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# Should patients be informed about the side effects of psychotropic drugs? According to us: Yes

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ABSTRACT

*Background:* In our daily clinical practice, we observe that patients who were informed about the probable side effects of any medication experience less side effects. For this reason, we decided to examine this in a systematic investigation.

*Methods:* We divided patients into two groups, the informed and uninformed one about side effects of the drugs. During the control examination, tolerability of the drugs given was questioned in detail.

*Results:* At the end of one month, the mean total UKU score was statistically significantly lower in patients from the informed group compared to that of the uninformed one ($p < 0.05$). The proportion of patients who discontinued the drug during the one month-period was statistically significantly higher in the uninformed group compared to informed group 9% in the informed group vs. 25% in the uninformed group) ($p < 0.05$).

*Conclusions:* Finally, we found that giving information about the side effects of a psychopharmacological agent seems to be useful and to provide beneficial effects on the tolerability of the drug, independent of the kind of psychotropic agent.

## 1. Introduction

The interaction between physicians and patients and the patient's treatment expectations can have remarkable results on the outcome of a course of medical treatment of patients. These remarkable effects may be positive and negative. Drugs utilizing in medicine have a lot of favorable effects, however, they have also some unwanted effects and may cause adverse reactions. Trials revealed that approximately 6.5% of patients applying to hospitals were associated with an adverse drug reaction (Davies et al., 2009). These adverse effects of drugs are unwanted, boring, and unintended consequences of medications which may occur at normal doses (WHO, 1972). As expected, adverse events of the drugs can considerably reduce the adherence and compliance to the treatment. On the other hand, this condition causes to increase the health costs because of changing treatment regimes. We should note that all adverse effects are not linked to the direct physiological action of drugs (Faasse and Petrie, 2013). A study revealed that solely one-tenth of adverse reactions experienced by patients who took the most prescribed drugs may be related to clearly attributable to the medication (Faasse and Petrie, 2013). At just this point, we should mention the nocebo phenomenon. The word nocebo was defined as new and worsening symptoms that are caused only by negative expectations and to give a name to the negative equivalent of placebo phenomena and distinguish between desirable and undesirable effects of placebos (Häuser et al., 2012).

In the literature of medicine, there is so limited knowledge about the effects of information on side effects of the drugs on drug compliance. (Howland et al., 1990) evaluated ninety-eight adults treated with an antibiotic agent for a variety of diseases were randomized to two separate groups, the informed group who received an information about side effects of the drug, and the uninformed one without any information about the side effects of the drug. The authors found that one-tenth of patients without information and 8% of the informed group reported any side effect and revealed that there were no significant differences in the existence of different individual side effects, with a similar compliance with treatment and the results of treatment for both groups. Consequently, in that study, informing patients about adverse events of treatment did not have any detectable adverse effects. (Webster et al., 2017) aimed to examine the patient information leaflets how to affect the expectations of adverse effects and to determine factors related to these side-effect expectations. In that cross-sectional online survey, the current use of verbal descriptors to communicate

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**Table 1**
Sociodemographic data of the subjects.

| | | Informed group | | Uninformed group | | p |
|---|---|---|---|---|---|---|
| | | *n* | % | *n* | % | |
| Gender | F | 40 | 71.4 | 46 | 76.7 | >0.05 |
| | M | 16 | 28.6 | 14 | 23.3 | |
| Marital status | Single | 19 | 3.,9 | 15 | 25.0 | > 0.05 |
| | Married | 35 | 62.5 | 45 | 75.0 | |
| | Widowed | 2 | 3,6 | 0 | 0 | |
| Education | Uneducated | 0 | 0 | 6 | 10.0 | > 0.05 |
| | Primary | 22 | 39.3 | 16 | 28.4 | |
| | Secondary | 5 | 8.9 | 11 | 18.3 | |
| | High | 16 | 28.6 | 14 | 23.3 | |
| | University | 13 | 23.2 | 12 | 20.0 | |
| Occupation | Housewife | 26 | 46.4 | 35 | 58.3 | >0.05 |
| | Student | 8 | 14.3 | 5 | 8.3 | |
| | Official | 9 | 16.1 | 7 | 11.7 | |
| | Worker | 2 | 3.6 | 2 | 3.3 | |
| | Others | 4 | 7.1 | 4 | 6.7 | |
| | Unoccupated | 7 | 12.5 | 6 | 10 | |
| | Retired | 0 | 0 | 1 | 1.7 | |
| Application type | First | 20 | 35.7 | 18 | 30.0 | >0.05 |
| | Under treatment | 36 | 64.3 | 42 | 70.0 | |
| Age | | 35.95 ± 11,88 | | 40,15 ± 11,88 | | >0.05 |

