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Effectiveness of Self-Help plus and problem management plus interventions in providing psychological support to clients of Opioid Agonist treatment programs in Ukraine

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ABSTRACT

Background: The paper presents an effectiveness study of two World Health Organization (WHO) scalable psychological interventions, Self-Help Plus (SH+) and Problem Management Plus (PM+), for the patients of the Opioid Agonist Treatment (OAT) programs in Ukraine during wartime.

Method: The study (pragmatic trial) was designed as an experiment with two intervention groups (for SH+ and PM+) and one control group (waiting list). The GAD-7, PHQ-9, LEC-5, and PCL-5 scales were used for the outcomes' screening three times (before, immediately after, and three months after the intervention). In addition, the number of missed visits on-site for medication in the last month was counted, and dose satisfaction was assessed. Data were collected from April to October 2023 (during the second year of the full-scale Russian invasion of Ukraine) at OAT centers in Lviv, Sumy, and Vinnytsia.

Results: Both interventions showed promising improvements in mental health outcomes within their groups, though no statistically significant differences were observed between intervention and control groups. The SH+ showed additional benefits, a decrease in missed medication doses, and a reduction in PTSD and depression symptoms.

Conclusions: The findings demonstrate the potential for scalable psychological interventions to be integrated into OAT programs to address the dual challenges of mental health and OAT adherence in resource-limited and crisis-affected settings.

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Opioid Agonist treatment; mental health; depression; anxiety; Self-Help Plus; problem management Plus

Introduction

Ukraine is facing a significant healthcare crisis due to the war waged by Russia in 2014 and exacerbated in 2022 with the full-scale invasion. The mental health of the Ukrainian population is deteriorating each year, creating a substantial treatment gap between the number of people in need of support and the system's ability to address the growing demand (Lushchak et al. 2024; Pinchuk et al. 2024).

In a crisis like this, the greatest burden of mental health problems falls on vulnerable populations, including children, people with disabilities, ethnic minorities, and people with preexisting mental health conditions (Charlson et al. 2019). People with Opioid Use Disorder (OUD) are among those who carry this mental health burden. In our recent studies, we explored the prevalence of depression, anxiety, PTSD symptoms, suicidal ideation, and their co-occurrence among patients receiving opioid agonist therapy in Ukraine. The prevalence of depressive symptoms was significant, rising from 26.73% in 2021 to 32.62% in 2023. The anxiety symptom prevalence increased from 14.72% to 25.51%. Suicidal ideations were found to be prevalent in 25% of this population. The overall rate of trauma exposure was 4.11 events per person, with a prevalence of PTSD symptoms at 34.43%, which is significantly higher in comparison to the general population (Klymchuk et al. 2024; Gorbunova et al. 2025).

In Ukraine, people with OUD receive support and medication treatment for OUD through a network of public health services (further referred to as OAT Centers) funded by the National Health Service of Ukraine (NHSU 2025). The network of services

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consisted of 205 state-funded OAT Centers, supporting 17210 in 2022 (Morozova et al. 2023).

OAT Centers were initially established to provide only the medications (methadone/buprenorphine and now–buvidal). However, following the clients' complex needs, these centers developed into support facilities, providing various harm-reduction programs, psychological support, medical checks, and assistance from family doctors, social workers, lawyers, etc. Depending on availability, they collaborate with community-based non-governmental organizations and integrate with HIV/AIDS and tuberculosis treatment programs (Morozova et al. 2017; Meteliuk et al. 2020; Fomenko et al. 2021). In recent years, pilot programs have been focused on integrating mental health support into the operational work of the OAT Centers. These initiatives aim to empower the Centers to employ psychiatrists, provide screening and support for mental health conditions, and antidepressant treatment (Machavariani et al. 2023).

Despite its importance, integrating highly specialized psychiatric support into health services, including OAT centers, may not help bridge the treatment gap due to the lack of workforce, the substantial demand, and the high costs associated with such specialized care. On the other hand, utilizing the task-shifting/task-sharing approach in combination with scalable psychosocial interventions might be the solution we are looking for (Bolton et al. 2023). Several interventions suitable for potential integration have passed translation and cultural adaptation stages in Ukraine: the WHO group intervention Self-Help Plus and the WHO individual intervention Problem Management Plus (WHO 2016, 2021).

SH+ and PM+ interventions have been tested in several trials across different target populations and countries, demonstrating effectiveness in reducing stress and symptoms of depression and anxiety (Purgato et al. 2021; Mwangala et al. 2024). However, no prior studies have been conducted involving individuals with comorbid OUD and other mental health conditions, and no studies have yet been published regarding the effectiveness of those interventions in Ukraine.

This study aimed to explore the effectiveness and acceptability of scalable psychological interventions among patients of OAT programs in Ukraine during wartime. The main research objectives were:

- To assess the effectiveness of the WHO group intervention Self-Help Plus, for patients of the OAT programs with symptoms of depression, anxiety, or PTSD;
- To assess the effectiveness of the WHO individual intervention, Problem Management Plus, for patients of the OAT programs with symptoms of depression, anxiety, or PTSD;
- To provide recommendations for scaling up the interventions at the national level for patients of the OAT programs based on the evidence received from the study.

This study report follows the CONSORT Statement, the extension on reporting of pragmatic trials (Zwarenstein et al. 2008).

