Original Research

Effectiveness and Safety of a Self-Management Program for Substance Addiction Consequences: A Pilot Clinical Trial

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Abstract

Background: Harmful substance use affects millions of people, producing health and social consequences that require both professional support and effective self-management. This study piloted a self-management program targeting the consequences of substance addiction in adults enrolled in medication-based program.

Methods: A parallel-group pilot trial compared the *Self-Management Substance Addiction Consequences Program* (ADS Program) with treatment as usual (TAU) to assess the program's effectiveness and identify the need for adjustments to the intervention or the trial design. Seventy-two randomly selected adults enrolled for at least 5 weeks in medication-based program for alcohol or other drugs participated. Data were collected at baseline and after 8 to 21 weeks to assess effects on substance addiction consequences (SAC) and positive mental health (PMH).

Results: Of the 236 patients screened, 72 were randomized: 38 to the ADS Program and 34 to TAU. Twenty-five participants completed the ADS Program (34.2% attrition), and 16 completed TAU (52% attrition). ADS participants attended more sessions (6 vs 2), although still fewer than planned. Participants in the ADS Program demonstrated significant reduction in SAC (paired $t(24) = -5.718$, $P < .001$, $d = -1.169$). Similar improvements were observed in the TAU group (paired $t(15) = -6.357$, $P < .001$, $d = -1.580$), with no significant differences between groups ($P > .05$). PMH also improved in both groups. The ADS group showed a statistically significant increase (paired $t(20) = -3.945$, $P < .001$, $d = -0.861$), whereas the TAU group demonstrated marginally non-significant improvement (paired $t(11) = -2.170$, $P = .053$, $d = -0.626$). No significant between-group differences were identified ($P > .05$).

Conclusions: This pilot trial indicates that the ADS Program is feasible, safe, and potentially effective in supporting self-management of SAC. Findings suggest an adjusted duration of 6 to 18 weeks may be beneficial. Given the substantial dropout rate, further research with larger samples is needed to confirm effectiveness and improve retention.

Keywords

substance use disorder, self-management, nursing interventions, program evaluation, pilot randomized control trial

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Highlights

- The Self-Management Substance Addiction Consequences Program (ADS Program) is applicable, safe, and potentially effective for improving the self-management of addiction-related impacts.
- Participants in the ADS Program demonstrated significant improvements in measures of addiction consequences and positive mental health, although the group receiving usual care also showed progress.
- The program was found to be feasible after being adjusted to between 6 and 18 weeks.
- The article emphasizes the need for a larger randomized clinical trial to confirm the program's effectiveness and acceptance in clinical practice.

Introduction

According to the World Report on Drug and Alcohol Problems, millions of people experience major health and social impacts related to substance use, and these numbers are expected to increase in the coming years.[1]

Different programs designed to support self-management, especially for substance use, have been offered in outpatient settings, individually or in groups, and led by different professionals.[2,3] These programs often rely on motivational strategies,[3] cognitive-behavioral therapy,[4] psychoeducation, relapse prevention,[5] and, in some cases, additional support, including physical activity.[6] However, they are frequently implemented as isolated interventions or combined approaches targeting specific problems, lacking the scope required to address the complexity of individuals' needs. Despite these approaches and the wide range of addiction consequences – physical, psychological, economic, social, and familial, no unanimous strategy or structured program for supporting self-management has emerged,[7] and no other recent systematic review with a primary focus on long-term maintenance of self-management processes (sustained self-management) in populations with alcohol and/or other drug dependence emerged. To address this, a new nurse-led training program for self-management of substance addiction consequences (SAC)[8] was piloted and compared to standard treatment, which involved nursing consultations within a medication-based program.

Background

In many chronic diseases, patients require training programs to enhance self-management capabilities.[3] Those with problematic substance use often have a chronic condition that directly affects their present and future.[9]

The severity of SAC often drives people to seek help and join medication-based programs, such as methadone, buprenorphine, or alcohol aversion therapy. SAC is defined as the degree of change in health and social function due to substance dependence.[10] On the other hand, improvement in positive mental health (PMH) can help track changes in health status over time. PMH is a value (feeling good) and a way to interpret and adapt to one's environment. It signals integration and adaptation,[11] but is often harmed by substance use. Viewing the consequences of substance addiction through the lens of PMH shifts the focus from loss and dysfunction to potential and growth and recovery is understood not only as harm reduction but also as developing self-management, resilience, and meaning. This perspective promotes empowerment and sustains well-being, moving from a reparative to a strength-based approach centered on human potential and autonomy.[11] This is reflected in the relationship between harm-related consequences and the domains of PMH (personal satisfaction, prosocial attitude, autonomy, interpersonal relationship skills, self-control and problem-solving and self-actualization capacities). Strengthening these 6 domains may contribute to reducing the 4 types of SAC.

Managing SAC is complex, sometimes involving both the patient and family,[12] and demands evidence-based approaches.[13] People with addictive behaviors and health needs value respect in healthcare, want to be able to make decisions about their own care plans, and require a more active role from nurses in their follow-up.[14] However, evidence on nursing intervention programs with substance-dependent patients remains limited.[7,15] As nursing advances innovative solutions for individuals with addiction, nurse-led models of care represent a key mechanism for delivering high-quality, evidence-based interventions, particularly given the chronic and multidimensional nature of this condition.[9] The continuous and relational nature of nursing practice, characterized by sustained patient contact and the provision of individualized, integrated support within routine care, positions nurses as central agents in the effective implementation of these interventions. Complex problems require a flexible range of complementary interventions. When properly organized, these can create an intervention program.[8] Before evaluating effectiveness, any program should be piloted.[16,17]

Building on these premises, this study reports outcomes from a pilot evaluation of a new, co-created training program (ADS Program) designed to enhance self-management of SAC. The selected outcomes – SAC and PMH – directly reflect the program's core objective

of strengthening self-management capacities. The aim of this pilot study was to evaluate effectiveness, assess safety, and identify needed changes before a larger randomized controlled study. The hypotheses tested were that the program is effective, safe, feasible, and acceptable before a future trial.

