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2 **PSYCHOTROPIC MEDICATION NON-ADHERENCE AMONG PSYCHIATRIC PATIENTS**
3 **AT KING ABDULAZIZ HOSPITAL-Makkah.**
4

5 **Running Title:** PSYCHOTROPIC MEDICATION NON-ADHERENCE AMONG PSYCHIATRIC
6 PATIENTS

7
8 **Abstract:**

9
10 **Background:** Non-adherence to psychotropic medication among psychiatric patients is one among the huge medical
11 problem in Saudi Arabia. Most of the psychiatric patients do not adhere to the instruction of the physician in such a
12 way that they reappear in the hospital after medication and getting well.

13 **Aim:** To assess psychotropic medication nonadherence among psychiatric patients at King Abdulaziz hospital in
14 Makkah city, Saudi Arabia.

15 **Method:** a cross-sectional study conducted on 342 psychiatric patients with age group between 18-65 years, and are
16 visiting the outpatient clinics and subjected to psychotropic medication at the department of psychiatry at King
17 Abdulaziz Hospital. Data were collected from the psychiatric patients using the designed questionnaire. The
18 Medication Adherence Rating Scale (MARS) were used to assess the level of adherence to medication.

19 **Results:** A total of 342 of patients participated in the study. One hundred ninety-one, 191(55.8%), were females.
20 About half (54.4%) of the patients were married, (53.5%) of them were between 30-39 years old. A significant
21 relation between the educational level of participants and adherence to medication ($P < 0.05$) were recorded. Patients
22 in this study reported that the impacts of nonadherence to the medication are a relapse of the symptoms (25%),
23 cannot sleep (15.2%), bad mood (10.2%), and agitation (4.7%).

24 **Conclusion:** Nonadherence remains a significant challenge for patients with psychiatric disorders, physicians,
25 healthcare systems which resulting in poorer outcomes for patients. Though the predictors of nonadherence among
26 psychiatric patients are multifactorial, the strongest determinants in this study were the increased number of
27 medication, the presence of side effect, and forgetting of taking medication. According to this we recommend
28 adhering to monotherapy except when the use of multiple drugs becomes compelling and takes into consideration
29 the side effects of medications.

30 **Keywords:** Psychotropic Medication, Non-Adherence, Psychiatric patients.
31

32 **1. Introduction**

33 Treatment of psychiatric disorders is in increasing concerns. Globally one in four people will be affected by mental
34 disorders at some point in their life. The current statistics depicts that approximately 450 million people worldwide
35 suffer from these conditions thereby placing mental health disorders among the leading causes of illness (WHO,
36 2001). Although psychotropic medication for specific psychological interventions has been demonstrated to be

37 beneficial, this has also been noted to be associated with relapse due to non-adherence to the medication regime [1].
38 Patients with psychiatric illness typically have big difficulty following a medication regimen, but they also have the
39 greatest potential from drug adherence. It has been noted that half of the patients prescribed with antidepressants will
40 not be taking the drug three months after the initiation of the therapy [2]. However, patients with acute conditions
41 have typically higher adherence rates as compared to those with chronic conditions. This tends to increase the time
42 for a patient continuing drug therapy. Medication nonadherence is a major barrier to favorable health outcomes in
43 psychiatric disorders such as schizophrenia, bipolar disorder, and depression [3]. The definition of non-adherence
44 includes failure to enter a treatment program, premature termination of therapy and incomplete implementation of
45 instructions (including prescriptions) [4]. Failure to adhere to medication can have a major impact on the course of
46 illness and treatment outcomes, including increasing the risk of relapse and re-hospitalization. Understanding
47 psychiatrists' perception of the causes and consequences of nonadherence is crucial to addressing adherence
48 problems effectively [5]. Taking the prescribed dose of medication, at the correct time, and for the full course of
49 treatment is fundamental to patients realizing the full potential benefits of medications. However, between 30 - 50%
50 of medicines for long-term conditions are not taken as prescribed, resulting in costs for individual patients and
51 healthcare systems (WHO, 2003). Ensuring patients continue with their medication over the long term is a
52 considerable challenge in psychiatry. There is a range of often overlapping patient, treatment, environment, and
53 physician-related factors that contribute to partial or nonadherence to medication. These factors include patients'
54 lack of insight, attitudes toward and previous experiences of medication, comorbidity and symptom severity, the
55 level of social and family support, and the strength of the therapeutic alliance between patient and physician [6, 7].
56 Nonadherence to medication can have a major impact on the course of illness and treatment outcomes and is
57 associated with an increased risk of relapse, the persistence of symptoms, functional impairments, and increased
58 hospitalization [8,9]. Risk factors for nonadherence including limited insight; a negative attitude or subjective
59 response towards medication; shorter illness duration; comorbid substance abuse; poorer therapeutic alliance; living
60 alone; more self-reported side effects; and limited family support [10,11,12]. Understanding determinants of
61 antipsychotic medication adherence are critical as nonadherence plays a significant role in psychotic relapse and
62 each relapse contributes to accrued social toxicity and disability. Thus, a negative medication attitude is critical
63 variables that have repeatedly been shown to be risk factors for non-adherence [13]. Nonadherence to medication
64 among psychiatric patients considered as one of the main medical problems in Saudi Arabia. Most of the psychiatric
65 patients do not adhere to the physician instruction and to the prescribed medication, which sometimes causes the
66 disease to be severe and chronic and prevents patients from getting the full benefits of their treatment.
67 Understanding and reducing nonadherence is, therefore, a key challenge to the quality of care for patients with
68 psychiatric disorders. This paper aims to assess psychotropic medication non-adherence and highlights findings
69 regarding the prevalence of non-adherence among psychiatric at King Abdulaziz hospital in Makkah city.