Materials and methods

Study design

To evaluate the effectiveness of the interventions, an experimental study design was employed for a pragmatic trial that involved two parallel intervention groups (for SH+ and PM+) and one control group (waiting list). Three screenings were conducted using the GAD-7, PHQ-9, LEC-5, and PCL-5 scales (before the interventions, immediately after, and three months later).

Data were collected from April to October 2023, during the second year of the full-scale Russian invasion of Ukraine.

Participants

The target population consisted of persons enrolled in the OAT program who, following an initial baseline screening, demonstrated mild to severe mental health difficulties in terms of anxiety and depression symptoms.

Eligibility criteria:

- Participation in the OAT program.
- Presence of depression or anxiety symptoms indicated by PHQ-9 or GAD-7 scores exceeding a cutoff of 10 (PHQ-9 or GAD-7 scores exceeding a cutoff of 10) during the baseline screening.
- Willingness to participate in the intervention.
- Signing a written informed consent to participate in the study.
- No planned change of residence or discontinuation of OAT within the intervention period and up to three months post-intervention.

Exclusion criteria:

- Withdrawal or inability to continue participation in the OAT program for any reason.
- Refusal to sign the informed consent form for participation in the study.

- PHQ-9 and GAD-7 scores were below the cutoff of 10.

The staff at each OAT center, who had previously been trained in screening and allocation procedures, were responsible for recruiting, enrolling, and assigning participants to one of the interventions. These staff members conducted eligibility screenings and baseline assessments and further stratified participants into two strata based on the severity of their mental health issues.

The stratification algorithm was as follows:

1. Participants with a 'severe' score on either the PHQ-9 or GAD-7 were assigned to the 'Severe' stratum.
2. Participants with 'moderate' or 'moderate-severe' scores on both the PHQ-9 and GAD-7 were assigned to the 'Moderate' stratum.
3. Participants with a 'moderate' or 'moderate-severe' score on one of the scales (PHQ-9 or GAD-7) and a 'mild' or 'none' score on the other were also assigned to the 'Moderate' stratum.
4. Participants who did not meet any of the above criteria were excluded from the study.

After the stratification, participants were randomized into one of three groups:

- Participating in the SH+ intervention.
- Participating in the PM+ intervention.
- Screened as eligible but not participating in any intervention (waiting list/control group).

Clients were not allowed to participate in more than one intervention simultaneously. Clients randomized to all the groups, including the control group, continued to receive routine OAT services, including pharmacological treatment, health monitoring, and other standard treatment services.

In the Ukrainian context, standard treatment services at OAT Centers include the daily administration or dispensing of opioid agonist medications (such as methadone, buprenorphine, or buvidal), routine clinical monitoring (e.g. vital signs, adverse effects), adherence support, and consultations with a narcologist (addiction specialist physician). These services are often complemented by HIV and tuberculosis screening and treatment integration, basic mental health screening (when available), social support provided by case managers or social workers, and legal counseling *via* NGO collaboration. While psychological therapy is not a routine component of standard care, OAT Centers may refer patients to external mental health specialists if needed and if available locally. Services are typically offered in a low-threshold, outpatient setting and covered under Ukraine's national health service framework.

Participants were recruited across three Ukrainian regions at designated OAT centers: Vinnytsia (Central Ukraine), Lviv (Western Ukraine), and Sumy (Eastern Ukraine).

Interventions

Two structured interventions (SH+ and PM+) were incorporated into the existing services of OAT Centers at three pilot sites: Vinnytsia, Lviv, and Sumy. These interventions were developed by the World Health Organization (WHO) using evidence-based approaches (SH+ is based on Acceptance and Commitment Therapy; PM+ is based on Cognitive-Behavioral Therapy). A summary of the features of both interventions is presented in Table 1.

Site staff, including case managers, psychologists, and nurses with basic mental health expertise, delivered interventions. Facilitators received structured training and supervision from senior mental health professionals, certified PM+ and SH+ Trainers, and Supervisors to ensure fidelity to the WHO guidelines.

Adherence to the WHO guidelines was monitored through supervision and fidelity checks, where a subset of sessions was observed by supervisors and reviewed to ensure compliance with the intervention protocols.

Outcomes

The primary outcome of this study was the improvement in mental health indicators among participants in the OAT program who participated in the SH+ and PM+ interventions. The effectiveness of the interventions was evaluated through changes in symptom scores for generalized anxiety disorder, depression, and posttraumatic stress disorder, as well as in dose satisfaction and missed visits across three assessment waves: (1) Baseline Assessment – before the intervention; (2) Post-Intervention Assessment – immediately after completing the intervention; (3) Follow-Up Assessment – three months post-intervention.

The following standardized psychometric tools were used to measure outcomes: the Generalized Anxiety Disorder Assessment (GAD-7) for anxiety symptoms (Spitzer et al. 2006), the Patient Health Questionnaire (PHQ-9) for depression symptoms (Kroenke et al. 2001), and the Posttraumatic Stress Disorder Checklist (PCL-5) combined with the LEC-5

Table 1. Interventions features.