The research question was: What is the effectiveness of the training program for self-management of SAC, compared to treatment as usual (TAU), in an outpatient medication-based program?

Methods

Trial Design

This pilot study was designed as a parallel group randomized controlled trial (RCT), comparing the ADS Program with TAU, with participants allocated in a 1:1 ratio. All CONSORT guideline extension for Pilot Trials were followed.[17]

Participants

Recruitment for this study took place between February 2023 and February 2024, in an outpatient specialized treatment facility in Lisbon, Portugal.

Inclusion criteria for patients were: adults (18 years or older) diagnosed with a substance use disorder (ICD-10 criteria, used in the national health system), who had been in an outpatient medication-based program for at least 5 weeks, agreed to participate in a nursing consultation, and had a score of 48 or less on the SAC scale.[18] Exclusion criteria were established through routine clinical judgment, without the use of standardized instruments, and included patients exhibiting impaired thoughts process or perception, aggressive behavior, and psychomotor agitation. Cognitive impairment was assessed using Mini-Mental State Examination.[19]

Participants underwent assessment as part of the standard medication-based program approach, which includes routine evaluation of all patients, including the SAC scale (Figure 1), carried out by nurses. Following confirmation of eligibility, clinical nurses invited patients to participate in the study and provided detailed information, as they were the first professionals to introduce the study to potential participants. Participants were informed that participation was voluntary, with no impact on their standard health care, and that they could withdraw at any time. Written informed consent was obtained to protect participant identity and clarify the requirements for result disclosure. No financial incentives were offered.

The eligibility criteria for nurses to implement the program were: (1) being a mental health and psychiatric nursing specialist or community nursing specialist, with at least 3 years of experience with people with substance use disorder or (2) being a registered nurse, with at least 5 years of clinical experience with people with SUD (supervised by a specialist nurse). All nurses had to enroll in a 6-hour training provided by the research team, during which they were introduced to the program's theoretical framework and key concepts (SAC, PMH, and self-management), as well as explanations of the clinical areas, diagnoses, and interventions agreed upon in previous studies. This was followed by a debriefing session to discuss their reactions and explore ways to implement the recommended interventions.[8] Throughout the research project, monthly supervision meetings were conducted to ensure fidelity to the intervention protocol and to standardize procedures.

Interventions

After the initial nursing consultation during the enrollment period, participants were placed into one of 2 groups: the experimental group (ADS Program) (Supplemental Appendix A) or the TAU group (Supplemental Appendix B). Figure 1 shows how participants were assigned and their progress through each group in the study. To improve program adherence, telephone reminders were employed to encourage attendance at nursing consultations.

Patient-Centered Outcomes

Since the aim of this pilot was to be the first step in evaluating the effectiveness of the ADS Program, the primary outcome to be evaluated was SAC and the co-primary was PMH (Table 1).

SAC (T0 and T1) – The SAC is a reliable tool to assess the severity of consequences of substance addiction in 4 dimensions (psychological and family factors; physical and cognitive factors; economic and work factors; and self-care factors). It consists of 16 items, using a 5-point Likert scale (1-5), ranging from "severe" to "none," with higher scores indicating less severity. Internal consistency in previous studies was acceptable ($\alpha = .854$).[18] On the results section of this article, when "severity" appears as an outcome, it is related to the total value of the SAC Scale.

PMH (T0 and T1) – The PMH Questionnaire contains a series of statements about thinking, feeling, and acting, with 18 questions grouped into 6 dimensions (personal satisfaction; prosocial attitude; self-control; autonomy; problem-solving ability and personal achievement; interpersonal relationship skills). It is rated on a 4-point Likert scale (1-4), ranging from "always or almost always" (1) to "rarely or never" (4), with higher scores indicating higher levels of PMH. Internal consistency in previous studies was adequate ($\alpha = .920$).[20]

These 2 outcomes were assessed at the first moment and after the planned 8th consultation, which was scheduled to take place between the 8th and 21st weeks, for all participants in both arms.

Secondary outcomes: patient attendance rate during data collection (number of attended sessions/Number of

