Measuring Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) in addiction treatment services: study protocol and baseline characteristics of the OMER-BE study

Amine Zerrouk, Charlotte Migchels, Clara De Ruysscher, Kim Fernandez, Jerome Antoine, Frieda Matthys, Wim van den Brink, Cleo Crunelle, Wouter Vanderplasschen

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[1]Department of Special Needs Education Ghent University (UGent) Ghent BE

[2]Department of Psychiatry Universitair Ziekenhuis Brussel (UZ Brussel) Vrije Universiteit Brussel (VUB) Brussels BE

[3]Department of Epidemiology and Public Health Sciensano Brussels BE

[4]Department of Psychiatry Amsterdam University Medical Centers University of Amsterdam Amsterdam NL

Corresponding Author:
Amine Zerrouk
Department of Special Needs Education
Ghent University (UGent)
Henri Dunantlaan 1
Ghent
BE

Abstract

Background: Traditionally, treatment outcomes in patients with a substance use disorder (SUD) are measured using objective and provider-reported indicators. Recently, there has been a shift towards incorporating Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) to capture service users' perspectives on treatment outcomes and experiences.

Objective: The OMER-BE study (Outcome Measurement and Evaluation as a Routine practice in alcohol and other drug services in Belgium) aims to assess the acceptability and feasibility of PROMs and PREMs in different SUD treatment services, using the recently developed ICHOM Standard Set for Addictions. In this paper, we describe the design and baseline characteristics of the study.

Methods: A convenience sample of 189 treatment seeking individuals with SUD from different inpatient services (therapeutic communities, psychiatric centers) and outpatient treatment services is followed for 6-months. Clinical factors, sociodemographic characteristics and PROMs are assessed at baseline, within 3 weeks after starting treatment. Additionally, PROMs and PREMs are measured 45, 90 and 180 days later.

Results: Baseline differences are observed between the three treatment modalities regarding education, SUD treatment history, primary substance and ADHD self-report scores. Overall, patients in PC are higher educated and have less polysubstance use, while outpatients have fewer previous SUD treatments but receive relatively more often opioid agonist treatment. Inpatients report more ADHD symptoms and higher SUD severity than outpatients. Additionally, recovery strength scores are found to be significantly lower in the outpatient group compared to the other groups, particularly in the subdomains of 'Substance Use,' 'Self-care,' and 'Outlook on Life'.

Conclusions: Measuring PROMs and PREMs appears to be feasible in a diverse group of treatment seeking patients with SUD in Belgium. Routine monitoring of these measures can empower patients, service providers and policymakers by providing a comprehensive understanding of service users' needs and treatment effectiveness.

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Amine Zerrouk[a]

Charlotte Migchels[b]

Clara De Ruysscher[a]

Kim Fernandez[d]

Jerome Antoine[d]

Frieda Matthys[b]

Wim van den Brink[c]

Cleo L. Crunelle[b]

Wouter Vanderplasschen[a]

a. Department of Special Needs Education, Ghent University (UGent), Ghent, Belgium

b. Vrije Universiteit Brussel (VUB), Universitair Ziekenhuis Brussel (UZ Brussel), Department of Psychiatry, Laarbeeklaan 101, Brussels, Belgium

c. Amsterdam University Medical Centers, Department of Psychiatry, University of Amsterdam, Amsterdam, the Netherlands

d. Department of Epidemiology and Public Health, Sciensano, Brussels, Belgium

Corresponding author:
Amine Zerrouk
elamine.zerrouk@ugent.be
Henri Dunantlaan 1
9000 Gent
Belgium

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Results:

Baseline differences are observed between the three treatment modalities regarding education, SUD treatment history, primary substance and ADHD self-report scores. Overall, patients in PC are higher educated and have less polysubstance use, while outpatients have fewer previous SUD treatments but receive relatively more often opioid agonist treatment. Inpatients report more ADHD symptoms and higher SUD severity than outpatients. Additionally, recovery strength scores are found to be significantly lower in the outpatient group compared to the other groups, particularly in the subdomains of 'Substance Use,' 'Self-care,' and 'Outlook on Life'.

Conclusions:

Measuring PROMs and PREMs appears to be feasible in a diverse group of treatment seeking patients with SUD in Belgium. Routine monitoring of these measures can empower patients, service providers and policymakers by providing a comprehensive understanding of service users' needs and treatment effectiveness.

INTRODUCTION

Alcohol and other substance use disorders (SUDs) are linked to a range of adverse psychological, physical and social consequences. Their chronic, relapsing nature and related judicial, housing and relational problems impact individuals with SUDs, as well as their environment and the broader community (Deak & Johnson, 2021, Dennis & Scott, 2007; Kelly, Greene, Bergman, White, & Hoeppner, 2019; McKay & Hiller-Sturmhofel, 2011). SUDs have a significant and growing impact on global morbidity and mortality (Castelpietra et al., 2022; Degenhardt et al., 2018; Whiteford et al., 2013). Worldwide, harmful alcohol use causes three million deaths annually, representing 5.3% of all deaths. Alcohol use accounts for 5.1% of the global burden of disease (WHO, 2022). Furthermore, an estimated 60,000 years of life lost (YLLs) were attributed to drug use in Europe in 2019 (Castelpietra et al., 2022).

