Efficacy of a Fully Automated Electronic Screening and Brief Intervention to Reduce Harmful Alcohol Consumption: A Randomized Clinical Trial

(PROSA e-SBI)

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Introduction / Background

Harmful alcohol consumption (HAC) is defined as an alcohol intake exceeding 14 standard drinks per week for men and 7 standard drinks per week for women, or the consumption of 5 or more drinks on a single occasion for men and 4 or more drinks for women (binge drinking). This pattern of consumption is termed "harmful" due to its well-established association with significant social, economic, and health-related risks.

According to the National Institute on Alcohol Abuse and Alcoholism (NIAAA), one standard drink corresponds to 14 grams of pure alcohol, which is contained in one can of beer (355 ml), one glass of wine (150 ml), or one shot of distilled spirits (45 ml) [1].

The observational clinical study entitled PROSA - Health & Alcohol Project [2] - Evaluation of Alcohol Consumption Patterns in Heart Disease Patients and Non-Heart Disease Individuals has previously demonstrated that poor lifestyle habits are significantly associated with harmful alcohol consumption in both patients with heart disease and individuals without heart disease.

Since 1951, the World Health Organization (WHO) has actively promoted actions to combat harmful alcohol use. In 2018, the WHO launched the SAFER program, an acronym representing the five most effective evidence-based interventions against harmful alcohol use: 1) Strengthen restrictions on alcohol availability; 2) Advance and enforce drink-driving countermeasures; 3) Facilitate access to screening, brief interventions, and treatment; 4) Enforce bans or comprehensive restrictions on alcohol advertising, sponsorship, and promotion; 5) Raise prices on alcohol through excise taxes and pricing policies [3].

Among these interventions, Screening and Brief Intervention (SBI), which corresponds to item 3 of the SAFER initiative, is endorsed by both the WHO and the U.S. Centers for Disease Control and Prevention (CDC). The AUDIT (Alcohol Use Disorders Identification Test) [4] is the recommended instrument for classifying the risk associated with alcohol consumption within SBI protocols.

In 2014, the CDC published a practical manual for the implementation of SBI in primary care settings [5]. Subsequently, several studies have reported positive experiences with SBI implementation across different populations and clinical settings [6,7,8,9].

More recently, the literature has documented experiences with electronic SBI (e-SBI). A systematic review on this topic indicates that e-SBI yields positive outcomes internationally [10]. However, it is important to note the findings of Bertholet et al., who reported good acceptance of an electronic SBI system in primary care waiting rooms but warned of the imperative need for human support to complement the electronic intervention [11].

Baldin et al. [12] evaluated the efficacy of a web-based intervention to reduce harmful alcohol consumption among nightclub patrons in São Paulo, Brazil. The authors observed that digital tools significantly reduced binge drinking by 38% six months after implementation. Nevertheless, this effect was not sustained throughout the entire follow-up period.

Several authors have discussed the need for cultural adaptation when applying electronic SBI in diverse populations. Brawn et al. [13] reported on these aspects in Russian women living with acquired immunodeficiency syndrome (AIDS). Similarly, Torres et al. [14] suggested that cultural adaptations may be more effective for Latin American immigrants residing in the Seattle, Washington (USA) area.

In parallel, the Clinical Unit of Cardiac Stimulation (UCEC) at the Heart Institute of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (InCor-HCFMUSP) has been gaining experience with electronic tools through a feasibility study of a system for anticoagulation control in patients using warfarin (study approval CAAE-44457321.3.0000.0068). This system includes chatbot-driven questions and answers delivered via the WhatsApp application. Preliminary, unpublished findings from that study indicate that over 70% of patients at our institution who are assisted by the Brazilian public health system (SUS) used the system appropriately. Furthermore, the system was non-inferior to the hospital's traditional routine in keeping patients within the target therapeutic range, achieving 74.2% of the sample within the desired range.

Objective

The aim of the present study is to construct a fully automated electronic screening and brief intervention tool (e-SBI) for reducing harmful alcohol consumption (HAC) and to compare this electronic approach with a traditional in-person screening and brief intervention, considering lifestyle-related behaviors as key covariates.

Outcome Variables

Primary Outcomes

Rate of use and adherence to the electronic SBI (e-SBI) – defined as the proportion of participants randomized to the electronic arm who complete all e-SBI components.

Rate of adherence to the in-person SBI system – defined as the proportion of participants randomized to the in-person arm who attend and complete the scheduled brief intervention.