	Self-Help Plus (SH+)	Problem Management Plus (PM+)
Description	Group-based, low-intensity stress management.	Individual-focused intervention for psychological distress and problem-solving.
Framework	WHO's Self-Help Plus	WHO's Problem Management Plus
Components	• Mindfulness and stress management techniques. • Cognitive-behavioral elements (self-regulation). • Audio and visual tools for enhanced delivery.	• Behavioral activation. • Relaxation techniques. • Problem-solving strategies and emotional regulation.
Duration	Five weekly 2-hour sessions.	
Delivery mode	Group-based.	Individual (one-on-one).
Intended facilitators	Trained, non-specialist facilitators under professional supervision.	
Target group	Adults with mild-to-moderate psychological distress.	

for PTSD symptoms (Ukrainian adaptations: Bezsheiko 2016; Karachevskiy 2016). All scales have been validated for use in Ukraine and approved by the Ministry of Health of Ukraine for healthcare settings (MOHU 2020). A cutoff score of 10 was used for screening depression and anxiety (Spitzer et al. 2006; Manea et al. 2012); for PTSD symptoms, a PCL-5 cutoff score of 31 was applied (Weathers et al. 2013).

The number of missed visits for medication during the past 30 days was collected from clinic records. This represents missed opportunities for medication administration based on each patient's prescribed schedule, which is typically daily for methadone, more flexible for buprenorphine, and weekly or monthly for buvidal.

Satisfaction with the medication dosage (methadone, buprenorphine, or buvidal) was assessed using the question: '*On a scale from 1 to 10, how satisfied are you with the dosage of your medication, where 10 represents maximum satisfaction?*'

Satisfaction with dosage was included in this study as a complementary indicator of treatment experience. While the primary aim was to evaluate mental health outcomes, satisfaction with medication dosage may indirectly reflect patients' engagement with OAT services and their broader treatment experience. Although not a comprehensive measure of service satisfaction, it can serve as a practical proxy, particularly in low-resource settings where more complex assessments are not always feasible. Furthermore, we hypothesized that participation in SH+ or PM+ may influence patients' perceptions of treatment adequacy and self-regulation, which could in turn affect their reported satisfaction with dosing.

Data collection

The staff of OAT centers who delivered the interventions mediated the data collection. Professionals obtained detailed instructions and performed individual screenings during clients' appointments (after completing the informed consent forms). All the measures were printed out and filled out together with each person. After filling out the forms, all pseudonymized data were transferred to the protected REDCap platform, accessible to the researchers.

To ensure data quality, each OAT center designated a dedicated staff member to manage data entry and conduct initial checks for missing data or errors. After data entry, the research team performed weekly quality checks, reviewing technical reports on allocating intervention and control groups, client numbers, and the number of sessions conducted. Additionally, monthly meetings were held with the teams from participating OAT centers to monitor the quality of all procedures and address any potential issues promptly.

Sample size

The trial's sample size included 172 participants (127 in the intervention groups, 46 in the PM+ group, 81 in the SH+ group, and 45 in the control group). This number was based on the expected effect sizes and the practical feasibility of recruiting participants and delivering interventions across the three regions using a pragmatic, constraint-led approach (Silcocks and Whitham 2015).

Randomization

Simple randomization within each stratum (two strata based on the severity of the mental health problems – 'Moderate' and 'Severe') was used for the participants' allocation into three groups (SH+ intervention group, PM+ intervention group, and waiting list group).

Third-party allocation was used as an allocation concealment mechanism. OAT centers' administrators who were not involved in other research-related procedures manually generated a random allocation sequence for the three participants from each stratum and passed the information to designated staff for participants' baseline assessment and enrollment.

Blinding/masking

Blinding/masking was not implemented in the study for several reasons: the nature of the interventions

(SH+/PM+) was impossible to conceal from clients and professionals; the pragmatic focus of the trial aimed to evaluate the implementation of interventions in real-world settings where concealment was not feasible; and ethical considerations required clients to give full informed consent regarding the nature of the interventions, forbidding the withholding of information relevant to clients' mental health.

Statistical methods

Data analysis and visualization were performed using JASP 0.14.3 (GNU Affero GPL v3 license, an open-source license). Descriptive statistics (mean, standard deviation, median, interquartile range, and frequency analysis) were used to describe the general results. The Shapiro-Wilk test was used to check the normality of the data distribution. The Mann-Whitney U test (independent samples, non-parametric as data were not distributed normally) was used to test statistical hypotheses about equivalences between independent samples. The Wilcoxon signed-rank test (dependent samples, non-parametric statistic) was used to test statistical hypotheses about equivalences between dependent samples. For the Wilcoxon test, the effect size was calculated by the matched rank biserial correlation. The non-parametric ANOVA (Kruskal-Wallis Test), following Dunn's Post Hoc Comparisons, was applied for the intergroup comparisons. To address the issue of multiple comparisons and control the family-wise error rate, the Bonferroni correction was used (for this study, with two family-wise comparisons, the adjusted significance level was set at $\alpha < 0.025$). A post hoc sensitivity power analysis was conducted to estimate the minimum detectable effect sizes for between-group comparisons, given the sample sizes and statistical parameters.

Results

Participants flow

A total of 984 participants were screened for eligibility, with 530 being ineligible and 133 declining to participate (633 were excluded) (Figure 1). The remaining 321 participants were randomized into three groups: the PM+ group ($n = 107$), the SH+ group ($n = 107$), and the control group ($n = 107$).

Immediately after the intervention, the PHQ-9 and GAD-7 scales were used to screen 46 participants in the PM+ group and 81 in the SH+ group. Additionally, the PCL-5 assessment was conducted for 27 participants in the PM+ group and 60 in the SH+ group.

At the 3-month follow-up, 22 participants from the PM+ group and 39 from the SH+ group were reassessed using the PHQ-9 and GAD-7 scales, while 14 participants in the PM+ group and 27 in the SH+ group completed the PCL-5 assessment.