adverse effect risk in the patient information leaflet caused to high side-effect expectations, probably linked to nocebo induced drug adverse events experienced by patients (Webster et al., 2017).

In Turkey, in daily practice, informing about the side effects of psychotropic drugs is not a common condition. Moving from the point that in our daily practice, we observe that patients who were informed about probable side effects of any medication experience less side effect and have much more tolerability to drugs, we decided to examine this in a systematic investigation.

## 2. Materials and methods

This study was performed at Firat University, School of Medicine, Department of Psychiatry, Elazig, Turkey. Included patients were outpatients who applied to our out-patient unit. The study was approved by the Local Ethics Committee at Firat University School of Medicine. All the study procedures were accordingly executed by the 1983 version of the Helsinki Declaration of 1975 (Kemperman, 1982). To include in the study, it was a requirement to take written informed consent. All subjects gave their written informed consent, with a document signed. As in our previous investigations, anonymity for patients was taken carefully. Totally two hundred consecutive patients were included into the present study. One hundred patients were included in the informed group and others were taken in the uninformed one. The study did not include strict inclusion and exclusion criteria. We included all patients who were in the age range of 18 to 65 years old and were given any psychotropic drugs because of any psychiatric indication arranged by the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) diagnostic criteria (APA, 2000). We excluded some patients who had mental retardation, or serious medical illness such as hepatic insufficiency, severe heart and renal failure which limited the use of psychotropic agents.

### 2.1. Study procedure

As mentioned above, we divided patients in two groups: informed group and uninformed one. Consecutive patients were included in groups in order. Participants were blind to study but the investigators were knowing that which patient was at which group. We did not make any explanation about side effects of the psychotropic agent given to the uninformed group at baseline. But, it was told to patients in the uninformed group that they could apply to us if they experienced any important side effect, as in the usual approach in daily clinical practice. However, we accounted for all probable side effects of the psychopharmacological agent in detail to patients from the informed group at baseline. After one month, all the subjects of the study were called for a control examination. During the control examination, tolerability of the drugs given was questioned in detail. Apart from this, Ugvalg for Kliniske Undersgelser (UKU) Side Effect Evaluation Scale was used for all subjects. UKU is a 48 item scale consisting of sections regarding psychological, neurologic, autonomous and general. It is the Likert type of scale evaluating each side effect between 0, none and 3, severe. Validity and reliability study of the Turkish form was performed and it was found to be valid and reliable. In the present study, the Turkish form of this scale was utilized (Lingjærde et al., 1987).

### 2.2. Statistical analysis

As in our previous study, the same statistical package program was used. For statistical analyses, we used the Statistical Package for the Social Sciences for Windows software (SPSS) version 16.0 (SPSS, Chicago, IL). For continuous variables, an independent *t*-test was used whereas for categorical variables, chi-square analyses were administered. Analysis of covariance (ANCOVA) was used to control gender and age. When required, for various correlational associations, Spearman's correlation analysis was used. Alpha level of $p < 0.05$ was accepted as statistical significance.

## 3. Results

A total of 116 patients (56 patients from informed and 60 from the uninformed group) completed the survey and were included in the final sample. Demographic information for the participants is presented in Table 1. As can be observed in the table, we did not detect any significant difference between age, socioeconomic status, mean year of education and occupation ($p > 0.05$). This was so important because these variables might have affected our results. When taking into consideration both groups, the most prominent drug group was antidepressant agent particularly selective serotonin reuptake inhibitors (SSRIs), following other antidepressants, atypical antipsychotics, benzodiazepines and mood stabilizers. Drugs used for patients are presented in Table 1. No significant differences concerning drug type between groups were found. At the end of one month period, when comparing UKU subscales between groups, the scores of psychic and