70

71 2. Methodology

72 **2.1 Study area**

73 This study was conducted at King Abdulaziz hospital in Makkah city of Saudi Arabia, specifically at the
74 department of psychiatry. King Abdul-Aziz hospital was chosen since it has the main and the largest
75 psychiatry department in the city, therefore, there is a greater possibility of obtaining reliable and relevant
76 data for this study.

77 **2.2 Research design**

78 This study is cross-sectional design employing both qualitative and quantitative data conducted on
79 psychiatric patients who are visiting the outpatient clinics and subjected to psychotropic medication at the
80 department of psychiatry in King Abdulaziz hospital. The estimated daily population of patients visiting the
81 psychiatry outpatient clinics are 150 patients. With four days working clinics per week, the total monthly
82 population is around 2,400 patients.

83 **2.3 Sample size**

84 The sample was calculated from the monthly population of 2,400 patients at 95% Confidence Interval by
85 this formula

$$86 n = \frac{N}{1 + Ne^2}$$

87 Where: n= sample size, N= Total population = 2,400, e= precision error = 5%=0.05

$$88 \text{Therefore } n = \frac{2,400}{1 + 2,400 \times (0.05)^2}$$

89 Therefore, the sample from this population will be 342 patients

90 **2.4 Sampling Techniques**

91 The sampling techniques were non-probability sampling. Therefore, it was purposive sampling for
92 psychiatric patients with age group between 18-65 years, Mental illness on psychotropic medication,
93 Capacity to give informed consent and in continuous therapy at least for three months before the study.
94 Those who are in serious medical condition or with mental retardation will not be considered.

95 **2.5 Data collection methods**

96 The study used primary data that were collected from the psychiatric patients using the designed
97 questionnaire which was administered verbally if necessary. Also, some other primary information about
98 the patient and general medication in terms of effects of nonadherence to medication to the psychiatric
99 patients were also taken from doctors, nurses and other specialists so as to complement the study.

100 **2.6 Questionnaire**

101 Questionnaires were used for the psychiatric patients at King Abdulaziz hospital. A questionnaire
102 containing open and closed questions were used and the researcher's role was interpreting the
103 questionnaire for the respondents to make sure data collected reflects the truth to their understanding.

104 **2.7 Data analysis methods**

105 Data were analyzed basing on the objectives of the study. The statistical package for social science
106 (SPSS) shall be used for the analysis. The data analysis method used linear regression analysis by
107 descriptive data were obtained and chi-square test used to test for significance of variables.

108 **2.8 Measurement of adherence**

110 The Medication Adherence Rating Scale (MARS) were used to assess the level of medication adherence
111 for the patients in this study. The scale includes 10 items and examines adherence behavior and attitude
112 toward medication during the past week with relatively simple scoring. Scoring less than 6 is considered
113 as non-adherence to medication.

