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Integrating a self-guided cognitive behavioral therapy app (CONEMO) into Brazilian primary health care: protocol for a hybrid type III implementation-effectiveness study

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Integrating a self-guided cognitive behavioral therapy app (CONEMO) into Brazilian primary health care: protocol for a hybrid type III implementation-effectiveness study

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ABSTRACT

Background: Depression and anxiety are common and disabling mental health conditions. Although cognitive behavioral therapy (CBT) is an evidence-based treatment, access remains limited, particularly in low- and middle-income countries. Internet-delivered CBT (iCBT) may expand access to psychological interventions, but integrating digital interventions into routine primary care remains challenging. This study protocol describes the implementation of CONEMO (Emotional Control), a self-guided iCBT app for depression and anxiety symptoms, in primary care units in 2 municipalities in Brazil.

Methods: This mixed-methods hybrid type III implementation-effectiveness study is being conducted in primary care units in Indaiatuba and Jaguariúna, São Paulo, Brazil. Adults screening positive for depression (Patient Health Questionnaire-9 score ≥10) or anxiety (Generalized Anxiety Disorder-7 score ≥10) are offered a six-week CONEMO app-based intervention supported by a WhatsApp chatbot and a monitoring dashboard for primary care professionals. Primary outcomes are implementation outcomes, including penetration, acceptability, feasibility, and safety, assessed using app usage data, self-report measures, and focus groups with users, health professionals, and managers. Secondary outcomes include changes in depression, anxiety, and insomnia symptoms, quality of life, and behavioral activation over 12 weeks. Quantitative data will be analyzed using mixed-effects models. No formal sample size calculation was performed because the intervention is offered to all eligible users in participating units.

Discussion: Recruitment began in January 2026 and is expected to continue through December 2026. As of October 2026, approximately 400 participants had been enrolled, and the intervention was available in 21 primary care units across the 2 municipalities. Expansion to additional units in Jaguariúna is planned, with 28 units expected to participate. The study will generate evidence on the integration of a digital mental health intervention into routine primary care and identify barriers and facilitators to implementation and scale-up in Brazil.

Trial registration: ClinicalTrials.gov, NCT06692842. First submitted on November 14, 2024, and first posted on November 18, 2024.

Keywords: telepsychoeducation; Primary care; Cognitive-behavioral therapy; Common mental disorders; Implementation science; Depression; Anxiety; Mobile applications.

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DECLARAÇÃO DE USO DE INTELIGÊNCIA ARTIFICIAL (IA)

During the preparation of this work, the authors used Claude Haiku 5.5 (Anthropic), a generative artificial intelligence (AI) tool, to assist with organizing and formatting the references and revising the manuscript for adherence to the journal's guidelines, including rewording sections. The authors reviewed and edited all AI-assisted content and take full responsibility for the content of the published article.

DATA AVAILABILITY STATEMENT

No datasets have been generated or analyzed for this protocol. The data collected during the study will be reported in future publications. Access to the study data will be subject to ethical approval and applicable data protection requirements.

CONTRIBUTIONS TO THE LITERATURE

- Digital mental health interventions remain challenging to integrate into routine primary care, particularly in resource-constrained settings.
- This study evaluates the implementation of CONEMO, a self-guided cognitive behavioral therapy app supported by a WhatsApp chatbot and a dashboard for primary care professionals.
- The hybrid type III design prioritizes implementation outcomes while examining changes in mental health symptoms.
- Findings will identify barriers and facilitators to integrating and scaling digital mental health interventions in Brazil's public health system.

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BACKGROUND

Symptoms of depression and anxiety are common worldwide and represent a major public health concern. According to the World Health Organization (WHO, 2020), Brazil has been reported to have the highest prevalence of anxiety disorders worldwide, at 9.3% of the population, and the fifth-highest prevalence of depression [1]. In a national telephone survey conducted in Brazil in 2023 (Covitel), 26.8% of adults reported a previous medical diagnosis of anxiety, and 12.7% reported a previous diagnosis of depression [2].

Cognitive behavioral therapy (CBT) is considered a first-line treatment for these conditions, with its effectiveness and tolerability proven by different studies [4]. However, access to evidence-based psychological treatments remains limited, particularly in low- and middle-income countries (LMICs) [5,6]. Several factors contribute to this treatment gap, including the difficulty primary care physicians face in diagnosing psychiatric disorders and the low availability of psychological treatments in primary care settings. These barriers may contribute to excessive referrals to specialized mental health services [7].