In the control group, 45 participants completed the PHQ-9 and GAD-7 assessments, 33 completed the PCL-5 assessment during a second screening, and 26 did not complete this stage. At the third screening, 14 participants completed the PHQ-9 and GAD-7 assessments, and 8 completed the PCL-5 assessment.

Baseline data

Descriptive statistics (all groups, before the intervention)

Table 2 shows the distribution of participants by sex, medications, and location. In each group, the majority of participants were males receiving methadone. Overall, most participants (104) were from the Lviv OAT center, while the others were approximately equally distributed between Vinnytsia (35) and Sumy (33).

The median age of the participants in the control group (CG, 45 participants) was 39 years (ranging from 31 to 60), the participants in the Self-Help Plus group (SH+, 81 participants)—40 years (ranging from 21 to 60), and the participants in the Problem Management Plus group (PM+, 46 participants)—40 years (ranging from 20 to 53) (Table 3, Annex, supplementary material).

The median satisfaction with the dose was 8 (on a scale from 0 to 10) across all groups, with the IQR equal to 3 (CG), 2.75 (PM+), and 2 (SH+). Missed doses were equal to 0.044 (SD 0.298) in the control group, 0.222 (SD 0.652) in the SH+ group, and 0.522 (SD 1.206) in the PM+ group. All means/medians of PHQ-9 and GAD-7 slightly exceeded the cutoff score of 10 (11–12 with IQR ranging from 3 to 5).

The distributions of study participants by levels of depression, anxiety, and PTSD symptoms across all groups, as per the stratification procedure, were calculated and presented in Annex, Table 4 (supplementary material).

A cutoff score of 10 was used for screening depression and anxiety (Kroenke et al. 2001; Spitzer et al. 2006; Manea et al. 2012). PCL-5 scores were calculated only for individuals who screened positive for trauma, meaning they had experienced at least one traumatic event as identified by the LEC-5. For PTSD symptoms, a PCL-5 cutoff score of 31 was applied (Weathers et al. 2013).

In the control group, above the cutoff score, 82% of participants had depression symptoms, 71% generalized

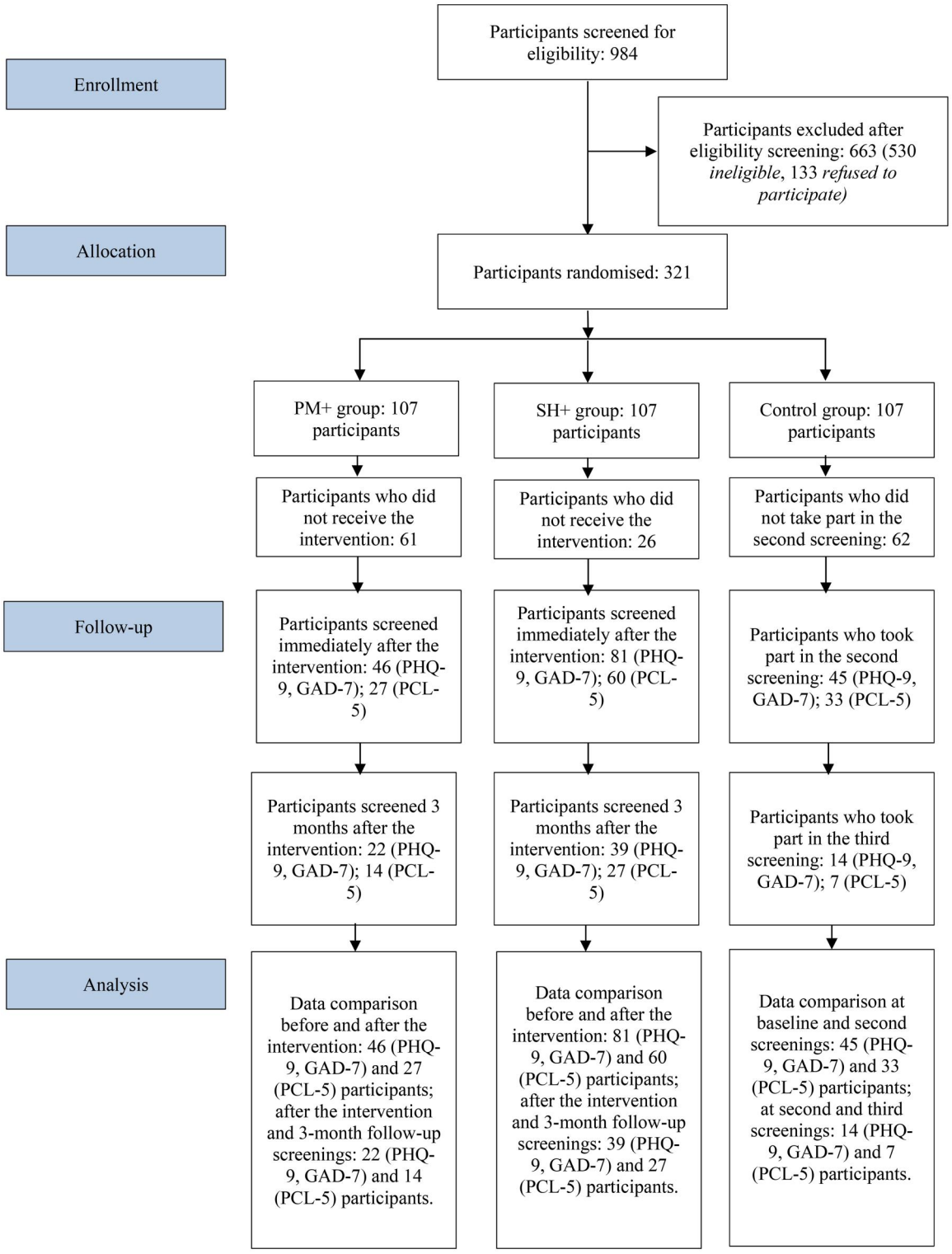

Figure 1. Participants' flow.