114 The study will be limited to the following criteria: age group between 18-65 years, mental illness on
115 psychotropic medication, capacity to give informed consent and continuous therapy at least for three
116 months before the study

117 Patients who are with serious medical condition and mental retardation are excluded from the study

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119 **3. Results:**

120 **3.1 Sociodemographic characteristics and background of the respondents:**

121

122 A total of 342 of patients participated in the study. One hundred ninety-one, 191(55.8%), were females.
123 About half, (54.4%), of the patients, were married. About half (53.5%) of them were between 30-39 years
124 old. The majorities, (78.1%), of the participants, were from urban regions. Only twenty-two (6.4%) of the
125 total participants could not read and write, (25.1%) were unemployed, while (33.6%) have bachelor's
126 degree. About (41.5%), of the patients, were living with low household monthly income, results presented
127 in table (1).

128 **3.2 Diseases and medication-related issues:**

129 About 37.7% and 30.1% of the patients have their disease for about 11 to 30 and 31 to 60 months,
130 respectively. Even that, our results showed that the patients follow their continuous therapy through their
131 illness, results of illness duration appeared to be the same of the period of continuous therapy. About half
132 of the patients have a duration of illness for about nine to twelve weeks from the last visiting. Most of
133 them (43.5%) and (49.4%) taking tablets from 1 to 4 tables and 3 to 4 tablets per day respectively, for
134 about (96.5%) of them, the physician follow up their medication, and 90.9% taking their medication by
135 themselves, table (2).

136

137 **Table (1): Socio-demographic characteristics of the respondents (N=342):**

138

| Variable | N (%) |
|-----------------------|--------------|
| Sex | |
| Male | 151 (46.9) |
| Female | 191 (55.8) |
| Age | |
| 18-29 | 45 (13.2) |
| 30-39 | 183 (53.5) |
| 40-49 | 70 (20.5) |
| 50-59 | 43 (12.5) |
| 60-65 | 0 (0.00) |
| Education | |
| Illiterate | 22 (6.40) |
| Pre-collage | 104 (30.4) |
| Diploma | 83 (24.3) |
| degree | 115 (33.6) |
| Master | 13 (3.80) |
| PhD | 5 (1.50) |
| Marital Status | |
| Single | 77 (22.5) |
| Married | 186 (54.4) |
| Divorced | 55 (16.1) |
| Widow | 24 (7.00) |
| Employment | |
| Employed | 146 (42.7) |
| Unemployed | 86 (25.1) |
| Self-employed | 65 (19.0) |
| Other | 21 (6.10) |
| Monthly Income | |
| Less than 3000 SR | 2 (0.60) |
| 3000-5000 | 142 (41.5) |
| 5000-10000 | 42 (12.3) |
| 10000-15000 | 156 (45.6) |
| Home Location | |
| Rural | 57 (16.7) |

| | |
|--------------|------------|
| Urban | 267 (78.1) |
| Not answered | 18 (5.30) |

139

140 **Table (2): Disease and medication background of the patients (N=342)**

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| Variable | N (%) |
|---|------------|
| Duration of Illness | |
| Less than 10 months | 53 (15.5) |
| 11-30 months | 130 (37.7) |
| 31-60 months | 103 (30.1) |
| 61-90 months | 47 (13.7) |
| More than 90 months | 9 (2.60) |
| Period of continuous therapy | |
| 1-10 months | 53 (15.5) |
| 11-30 months | 130 (37.7) |
| 31-60 months | 103 (30.1) |
| 61-90 months | 47 (13.7) |
| More than 90 months | 9 (2.60) |
| Duration of illness from the last visiting | |
| 1-4 weeks | 8 (2.4) |
| 5-8 weeks | 64 (18.7) |
| 9-12 weeks | 157 (45.9) |
| 13-16 weeks | 77 (22.5) |
| 17-20 weeks | 26 (7.60) |
| More than 20 weeks | 10 (2.90) |
| Number of tables taking per day | |
| 1-2 | 149 (43.5) |
| 3-4 | 169 (49.4) |
| 5-6 | 14 (1.50) |
| 7-8 | 1 (0.30) |
| 9-10 | 2 (0.60) |
| Don't answer | 7 (2.00) |
| How do administer medication | |
| By self | 311 (90.9) |
| Relatives | 82 (8.20) |
| Physician follow-up medication | |

| | |
|-----|------------|
| Yes | 330 (96.5) |
| No | 12 (3.50) |

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3.3 Patient’s adherence to medication:

146 Medication Adherence Rating Scale (MARS) was used to assess the level of medication adherence for
147 the participants. The scale includes 10 items and examines adherence behavior and attitude toward
148 medication during the past week with relatively simple scoring. Table (3), shows the answers of the
149 participants. Most of the participants (71.6%) said that they forgot to take their medication and 58.1%
150 careless about the time of taking medication. While (59.1%) of them complained that medication makes
151 them feeling tired and sluggish. Scoring less than 6 is considered as non-adherence to medication, table
152 (4). The results showed that 74% of our sample not adherence to medication. Figure (1)

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Table (3): Medication Adherence Rating Scale (MARS) distribution among participants (N=342)

| MARS scale | N (%) | |
|--|------------|------------|
| | Yes | No |
| Do you ever forget to take your medication? | 245 (71.6) | 94 (27.5) |
| Are you careless about the time of taking your medication? | 201 (58.1) | 141 (41.2) |
| When you feel better, do you sometimes stop taking your medication? | 148 (43.3) | 194 (56.7) |
| I take my medication only when am sick? | 94 (27.5) | 248 (72.5) |
| I stop medication when I feel worse | 154 (45.1) | 188 (55.0) |
| Is it unnatural for my mind and body to be controlled by medication? | 102 (29.0) | 240 (70.2) |
| Are my thoughts clearer on medication? | 157 (45.9) | 185 (54.1) |
| By staying on medication, I cannot prevent getting sick? | 96 (28.1) | 243 (71.1) |
| I feel wired like a “Zombie” on medication | 139 (40.7) | 203 (59.4) |
| Medication makes me feel tired and sluggish | 202 (59.1) | 140 (40.9) |

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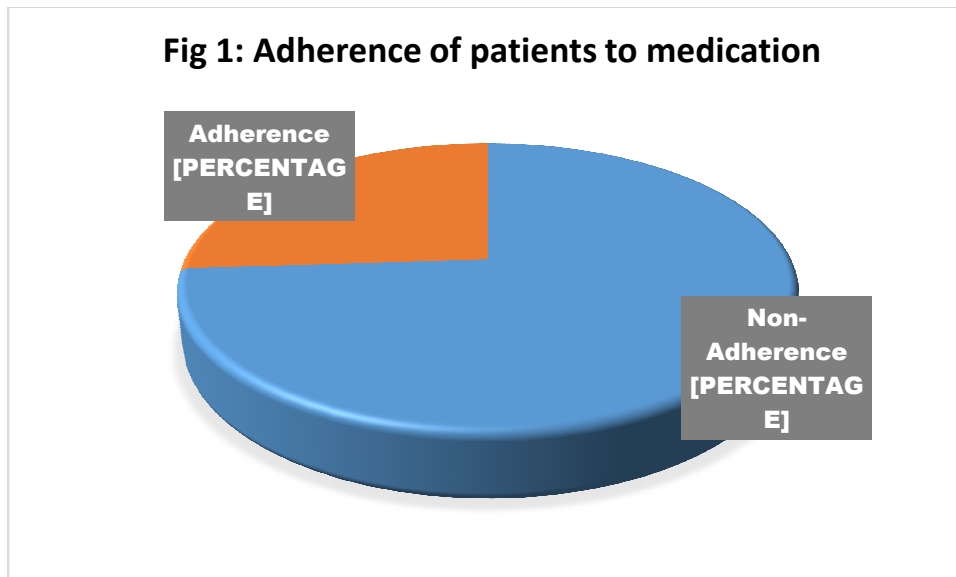
163 **Table (4): Adherence of patients to medication according to MARS scale**

164

| MARS | N | % |
|---------------|-----|----|
| Non-adherence | 253 | 74 |
| adherence | 89 | 26 |

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Figure (1): Adherence of patients to medication according to MARS scale

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170 Results of this study showed a significant relationship between the educational level of participants and
 171 adherence to medication ($P < 0.05$). Patients with Ph.D. were more adherent to medication (80%) followed
 172 by patients with master degree (53.8%). In addition, a significant relation was found between diagnosis
 173 and adherent; patients diagnosed with the psychotic disorder (12.3%) were the least adherent while
 174 whom with an anxiety disorder were the most adherent (37.4%) in this study.

