

# Psychoactive Prescription Drug Abuse: Selected Psychological Symptoms and Quality of Life in Addiction Treatment. Study Protocol

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**BACKGROUND:** The abuse of psychoactive prescription drugs has become increasingly common in the Czech Republic. These drugs include sedatives, hypnotics, anxiolytics (benzodiazepines and Z-hypnotics), and opioids. Patients with an addiction to these prescription drugs exhibit symptoms associated with long-term use, particularly psychological and somatic problems, sleep disturbances, impaired cognitive functioning, and irritability. There is a need for a flexible response to their needs. **AIMS:** The aim of the research is to describe selected psychological symptoms and the quality of life of psychoactive drug abusers in addiction treatment. The main outputs of the research will include an overview study and the results of a data analysis.

**METHODS:** Data collection will be carried out in three waves using a questionnaire survey consisting of standardised questionnaires. It will be conducted at the patient's admission to the addiction treatment clinic, and, while in treatment, three and six months after the first survey. The research will also include a study of

supporting documentation. The questionnaires will be evaluated according to the procedure manual for each standardised questionnaire. The qualitative data analysis will use a combination of a descriptive approach and selected qualitative data analysis techniques (pattern capture method, compare & contrast method). For the quantitative data analysis, exploratory analysis procedures will be used in combination with a descriptive approach. **DISCUSSION:** The prevalence of psychoactive prescription drug abuse continues to rise. Although much research on this topic has been conducted in recent years, we lack studies focusing specifically on the effective treatment of people addicted to psychoactive prescription drugs. The results of this study will provide information on selected psychological manifestations and the quality of life of psychoactive drug abusers in addiction treatment. The data on the relationships between types of substances used, patterns of use, the treatment phase, selected psychological symptoms, and the quality of life may also be of value.

**Keywords** | Prescription Drug Abuse – Prescription Medication Abuse - Psychological Symptoms – Psychiatric Symptoms – Quality of Life – Addiction Treatment

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## 1 THEORETICAL BACKGROUND

### 1.1 Psychoactive prescription drug abuse

In the Czech Republic the abuse of psychoactive prescription drugs has increased dramatically in recent years. Definitions of drug abuse often overlap; that is why the following definition has been proposed: *“Any use of a prescription drug, the consumption of which has been proved to be problematic. e.g. the use of a drug with or without a prescription, but clearly outside accepted medical practice or guidelines, for recreational purposes (for the intoxicating effects of the treatment), or as self-medication, where the risks and problems associated with the use outweigh the benefits.”* (Mravčík et al., 2021).

The most problematic groups of drugs include sedatives, hypnotics, anxiolytics (especially benzodiazepines and Z-hypnotics), and opioids. Other frequently abused prescription drugs include stimulants or antiepileptic drugs (especially pregabalin). The indication of these drugs is a simple and often very effective way to address common symptoms of a wide range of illnesses. These symptoms may include anxiety and depressive disorders, sleep disorders, tension, restlessness, and acute or chronic pain. Drug abuse can cause serious health problems, especially addiction, which is often iatrogenic in origin, but can also lead to many social and economic problems (Hřebíková, 2012; Isaacson et al., 2005; Mravčík et al., 2021; Lipari et al., 2017; Schifano et al., 2018; Tardelli et al., 2021).

There are certain precautions and procedures that should be adhered to in prescribing psychoactive drugs. These medications should only be prescribed by a physician for a short period of time, not exceeding four weeks (Lader et al., 2009); at the same time, the underlying problem should be addressed intensively in different ways so that the patient can use other treatment after discontinuing the above medications. However, there is a problem with chronic disorders and multiple physicians prescribing these medications. The e-prescribing system is meant to avoid the issue of the inappropriate prescription of medicine or over-prescribing. The system is linked to a repository of information about a particular patient in order to avoid the problems described above (Švihovec et al., 2018).