Treatment cohort studies conducted in the United States, Australia, and various European countries have shown the benefits of engaging in SUD treatment, generally resulting in increased abstinence rates, improved social integration, and reduced psychopathology (Cox & Comiskey, 2007; Fletcher, Tims, & Brown, 1997; McKeganey, Bloor, McIntosh, & Neale, 2008; Teesson et al., 2008). Various SUD treatment modalities, however, seem to impact treatment outcomes in different ways. Stahler, Mennis and DuCette (2016), for example, found that people with problematic opioid use benefitted more from residential treatment than individuals with alcohol as their primary substance. Conversely, people with problematic cannabis use were less likely to benefit from residential treatment compared to people with alcohol as their primary substance. Several studies found higher treatment completion rates in residential programs compared to outpatient settings (Brorson, Arnevik, Rand-Hendriksen, & Duckert, 2013; Stahler, Mennis, & DuCette, 2016). Treatment engagement and retention have been consistently associated with positive outcomes, irrespective of the treatment modality (Katz et al., 2004; Lappan, Brown, & Hendricks, 2020; Simpson & Joe, 2004). Individuals who stay in treatment for a longer period of time are more likely to remain abstinent, experience fewer relapses and readmissions, engage less in criminal activity, and show greater improvements in general health measures (Brorson, Arnevik, Rand-Hendriksen, & Duckert, 2013; Goldklang et al., 2003; Stahler, Mennis, & DuCette, 2016). Despite evidence for the effectiveness of SUD treatment, significant challenges such as high drop-out and relapse rates persist and warrant further research and innovative approaches (Lappan, Brown, & Hendricks, 2020).

SUD treatment outcomes are typically measured using objective (e.g. abstinence, re-arrest/reincarceration) and/or provider-reported indicators (e.g. treatment completion/compliance, absence of symptoms). Increasing emphasis on service users' perspectives in measuring treatment

outcomes and experiences has recently led to the introduction of Patient-Reported Outcome Measures (PROMs) and Patient-Reported Experience Measures (PREMs) in SUD and other mental health services (Churruca et al., 2021; Davis et al., 2020; Migchels et al., 2023; Trujols et al., 2013). PROMs refer to individual, subjective treatment outcomes, including information about psychological well-being, quality of life, symptomatology and physical functioning. PREMs provide information on how individuals experience healthcare and measure practical aspects of care, such as coordination, continuity and accessibility of care, and quality of patient-provider relationships (Kingsley & Patel, 2017). International organizations, such as the International Consortium for Health Outcomes Measurement (ICHOM; Black et al., 2024), promote the implementation of patient-reported measures for routine assessment of health outcomes and experiences in all health care areas, including primary care, psychotherapy and SUD services (Migchels et al., 2023). The use of PROMs and PREMs is advised to systematically monitor and improve the delivery of effective, patient-centered care and shared-decision making, which is not a standard practice in SUD and other mental health services (Alves, Sales, & Ashworth, 2017; Davis et al., 2020; Friedrichs, Spies, Härter, & Buchholz, 2016; Garnick, Horgan, Acevedo, McCorry, & Weisner, 2012; Kendrick et al., 2016; Kolind & Hesse; 2017; Roe, Mazor, & Gelkopf, 2022; Migchels et al., 2023). Additionally, adopting standardized outcome measures opens opportunities to compare performances between treatment services within regions, countries, and even globally. This evolution will facilitate knowledge sharing among practitioners and provides policy makers with the tools and evidence needed to improve the quality and effectiveness of care (Black et al., 2024). The systematic use of PREMs is also likely to advance the field towards more personalized and effective support, since it provides a direct evaluation of the accessibility, continuity, and coordination of care by service users (Migchels et al., 2023; Kingsley & Patel, 2017). Yet, although PROMs and PREMs show clear promise in improving the quality of SUD treatment, there is a lack of research on (the implementation of) these measures in clinical practice within SUD treatment settings (Migchels et al., 2023). The OMER-BE study (Outcome Measurement and Evaluation as a Routine practice in alcohol and other drug services in Belgium, 2022-2025) aims to introduce and integrate the use of PROMs and PREMs in different SUD treatment modalities and to evaluate and enhance the quality of care provided in SUD treatment services in Belgium. The primary objective of the OMER-BE study is to assess the routine measurement of PROMs and PREMs in SUD treatment services, based on the recently developed and internationally validated ICHOM Standard Set for Addictions (Black et al., 2024). Therefore, we translated and validated the ICHOM Standard Set for Addictions into Dutch and French, enhancing its applicability in Belgium and other Dutch- and French-speaking countries. By incorporating

PROMs and PREMs in routine assessments, SUD treatment services are provided with information to better align treatment approaches with service user needs. The secondary objective of the OMER-BE study is to measure and compare various recovery indicators and treatment experiences between different treatment modalities and assess their evolution during and after treatment.

METHODS

Study setting

The OMER-BE study is a naturalistic, longitudinal, multicenter cohort study, in which 189 individuals with SUDs are followed up over a 6-month period in various residential and outpatient treatment modalities in the Dutch- and French-speaking regions of Belgium. Data collection for the study started in July 2022. Participants are recruited from eight residential services (four psychiatric treatment centers (PCs) and four therapeutic communities (TCs)) and nine outpatient treatment services.

Specialized wards of PCs offer long-term (3 to 6 months) residential care that provides intensive medical and psychological support, addressing SUDs and in some cases co-occurring mental health disorders. Treatment consists of group counseling, psychoeducation, individual psychotherapy, and occupational activities.

TCs for addictions have a long history and were set up for individuals with SUDs, complementing traditional mental health care services that were traditionally not open to persons with drug problems (Vanderplasschen et al., 2013). In a TC, individuals with SUDs live together in a structured environment, typically for a period of 6 to 12 months, aiming for positive changes that lead to a drug-free life in society. The TC approach centers around the concept of "community as a method", thus, highlighting the influential role of peers and the power of mutual support in fostering recovery (De Leon, 1997; Vanderplasschen, Vandevelde, & Broekaert, 2014).