175 No significant existed between sex and ages with related to medication adherence. Either, there is no
 176 significant between duration of illness, a period of continuous therapy, and medication adherence ($P >$
 177 0.05), table 5.

178 Percentage and frequency of the ways to reduce non-adherence to medication are shown in figure 2

179 **Table (5): cross-tabulation about the relation between adherence and sociodemographic and**
 180 **background of the patients (N=342).**

| Variable | Adherence | Nonadherence | P value |
|-------------------------------------|------------------|---------------------|----------------|
| Sex | | | 0.247 |
| Male | 35 (23.5) | 114 (76.5) | |
| Female | 52 (27.4) | 138 (72.6) | |
| Age | | | 0.354 |
| 18-29 | 7 (15.6) | 38 (84.4) | |
| 30-39 | 50 (27.5) | 132 (72.5) | |
| 40-49 | 20 (29.0) | 49 (71.0) | |
| 50-59 | 10 (23.3) | 33 (76.6) | |
| 60-65 | | | |
| Education | | | 0.001* |
| Illiterate | 3 (15.0) | 17 (85.0) | |
| Pre-college | 17 (16.3) | 87 (83.7) | |
| Diploma | 19 (23.2) | 63 (76.8) | |
| degree | 37 (32.3) | 78 (67.8) | |
| Master | 7 (53.8) | 6 (46.2) | |
| PhD | 4 (80.0) | 1 (20.0) | |
| Diagnosis | | | 0.007* |
| Depressive disorder | 28 (23.3) | 92 (76.7) | |
| psychotic disorder | 9 (12.3) | 64 (87.7) | |
| Bipolar disorder | 15 (30.0) | 35 (70.0) | |
| Anxiety disorder | 34 (37.4) | 57 (62.6) | |
| Experience co-morbidity | | | |
| Yes | 47 (27.6) | 123 (72.4) | 0.238 |
| No | 40 (23.7) | 129 (76.3) | |
| Duration of illness | | | 0.926 |
| Less than 10 months | 15 (28.8) | 37 (71.2) | |
| 11-30 months | 31 (24.4) | 97 (57.6) | |
| 31-60 months | 25 (24.8) | 79 (75.2) | |
| 61-90 months | 14 (29.8) | 33 (70.2) | |
| More than 90 months | 2 (22.2) | 7 (77.8) | |
| Period of continuous therapy | | | 0.909 |
| 1-10 months | 15 (28.8) | 37 (71.2) | |
| 11-30 months | 29 (24.0) | 92 (76.0) | |

| | | | |
|---|------------|------------|-------|
| 31-60 months | 23 (24.0) | 73 (76.0) | |
| 61-90 months | 14 (29.8) | 33 (70.2) | |
| More than 90 months | 2 (22.2) | 7 (77.8) | |
| Duration of illness from the last visiting | | | 0.380 |
| 1-4 weeks | 1 (16.7) | 5 (83.3) | |
| 5-8 weeks | 18 (28.2) | 46 (71.9) | |
| 9-12 weeks | 42 (26.8) | 115 (73.2) | |
| 13-16 weeks | 15 (19.5) | 62 (80.5) | |
| 17-20 weeks | 6 (23.1) | 20 (76.9) | |
| More than 20 weeks | 5 (50.0) | 5 (50.0) | |
| How do administer medication | | | 0.592 |
| By self | 81 (26..0) | 230 (74.0) | |
| Relatives | 6 (21.4) | 22 (78.6) | |
| Physician follow up medication | | | 0.866 |
| Yes | 85 (25.8) | 245 (74.2) | |
| No | 2 (28.6) | 5 (71.4) | |