### 1.2 Psychoactive prescription drug use in the adult population in the Czech Republic

A total of 14.9% of adults aged 15 years and over (9.9% of the men and 19.7% of the women) fell into the category of problematic use of psychoactive prescription drugs (i.e. these people had taken the medication for more than six weeks, they felt they had taken the medication in larger quantities over the last 12 months, or they obtained medication other than by prescription); of these adults, 12.1% (7.1% of the men and 17.0% of the women) and 6.1% (5.1% of the men and 7.1% of the women) had a problematic pattern of use of sedatives/hypnotics and opioids, respectively. When extrapolated to the entire population of the Czech Republic aged 15+ years, this is a total of 1.35 million people showing signs of the problematic use of psychoactive prescription drugs (Mravčík et al., 2021).

### 1.3 Effects of psychoactive prescription drug abuse

The abuse of psychoactive prescription drugs is associated with adverse effects and long-term negative psychological, physical, and even social consequences. The overall quality of life decreases, and the individual's family, work, and social functioning, as well as mental health, are disrupted. The most common problems include anxiety and depressive states, sleep disturbances, internal tremors or shivers, physical tension, muscle aches, headaches, weakness, fatigue, or inefficiency. Patients may also suffer from cognitive impairment (memory impairment, sometimes leading to states of confusion and a differential diagnosis of dementia), and also paradoxical reactions in the form of rage, aggressiveness, irritability, loss of motivation, paranoid delusions, or hallucinations; the rebound phenomenon is also among those described. Somatic symptoms (e.g. abdominal pain, neuralgia, paraesthesia, tachycardia) may mimic a severe acute somatic disease (Chalany, 2014; Kalina, 2015; Mravčík et al., 2021; Lattová, 2009). Particularly seniors are at risk of developing addiction and the associated psychiatric and somatic complications, loss of vitality, and impaired motor coordination, including the risk of falls, injuries, and accidents (Mravčík et al., 2021). Psychoactive prescription drug abuse is also associated with other substance use, behavioural addictions, a higher risk of suicide, premature death, and poorer overall resilience (Haukka, 2017; Tam, 2020; Tardelli et al., 2021).

Recognising the abuse of psychoactive prescription drugs can take quite a long time, especially if the drugs are prescribed to a person for chronic conditions. Medication may be taken covertly, when the person is alone, which can delay the resolution of the problem. Often, however, the family and healthcare system support the patient in taking medication (Marádová, 2006). There are many factors contributing to the emergence or exacerbation of the problem, which involve the user, the addictive substance, or the environment, and which can be analysed, for example, from the point of view of the bio-psycho-socio-spiritual model of the emergence and development of addiction (Griffiths, 2005).

The abuse of these prescription drugs, like the abuse of other addictive substances in general, requires individual and continuous treatment. In the Czech Republic in 2018, 56% of cases received supportive pharmacotherapy in the treatment of addiction to sedatives and hypnotics (ÚZIS, 2019a); it is the highest percentage of all the addiction groups studied. Detoxification was provided in 21% of cases and included the longest average length of hospital stay for detoxification compared to other substances (ÚZIS, 2019b).

### 1.4 Present state of knowledge

The effects of the use of psychoactive prescription drugs are not systematically monitored in the Czech Republic. The number of users has gradually increased in recent years. The number of people addicted to psychoactive prescription drugs can be estimated at up to 1 million. The treatment of

these users is an integral part of the addiction treatment system and takes place in both outpatient and residential settings (Mravčík et al, 2021). It has its own specific features, with users being more likely to fail to complete their addiction treatment programme and to relapse. There is also a need to respond flexibly to their needs, given the steadily increasing trend of psychoactive drug use.

## 2 RESEARCH PROBLEM

The prevalence of psychoactive drug abuse continues to rise. Although much research on this topic has been conducted in recent years, we lack studies focusing specifically on the effective treatment of people addicted to psychoactive prescription drugs.

In the Czech Republic, the population's attitudes towards the use of psychoactive prescription drugs have long been tolerant, and the use of these drugs is more acceptable than the use of other addictive substances, including tobacco. Patients show symptoms resulting from the long-term use of these drugs, especially psychological or somatic symptoms, sleep disturbances, impaired cognitive functioning, or irritability. One of the possible ways to describe this phenomenon could be to systematically assess psychological symptoms as the actual psychological distress they experienced as a result of their self-rated health problems. This will enable the verification of the presence of most of the existing psychological symptoms and appropriate reactions to them.