Outpatient treatment services provide more autonomy to service users and offer various non-residential care options consisting of drug-free counselling interventions and harm-reduction approaches like Opioid Agonist Therapy (OAT) and needle exchange programs. OAT refers to the use of opioid replacement medication such as methadone or buprenorphine to help manage withdrawal symptoms and reduce craving, often combined with some form of counseling and social support. Drug-free counselling focuses on psychosocial interventions, such as motivational interviewing and cognitive-behavioral therapy, aimed at helping individuals develop coping strategies and support systems to become/remain abstinent.

Study population

The OMER-BE study aims to follow up a naturalistic cohort of service users with SUDs as they start

a new treatment episode in a selected number of SUD treatment services, focusing on individuals with a primary alcohol and/or primary (illicit) drug problem. Eligibility criteria are: (i) having a documented SUD (e.g. a DSM-5 diagnosis of a SUD or previous treatment for a SUD), (ii) being at least 18 years old, (iii) being able to communicate in Dutch or French and (iv) having started treatment no longer than 21 days ago. First-time as well as returning service users are considered eligible for this cohort study, as long as they start a new treatment episode during the recruitment period (Zerrouk, 2022).

Upon treatment entry, service users are informed about the aims and design of the OMER-BE study through posters, leaflets and staff members of the selected treatment facilities. During the initial meeting with the researcher, participants are informed extensively about the (follow-up) study and implications of study participation and are asked for written informed consent to participate (Zerrouk, 2022).
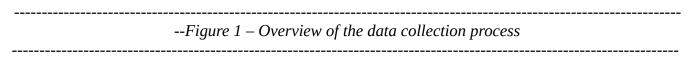
Study procedure

Baseline assessment

Sociodemographic and clinical factors (see Table 1) are assessed at baseline, followed by the assessment of PROMs (Table 1). Data is collected through self-report using a tablet provided by one of the researchers, who are available throughout the assessment to address any questions participants may have. Administering the set of baseline variables and PROMs is supposed to take between 20 and 45 minutes. After completion of the baseline assessment, participants receive a voucher of 10 EUR as remuneration.

Follow-up assessments

Study participants are contacted again 45, 90 and 180 days after the baseline assessment (see Figure 1). We use a time window of four weeks for the 45- and 90-day follow-up and five weeks for the 180-day follow-up assessment to collect and complete the questionnaires. Researchers contact all study participants either via email, text messages, directly by phone, or through the treatment setting where they were enrolled in the study. Participants can complete the online survey via a personalized link provided by e-mail or during a face-to-face or telephone interview, depending on their preference. The follow-up assessments include a measurement of both PROM and PREM variables (see Table 1), which are supposed to take 20 to 30 minutes to complete. Participants receive a 10 EUR voucher for each completed follow-up assessment.

As the OMER-BE project is a naturalistic study, some participants will no longer be in treatment at

the 45-, 90- or 180-day follow-up. Consequently, the PREM-instrument is only administered when service users are still in treatment and at the first follow-up moment after leaving treatment. For example, if a participant stops treatment after 50 days, the PREM questionnaire will be administered at the 45- and 90-day follow-up moments.

--Figure 1 – Overview of the data collection process

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Instruments

The baseline and follow-up assessments (see Table 1) are largely based on the ICHOM Standard Set for Addictions (ICHOM SSA, Black et al., 2024), a set of brief, existing, validated questionnaires to measure and monitor treatment outcomes routinely in SUD services that was developed by an international panel of SUD specialists. The ICHOM SSA focuses on patient-centered outcome indicators and provides an internationally agreed upon method for measuring a variety of outcome domains. The tool offers potential for routine use since it is relatively short and has been specifically developed for and validated in the population of SUD service users. It can be easily administered and is applicable in a wide range of treatment settings (Black et al., 2024). To facilitate its application in Belgium, non-translated questionnaires were translated into French and Dutch using forward/backward translation, following guidelines provided by Tsang, Royse & Terkawi (2017), and subsequently validated. Compared to the ICHOM SSA procedure, we added a 45-day follow-up assessment which allowed to have an additional measurement point, keep participants more engaged in the study and reduce attrition.

The OMER-BE measurement tool consists of three sections (see Table 1): (1) sociodemographic and clinical factors, (2) PROMs, and (3) PREM.

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Table 1 - Overview of included instruments in the OMER-BE outcome measurement tool

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Sociodemographic and clinical factors

The first section of the tool includes sociodemographic and clinical factors that may influence treatment outcomes.

Following sociodemographic variables are assessed: age, sex, education level, current living situation, country of birth of the participants and country of birth of their parents.

Clinical factors include questions regarding SUD treatment history and three validated and widely

used screening instruments to assess common comorbid psychiatric disorders (trauma, depression/anxiety and ADHD) that are likely to affect treatment outcomes. These clinical factors are included to ensure a comprehensive understanding of how these variables influence recovery trajectories.

PC-PTSD-5 (Primary Care PTSD Screen for DSM-5)

The Primary Care Posttraumatic Stress Disorder Screen (PC-PTSD-5; Prins et al., 2016) was developed to assess the occurrence of symptoms of posttraumatic stress disorder (PTSD) over the last month. This five-item screening tool is rated on a binary scale (No = 0, Yes = 1). Higher total sum scores suggest the presence of more PTSD symptoms. The reliability of the English version has been found satisfactory in a sample of people with SUDs, as measured by a Cronbach's α value of 0.73 (Patton, Hinojosa, Lathan, Welsh, & Powers, 2023).