181 * Significant different: P < 0.05

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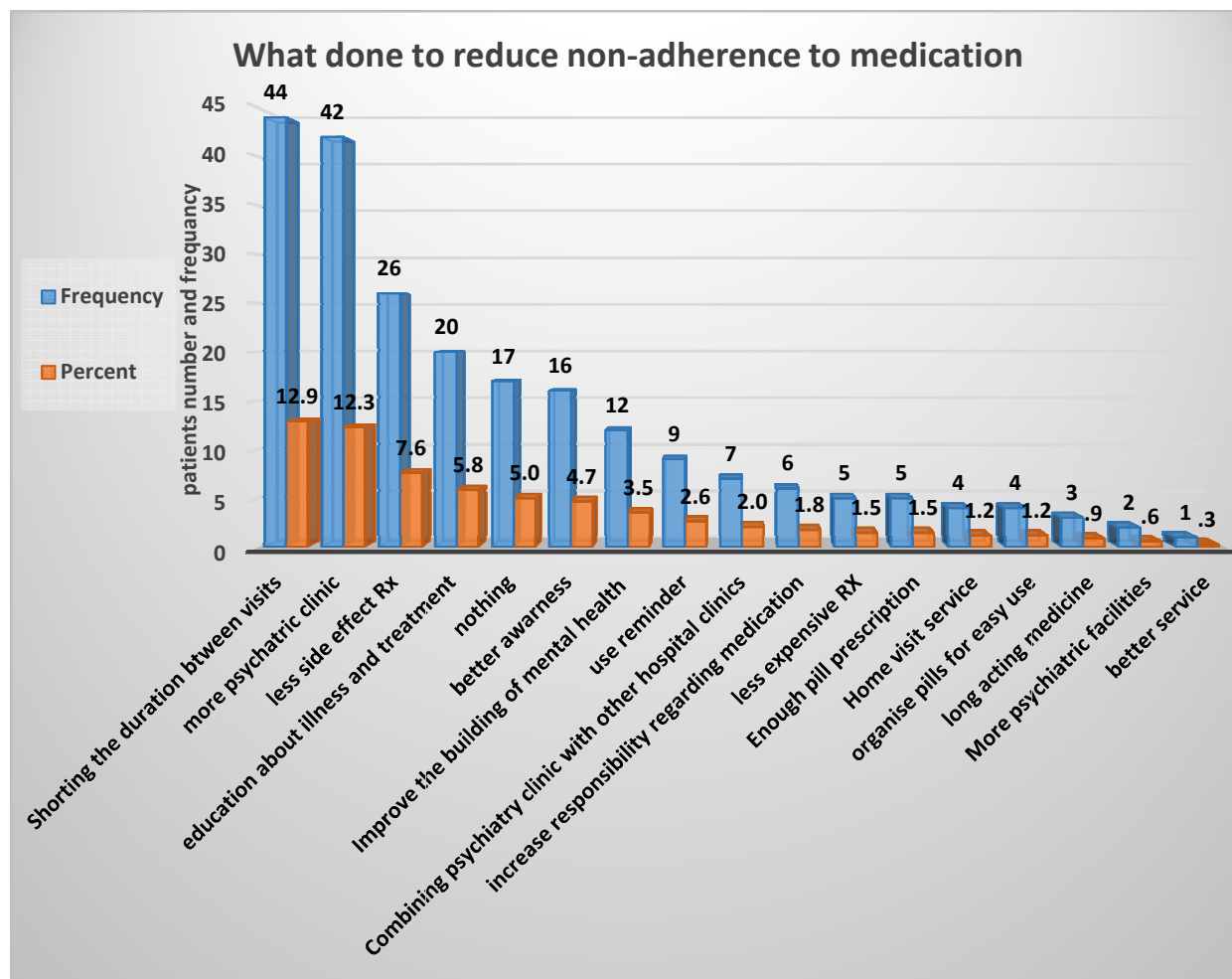
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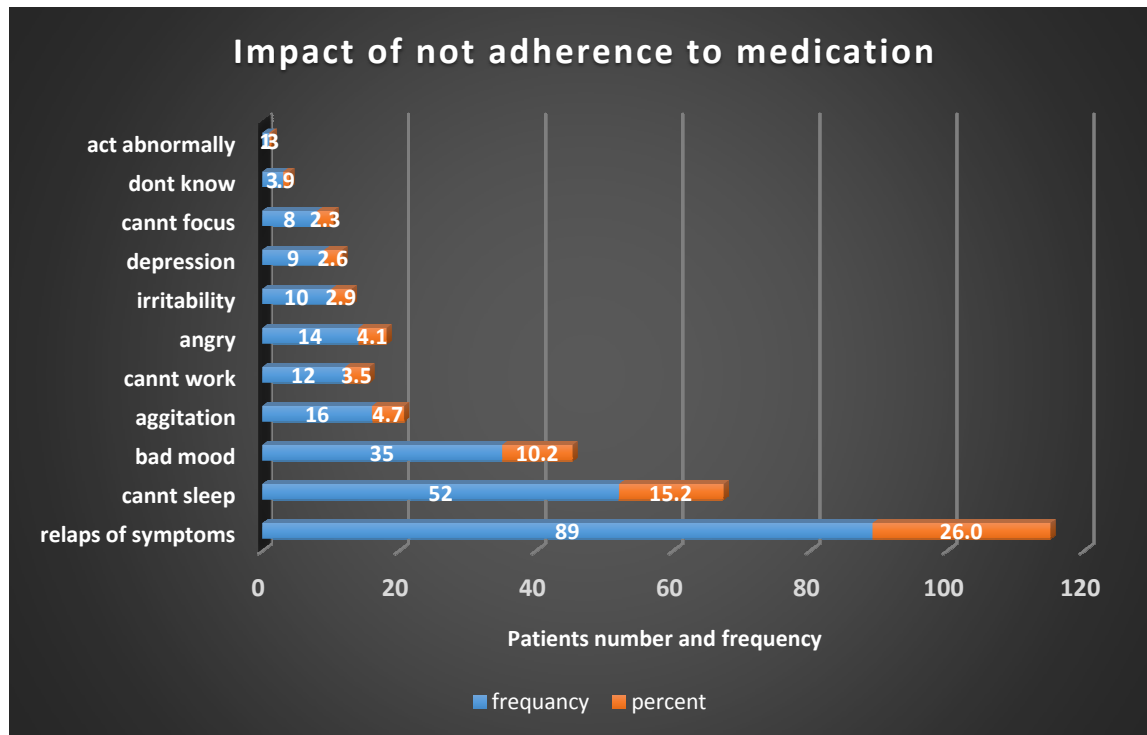
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189 **Figure (2): what done to reduce nonadherence to medication**