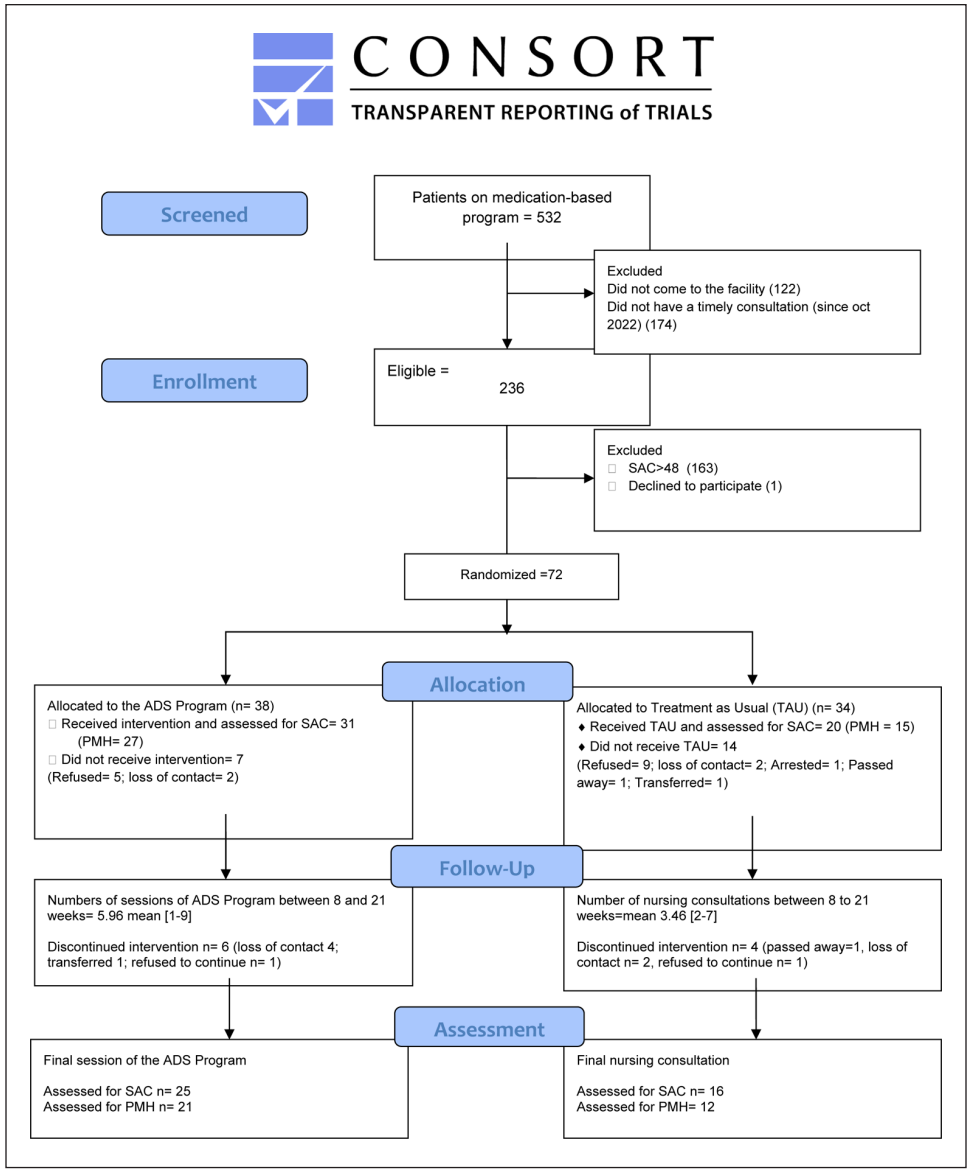

Figure 1. Flow chart of participants in the pilot trial.

programmed sessions × 100) and decrease in the number of active nursing diagnoses rated by clinical nurses, this means the number of diagnoses identified by nurses and then assessed as favorable for closure. The safety of the program and any required refinements, before extending to a larger randomized controlled study, were also considered secondary outcomes.

Sample Size

There is no universally accepted method for determining sample size in RCTs, particularly for pilot studies, where formal calculations may not be appropriate.[21] Therefore, a sample size was estimated using a rule of thumb.[22] An initial estimate of 60 participants (30 per group) was considered the minimum for assessing effect size.[21] However, based on participant attrition rates in similar studies and anticipated recruitment challenges, the final sample size was set at 15 participants per group. This approach aimed to enable group comparisons, although a strong effect size was not anticipated. Participant attrition was monitored and analyzed for its impact on sample homogeneity. This sample size aligns with common practice for pilot studies involving new interventions and hard-to-reach populations.[21,23]

Randomization

A free online random number generator was used to create the allocation sequence. Stratification was planned by sex (75% men, 25% women) and by type of medication

Table 1. Enrollment, Interventions, and Assessments.

	Study period				
	Enrollment	Allocation	Post-allocation		Follow-up
Timepoint	T0		Week 1–8/21 week (intervention)	T1 8-21 weeks	t_x 52 weeks
Enrollment					
Eligibility screen on unit records	X				
Eligibility screen on nursing consultation	X				
Informed consent	X				
Allocation		X			
Interventions					
ADS program			—		
TAU			—		
Assessments					
Age; sex	X				
Type and length of program	X				
SAC scale	X			X	X
PMH scale	X			X	X
Patient attendance rate				X	
Nr. of nursing diagnoses				X	

Abbreviations: TAU, treatment as usual; SAC, substance addiction consequences; PMH, positive mental health.

program (70% on opioid agonist medication, and 30% on aversive alcohol medication) to reflect the typical outpatient population profile.[24] Two sets of numbers were generated for all eligible and consenting participants. The principal investigator regularly received information on eligible participants, performed randomization according to the predetermined sequence, and subsequently informed the team of group allocation.

Allocation

Patients were randomly assigned to the ADS Program or TAU (Figure 1) using a 1:1 ratio, after informed consent was obtained by the nursing team. When someone refused to participate, their decision was recorded for accounting purposes, and the assignment proceeded with the next patient who met the eligibility criteria and agreed to be part of the study.

Masking

A partial blinding design was used: participants were unaware of the activities of the alternative group, while nurses delivering the interventions were aware of group allocation. Outcome assessments were conducted by assistant researchers blinded to group assignment. The principal investigator, who generated the randomization sequence, had no direct contact with participants and received only anonymized data.