DASS-21 (Depression, Anxiety, Stress Scale)

The Depression, Anxiety and Stress Scale (DASS-21; Lovibond, 1995) is a commonly used instrument consisting of 21 items, divided into three subscales (depression, anxiety and stress), each containing seven items. Each question is rated on a scale from 0 ('did not apply to me at all') to 3 ('applied to me very much'). Subscales and total scores are calculated by adding up the scores on the items and multiplying these by a factor 2. In a population of Dutch-speaking SUD service users in the Netherlands, Beaufort et al. (2017) found the total score to be highly reliable (Cronbach's α = 0.91).

ASRS-v1.1 (Adult ADHD Self-report Scale)

The Adult ADHD-Self-report Scale v1.1 (ASRS) consists of several questions encompassing each of the 18 symptoms cited in the DSM-IV (Adler, Kessler, & Spencer, 2003). The current study uses the short version, consisting of six items which have been found the most predictive of an attention-deficit/hyperactivity disorder (ADHD) diagnosis. These items are rated on a scale from 0 ('never') to 4 ('very often'). Scores equal to or higher than 2 for items 1-3 and equal to or higher than 3 on items 4-6 are indicative for a diagnosis of ADHD. A Spanish study by Daigre et al. (2009) showed a sensitivity of 0.88 and a specificity of 0.69 for a diagnosis of ADHD in a sample of outpatients with SUDs. In an international study among treatment seeking in- and out-patients with a SUD, very similar results were obtained with a sensitivity of 0.83 and a specificity of 0.68 for DSM-5 ADHD (van de Glind et al., 2013).

Patient-Reported Outcome Measures (PROMs)

The second section of the tool is focused on PROMs and based on the ICHOM SSA (Black et al., 2024). To extend the focus to subjective well-being beyond substance use and health outcomes, we

added a widely used instrument to assess quality of life and overall well-being (i.e., WHOQoL-BREF).

PROMIS SF-Alcohol (Patient-Reported Outcomes Measurement Information System (PROMIS) Alcohol Use Short Form 7a)

The PROMIS Alcohol Use Short Form (Pilkonis et al., 2013) is a seven-item self-report questionnaire, derived from the 37-item PROMIS Alcohol Use item bank. This tool is designed to assess alcohol use in the last 30 days. Respondents were instructed to complete the seven questions only if they consumed alcohol in the last 30 days. Answers are rated on a 5-point scale ranging from 'never' (0) to 'almost always' (4). The internal consistency of the total score has proven to be excellent in participants from the general population and a clinical sample of service users in treatment for SUDs (Cronbach's α = 0.95) (Pilkonis et al., 2013).

PROMIS SF-Substance (PROMIS SF v1.0 – Severity of Substance Use 7a)

The PROMIS Severity of Substance Use Short Form (Pilkonis et al., 2015) consists of seven items and is a shorter version of the 37-item PROMIS Severity of Substance Use item bank. This tool is designed to assess severity of substance use in the last 30 days. Answers are rated on a 5-point scale ranging from 'never' (0) to 'almost always' (4). The internal consistency of the total score was found to be excellent in participants from the general population and a clinical sample of service users in treatment for SUDs (Cronbach's α = 0.94) (Pilkonis et al., 2015).

HSI (Heaviness of Smoking Index)

The Heaviness of Smoking Index (HSI) consists of two items: "How soon after waking up do you usually have your first smoke?" and a question assessing the number of cigarettes smoked each day. The first question was rated on a 4-point scale ranging from 'more than 60 minutes' (0) to 'less than 5 minutes' (3). The second question was replaced by an assessment of the number of cigarettes smoked in the last 30 days to maintain consistency with the assessment of the other substances. Internal consistency for the total HSI score was found to be relatively low in a sample of males with SUDs and nicotine dependence (Cronbach's α = 0.49) (Burling & Burling, 2001).

TOP-S1 (NHS Treatment Outcomes Profile for Substance Misuse – section 1)

The Treatment Outcomes Profile (TOP; Marsden et al., 2008) is a multi-dimensional assessment instrument for monitoring outcomes in SUD treatment. This questionnaire measures four key life domains (substance use, crime, health and social functioning). For this study, we only assessed the substance use domain and made modifications to the time frame in line with the other questionnaires. Specifically, participants were asked about their primary substances of use and the

number of days and quantity consumed over the past 30 days.

PROMIS-GH-10 (PROMIS Scale v1.2 – Global Health)

The PROMIS Global Health (PROMIS-GH) consists of ten items, scored on a 5-point scale. Due to overlap with other questionnaires, and in accordance with the ICHOM SSA, we only included two items of this scale relating to physical and mental health. The response options of these items are 'excellent', 'very good', 'good', 'fair' and 'poor'. Its psychometric properties were evaluated using a sample of 4370 individuals from the Dutch general population. Results indicated a 2-factor structure with good internal consistency. The subscales 'Global Mental Health' and 'Global Physical Health' had a Cronbach's α of 0.83 and 0.78, respectively (Pellicciari et al., 2021).