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191 Percentage and frequency of impact of not adherence medication are shown in figure 3
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 194 **Figure (3): Impact of not adherence to medication**

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197 **3.4 Linear regression analysis for variables associated with nonadherence**

198 The independent medication-related predictors of nonadherence that found in this study were; the
 199 number of tablets taken per day followed by diagnosis and experiencing comorbidity (Odds Ratio (O.R) =
 200 1.056, P ≤ 0.05). (table 6)

201

202 **Table (6): Linear regression analyses of variables.**

| | Coefficients^a | | | | |
|---|------------------------------------|-------------------|----------------------------------|----------|-------------|
| | Unstandardized Coefficients | | Standardized Coefficients | | |
| | B (odd ratio) | Std. Error | Beta | t | Sig. |
| Age | .447 | .286 | .090 | 1.563 | .119 |
| Marital status | -.154 | .173 | -.050 | -.888 | .375 |
| Employment | .184 | .205 | .052 | .897 | .370 |
| Monthly income | .253 | .262 | .055 | .967 | .335 |
| Diagnosis | -.515 | .187 | -.150 | -2.750 | .006* |
| Experiencing comorbidity | 1.270 | .482 | .148 | 2.634 | .009* |
| Duration of illness | .903 | 4.056 | .605 | .223 | .824 |
| How long have you been in continuous therapy | -.749 | 4.055 | -.502 | -.185 | .854 |
| Duration of illness from last visiting | -.275 | .241 | -.064 | -1.144 | .254 |
| Number of tablet taking per day | 1.056 | .201 | .306 | 5.241 | .000* |
| How do administer medication | .331 | .935 | .021 | .354 | .724 |
| Physician follow up medication | 2.217 | 1.735 | .072 | 1.278 | .202 |

^a: Dependent Variable: nonadherence scale

*: Significant difference

203

204 **4. Discussion:**

205 This study estimated the prevalence rate of nonadherence and determined the medication-related correlates of non-
 206 adherence among patients with the psychiatric disorder. In the present study, among the 342 psychiatric patients,
 207 (74%) were nonadherent to medication. Level of non-adherent found in our study was agreed with that found by Taj
 208 *et al.* [14] who also showed that 76% of patients were non-adhere. Our finding is more than findings reported by
 209 Nirojini, *et al.* [15] who found that (67%) of the patients became nonadherent. Also, Mukattash, *et al.*, [16] where
 210 (64.2%) of psychiatric patients were nonadherent. Findings also higher than that found by Ibrahim, *et al.*, [17] where

211 (54.2%) of the subjects were nonadherent, Gurmu, *et al.*, [18] whom recorded (50.2%) of non-adherent patients and
 212 Kenfe, *et al.*, [19] whom reported a non-adherence of (41.2%).