Statistical Analysis

All statistical analyses were conducted using IBM SPSS 29. Descriptive statistics were used for the independent variables (sex, age, type of program, and program length) and the dependent variables (SAC and PMH). For all variables, normality of data distribution was assessed using the Shapiro-Wilk test to determine the appropriate type of statistical analysis. Variables that met the assumption of normality were analyzed using appropriate parametric tests (t-test, paired t-test, Pearson correlation test, ANOVA comparison test with Bonferroni correction), whereas variables that did not follow a normal distribution were analyzed using non-parametric tests (Mann–Whitney U test, Wilcoxon signed-rank test, Spearman correlation test).[25] To address the small sample size, bivariate relationships were done with a two-sided Fisher's exact test (2×2 contingency tables). These results, with the retention and attendance rates, could be used to inform the sample size calculation for a future larger trial.[25] Analyses were conducted according to the per-protocol principle, including only participants who completed all scheduled assessments (complete-case analysis). Baseline characteristics were compared between completers and non-completers, with no significant differences observed, minimizing potential attrition bias. This approach was considered appropriate given the exploratory and feasibility focus of this pilot study, and it allowed estimation of preliminary effect sizes.[26]

To address the possible required refinements to the program, after the first 21 weeks, the data was analyzed to support the ongoing pilot trial.

Ethical Issues

All participants were asked whether they consented to participate in the study, either in the TAU or the experimental group (Figure 1). The objectives were explained, and all participants had the opportunity to ask for further information. Participants could refuse or accept participation by completing an informed consent form. If a participant assigned to the ADS Program wished to leave the study, they could inform the clinical nurses, who would refer them to TAU.

This pilot trial was conducted in accordance with the principles outlined in the Declaration of Helsinki regarding the study of human subjects, and a previous approval from an Ethics Committee was obtained. All data collection procedures were conducted in accordance with national data protection laws. All data shared with the non-clinical research team was anonymous. The research team at the unit, after admitting any patient into one of the study arms, entered the participant identification into an Excel database on a service computer, protected by a firewall and password. The person's medical record number was added to allow a second follow-up assessment. After the T1 assessment, the data were extracted from the database and sent to the principal investigator in a sequential order that prevented any identification.

Results

From the initial population of 532 registered outpatients at the specialized treatment facility, 122 were excluded because they received medication at another extension unit of the same service, and 174 were enrolled in the medication-based program but did not attend a nursing consultation during the study period. Of the remaining 236 patients invited to participate and assessed using the predefined instruments, 144 were considered ineligible due to lower severity levels, as the study focused on individuals with more severe clinical and social consequences. All eligible participants were randomized, resulting in a final sample of 72 patients. These patients were then randomly assigned, with 38 to the ADS Program and 34 to TAU. In the experimental group, 31 patients initially received the intended treatment, but only 25 were assessed at the end. In TAU, 20 patients attended consultations, but only 16 completed the full assessment. Recruitment remained active until at least 30 patients were allocated to each group. Even after consenting to participate, some patients dropped out of the study. The number of patients who discontinued treatment follow-up was significant (ADS Program 34%/TAU 52,9%) for various reasons (eg dropping out after being enrolled, refused to continue as a participant (Figure 1), a common occurrence in longitudinal research with individuals with substance use disorders.[12]

Baseline demographic characteristics presented no differences across groups in many variables, including sex, age, marital status, number of children, number of cohabitants, labor situation, occupation, and economic income; however, economic income showed a trend toward statistical significance ($P = .097$) (Table 2).

In the experimental group, there were slightly fewer men (83.9%) than in TAU (85%), with a mean age of 49.52 years (± 8.7). Participants were mainly single (51.6%), with a median of 1 child and 2 cohabitants. They were mainly unemployed and had no professional qualifications.

In TAU, participants had fewer cohabitants, higher unemployment rates, but approximately the same rate of non-qualified professionals.

There were no differences in clinical characteristics between the 2 groups (Table 3). In relation to the type of medication program, those in alcohol aversive medication were slightly more in the ADS Program, compared to those in TAU. Additionally, alcohol was the main substance used, and it was more prevalent than the use of alcohol aversive medication, indicating that patients on the methadone program also consume alcohol. Patients in the ADS program had a higher adherence rate, completed the targeted number of appointments in a shorter time, and experienced a greater reduction in the number of active nursing diagnoses.

Main Outcomes

Both SAC and PMH scores improved from T0 to T1 (Table 4). The ADS Program showed a larger increase in PMH, reaching adequate statistical power, whereas the PMH change in the TAU group did not reach statistical significance and was associated with lower power. TAU participants exhibited a greater change in SAC scores. No significant between-group differences were observed at either time point.

Comparing Outcomes with Independent Variables

Sociodemographic Differences. At baseline (T0), men presented higher severity scores than women in both the ADS group (men: $M = 35.58$, SD = 6.17; women: M=40.60, SD = 6.06) and TAU group (men: $M = 34.23$, SD = 6.87; women $M = 44.00$, SD = 2.00). The same pattern was observed at T1 in both ADS (men: 45.90, SD = 8.74; women: $M = 55$, SD = 5.14) and TAU (men: $M = 51.64$, SD = 12.30; women: $M = 58.00$, SD = 5.65). However, none these sex differences reached statistical significance

Table 2. Demographic Characteristics for Each Group.