anxiety symptoms, and 55% PTSD symptoms. In the SH+ group, 79% of participants had depression symptoms, 69% generalized anxiety symptoms, and 53% PTSD symptoms. In the PM+ group, 87% of participants had depression symptoms above the cutoff score, 74% generalized anxiety symptoms, and 31% PTSD symptoms.

Comparison of all groups (before the intervention)

To analyze the impact of the interventions, it was necessary to ensure the equivalence of all groups before the interventions.

There were no significant differences in most measures ($p > 0.025$) across all groups, except for the

Table 2. Distribution of study participants by sex, medication, and the OAT center location.

		Sex		Medication			OAT center location			
Group		Male	Female	Methadone	Buprenorphine	Buvidal	Lviv	Vinnytsia	Sumy	Total
SH+	Count	73	8	63	17	1	57	7	17	**81**
	% within row	90%	10%	78%	21%	1%	70 %	9%	21%	
PM+	Count	34	12	33	13	0	28	9	9	**46**
	% within row	74%	26%	72%	28%	0 %	60%	20%	20%	
CG	Count	43	2	33	12	0	19	19	7	**45**
	% within row	96%	4%	73%	27%	0 %	42%	42%	16%	
Total	Count	150	22	129	42	1	104	35	33	**172**
	% within row	87%	13%	75%	24%	1 %	61 %	20 %	19%	

significantly lower number of missed doses in the control group (0.044; SD 0.298) compared to the PM+ group (0.522; SD 1.206), $p < 0.01$. The complete results of testing the statistical hypotheses are in the Annex, Table 5 (supplementary material).

Outcomes analysis

Control group, intragroup comparisons of the three screenings' results

Three screenings were conducted in the control group, corresponding to the screenings in the experimental groups that occurred before (the first screening), immediately after (the second screening), and three months after (the third screening) the interventions. The descriptive statistics and Wilcoxon signed-rank test results are provided in Tables 6 and 7 in the Annex (supplementary material).

Between the first and second screenings, significant differences were found for depression, anxiety, and PTSD symptoms. Median of the PHQ-9 scores significantly decreased from 12 (IQR 5) to 9 (IQR 11), $p < 0.025$; GAD-7 scores – from 11 (IQR 5) to 7 (IQR 7), $p < 0.001$, and PCL-5 scores – from 33 (IQR 18) to 12.5 (IQR 22), $p < 0.001$. Notably, as the scores increased, so did the variances (IQR). There were no significant differences in satisfaction with the dose.

Between the second and third screenings, no significant changes were revealed in any of the variables.

Problem Management Plus group, intragroup comparison

The first screening took place before the intervention (0–30 days prior to the 1st PM+ session), the second occurred immediately after the last PM+ session, and the third was conducted three months post-intervention (with a screening window of 2–4 months following the last PM+ session). The descriptive statistics and Wilcoxon signed-rank test results are provided in the Annex, Tables 8 and 9 (supplementary material).

Between the first and second screenings, taking into account the Bonferroni correction, one statistically significant change was observed: median GAD-7 decreased from 11 (IQR 3.75) to 9 (IQR 4); $p < 0.01$. No significant changes were revealed in the missed doses records, dose satisfaction, PHQ-9 and PCL-5 scores.

Between the second and third screenings, no significant changes were observed in any of the variables.

Self Help plus group, intragroup comparison

Three screenings were conducted, in the same way as for the Problem Management Plus group. The descriptive statistics and Wilcoxon signed-rank test results are provided in the Annex, Tables 10 and 11 (supplementary material).

Between the first and second screenings, statistically significant changes were observed in the mean missed doses (decreased from 0.222 to 0.062; $p < 0.01$), median PHQ-9 scores (decreased from 12 (IQR 5) to 9 (OQR 8); $p < 0.001$), GAD-7 (decreased from 11 (IQR 3) to 7 (IQR 7); $p < 0.001$) and PCL-5 (decreased from 31.5 (IQR 16.25) to 20 (IQR 22.25); $p < 0.001$).

Between the second and third screenings, no significant changes were observed in any of the variables.

All groups, intergroup comparison

Additional analysis of the intergroup differences was conducted, using the non-parametric ANOVA (Kruskal-Wallis Test) with following Dunn's Post Hoc Comparisons was applied (Table 13 and 14, Annex, supplementary material). No significant differences were revealed after the application of the Bonferroni correction (Figure 2).

Comparison of effect sizes

Table 3 provides summary data on the effect size of each intervention (only effect sizes for the statistically significant changes ($p < 0.05$) are presented), summarizing the effects of PM+ and SH+.

The comparative analysis reveals distinct strengths and areas of impact for each group. The control group (CG)

demonstrates some improvements in mental health outcomes, particularly for anxiety (GAD-7) and PTSD symptoms (PCL-5), with substantial effect sizes observed, and for depression, with moderate effect sizes (between the first and the second screening). No significant effect was observed between the second and the third screenings.