Internet-delivered CBT (iCBT) has emerged as a potential strategy to expand access to psychological interventions [8,9]. These interventions deliver therapeutic content through text, audio, interactive presentations, videos, and other digital resources [10], and may be guided by professionals or self-guided. Evidence supports the effectiveness of iCBT for anxiety and depression, including self-guided interventions [11–15]. Digital interventions may also reduce the time and costs associated with treatment while maintaining effectiveness and patient privacy [16–18]. The WHO has recognized the potential of digital health interventions, including smartphone-based approaches, to expand access to mental health care, particularly in LMICs [19–22]. In addition, task-sharing approaches involving appropriately trained professionals may help increase the availability of mental health interventions in primary care [23]. Nevertheless, integrating digital interventions into routine health services remains challenging and requires evaluation of their implementation in real-world settings. In this context, the CONEMO (Controle Emocional/Emotional Control) platform provides an opportunity to examine how a digital CBT intervention can be integrated into routine primary care.

The CONEMO platform was initially evaluated in primary care settings in Brazil and Peru and demonstrated effectiveness in reducing depressive symptoms [24]. However, between-group differences were not statistically significant at the six-month follow-up [25]. In its initial version,

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CONEMO was configured as a low-intensity, six-week cognitive-behavioral psychological intervention carried out via a smartphone app supported by nursing professionals [24–27]. The current version is self-guided with monitoring of the healthcare team via the dashboard, and includes an intervention pathway for anxiety in addition to the depression pathway.

Before the present study, a single-arm feasibility pilot of the self-guided version of CONEMO was conducted in primary care units in Indaiatuba, São Paulo, Brazil, between August and November 2024 - manuscript in preparation. According to the current study records, the pilot included 85 participants. Although nearly all participants installed the app, engagement was low, with high rates of no initiation and attrition during the six-week intervention. These findings suggested that delivering the intervention through primary care was feasible, but that user engagement represented a major implementation challenge. The pilot informed adaptations to the intervention and its implementation strategies in the present study, including the introduction of a WhatsApp chatbot, changes to professional training, and enhancements to the monitoring dashboard. These adaptations aim to support user engagement and facilitate integration into routine primary care.

Although previous studies have evaluated earlier versions of CONEMO and a feasibility pilot has informed adaptations to the self-guided version, further evidence is needed on how this intervention can be integrated into routine primary care and implemented at scale. In particular, understanding its penetration, acceptability, feasibility, safety, and the barriers and facilitators experienced by users and health professionals is essential to inform implementation in Brazil's public health system.

OBJECTIVES

The primary objective of this study is to evaluate the implementation of the self-guided CONEMO intervention in routine primary care, focusing on penetration, acceptability, feasibility, and safety, and to identify barriers and facilitators to its use. The secondary objective is to describe changes in symptoms of depression and anxiety, insomnia symptoms, quality of life, and behavioral activation among users. We hypothesize that the CONEMO intervention can be integrated into routine primary care.

METHODS

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Study design

This study employs a hybrid type III implementation-effectiveness design, with a primary focus on implementation outcomes and a secondary focus on clinical effectiveness outcomes [29]. The study uses an explanatory sequential mixed-methods approach comprising 2 distinct phases: an initial quantitative phase followed by a qualitative phase. This approach is indicated when qualitative data are intended to help interpret, explain, and expand upon the initial quantitative findings. Elements from both methods are analyzed separately and subsequently merged, in order to identify convergence, divergence, contradictions, or relationships between the 2 datasets [30,31]. Qualitative data collection and analysis will follow the Consolidated Criteria for Reporting of the qualitative component will follow the Consolidated Criteria for Reporting Qualitative Research (COREQ), a 32-item checklist for reporting qualitative research that is available in Brazilian Portuguese [32].

Study setting

The study takes place in the public primary care units (Unidades Básicas de Saúde [UBS]) of Indaiatuba and Jaguariúna. A total of 28 units are expected to take part. Implementation is staggered: it began in January 2026 in 6 units (3 in each municipality) and was expanded in September 2026 to the other 15 units of Indaiatuba, covering all units in that municipality. Expansion to the remaining seven units in Jaguariúna is planned for a subsequent phase of implementation. The 2 units that hosted the pilot are among the participating units.

Study population

The quantitative study population comprises adults (≥18 years) residing in Indaiatuba or Jaguariúna who attend a UBS and screen positive for depression (Patient Health Questionnaire-9 [PHQ-9] score ≥10) or anxiety (Generalized Anxiety Disorder-7 [GAD-7] score ≥10). Insomnia symptoms are screened in all participants with the Insomnia Severity Index (ISI) but are not an inclusion criterion. Because the intervention is delivered through an app, participation requires access to a smartphone. Participants classified in category B2 and C of the Suicide Risk Assessment Protocol (S-RAP), which indicates imminent suicide risk, are excluded. Those participants will be referred to appropriate care, according to the municipality's service workflow.