One of the main components of high-quality healthcare is what is termed patient-centred care. An important component that contributes significantly to this care is the activation of the patient, who is encouraged to participate in the treatment of the illness. The degree of self-efficacy determines how much effort and time the individual puts into solving the problem so as to achieve the expected outcome or goal, and how long he or she persists in the face of obstacles and complicating circumstances (Hodačová et al., 2020). The self-efficacy measure is a predictor of health behaviours, which is why it was selected for the study.

The quality of life of people abusing psychoactive prescription drugs is another important indicator that will be investigated. The study of the quality of life reflects the current trend of blending social science and biomedical approaches into the study of human behaviour. In medicine and healthcare, its practical impact is an effort to change the approach to the care provided to patients. The use of this tool provides information about an individual's satisfaction and perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, and standards.

## 3 AIMS

The main purpose of the research is to describe selected psychological manifestations and the quality of life of people abusing psychoactive prescription drugs in addiction treatment. The aim is to describe selected psychological manifestations (e.g. psychiatric symptoms such as anxiety or depression, self-confidence, subjective perception of pain, self-efficacy) and the quality of life in treatment over time (at admission to treatment and after three months and after six months in treatment) using a battery of questionnaires.

### Research questions:

- Do psychoactive prescription drug abusers show impairment in selected psychological functions and quality of life? If so, how do they differ from the norms?
- How do selected psychological functions and quality of life develop in psychoactive prescription drug abusers over the course of addiction treatment (after three and six months)?

The main outputs of the research will include a minimum of two articles in impact journals. One article will present the results of the preliminary phase in the form of an overview study focusing on psychological manifestations and the quality of life of psychoactive drug abusers in addiction treatment. The second article will actually present the results of the analysis of data obtained from the patients of an outpatient addiction treatment clinic.

## 4 METHODS

### 4.1 Research sample

The population consists of adult psychoactive prescription drug abusers living in the Czech Republic. In this project, I follow the definition of abuse according to Mravčík et al. (2021); see Chapter 1 – Background.

Extrapolated to the entire population of the Czech Republic aged 15+, there are a total of 1.35 million individuals showing signs of problematic use of psychoactive prescription drugs, of whom 430 thousand are men and 900 thousand are women. The use of psychoactive prescription drugs increases with advancing age, with prevalent use in the population aged 45 and over. Women use sedatives and hypnotics more than men. According to the National Register of Drug Users in Treatment, 63.7% of the users in treatment are women. While the use of opioid analgesics is prevalent in younger age groups, the use of sedatives and hypnotics significantly prevails over opioids in age groups over 35 (Mravčík et al., 2020; Mravčík et al., 2021).

According to the Czech National Register of Drug Users in Treatment, the number of applicants for treatment for addiction to sedatives and hypnotics totalled 350 in 2019. The number of applicants for treatment for opioid addiction was 1470, of whom 162 were users of opioid analgesics or opioids other than heroin (Mravčík et al., 2020). The Register nevertheless

does not cover the entire addiction network; consequently, we can estimate much higher numbers. 37,156 patients with substance-related problems were treated in psychiatric outpatient clinics in 2019, of whom 1,933 were treated for disorders caused by the use of sedatives and hypnotics; of that number, 899 used benzodiazepines, 47 used barbiturates, and 987 used other prescription drugs. 4,082 opioid users were in contact with psychiatric outpatient clinics in 2019, of whom 848 were heroin users, 326 used non-indicated buprenorphine, 23 used non-indicated methadone, and 2,885 used other substances.

The research sample consists of adult individuals who live in the Czech Republic, are abusing psychoactive prescription drugs, and used the services of an outpatient addiction clinic during the research.