SH+ stands out for its impact on reduction in missed doses, and it also shows moderate improvements in depression (PHQ-9), anxiety (GAD-7), and PTSD symptoms (PCL-5) immediately after the interventions—no significant effect observed between the second and the third screening.

PM+, however, has a more limited overall impact. Its effect on anxiety level is similar to that of SH+. No significant influence on other variables was observed, and no significant effect was observed between the second and third screenings.

A post hoc sensitivity power analysis was conducted to estimate the minimum detectable effect sizes given the final sample sizes and statistical parameters used in the study. For the comparison between the SH+ ($n = 81$) and control ($n = 45$) groups, using an alpha level of 0.025 (Bonferroni-adjusted) and a desired power of 0.80, the study was powered to detect a minimum effect size of Cohen's $d = 0.43$, corresponding to a moderate effect. In contrast, the comparison between the PM+ group ($n = 46$) and control group ($n = 45$) yielded a minimum detectable effect size of Cohen's $d = 0.65$, indicating that only large effects would have been statistically detectable. These results suggest that the study was not sufficiently powered to detect small or even moderate between-group differences in the PM+ arm. Consequently, the absence of statistically significant differences in

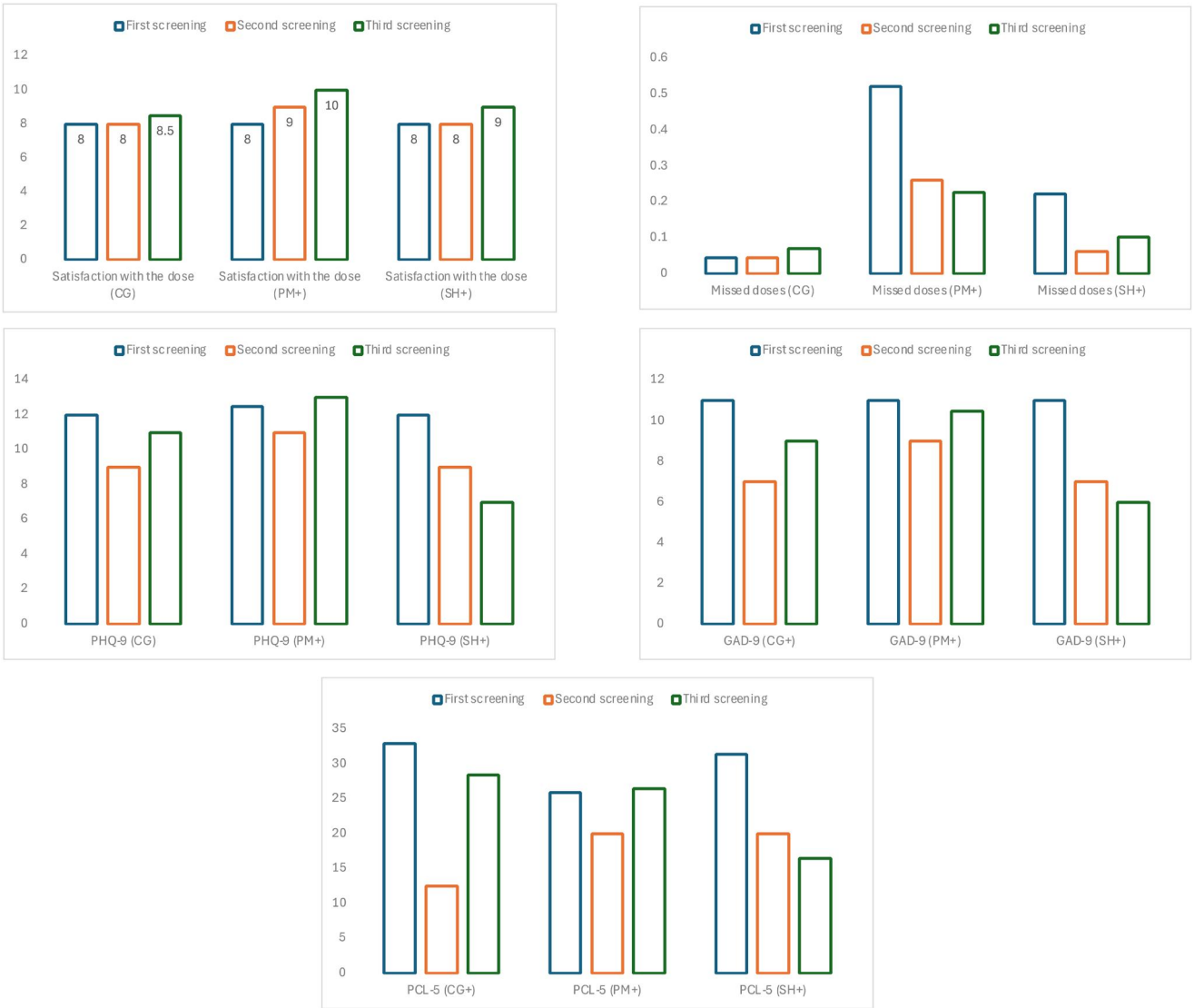

Figure 2. Medians of all variables, all groups, three screenings.

Table 3. Summary of the effect sizes (based on the intra-group comparisons).