Rate of change in alcohol consumption patterns – measured by the difference in AUDIT risk zone classification (I, II, III, IV) and continuous AUDIT scores between baseline and follow-up, comparing electronic versus in-person SBI approaches.

Rate of referral to other municipal services – specifically, the proportion of participants in each arm identified as severe risk (Zone IV) who are successfully referred to specialized substance use support services (e.g., CAPS-AD – Psychosocial Care Center for Alcohol and Drugs), comparing electronic versus in-person SBI approaches.

Secondary Outcomes (to be specified – suggested for completeness)

Changes in lifestyle behaviors (e.g., smoking, physical activity, diet) assessed by standardized questionnaires.

Participant satisfaction and acceptability of each intervention modality.

Retention rates at follow-up assessments.

Population

Family members of patients treated at the Heart Institute of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo (InCor-HCFMUSP) through the Brazilian Unified Health System (SUS) were invited to participate in the study. All participants provided written informed consent prior to any study procedures. Eligible participants must be 18 years of age or older.

Methodology

Study Design

This is a single-center, open-label, parallel-group, randomized controlled trial comparing an electronic SBI (e-SBI) delivered via a WhatsApp-based chatbot with a traditional in-person SBI.

Study Phases
The study consists of two distinct phases:

Phase 1 – Feasibility Assessment
Duration: 105 days
This phase is dedicated to the assessment of the digital system's feasibility. Activities include the preparation and testing of the digital system (WhatsApp-based chatbot for e-SBI) and the training of the healthcare professional designated to perform the in-person SBI.

Phase 2 – Follow-up and Monitoring
Duration: 180 days plus approximately 15 days for data analysis and report preparation.
This phase includes the following sequential steps:

Patient recruitment

Obtaining written informed consent (ICF)

Baseline data collection, including lifestyle assessment

Group randomization

Screening using the Alcohol Use Disorders Identification Test (AUDIT)

Application of the brief intervention (BI) according to group allocation

Data analysis will be conducted at the end of follow-up, considering information on population characteristics, a record of observed difficulties, and the success rate for process completion, all stratified by randomization group and lifestyle behavior.

In Phase 2, the outcomes of the brief intervention will be evaluated, with special attention to the reclassification of alcohol consumption according to the AUDIT risk zone (Zones I to IV). Participants classified as being at severe risk due to alcohol consumption (Zone IV) will be advised to seek the services of the Psychosocial Care Center for Alcohol and Drugs (CAPS-AD) nearest to their place of residence.

Randomization and Sample Size
Randomization will be performed automatically via an electronic system (Interactive Web Response System – IWRS) integrated with an electronic Case Report Form (CRF) prepared in Research Electronic Data Capture (REDCap) –

Vanderbilt University. Confidentiality will be ensured by this same system for all participants.

To ensure balance between study arms and across AUDIT risk classifications, stratified randomization will be performed. For this purpose, the population distribution will be based on our own unpublished data, which estimates: 5% of patients in Zone IV (severe risk), 5% in Zone III (moderate risk), 20% in Zone II (mild risk), and 70% in Zone I (low risk).

Based on these estimates, recruitment of 516 patients will be sufficient to guarantee approximately 26 patients in each risk zone, ensuring adequate representation for stratified analyses.

Furthermore, an estimated 258 participants per group (516 total) are required to detect a clinically significant difference between groups for the primary endpoint, with a two-sided significance level of 5% ($\alpha = 0.05$) and statistical power of 80% ($\beta = 0.20$).

Statistical Analysis
Data will be described as mean and standard deviation (SD) or median and interquartile range (IQR), depending on the underlying distribution. Categorical variables will be described as frequencies and percentages.

Between-group comparisons will be performed using Student's t-test for continuous variables (or its non-parametric equivalent, such as the Mann-Whitney U test, when appropriate) and the chi-square test (or Fisher's exact test) for categorical variables.

The primary analysis will be conducted according to the intention-to-treat (ITT) principle. Given the expected high rate of patient attrition, the ITT analysis will be validated using three complementary approaches:

Multiple imputation using chained equations (MICE) – under a missing-at-random (MAR) assumption.

Complier average causal effect (CACE) analysis – to estimate the true treatment effect among compliers according to randomization assignment.

Multivariable predictor analysis – to identify factors associated with harmful alcohol consumption (HAC) reduction.

All statistical tests will be two-tailed, and p-values ≤ 0.05 will be considered statistically significant.

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