SURE (Substance Use Recovery Evaluator)

The Substance Use Recovery Evaluator (SURE; Neale et al., 2016) is a self-report questionnaire consisting of 21 items, which is completed on a 5-point scale but scored on a 3-point scale (1-3). The first 2 response options correspond to a score of 3, the third response option to a score of 2 and the final 2 response options to a score of 1. Response options for the first 3 questions are 'never', 'on 1 or 2 days', 'on 3 or 4 days', 'on 5 or 6 days', and 'every day', while for the remaining questions response options are 'all of the time', 'most of the time', 'a fair amount of the time', 'a little of the time', and 'none of the time'. Higher total sum scores suggest greater recovery strengths. The items are categorized into five subscales: 'substance use', 'relationships', 'self-care', 'outlook on life' and 'material resources'. Internal consistency of the SURE total score was found to be high in a sample of current and former SUD service users (Cronbach's α = 0.92) (Neale et al., 2016). Psychometric properties of the translated Dutch version of the SURE (SURE-NL) showed good internal consistency (Cronbach's α = 0.83) (Migchels et al., 2024).

WHOQoL-BREF (WHO Quality of Life Scale)

The brief version of the World Health Organization Quality of Life questionnaire (WHOQoL-BREF; Skevignton, Lofty, & O'Connell, 2004) consists of 26 items and is a short version of the WHOQoL-100 questionnaire. Questions are rated on a 5-point scale (1-5) and response options, from the lowest to highest score, are 'very poor/very dissatisfied/not at all/never', 'poor/dissatisfied/a little/seldom', 'neither poor nor good/neither satisfied nor dissatisfied/a moderate amount/moderately/quite often', 'good/satisfied/very much/mostly/very often', and 'very good/very satisfied/an extreme amount/extremely/completely/always'. Higher sum scores are an indication of a better quality of life. The items are grouped in four domains: 'psychological health', 'physical health', 'environment' and 'social relationships'. The WHOQOL-BREF has demonstrated good internal consistency with

Cronbach's α values for each of the domains ranging from 0.66 to 0.84 (WHOQOL Group, 1998).

Patient-Reported Experience Measures (PREMs)

As the objectives of the OMER-BE study also included the measurement of PREMs, the third section of the OMER-BE outcome measurement tool is not part of the ICHOM SSA. We use a newly validated PREM, the Patient Reported Experience Measure for Addiction Treatment (PREMAT), to assess service users' experiences regarding the treatment they received.

PREMAT (Patient Reported Experience Measure for Addiction Treatment)

The PREMAT is a recently developed relatively brief (23-item) questionnaire that aims to capture the experiences of people in residential SUD treatment services (Hinsley, Kelly, & Davis, 2019; Kelly, Hatton, Hinsley, Davis, & Larance, 2021). More precisely, the following topics are addressed in the PREMAT: 'Individualized support', 'Self-determination and Empowerment', 'Program structure', 'Treatment environment', 'Coordination of care' and 'Personal responsibility' (Kelly, Hatton, Hinsley, Davis, & Larance, 2021). The instrument consists of 23 statements rated on a 5-point Likert scale: 1 (strongly disagree), 2 (disagree), 3 (neither agree nor disagree), 4 (agree), and 5 (strongly agree). The total score ranges from 23 to 115, with higher scores reflecting a more positive experience. Additionally, the PREMAT includes 2 open-ended questions ('How could your experience at this service have been improved?' and 'What have been the best things about your experience here?'), which allow respondents to elaborate on certain aspects of the questionnaire or discuss topics that are not covered by the PREMAT items (Hinsley, Kelly, & Davis, 2019). Internal consistency for the total score was found excellent in a sample of participants from specialist residential SUD treatment services in Australia (Cronbach's α = 0.91) (Kelly, Hatton, Hinsley, Davis, & Larance, 2021).

Ethics and dissemination

This study was granted ethical approval from the Medical Ethics Committee of the University Hospital Brussels on 11th of May 2022 (UZ Brussel; BUN: 1432022000071). The participants are informed about the confidentiality of the data they provide and written informed consent is acquired from all participants before being included in the study. All data will be treated confidentially and reported anonymously. This study is conducted in accordance with the Declaration of Helsinki.

Data analysis of baseline characteristics

This paper presents baseline characteristics of the study cohort and comparative analyses between participants from different treatment modalities. For categorical demographic and patient

characteristics, significant differences between treatment modalities were assessed using either the Chi-square test or Fisher's exact test when the data did not meet the assumptions required for the Chi-square test. For continuous variables, we used ANOVA to assess group differences. Welch t-test was used when the assumption of equal variances was not met. Post hoc comparisons between groups were made using Tukey test when variances were equal or Games-Howell test when the assumption of equal variances was violated. All statistical analyses were conducted using IBM SPSS statistic version 29.

Future analyses will center on longitudinal changes in PROMs and PREMs, using repeated measures and mixed model analyses. The role of mediating and moderating variables (e.g., socio-economic status, comorbidity, recovery strength) will be assessed, along with differences between treatment modalities. All statistical analyses will be conducted using R studio and IBM SPSS statistic version 29.
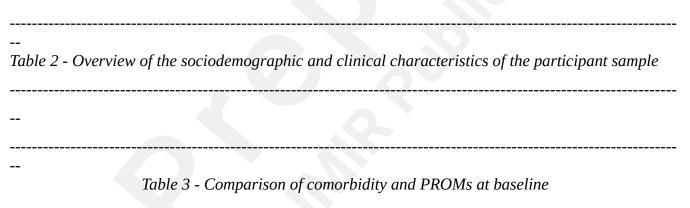
RESULTS

In total, 189 individuals will participate in the OMER-BE study, of which 161 participants (85.2%) undergoing residential treatment (81 treated in a SUD treatment ward in a psychiatric facility and 80 in a drug-free TC). Additionally, 28 participants (14.8%) are recruited in outpatient services. Details regarding the baseline sociodemographic and clinical characteristics of the participant sample are presented in Table 2. The average age is 35.5 years (SD = 9.9). The majority of participants are males (N=156, 82.5%), completed secondary education as their highest level of education (N=114, 60.3%) and live alone (N=90, 47.6%). Most participants were born in Belgium (N=178, 94.2%) and reside in psychiatric facilities (N=81, 42.9%) and therapeutic communities (N=80, 42.3%) during the baseline assessment. 153 participants (81.0%) have received previous treatment for SUDs. The most frequently reported main substances are alcohol (N=100, 53.8%), cocaine (N=81, 43.5%) and cannabis (N=64, 34.4%), indicating the presence of many problematic poly-substance users.