Considering the research aim and objectives, a random selection method has been chosen, working with an institution where the research participants will be selected according to predetermined criteria (Miovský, 2006). Only persons meeting the following criteria are eligible to be included in the research: patients treated at the outpatient addiction treatment clinic at the Department of Addictology of the 1st Faculty of Medicine, Charles University, and the General University Hospital, over 18 years of age, who meet the definition of psychoactive drug abuse, agree to participate in the study, and enter the research voluntarily. Participation in the research will be offered to the patient, so the patient's consent is a condition.

In 2021, 33 psychoactive prescription drug abusers were treated at the outpatient addiction treatment clinic (internal material). The estimated number of respondents for the period 2022 to 2025 is 70; however, to determine the minimum sample size a power analysis will be used.

## 4.2 Data collection

The data collection will be carried out at the Department of Addictology, specifically at the outpatient addiction treatment clinic. The Department of Addictology is a scientific and clinical workplace of the First Faculty of Medicine, Charles University in Prague and the General University Hospital in Prague. The Department engages in outpatient treatment, inpatient clinical treatment, and education and research in the field of addictology (Department of Addictology, 2020).

The data will be collected in three waves using a questionnaire survey consisting of the standardised questionnaires described below. It will be conducted upon a patient's admission to the outpatient addiction treatment clinic and after three months and after six months in treatment from the date of the first survey. The research will also include a study of the respondents' documentation.

At the beginning of the questionnaire, several questions are included that examine the socio-demographic situation of the respondents, which is essential to describe the research population. For the purpose of the research, a questionnaire battery has been selected as the research instrument, which is

designed to contain the necessary items to fulfil the research aim. The questionnaire battery includes a brief introduction, socio-demographic questions, a question focusing on addiction and psychiatric history, and a combination of several standardised questionnaires:

**SCL-90** – The Symptom Checklist is designed to assess the current psychological distress through subjective assessment of health problems. It allows the verification of the presence of most existing psychological symptoms such as depression, hypochondriasis, psychotic behaviour, anxiety, obsession, interpersonal sensitivity, phobia, hostility, and paranoia. The reliability and validity of the questionnaire indicate the high discrimination of this questionnaire in sifting and determining mental health condition in individuals (Bieščad & Szeliga, 2005; Hoseinifar et al., 2011). It is frequently used in psychotherapy research and clinical practice (Schmitz et al., 2000).

**BAI and BD II** – Beck Anxiety Inventory and Beck Depression Inventory are chosen to be used because depression and anxiety are perhaps the two most common psychological symptoms and they often coexist. In fact, depressive and anxiety disorders are the most common comorbid psychiatric illnesses in both the general and clinical populations. Psychoactive prescription drug abusers often suffer from anxiety and/or depression. The BAI is a 21-item instrument to measure the severity of anxiety symptoms. The BDI is a 21-item questionnaire designed to assess the degree of depressive symptoms present over a two-week period (Lee et al., 2018).

**GSES** – the Czech version of the General Self-Efficacy Scale (GSES) by Jerusalem and Schwartz (Křivohlavý, 1993). One factor that is closely associated with addiction is the concept of self-efficacy. It is the confidence in one's ability to cope with difficult and challenging situations. Therefore, considering the importance of self-efficacy beliefs in health-related behaviours and psychopathology, tool validation to measure the self-efficacy construct among psychoactive prescription drug abusers seems necessary (Farnia et al., 2020).

**WHOQOL-BREF** – World Health Organization Quality of Life Assessment is a test to measure the quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, and standards. It is an established outcome measure of substance use disorder treatment as it captures the repercussive impacts of the illness in many areas of life that may not be identifiable through normal clinical practice. (Bowling, 2005; Muller et al., 2019; WHO, 2004).

Before the commencement of the actual research, a pilot study will be carried out to serve as a basis for any necessary adjustments to the structure of the questionnaire battery to arrive at the final version.