Variables	ADS program	TAU	Comparison between groups
Males/females	26 (83.9%)/5 (16.1%)	17 (85%)/3 (15%)	$X^2(1) = 0.012$; $P = .619$
Age[a]	49.52 (SD = 8.7) [29-66]	50.33 (SD = 7.21) [38-72]	t student (47) = −0.336; $P = .460$
Marital status	Married/legal relationship: 4 (12.9%) Divorced: 8(25.8%) Single: 16 (51.6%) Other: 1 (3.2%) Omitted: 2 (6.5%)	Married/legal relationship: 2 (10%) Divorced: 6 (30%) Single: 9 (45%) Other: 1 (5%) Omitted: 2 (10%)	$X^2(3) = 0.357$; $P = .949$
Number of children or dependent children[b]	1 (IQR = 2)	0.5 (IQR = 2)	U = 250.500; $P = .806$
number of cohabitants	2 (IQR = 2)	1 (IQR = 2)	U = 200.500; $P = .271$
Labor situation	$n = 29$	$n = 18$	$X^2(1) = 0.370$; $P = .543$
Employed/unemployed	7 (24.1%) / 22 (75.9%)	3 (16.7%) / 15 (83.3%)	
Occupation[c]	$n = 23$ Non-qualified workers 10 (43.5%) Skilled workers in industry. construction and craftsmen 8 (34.8%)	$N = 17$ Non-qualified workers 7 (41.2%) Skilled workers in industry. construction and craftsmen 7 (41.2%)	Fisher exact test = 3.850; $P = .898$
Economic income	$N = 29$ No income 16 (55.2%) <200 4 (13.8%) >800 4 (13.8%)	$N = 18$ No income 3 (16.7%) <200 4(22.2%) 20-400 4(22.4%) >800 3 (16.7%)	$X^2(5) = 9.306$; $P = .097$

Abbreviation: SAC, substance addiction consequences.
In some variables, only the most prevalent data is presented.
[a]Mean.
[b]Median
[c]Without conditions to use X^2

($P > .05$). No significant correlation was identified between age and SAC or PMH scores at either TO or T1 in both groups.

In the ADS group, the number of children was positively correlated with lower SAC severity ($r_p = 0{,}400$, $P = ,047$). A similar association was observed for the Psychological and Family Factors subscale ($r_p = 0.475$, $P = .016$). This association was not observed in the TAU group.

Employed participants showed lower SAC severity than unemployed participants at both T0 and T1 in both groups. While baseline differences were not statistically significant, at T1 a significant difference was observed in the ADS group, with employed participants presenting lower severity (t-test(23) = 2.153, $P = .042$).

Treatment Characteristics. No significant differences in SAC severity were found between participants enrolled in methadone maintenance programs and those in alcohol aversive therapy in either group ((ADS group on methadone $M = 36.33$, SD = 6.35, on aversive $M = 37.33$, SD = 7.06: t-test(25) = −0.387, $P = .702$) / (TAU on methadone $M = 36.15$, SD = 6.93, on aversive $M = 42.80$, SD = 3.03: t-test(16) = −2.038; $P = .058$). However, patients in methadone programs tended to have higher severity. Similarly, no significant differences were observed across primary substance types (heroin, cocaine, alcohol) in both groups. Regarding consumption methods, no significant differences were found in the ADS group ($F_{(2,23)} = 2.578$, $P = .098$). In contrast, significant differences were found in the TAU program ($F_{(2,15)} = 5.122$, $P = .020$), with participants who injected substances presenting higher severity (SAC $M = 26.5$, SD = 3.53) compared to those who smoked ($M = 38.29$, SD = 7.27) or ingested orally ($M = 40.33$, SD = 4.03).

Relationship Between Mental Health and SAC. No significant association between PMH and SAC severity was observed at T0 in either group. However, at T1, a significant positive correlation emerged in both the ADS) ($r_p = 0.546$, $P = .010$) and the TAU group ($r_p = 0.616$, $P = .033$).

Clinical Indicators and Program Engagement (ADS Group). In the ADS group, higher PMH scores at T1 were associated

Table 3. Clinical Characteristics and Other Outcomes.

Variables	ADS program	TAU	Comparison between groups
Type of program	$N = 29$[a] Methadone 15 (51.7%) alcohol aversive medication 12 (41.1%)	$N = 18$[a] Methadone 13 (72.2%) alcohol aversive medication 5 (27.8%)	$X^2(3) = 2.593$; $P = .527$
Time in the medication-based program (months)	$N = 29$ Median = 4 IQR = 17	$N = 18$ Median = 4. IQR = 58	U = 222.000; $P = .385$
Number of entries in the program	$N = 29$ Median = 1 IQR = 1	$N = 18$ Median = 1 IQR = 1	U = 235.500; $P = .531$
Main substance currently used	$N = 29$[a] Heroine 10 (34.5%) Alcohol 13 (44.8%) Cocaine 3 (10.3%) Others 3 (10.3%)	$N = 18$[a] Heroine 6 (33.3%) Alcohol 10 (55.6%) Cocaine 2 (11.1%)	X^2mc(4) = 2.134; $P = .798$
Consumption mode of the main substance	$N = 29$[a] Oral 12 (46.2%) Smoked 10 (38.5%) Injection 4 (15.4%)	$N = 18$[a] Oral 9 (50%) Smoked 7 (38.9%) Injection 2 (11.1%)	$X^2(2) = 0.176$; $P = .916$
Period since last use	$<$ 1 month 84.6% Between 3 and 6 months 11.5% More than 6 months 3.8%	$<$ 1 month 100%	X^2mc(2) = 3.046; $P = .257$
HCV	11 (37.9%) yes	6 (33.3%) yes	$X^2(1) = 0.102$; $P = .750$
HIV	1 (3.4%) yes	2 (11.1%) yes	$X^2(1) = 1.091$; $P = .296$
Other comorbidities	16.7% respiratory disease 41.7% mood disease 16.7% liver disease	50% respiratory disease 16.7% mood disease 16.7% liver disease 16.7% cardiovascular disease	X^2mc(1) = 0.021; $P = .480$
Consultation's appointments	$N = 29$ Median = 7 IQR = 2	$N = 17$ Median = 4 IQR = 2	U = 60.500; $P < .001$
Presence at consultations	$N = 29$ Median = 6 IQR = 2	$N = 15$ Median = 3 IQR = 1	U = 55.000; $P < .001$
Adherence rate to consultations	$N = 29$ Mean = 87.1 (%) SD = 11.23	$N = 14$ Mean = 76.75 (%). SD = 21.27	t-test 2.116; $P = .040$
Number of weeks	Median = 10 (IQR = 3) Min 7. Max 22	Median = 11.5 (IQR = 4) Min 8. Max 20	U = 144.000; $P = .358$
Nursing diagnoses–initial	Median = 5 (IQR = 3)	Median = 2 (IQR = 1)	U = 14.000; $P < .001$
Nursing diagnoses–final	Median = 3 (IQR = 2)	Median = 2 (IQR = 0)	U = 61.000; $P = .002$
Comparison between the initial and final number of diagnoses	Wilcoxon z = −3.966; $P \leq .001$	Wilcoxon z = −0.966; $P = .334$	