Initial comparisons are made between the three treatment modalities (Table 2). When considering sociodemographic and clinical characteristics, no significant differences are found in terms of age, sex, living situation and country of birth. However, significant differences are observed regarding education level, history of SUD treatment, OAT and the primary substances reported. Post hoc analyses reveal that participants in the PC group have the highest level of education, followed by those in the outpatient group and finally the individuals from the TC group. On average, 82.7% of participants from the PC and 85.0% of the participants TC group have previous history of SUD treatment, with no statistically significant difference between the two groups. Moreover, a significantly higher percentage of participants in the outpatient group (46.4%) is engaged in some

form of OAT. This is followed by participants in TC group (18.8%) and lastly the PC group (11.1%). In terms of substance use, alcohol is more frequently reported as the primary substance in the PC group, followed by TC and outpatient groups. In contrast, opioids are most frequently reported in the outpatient group, followed by TC and PC groups. Amphetamine, cocaine and GHB are significantly more reported in the TC group, followed by the outpatient and finally the PC group. A significantly higher percentage of participants in the TC group report more than one primary substance, followed by the outpatient and PC group.

Further comparisons are made regarding comorbid psychiatric conditions and PROMs at baseline (Table 3). No significant differences are found in levels of PTSD, depression, anxiety, and stress scores between the treatment modalities. However, significant differences are observed in scores on the ADHD self-report scale, with participants in the outpatient group scoring significantly lower compared to the TC group. No significant differences are found in general health and QoL scores. In contrast, the total score on the SURE questionnaire reveals significant differences at baseline between the groups, with participants in the outpatient group scoring lower overall than those in the other groups. This trend is significant in the subdomains of 'Substance Use,' 'Self-care,' and 'Outlook on Life'.

Table 2 - Overview of the sociodemographic and clinical characteristics of the participant sample

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Table 3 - Comparison of comorbidity and PROMs at baseline

--DISCUSSION

The use of PROMs and PREMs in SUD treatment services is limited to date and no systematic monitoring system of patient-reported outcomes in Belgium is currently available (Zerrouk, 2022). Therefore, the OMER-BE study is set up to assess PROMs and PREMs systematically and to improve the quality of SUD services through the routine measurement and monitoring of patient-reported outcomes and experiences at regular times during and after treatment.

Preliminary comparisons across the three treatment modalities at baseline reveal some noteworthy differences and similarities. While no significant differences are observed in age, sex, living situation, or country of birth, significant variations in education levels, history of SUD treatment, engagement in OAT, and primary substance of problematic use are observed. Regarding co-occurring

mental health disorders, no significant differences are found in PTSD, depression, anxiety, and stress scores between the treatment modalities. However, significant differences are noted in ADHD scores, with the TC group scoring significantly higher than the outpatient group. These differences can be attributed to several factors. TCs are often more suitable for individuals with more severe ADHD symptoms, as these environments provide the structured support and comprehensive care needed to manage both SUDs and co-morbid conditions. This setting allows for intensive monitoring and interventions, which are crucial for individuals struggling with ADHD symptoms, such as impulsivity. In contrast, outpatient settings typically cater to individuals with milder symptoms who require less intensive support.

Regarding the PROM scores, no significant treatment modality differences are found in the domains of general health and QoL, but significant differences are observed in recovery strengths, with participants in the outpatient group scoring lower overall than those in the other groups. These differences, particularly noted in the subdomains of 'Substance Use', 'Self-care', and 'Outlook on Life' suggest that the structure of the treatment environment play a role in shaping recovery trajectories. For example, we observe that participants in residential treatment score significantly higher on the 'substance use' subscale compared to those in outpatient treatment, suggesting lower levels of substance use among those in residential settings. This difference can be attributed to the structured and controlled environment of residential treatment settings, where strict measures are often in place to encourage abstinence and limit access to substances. The supervision and supportive community in residential facilities may also play a crucial role in reducing substance use, which is less enforceable in outpatient settings where individuals have more autonomy and access to substances. The significant difference in the 'Self-care' subscale, with residential participants scoring higher, may reflect the comprehensive care and support provided in residential settings. These environments typically offer structured daily routines and more intensive psychological and physical care. In contrast, outpatient treatment often places a greater emphasis on self-management, which can be challenging for individuals with limited resources or support networks. Participants in residential treatment also score significantly higher on the 'Outlook on Life' subscale, which may be attributed to the supportive environment of residential treatment settings, where participants are provided with continuous care and peer support, all of which contribute to a more positive and optimistic outlook on life. Notably, the group difference in the 'Relationship' subscale is close to significance. As participants are assessed in the first weeks of treatment, it is possible that participants in residential facilities don't have enough time to build a meaningful relationship with other service users and providers.