## 4.3 Data analysis

The data processing and the preparation for data analysis depend on the data obtained in the form of questionnaire survey

scores. The questionnaires will be evaluated according to the procedure manual for each standardised questionnaire used and the data will be further processed. The whole process – i.e. data collection, processing, validation, and retention – will be in compliance with the Clinical Data Management process (CDM), which guarantees the reliability and accuracy of the data and, ultimately, the reliability and correctness of the results of the entire study (Kadlecova, 2007). The qualitative data analysis will use a combination of a descriptive approach and selected qualitative data analysis procedures (pattern capture method and compare & contrast method). The descriptive approach can be seen as the foundation of analytical work that allows us to proceed with high-quality interpretation; according to Miovský (2006), the use of description alone is deficient, and therefore the descriptive approach will be combined with other analytical methods: the pattern capture method will be used to capture common patterns in patients abusing psychoactive prescription drugs and, subsequently, the contrast & compare method will be used to compare the differences between those patients over time. As stated by Miovsky (2006), the contrast method is well suited if we want to distinguish and highlight the differences between pre-defined categories. Exploratory analysis procedures will be used for the quantitative data analysis. The method will be combined with a descriptive approach.

Specific generated codes will be randomly assigned to patients. Each patient will be maintained under this code throughout the entire study. Data that could lead to the identification of the patients will be anonymised.

#### 4.4 Ethics

The ethical aspects of the research will be addressed both in writing and verbally in the form of an informed consent. A proposal has been submitted to the Ethics Committee of the General University Hospital in Prague to approve the conduct of the research. Respondents will be enrolled in the study after giving their informed consent. Compliance with the ethical standards of the project will also be guaranteed in the data processing; data that may lead to identification of the patients will be anonymised, which will be emphasised when informing the respondents. The respondents will be assigned special codes and any data that could lead to the identification of the respondents will be deleted or altered. The original raw data records will be securely deleted or shredded. Each respondent will be informed in advance about the research process, the content of the questionnaire battery, and the methods to be used in the research. The respondents will have an option to withdraw from the study at any time.

## 5 DISCUSSION

The prevalence of psychoactive drug abuse continues to rise (SAMHSA, 2020). The results of this study will provide information on selected psychological manifestations and the quality of life of psychoactive drug abusers in addiction treatment. The data on the relationships between the types of substances used, patterns of use, the treatment phase, selected psychological symptoms, and the quality of life may also be of value.

The abuse of and/or dependence on psychoactive prescription drugs is one of the health, mental, and social problems in societies. Various studies have reported a high rate of mental disorders among addicts (Hoseinifar et al., 2011). The study will provide a comprehensive profile of an individual with psychoactive prescription drug abuse or dependence and describe the progress and changes in the treatment. On the basis of this information, we can modify addiction treatment to focus on treating the most significant psychological manifestations. This can play an essential role in the treatment and relief of the addiction.

The results of the research will be presented at least at one Czech conference (e.g. the AT conference) and at a foreign conference (e.g. Lisbon Addictions) over the course of the project. The interim results will also be presented to experts at the Society for Addictive Diseases attached to the Czech Medical Association of J. E. Purkyně, or to other experts, especially in the fields of addictology and psychiatry. Last but not least, the results of the project will form part of a dissertation, now in progress.

One of the limitations of the work may be the method used for recruiting respondents, and a risk may be that there will be a small research population which will not allow a good statistical analysis. The random selection method across institutions may also have a negative effect on the reliability of the data. Persons in the same institution may exhibit similar characteristics. The respondents are likely to be from the capital city area only, and, given the nature of the facility, they will be from relatively stable social backgrounds. Therefore, this is another reason why the results may be biased. Last but not least, there may be a risk of a user dropping out of the service and therefore not enough of all three tests being collected.

Patients abusing psychoactive prescription drugs have specific needs and require a specific approach in the context of addiction care. The study may support the quality of addiction care and the need for collaboration across healthcare disciplines. This phenomenon can be used in professional discussions concerning psychiatric reform. The results of the research and their publication may help increase the awareness of professionals and improve the quality of the healthcare provided to the target group of psychoactive drug abusers. Last but not least, they may contribute to the destigmatisation of clients, patients, and the field of addictology per se.

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**Authors' contributions:** KR is the main author and corresponding author. LŠ is the supervisor of the study; she will participate in the data analysis. KR and LŠ proposed the study design.

**Declaration of interest:** There is no conflict of interests involved in this research.

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