Abbreviation: IQR, interquartile range.
[a]Some variables contain missing values.

with fewer entries in the medication programs (rho = −0.470, $P = .028$). Consultation adherence was positively associated with lower severity at T1 (rho = 0.414, $P = .039$) and better economic and labor status (rho = 0.444; $P = .026$). A higher number of nursing diagnoses at baseline was associated with greater SAC severity at T0 (rho = −0.586, $P <$,001) and T1 (rho = −0.444, $P = .026$), as well as lower PMH scores at T0 (rho = −0.458, $P = .016$) and T1 (rho = −0.506, $P = .019$).

SAC Subscale Analysis. At baseline, no statistically significant differences were observed between groups across the 4 dimensions. Economic and labor factors presented the highest severity levels in both groups (Table 5). Over time, greater improvements in Psychological and Family Factors and Physical and Cognitive Factors were observed in the ADS group. In contrast, improvements in Self-Care factors and Economic and Labor Factors were greater in the TAU group.

Discussion

The CONSORT guidelines advise against testing clinical outcomes in pilot trials, as these studies are typically underpowered to detect such differences. Instead, primary evaluation in pilot trials should focus on descriptive analysis of

Table 4. Main Outcomes Pre and Post.

Variables	ADS program	TAU	Comparison between groups
SAC initial ($\alpha = 0.627$)	$N = 31$ 36.39 (SD = 6.33) [24-48]	$N = 20$ 38.70 (SD = 6.74) [23-46]	t-test (49) = −1.241; $P = .220$
SAC final	$N = 25$ 47.60 (SD = 9.02) [34-66]	$N = 16$ 52.50 (SD = 11.78) [30-73]	t-test (99) = −1.504; $P = .141$
Compared initial and final SAC	Paired t-test (24) = −5.718; $P < .001$ Cohen value = −1.169	Paired t-test (15) = −6.357; $P < .001$ Cohen Value = −1.580	
PMH – initial ($\alpha = 0.720$)	$N = 27$ 51.67 (SD = 7.66) [35-64]	$N = 15$ 55.20 (SD = 7.39) [41-68]	t-test = −1.449(40); $P = .155$
PMH–final	$N = 21$ 55.23 (SD = 7.94) [41-70]	$N = 12$ 57.5 (SD = 7.31) [45-69]	t-test = 0.572 (32); $P = .571$
Compared initial and final PMH	Paired t-test (20) = −3.945; $P < .001$ Cohen value = −0.861	Paired t-test (11) = −2.170; $P < .053$ Cohen value = −0.626	

Abbreviations: ADS Program, program for self-management of substance addiction consequences; TAU, treatment as usual; SAC, substance addiction consequences.

Table 5. SAC Subscales Results.

Variables	ADS Program	TAU	Comparison between groups
Initial psychological and family factors	Mean = 1.78; SD = 0.54	Mean = 1.76; SD = 0.52	t-test = 0.128 (49); $P = .899$
Final psychological and family factors	Mean = 2.83; SD = 0.82	Mean = 2.95; SD = 1.02	
Compared initial and final psychological and family factors	Paired t-test (24) = -−6.753; $P < .001$ Cohen value = −1.351	Paired t-test (24) = −5.333; $P < .001$ Cohen value = −1.333	
Initial physical and cognitive ability	Mean = 2.69; SD = 0.83	Mean = 2.90; SD = 0.56	t-test = −0.956(49); $P = .344$
Final physical and cognitive ability	Mh3.31; SD = 0.74	Mean = 3.80; SD = 1.15	
Compare initial and final physical and cognitive ability	Paired t-test (24) = −4.539; $P < .001$ Cohen value = −0.908	Paired t-test (24) = −3.368; $P < .004$ Cohen value = −0.842	
Initial self-care	Mean = 2.79; SD = 0.63	Mean = 2.91; SD = 0.97	t-test = −0.507(49); $P = .615$
Final self-care	Mean = 3.03; SD = 0.53	Mean = 3.18; SD = 0.50	
Compare initial and final self-care	Paired t-test (20) = −0.573; $P = .573$ Cohen value = −0.125	Paired t-test (11) = −2.968; $P = .013$ Cohen value = −0.857	
Initial economic and labor	Mean = 1.52; SD = 0.86	Mean = 1.70; SD = 0.97	t-test = −0.663(49); $P = .510$
Final economic and labor	Mean = 2.09; SD = 1.15	Mean = 2.91; SD = 1.24	
Compare initial and final economic and labor	Paired t-test (24) = −1.665; $P = .109$ Cohen value = −0.333	Paired t-test (24) = −3.377; $P = .004$ Cohen value = −0.844	

Abbreviation: ADS Program, program for self-management of substance addiction consequences; TAU, treatment as usual; SAC, substance addiction consequences.
All variables are subscales of SAC Scale.

feasibility and process outcomes, such as recruitment, adherence, and treatment fidelity, where differences may be substantial and detectable with small samples.[26] This pilot report adherence to these recommendations by prioritizing feasibility and process outcomes, in addition to conducting some comparative analyses.