The proposed study also has some limitations. First, recruiting participants in outpatient facilities proves to be extremely challenging, leading to a limited number of participants in these settings. One significant obstacle is the presence of long waiting lists, resulting in a limited number of new treatment episodes and low turnover rates. Additionally, in many outpatient facilities, the frequency of contact between potential participants and service providers is limited. Some service users have only weekly or biweekly appointments. This restricted availability poses significant scheduling constraints since participants have to complete the baseline questionnaires within three weeks of treatment initiation. Moreover, there is a high occurrence of no-shows for scheduled appointments with the researchers, which results in missed opportunities to engage potential participants. To address these challenges, considerable efforts are made. Researchers provide flyers and posters in waiting areas to inform potential participants about the study. They are present at the facilities, calling potential participants, and checking in advance to ensure their attendance. Regular contact is maintained (through e-mail and phone) with service providers to remind them of the study and discuss potential participants. Despite these efforts, maintaining consistent long-term contact with outpatients appears to be particularly difficult, which results in some outpatient centers dropping out of the study. Consequently, future comparative analyses will only focus on the residential treatment services due to the limited number of outpatient participants. Second, recruiting facilities and participants from the French-speaking regions of Belgium proves to be extremely challenging, primarily due to different attitudes towards evaluation and measuring outcomes. Although some success is achieved, practical challenges such as staffing shortages and significant differences in the treatment programs of other potential centers hinder broader participation. Despite repeated attempts to engage additional French-speaking services, responses are limited and further recruitment efforts do not seem successful. Finally, the study is limited by the lack of standardized diagnostic assessment of participants entering the study. Inclusion is based on proxy indicators (previous treatment for SUD, clinical assessment or history of substance misuse), rather than on clinical diagnoses. This lack of structural diagnosis may introduce variability in our findings and limit generalization to other populations.

Yet, this study is one of the first studies to explore the assessment of PROMs and PREMs in SUD treatment services using the ICHOM SSA set of instruments. By systematically and routinely monitoring PROMs and PREMs, the project aims to empower service providers and give them tools to evaluate subjective treatment outcomes and experiences. This approach can provide service providers and policymakers with benchmarks for assessing outcomes and experiences during and after treatment across various treatment modalities. By applying an internationally validated tool, the

study allows international comparison with similar interventions and treatment modalities globally. Future analyses will explore longitudinal changes in PROMs and PREMs, with a particular focus on the influence of baseline mediating and moderating variables (e.g., socio-economic status, comorbidity, recovery strength) and differences between treatment modalities. The findings from this study will offer new perspectives and insights into the effectiveness of different SUD treatment modalities and their impact on diverse service user populations. This shift towards patient-centered care not only supports better recovery outcomes, but also fosters continuous improvement and innovation in SUD treatment services. Ultimately, systematically monitoring PROMs and PREMs has the potential to enhance the quality of care by offering a comprehensive understanding of service users' needs and treatment effectiveness.

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Competing interests

Wim van den Brink discloses relationships with Clearmind, Camurus AB, and Takeda Pharmaceutical Company Limited, involving consultancy or advisory roles.

All remaining authors declare that they have no financial conflicts of interest or personal relationships that might influence the work reported in this paper.

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Table 1 - Overview of included instruments in the OMER-BE outcome measurement tool

Socio-demographic factors
Year of birth, sex, highest level of education completed, housing status, ethnicity
Clinical factors
Treatment history for SUDs
PC-PTSD-5 (Primary Care PTSD Screen for DSM-5)
DASS-21 (Depression, Anxiety, Stress Scale)
ASRS-v1.1 (Adult ADHD Self-report Scale)
Patient-Reported Outcome Measures (PROM)
PROMIS-Alcohol (PROMIS SF v1.0 – Alcohol Use 7a)
PROMIS-Substance (PROMIS SF v1.0 – Severity of Substance Use 7a)
HSI (Heaviness of Smoking Index)
TOP-S1 (NHS Treatment Outcomes Profile for Substance Misuse – section 1)
PROMIS-GH-10 (PROMIS Scale v1.2 – Global Health)
SURE (Substance Use Recovery Evaluator)
WHOQoL-BREF (WHO Quality of Life Scale)
Patient-Reported Experience Measures (PREM)
PREMAT (Patient Reported Experience Measure for Addiction Treatment)

Table 2 - Overview of the sociodemographic and clinical characteristics of the participant sample

Variables	Total n = 189	PC n = 81	TC n = 80	Outpatient n = 28	Chi-square
Age *mean* (SD)[a]	*35.5* (9.9)	*36.6* (11.7)	*34.1* (7.9)	*36.5* (9.3)	.203[b]
Sex					
Male	156 (82.5%)	63 (77.8%)	71 (88.8%)	22 (78.6%)	.156
Education level					
Primary	45 (23.8%)	14 (17.3%)	23 (28.7%)	8 (28.6%)	**.035**
Secondary	114 (60.3%)	47 (58.0%)	51 (63.7%)	16 (57.1%)	
Higher	30 (15.9%)	20 (24.7%)	6 (7.5%)	4 (14.3%)	
Current living situation					
Alone	90 (47.6%)	36 (44.4%)	39 (48.8%)	15 (53.6%)	.373[c]
Alone with children	9 (4.8%)	4 (4.9%)	5 (6.3%)	0 (0.0%)	
Living together with partner & children	18 (9.5%)	8 (9.9%)	6 (7.5%)	4 (14.3%)	
Living together with partner without children	13 (6.9%)	8 (9.9%)	2 (2.5%)	3 (10.7%)	
Living together with others	59 (31.2%)	25 (30.9%)	28 (35.0%)	6 (21.4%)	
Country of birth					
Belgium	178 (94.2%)	74 (91.4%)	76 (95.0%)	28 (100.0%)	.271[c]
Country of birth (father)					
Belgium	156 (82.5%)	64 (79.0%)	65 (81.3%)	27 (96.4%)	.103
Country of birth (mother)					
Belgium	161 (85.2%)	68 (84.0%)	66 (82.5%)	27 (96.4%)	.186
Previous treatment for SUDs					
Yes	153 (81.0%)	67 (82.7%)	68 (85.0%)	18 (64.3%)	**.048**
Opioid Agonist Therapy (OAT)	37 (19.6%)	9 (11.1%)	15 (18.8%)	13 (46.4%)	**<.001**