213 According to our findings, forgetting to take medications (71.6%), careless about the time of taking medication
 214 (58.1%), and feeling tired and sluggish when taking medication (59.1%) were the most commonly reported reasons
 215 for nonadherence. These reasons were also reported by Kenfe, *et al.*, [19]. They reported that 78.2% forgetting to
 216 take medication and 35.6% felt better when they stop the medication. Fawad and Mansoor [20] also found that
 217 forgetting to take medication (36%) is the main reason for medication nonadherent.

218 Our results showed that (96.5%) of the participants, the physician follow up their medication, and 90.9% taking their
 219 medication by themselves, while (49.4%) consuming 3-4 medication per day. This result is higher than that reported
 220 by Nirojini, *et al.* [15] who reported that 63% of the patients are consulting the physicians regularly and 58% of the
 221 patients are taking the medications on their own while 42 % of the patients are depending on their care takers. Also,
 222 Taj *et al.* [14] where 58% of the patients are taking the medications on their own and 42 % of the patients are
 223 depending on their caretakers. Nirojini, *et al.* [15] reported that 67% of the patients became non-adherent because of
 224 lack of knowledge about the medicines and their benefits and 24% of the patients became non-adherent because of
 225 the increased number of medications as most of these patients are consuming 5 to 8 medications per day.

226 Dosing frequency was the strongest predictor of medication-related nonadherence in this study. Linear regression
 227 analysis showed that the independent medication-related predictors of nonadherence found in this study were; the
 228 number of tablets taken per day ($P = 0.000$) followed by diagnosis ($P = 0.06$) and experiencing comorbidity ($P =$
 229 0.09). In agreement with our result, Ibrahim *et al.*, [17] found that the independent medication-related predictors of
 230 nonadherence were the multiple dosing frequencies (Odds Ratio (O.R) = 7.843, $P \leq 0.001$), in addition, Nirojini,
 231 [15] found that the most reported reasons for nonadherence included increased number of medications (24%).
 232 Pfeiffer *et al.* [21] have also reported an inverse relationship between dosing frequency and medication adherence
 233 among patients. Ibrahim, *et al.*, [17] found that the possible reasons for this outcome are the tendency of forgetting
 234 to take the medications as prescribed when the dosing frequency is high, some of the medications side effects
 235 particularly sedation and cognitive impairment may hinder adherence in subjects with busy work schedules, and the
 236 discomfort associated with taking the medications severally on daily basis.

237 Regarding the impact of non-adhering to medication, our findings indicated that (25%) of patient recorded that
 238 nonadherent to medication relapse their symptoms, (15.2%) cannot sleep, (10.2%) will have a bad mood. To reduce
 239 nonadherence to medication, (26%) of patients preferred to use less side effect medication and 20% need more
 240 education for more adherence. Ibrahim *et al.*, [17] agreed that the side effect profile of medication contributes
 241 significantly to non-adherence to psychotropic medications. A study by DiBonaventura *et al.* [22], on the impact of
 242 side effects on medication adherence among psychiatric patients, also revealed a similar outcome.

243

244 **5. Conclusion:**

245 The result of the study showed that nonadherence among psychiatric patients is high. Nonadherence
 246 remains a significant challenge for patients with psychiatric disorders, physicians, and healthcare systems
 247 which resulting in poorer outcomes for patients. Though the predictors of nonadherence among
 248 psychiatric patients are multifactorial, the strongest determinants in this study were the increased number
 249 of medication, the presence of side effect, and forgetting of taking medication. According to this we
 250 recommend adhering to monotherapy except when the use of multiple drugs becomes compelling and
 251 takes consideration the side effects of medications.

252 **6. Consent form:** Informed consent was obtained before entry into the study.

253

254 **7. Ethical Approval:**

255 The research was conducted according to the ethical principles of medical research developed by the
256 World Medical Association Declaration of Helsinki. Approval was obtained from the admiration of King
257 Abdulaziz hospital and the ethical committee.

258

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