world data from patients with schizophrenia who are users of the SUS in the metropolitan re-

gion of Belo Horizonte and uses an approach that is rarely explored in the literature to evaluate HRQoL.

A longitudinal evaluation was conducted, providing insight into the dynamics of HRQoL and its variations over time. The lack of similar studies in the literature made it difficult to discuss the findings of this study. It is worth noting that prospective cohorts (like SCHEEA) allow for the establishment of causality while reducing the risk of recall bias.[30]

With regard to loss to follow-up between the two interviews, a reduction in sample size was observed over the follow-up period. The SCHEEA did not select participants based on disease stability, which may have contributed to the loss of participants with clinical instability[12]. Additionally, the absence of an upper age limit in the inclusion criteria increases the chances of loss due to death. The maintenance of different profiles in the analysis allows for generalization of the results, consistent with real-life scenarios.

Convenience sampling and selection criteria (only participants present in both data collections) may have introduced a selection bias. This limitation is a consequence of the inherent difficulties in data collection, such as access to individuals and their willingness to provide information. However, the study stands out for evaluating longitudinal data not observed in other cohorts, which, despite minimizing collection difficulties, do not assess aspects such as HRQoL, physical exercise practice, income, and use of legal and illegal drugs. The robustness of the applied statistical analyses can mitigate the potential bias.

The factors related to changes in HRQoL identified in this study were specific to a particular population and time frame. Further studies and analyses are needed to determine if the results are consistent, including with different sample parameters and time frames.

Identifying and treating symptoms, signs, and problems early and appropriately can improve the quality of life for patients with schizophrenia.

**Authors' Contributions**
ABNM contributed to the formal analysis and writing of the manuscript. CMR, EAR, and HNO contributed to the conceptualization, methodology, formal analysis, writing, review, and editing of the manuscript. All authors read and approved the final submitted version and take public responsibility for all aspects of the work.

**Conflicts of Interest**
There are no conflicts of interest to declare in relation to this work.

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**Data Availability Statement**
The data will be available to authors on demand – a condition justified in the manuscript.

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