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The S-RAP is available in Supplementary Material. People who took part in the pilot are not excluded.

No formal sample size calculation was performed. The primary aim is to evaluate implementation under routine conditions, and CONEMO is offered to all eligible users of the participating units during the recruitment period; the number of participants enrolled is itself an indicator of penetration.

For the qualitative component, focus groups will include app users, technical-level health professionals, higher-education-level health professionals, UBS coordinators and managers, and municipal health department or primary and mental health care coordinators from both municipalities. Focus groups will be conducted separately by participant category and stratified by municipality. Within each category, participants will be selected through simple random sampling and contacted by telephone to assess their willingness to participate. All selected individuals who agree to participate will be included. Users will be invited regardless of their level of engagement with the app, including those who have not initiated the intervention and those who have completed the program, to capture a broad range of experiences and perspectives. The focus groups will be audio-recorded, transcribed, and checked for transcription accuracy.

Study stakeholders also include UBS health professionals, service managers, and local health department or primary/mental health care coordinators from both municipalities, regarded as key informants alongside users in shaping the implementation study's outcomes.

Recruitment and procedures

To ensure effective engagement and collaboration from health professionals, the research team establishes prior agreements with physicians, nurses, and community health workers at each UBS, who play a key role in introducing the research team to users and reinforcing the study's credibility and endorsement by the health center. Promotional banners and brochures are placed in each UBS so the potential participant can access the CONEMO directly via QR code or link. As a retention strategy, the team collects at least 2 phone numbers of close family members or friends for each participant, to be used only after unsuccessful attempts to contact the participant directly and with the participant's prior consent, allowing continued communication in cases of contact information changes. Eligible participants are assigned to the depression or anxiety journey according to their screening results. Those who screen positive for both choose their main

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treatment focus. Assessments and follow-ups are conducted through the app at the time points detailed in the Measures section.

The Research Management Committee (Comitê Gestor da Pesquisa [CGP]) is essential to implementation research. This multidisciplinary committee, comprising academic researchers, local managers, and service workers, monitors and evaluates implementation outcomes and facilitates active stakeholder participation, ensuring that contextual elements and real-world conditions are understood and addressed. Meetings take place monthly to discuss research progress, assess strategy implementation, and provide feedback. This participatory approach helps identify and overcome implementation challenges, promoting the effectiveness and sustainability of mental health policies [33]. Figure 1 summarizes the study flow diagram. Recruitment began in January 2026 and is scheduled to end in December 2026; the last 12-week assessments are therefore expected by March 2027.

Intervention

CONEMO is a digital intervention designed to promote behavioral changes that improve quality of life and emotional well-being. It includes structured sessions with texts, audio, videos, and exercises based on cognitive-behavioral techniques. It consists of a six-week, low-intensity psychoeducational program delivered via the CONEMO smartphone app, which is compatible with Android and iOS. The depression intervention is delivered 3 times a week and covers psychoeducation and behavioral activation; the anxiety intervention is delivered once a week and covers psychoeducation, mindfulness and relaxation techniques.

A chatbot is used via WhatsApp to send notifications related to app use. Its functions include notifying users about their intervention journeys, alerting them to overdue sessions, reminding them to complete assessment instruments, and answering frequently asked questions throughout the study. After completing the assessments, participants receive automated feedback in the app according to symptoms severity. Participants with an ISI score of 11 or higher are advised to seek guidance on insomnia at their UBS.

Implementation strategies

The implementation strategies are (1) in-person and remote training of UBS teams, delivered during their regular team meetings; (2) meetings with health professionals and municipal managers to plan and adjust implementation; (3) the CGP, described above; (4) promotional

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materials in the units (banners and brochures with a QR code); (5) the WhatsApp chatbot, which supports user engagement; and (6) a monitoring dashboard for UBS professionals.

The dashboard is used for screening and monitoring and displays, for each user registered at the unit, their name, baseline depression, anxiety, and insomnia symptom severity, intervention journey status (active or inactive), sessions in progress, and suicide risk classification. When a user is classified in S-RAP category B1 or higher, the UBS also receives an email notification.

Adaptations following the pilot

Table 1 summarizes the changes made to the intervention and implementation strategies following the pilot study.

Table 1. Adaptations made between the pilot and the present study.