Group	Changes	CG	PM+	SH+
Satisfaction with the dose	First to Second Screening	No significant changes	No significant changes	No significant changes
	Second to Third Screening	No significant changes	No significant changes	No significant changes
Missed doses	First to Second Screening	No significant changes	No significant changes	**1.000 (very strong)**
	Second to Third Screening	No significant changes	No significant changes	No significant changes
PHQ_9	First to Second Screening	**0.423 (moderate)**	No significant changes	**0.484 (moderate)**
	Second to Third Screening	No significant changes	No significant changes	No significant changes
GAD_7	First to Second Screening	**0.695 (strong)**	**0.527 (moderate)**	**0.52 (moderate)**
	Second to Third Screening	No significant changes	No significant changes	No significant changes
PCL_5	First to Second Screening	**0.724 (strong)**	No significant changes	**0.571 (moderate)**
	Second to Third Screening	No significant changes	No significant changes	No significant changes

intergroup comparisons—particularly for PM+—should be interpreted with caution, as meaningful clinical effects may have gone undetected due to limited statistical sensitivity.

The divergent effect sizes observed—with SH+ improving adherence and PM+ contributing less markedly to mental health outcomes—call for a deeper understanding of the underlying mechanisms. The stronger anxiety and PTSD reductions in the control group underscore the potential role of supportive human contact, hope induced by research participation, or other contextual factors. Rather than dismissing these findings, we interpret them as valuable signals about the layered nature of mental health recovery in highly disrupted environments.

Discussion

The findings of this study underscore the potential effectiveness of the Self-Help Plus and Problem Management Plus interventions in improving mental health outcomes among individuals enrolled in Opioid Agonist Treatment programs in Ukraine.

Both interventions, SH+ and PM+, reduced anxiety symptoms (moderate effect size). SH+ additionally demonstrated a notable decrease in missed medication doses (very strong effect size, based on the official records) and a decrease in depression and PTSD symptoms (moderate effect size). These findings show that both interventions have the potential to positively impact mental health outcomes and adherence to OAT, although there are differences in the extent and nature of these impacts.

The observed decrease in missed doses (from 0.222 to 0.062 after the second screening) indicates that SH+ can help clients consistently engage with treatment programs. The difference between the impact of PM+ and SH+, with the latter having a broader spectrum of mental health effects, warrants scaling up the SH+ intervention and further investigation of the PM+ intervention with people enrolled in the OAT programs.

This study's findings on SH+'s effectiveness in reducing symptoms of depression and anxiety align closely with numerous results from other studies demonstrating SH+'s capacity to support the mental health of refugees and asylum seekers. The intervention's group-based format and emphasis on mindfulness and stress management proved effective in fostering resilience and enhancing mental health outcomes (Purgato et al. 2021; Augustinavicius et al. 2023; Karyotaki et al. 2023). Other study reports long-term improvements in mental health outcomes up to 12 months post-intervention among refugees and asylum seekers (Purgato et al. 2022).

In our study, SH+ also significantly improved adherence to OAT, evidenced by reduced missed doses. This finding makes a novel contribution to the literature, since previous studies have primarily focused on mental health outcomes without assessing adherence in healthcare settings. The emphasis on real-world delivery in this study highlights the dual role of SH+ in improving both psychological well-being and treatment adherence, especially for vulnerable populations in crisis-affected contexts like Ukraine.

The results of this study also align with previous research on PM+, which demonstrated its effectiveness in reducing symptoms of common mental health disorders in humanitarian settings across different countries. Similar to the current study's findings, PM+ has been shown to provide individualized emotional support and problem-solving skills, addressing diverse needs in culturally varied populations (Sijbrandij et al. 2015; Acarturk et al. 2024; de Graaff et al. 2024). However, the limited impact of PM+ on PTSD and depression symptoms was observed in our study, pointing out the need to carefully tailor the type of support to the population's needs and avoid overinflation of the usability of scalable psychosocial interventions.

However, it is important to note that the intergroup comparisons did not yield statistically significant differences after applying the Bonferroni

correction. This may be due to the limited statistical power resulting from sample attrition, variability in fidelity of intervention delivery, or the presence of nonspecific therapeutic effects in the control group. The notable improvements in the control group, including reductions in mental health symptom scores, may reflect supportive interactions, increased mental health awareness due to repeated assessments, or regression to the mean. These findings underscore the need for cautious interpretation of effectiveness claims and highlight the importance of including robust comparator arms in future trials.

The numerous analyses conducted across various outcomes, including mental health symptoms, adherence, and PTSD, pose a risk of type I error. However, the study's utilization of validated psychometric tools (e.g. PHQ-9, GAD-7, PCL-5) and thorough statistical analyses (including Bonferroni correction) somewhat alleviates this concern. Furthermore, the pragmatic trial design mirrors real-world conditions, allowing for variability in delivery, which enhances the applicability of the findings but may dilute the effect estimates.

A notable and somewhat paradoxical finding is that the control group demonstrated stronger effect sizes than both intervention groups for anxiety (GAD-7: 0.695) and PTSD symptoms (PCL-5: 0.724) immediately post-intervention. Without a more rigorous control for such influences, attributing observed effects in SH+ or PM+ groups solely to the interventions becomes problematic. This pattern calls for more nuanced interpretation and further exploration before recommending SH+ for scale-up. Larger trials with enhanced control arms—such as attention-matched comparators—are needed to isolate the active components of SH+ and assess its added value beyond standard care.