Main substance(s) (n=186) [d, e]					
Alcohol	100 (53.8%)	52 (64.2%)	38 (48.7%)	10 (37.0%)	**.025**
Amphetamines	41 (22.0%)	9 (11.1%)	23 (29.5%)	9 (33.3%)	**.006**
Benzodiazepines	20 (10.8%)	8 (9.9%)	12 (15.4%)	0 (0.0%)	.080
Cannabis	64 (34.4%)	23 (28.4%)	31 (39.7%)	10 (37.0%)	.307
Crack	33 (17.7%)	9 (11.1%)	19 (24.4%)	5 (18.5%)	.091
Codeine + Promethazine	2 (1.1%)	2 (2.5%)	0 (0.0%)	0 (0.0%)	.633[c]
Cocaine	81 (43.5%)	21 (25.9%)	50 (64.1%)	10 (37.0%)	**<.001**
GHB	14 (7.5%)	1 (1.2%)	10 (12.8%)	3 (11.1%)	**.016**
Hallucinogens	3 (1.6%)	0 (0.0%)	2 (2.6%)	1 (3.7%)	.205[c]
Ketamine	20 (10.8%)	13 (16.0%)	5 (6.4%)	2 (7.4%)	.122
New Psychoactive Substances	6 (3.2%)	2 (2.5%)	3 (3.8%)	1 (3.7%)	.870[c]
Opioids	35 (18.8%)	10 (12.3%)	14 (17.9%)	11 (40.7%)	**.005**
Number of main substances (n=186) [a, d, e]	2.3 (1.4)	1.9 (1.3)	2.7 (1.4)	2.3 (1.4)	**.001**
More than one main substance (n=186) [d, e]	111 (59.7%)	33 (40.7%)	60 (76.9%)	18 (66.7%)	**<.001**

[a] *ANOVA*
[b] *Welch test*
[c] *Fisher exact test*
[d] *Some service users reported more than one main substance used*
[e] *Data missing for 3 participants*

Table 3 - Comparison of comorbidity and PROMs at baseline

Questionnaires	Total n = 189	PC n = 81	TC n = 80	Outpatient n = 28	*p*
PC-PTSD-5	2.24 (2.00)	2.09 (1.92)	2.51 (2.07)	1.89 (1.95)	.245
DASS 21:					
- Depression	18.94 (10.92)	17.58 (10.80)	20.23 (10.80)	19.21 (11.54)	.306
- Anxiety	14.03 (9.50)	12.94 (9.12)	15.53 (9.96)	12.93 (8.92)	.180
- Stress	19.31 (10.15)	18.00 (10.47)	21.00 (9.72)	18.29 (10.09)	.146
ASRS	3.44 (1.68)	3.36 (1.73)	3.75 (1.50)	2.79 (1.89)	**.027**
PROMIS GH					
- Physical	2.77 (.86)	2.73 (.92)	2.85 (.83)	2.77 (.86)	.553
- Mental	2.59 (.92)	2.62 (.94)	2.61 (.88)	2.46 (.96)	.726
SURE TOTAL	52.05 (7.70)	52.19 (7.99)	54.03 (5.46)	46.00 (9.31)	**<.001**[a]
- Substance use	14.97 (2.89)	15.07 (2.98)	15.60 (2.42)	12.89 (3.01)	**<.001**
- Self-care	12.02 (2.78)	11.81 (3.00)	12.91 (1.97)	10.07 (3.07)	**<.001**[a]
- Relationships	10.90 (1.61)	10.98 (1.60)	11.13 (1.26)	10.04 (2.20)	.054[a]
- Material Res.	7.56 (1.76)	7.72 (1.73)	7.48 (1.80)	7.36 (1.77)	.554
- Outlook on life	6.59 (1.88)	6.60 (1.92)	6.91 (1.66)	5.64 (2.08)	**.008**
WHOQOL BREF					
- QoL	2.94 (.82)	2.93 (.77)	2.95 (.87)	2.96 (.84)	.971
- Health	2.85 (.96)	2.91 (.91)	2.81 (.98)	2.79 (1.03)	.740
- Domain 1	13.52 (2.63)	13.33 (2.77)	13.85 (2.41)	13.14 (2.80)	.327
- Domain 2	11.43 (2.81)	11.68 (2.67)	11.33 (2.88)	10.98 (3.01)	.479
- Domain 3	12.14 (3.70)	12.59 (3.72)	11.65 (3.55)	12.24 (3.98)	.268
- Domain 4	13.24 (2.87)	13.74 (2.84)	12.98 (2.85)	12.55 (2.84)	.092

[a] *Welch test*

Supplementary Files

Untitled.
URL: http://asset.jmir.pub/assets/99f19c58b4b3df3fa47049be986bd2ff.docx

Figures

Overview of the data collection process.