Following continuous recruitment until at least 30 patients were allocated to each arm, a significant proportion of participants discontinued treatment [ADS Program (34%), TAU (52.9%)]. Barriers to recruitment and retention in this population are well documented and frequently include refusal to participate in research, loss of contact

with services, and contextual factors such as legal or judicial issues. High dropout rates are therefore common in longitudinal studies involving patients with substance use disorders or other hard-to-reach populations.[23] Importantly, the experimental group exhibited a lower dropout rate, representing a key feasibility outcome of this pilot study. However, the differential attrition observed between groups raises the possibility of attrition bias, as participants who remained in the study may differ from those who discontinued. This may have influenced the magnitude of observed outcomes and should be considered when interpreting between-group comparisons. Nonetheless, the higher retention in the ADS group suggests good acceptability and engagement with the intervention. After the pilot, it was observed that the experimental group scheduled and attended more appointments and reached the adherence target in less time compared to the TAU group; however, they did not meet the planned minimum of 8 consultations over 8- to 21-week period to address the different key intervention components. No specific barriers to session completion were identified beyond the usual difficulties in treatment adherence within this population, as well as contextual factors such as some participants returning to employment during follow-up. This pattern is consistent with research on tailored interventions that may improve engagement and outcomes, although not necessarily attendance rates.[27,28] This "under-dosing" is better interpreted as indicating the need for further optimization and adjustment of the intervention delivery model rather than a limitation of this potential effectiveness. Similarly, there was a greater reduction in nursing diagnoses in the ADS Program group, as indicated by both effect size and statistical significance. In this pilot study, patients with a higher number of nursing diagnoses at baseline also had a higher severity score on the SAC scale. The evidence suggests that limited access to treatment[29] and lack of support are associated with other complex problems, such as the risk of overdose,[30] which supports the need for targeted interventions. The study also investigated safety and procedural refinements for a future larger trial. No adverse events or clinical deterioration (eg, relapses or hospitalization) were identified during the 8- to 21-week program period. All dropouts were related to loss of contact with the service, transfer to another service, or refusal to continue participation, with no discontinuations attributable to the study design or the intervention itself. Participants who completed the program showed improved outcomes.

The sample in this study showed characteristics consistent with those reported in other medication-based harm reduction programs. Most participants were men (84%), single, had low educational attainment, were unemployed, and faced substantial financial hardship.[24,31] Patterns of problematic alcohol use were also comparable to those observed in patients receiving methadone-based treatment, in which improvements in alcohol consumption are commonly documented following reductions or cessation of opioid use.[32] In this pilot sample, more than 44% identify alcohol as their primary substance, a proportion aligned with previous studies indicating that alcohol frequently co-occurs with other substance use.[33]

The literature indicates that when there is harmful consumption or dependence on alcohol or drugs, women are more severely affected, mainly in psychiatric and partner-related problems.[34] However, this pattern was not observed in our study; instead, men showed slightly more severity than women in both arms, before and after the intervention, although the difference was not statistically significant. This finding may be related to the higher rates of transmissible diseases observed in men.[35] Furthermore, no correlation was observed between participants' age and the severity of the impacts, which contrasts with the findings of other studies that older participants are at a higher risk.[36]

In our study, participants who were single and living alone experienced poorer outcomes, while those with more children demonstrated less severity on psychological and family subscale. It seems to be a protective factor. These findings are consistent with research highlighting the benefits of well-being, family relationships, and family-based interventions, that are positively associated with better outcomes.[37] Again in our study, unemployment and low income were also identified as factors associated with poorer outcomes in line with previous research.[37] Notably, even unemployed participants who received follow-up in the ADS Program exhibited reduced severity, further highlighting the program's potential impact.

It was evident in this study that those who use IV substances have more severe consequences, even though they were the smallest part of our sample. It is known that people who inject drugs experience greater health severity than those using other ways. They face higher risks of infections, such as HIV, hepatitis B or C, and overdose. They also face heightened social challenges, including stigma, marginalization, and barriers to healthcare access, which further worsen their clinical outcomes.[38,39]

Our primary clinical outcome (dependent variable) was the SAC Scale score. Although both groups demonstrated a reduction in addiction-related consequences, the larger effect size observed in the TAU group, contrary to our initial hypothesis, warrants further consideration. One possible explanation relates to baseline differences, as participants in the experimental group presented higher initial severity levels. Greater baseline severity and vulnerability are often associated with slower and complex recovery trajectories to improve their health and social status,[28,40,41] which may attenuate short-term observable gains. Additionally, the larger improvements observed in the TAU group may be partially related to their lower baseline severity, which can allow for more rapid short-term

gains compared to participants with more complex clinical presentations, as well as the possibility that awareness of participating in a study may have influenced behavior and engagement with care, leading to improved outcomes across groups. Differences in substance use profiles between groups may also have contributed, as the TAU group included a higher proportion of individuals with alcohol dependence and more recent use (100% with less than 1 month since last use), but lower SAC severity. Alcohol users have been exhibiting higher retention and responsiveness to behavioral interventions compared to users of other substances. Furthermore, engagement in treatment itself, regardless of specific modality, has consistently been associated with a reduction in substance-related harm,[42] suggesting that common therapeutic factors such as regular contact and support may have driven improvements across both groups. These findings should be interpreted in light of the pilot nature of the ADS intervention and the real-world clinical context in which it was implemented, where usual care already includes relevant therapeutic components. Consequently, detecting incremental benefits may require longer follow-up or larger samples, and results should be considered in relation to baseline severity and patient clinical complexity. This lack of baseline homogeneity likely contributed to the observed differences in relative improvement, as participants with lower initial severity in the TAU group had greater potential for short-term gains compared to those with more complex clinical profiles in the ADS group.