The findings of this study are highly relevant to settings with similar healthcare constraints, high burdens of mental health conditions, and populations requiring OAT services. Ukraine's ongoing war and its associated psychosocial stressors uniquely frame the study's context, but the observed benefits of SH+ and PM+ are likely transferable to other crisis-affected or resource-limited environments. The study design, which integrated interventions within existing OAT centers, enhances the feasibility of scaling these approaches in similar healthcare systems. Key factors influencing the trial's success involve integrating trained facilitators and collaborating with multidisciplinary teams.

Variations in healthcare infrastructure, cultural attitudes toward mental health, and resource availability may influence the generalizability of results. For instance, SH+'s group-based delivery requires adequate physical spaces and facilitator availability, which may not be feasible in under-resourced OAT centers. Similarly, PM+'s one-on-one format is time-intensive, making it challenging to scale in high-demand settings.

This study makes a novel contribution to the growing literature on scalable psychological interventions by being one of the first to test SH+ and PM+ among people receiving opioid agonist treatment (OAT) in a humanitarian context. While prior evidence supports these interventions among refugees or community populations, little is known about their feasibility or impact in substance use care settings. Our findings suggest that SH+ may positively influence treatment adherence—an area rarely explored in this context—and highlight the complex psychosocial needs of OAT clients during wartime in Ukraine.

Importantly, the observation of significant mental health improvements in the control group also raises questions about the mechanisms driving change. It points to possible nonspecific effects such as increased attention, emotional validation through repeated assessments, or enhanced self-awareness, which may themselves be therapeutic. This highlights the need for future studies to disentangle specific from nonspecific intervention effects and consider more robust control conditions.

Limitations of the study

The study has several limitations. The stage of the OAT treatment was not recorded for each client; therefore, it is impossible to conclude the impact of the OAT lengths and stages on the interventions' outcomes. The study faced high dropout rates, particularly between the post-intervention and follow-up assessments, which may have reduced the robustness of longitudinal comparisons. The absence of blinding may have introduced potential biases in participant responses and researcher assessments. The use of self-reported measures for mental health symptoms, while practical in the context, carries inherent risks of response bias. Because dosing schedules differ across medications (e.g. daily for methadone, monthly for buvidal), the raw number of missed doses may not fully capture treatment adherence. Future studies should calculate adherence as a proportion of expected doses based on individualized regimens. Additionally, variability in intervention delivery, particularly in SH+ group sizes and scheduling flexibility, may have impacted the consistency of outcomes. The changes in

the control group also indicate the need to interpret study findings with reservation, pointing out the necessity of further investigations.

Building on these findings, future research should explore the long-term effectiveness of SH+ and PM+ among individuals with opioid use disorder, particularly beyond the three-month follow-up period. It would also be valuable to investigate the integration of trauma-specific modules into SH+ and PM+ to address better PTSD symptoms, which remained relatively persistent in some subgroups. Additionally, qualitative studies could help illuminate the mechanisms through which these interventions influence adherence and satisfaction with treatment. Comparative trials assessing SH+ and PM+ against other psychosocial approaches or in combination with pharmacotherapy optimization could further refine intervention strategies in resource-constrained settings.

Conclusions

This study highlights the effectiveness of the scalable psychological interventions in improving mental health outcomes among individuals enrolled in Opioid Agonist Treatment programs in Ukraine during wartime. Both interventions demonstrated significant reductions in symptoms of anxiety, with SH+ also improving adherence by reducing missed doses and decreasing PTSD and depression symptoms.

However, while this study demonstrated statistically significant improvements within the SH+ and PM+ groups in anxiety, depression, and missed doses, it did not reveal statistically significant differences between intervention and control groups in intergroup comparisons after applying conservative corrections for multiple testing. This lack of between-group significance suggests that while both interventions may contribute to positive changes in individual mental health and adherence indicators, the observed effects cannot be definitively attributed to the interventions themselves when compared to standard care alone. Therefore, these findings should be interpreted with caution, and further research using more robust designs with larger sample sizes and lower attrition rates is needed to confirm the added value of these interventions beyond usual care.

While the effects observed may not be attributable solely to the interventions tested, this study adds meaningful insight into how brief, scalable psychosocial interventions could operate in complex care settings like Ukraine's OAT programs. It also draws attention to the powerful impact that even minimal human interaction and repeated self-assessment may have on psychological well-being in low-resource, high-adversity settings. These findings invite a reexamination of assumptions about what constitutes an 'active' intervention and underscore the importance of embedding psychosocial care within routine substance use treatment programs.

Future research should focus on exploring models, integrating trauma-specific components, and assessing long-term outcomes to maximize the impact of these interventions. By addressing these gaps, scalable psychological interventions can become integral components of comprehensive care strategies, bridging critical gaps in mental health and adherence for vulnerable populations in Ukraine and beyond.

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Data availability statement

Data supporting these findings are available within the article or upon request made to the State Institution 'Public Health Center of the Ministry of Health of Ukraine' according to approved procedures outlined at the Center′s website: https://phc.org.ua/naukova-diyalnist/doslidzhennya.

Institutional review board statement

The study protocol was developed in close collaboration with representatives of the OAT sites. Experts from the OAT sites evaluated all research tools. The research team adhered to the Declaration of Helsinki and the National Psychological Association of Ukraine Ethical Regulation. The Study Protocol was approved by the Institutional Review Board of the State Institution 'Public Health Center of the Ministry of Health of Ukraine,' approval number 326.

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