The other dependent variable, the PMH Scale, showed no difference at baseline, but both groups improved, with a larger effect size in the ADS Program group. Based on this PMH framework, the intervention appears to have enhanced participants' awareness of their specific circumstances and strengthened their capacity to adapt more effectively to their individual needs. Unfortunately, we found no studies on PMH with people using substances, but PMH programs have been shown to be effective in populations with mental health problems,[43] particularly those who benefit from improved decision-making ability. It is recommended that these programs be implemented across different populations.[20]

Considering our 2 dependent variables, it was found that those with better PMH had less severity related to substance use. This association appeared only at T1, suggesting that in the initial phase, when patients are more unstable or have high severity, there is no correlation with PMH. However, no research was found to support this discussion. This observation may be associated with another important finding of this study: patients with better SAC Scale scores attended a higher number of consultations; however, it is not possible to determine the direction of this relationship or establish causality. Patients who improved in the economic and labor subscale demonstrated that the intervention can address economic and social determinants of health[37] although a more pronounced effect was observed in the TAU group. Within the nurse-led self-management framework, this impact operates through the identification of socioeconomic needs and structured referral to social support services, as well as through strengthening self-efficacy, self-care capacity, and self-image. These processes support reductions in substance use or abstinence, which facilitate improved functional stability and enable participants to re-engage with the labor market, including in precarious employment contexts, contributing to gradual improvements in socioeconomic conditions within existing structural constraints. Improvement in self-care was also greater in the TAU group, potentially reflecting lower baseline severity and a predominance of alcohol use, which is associated with fewer harmful consequences compared to other substances.[41] In contrast, physical and cognitive subscale scores improved more in the ADS group, likely due to higher baseline severity, supporting the notion that a needs-centered approach facilitates more rapid changes in domains directly affected by substance-related functional impairments.[27]

Additionally, this pilot study confirmed that patients with fewer movements in or out (dropouts and readmissions) from treatment programs had lower severity, as in previous studies[44] and better PMH. Patients who were already followed in medication-based programs at T0 presented less severe SAC Scale scores than those newly admitted to the ward. However, throughout the ADS Program, even these patients reduced the severity. Patients with more severity need longer to achieve planned consultations, a pattern also seen in those with more polydrug use or difficulty achieving abstinence in other studies.[42] Considering the aim of this program, the relative improvement in these 2 outcomes reinforces that self-management interventions are fundamental for mental health recovery.[45]

Regarding implications for clinical practice, it must be considered that structured programs for people with problematic drug or alcohol use can benefit those with more complex and multidimensional issues related to their condition. This pilot supports the implementation of a robust RCT to demonstrate effectiveness and isolate the independent effects of the ADS program.

Limitations

Pilot trials are typically limited by small sample sizes, which restrict the generalizability of their findings. Although this initial experience offers valuable data with observable effects, caution is warranted when interpreting the results. A relevant limitation of this study concerns the high attrition rates, which may have affected the internal validity by introducing potential bias, and the absence of an *intention-to-treat* analysis, as only participants who completed the protocol were included in the analyses. Although this approach may introduce some bias, it is considered acceptable in pilot studies, whose primary aim is to test the

feasibility of the design and methodological procedures. Further limitations are the enrollment of patients who were already in a medication-based program (which may have influenced satisfaction and well-being outcomes), self-report bias, the potential for expectation effects, as both participants and nurses were aware of group allocation, the 8-21 flexible weeks window for follow-up that can affect results and a lack of long-term follow-up. Although nursing diagnoses assessment and closure were based on rigorous clinical criteria and externally validated by other nurses involved in care to reduce bias, a residual risk of observer bias cannot be entirely excluded. Finally, as the study was conducted in a single specialized unit, further multicenter RCTs are needed to enhance external validity and support more robust conclusions.

Conclusion

This new program addresses a gap in structured nursing interventions for individuals experiencing severe consequences of addiction. It represents an initial step toward further research on self-management support for individuals with substance dependence who participate in medication-based programs. The findings indicate that the ADS Program is safe and feasible, with observed improvements in health and social status. Although some clinical results between the groups are inconclusive, this is likely related to the limited statistical power of the study due to the small final sample size (15 participants per group), rather than the absence of an intervention effect. Several outcomes demonstrate relevance. The observed safety and adherence rate support conducting a larger RCT with at least double the initial sample size. While preliminary, these findings suggest that structured, flexible, needs-centered nursing interventions may help improve self-management and social functioning and could inform the development of clinical guidelines or policy initiatives aimed at integrating nursing-led support into addiction care. The program appears promising and suitable for evaluation on a larger scale.

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Ethical Considerations

This study had the previous approval of the Health Ethics Committee of the Regional Health Administration of Lisboa and Vale do Tejo (7211/CES/2020) and from the Director of the specialized unit.

Author Contributions

All authors have made substantial contributions to all research process. PS and CS had the idea for the research project and for the article. PS, RS, AS, FF, PA, CS, design the work, PS, RS, IN performed the literature search and data analysis. PS, IN, CS, RS, drafted and all authors critically revised the work. Finally, all are responsible for writing the article. All authors approved the version being submitted.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Registration

The trial has been registered at ClinicalTrials.gov ID: NCT05397925 in 31 May 2022.

Supplemental Material

Supplemental material for this article is available online.

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