Component	**Change in the present study**
Insomnia journey	Not included in the current study, because of technological challenges in implementing the sleep-window component. Insomnia symptoms continue to be assessed using the ISI.
Telephone contacts replaced by WhatsApp chatbot	Due to low response rates to telephone contact attempts, a WhatsApp chatbot was introduced to send reminders and answer frequently asked questions.
App videos	Video format was modified based on feedback from users' CGP meetings.
Training of UBS teams	Training is delivered in person and remotely during regular team meetings, covering the intervention workflow, dashboard functionalities, and the tasks expected of health professionals.
Monitoring dashboard	Dashboard functionality was expanded to include symptom severity.
Feedback to users	Automated feedback based on symptom severity was introduced.
Suicide risk	Email notifications to the UBS were introduced for users classified as S-RAP category B1 or higher.

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Measures

After accessing CONEMO via QR code or link, participants complete symptom scales and a sociodemographic questionnaire. The symptom scales are administered at baseline, and at 2, 4 and 12 weeks after baseline. The scales are described below, and the sociodemographic questionnaire is available in Supplementary Material. The 12-week assessment is the primary time point for clinical outcomes.

- Patient Health Questionnaire-9 (PHQ-9): A self-administered questionnaire [34–36]. A cut-off score of 10 indicates clinically significant depressive symptoms. The scale is validated for use in the Brazilian population.
- Generalized Anxiety Disorder-7 (GAD-7): A self-administered scale [37]. A cut-off score of 10 indicates clinically significant anxiety symptoms. The scale is validated for use in the Brazilian population [38].
- Insomnia Severity Index (ISI): A self-applied instrument [39,40]. A cut-off score of 11 or higher indicates clinically significant insomnia symptoms [41]. In this study, the ISI is administered alongside the PHQ-9 and GAD-7 to assess insomnia symptoms but does not determine eligibility or allocation to an intervention journey.
- Suicide Risk Assessment Protocol (S-RAP): These criteria are based on international guidelines (WHO), and include suicidal ideation, suicidal plan, access to means, history of suicide attempts, personal and contextual risk factors, protective factors, and support networks. This protocol classifies suicidal behavior into five categories: A1, A2, B1, B2, and C, in increasing order of risk. Participants classified as B2 and C are excluded from the study and referred to appropriate care (see supplementary material). Those classified as B1 remain in the study, are advised through the app to seek care within the health network, and their UBS is notified by email.
- EuroQol 5-Dimension (EQ-5D): A standardized, generic measure of health status, used for clinical and economic appraisal [42], with a Brazilian value set [43]. It is administered at baseline and at 12 weeks.
- Behavioral Activation for Depression Scale (BADS): A self-report measure of behavioral activation [44], administered at baseline and at 12 weeks.

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- Alcohol Use Disorders Identification Test (AUDIT) short version: A screening instrument developed by the World Health Organization to identify hazardous and harmful alcohol use [45] and validated in a Brazilian sample [46]. It is administered at baseline and at 12 weeks.
- Tobacco use: Questions on current tobacco use, administered at baseline and at 12 weeks.
- Perceived social support: Questions developed by the research team (Supplementary Material), administered at baseline and at 12 weeks.
- Use of health resources: An online form assessing medical consultations, hospital admissions, visits by health teams, and prescribed medications, completed at baseline and at 12 weeks.
- Satisfaction, usability, and user experience: Questions developed by the research team and apply during the intervention
- App usage data

In addition, qualitative data will be obtained from the records of the CGP meetings held since the beginning of the project, involving key stakeholders in the implementation process.

Outcomes

The primary outcomes are implementation outcomes, based on the taxonomy proposed by Proctor et al [47]: penetration, acceptability, feasibility, and safety. These outcomes are assessed using quantitative indicators and, where applicable, qualitative data (Table 2). Barriers to and facilitators of implementation and the reach of screening for symptoms of depression, anxiety, and insomnia are also assessed. Engagement is classified into three categories: nonstarters (did not start a journey), partial completers (started a journey and completed fewer than 50% of its sessions), and completers (completed 50% or more of the sessions). These outcomes are detailed in the logic model presented in Figure 2.

Table 2. Implementation outcomes, indicators, and data sources.

Outcome	**Indicators**	**Data source**
Penetration	Number of users enrolled per UBS and municipality; proportion of participating UBS	App registration data

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	with enrolled users; territorial coverage, based on the addresses given at registration	
Acceptability	Satisfaction, usability, and user experience; perceptions of users, health professionals, and managers	Self-report questions in the app; focus groups
Feasibility	Recruitment, app installation, engagement category, time spent in the app, and retention at each assessment	App usage data
Safety	Number of users classified in S-RAP category B1 or higher	App assessment data; notifications to the UBS
Barriers and facilitators	Perceptions of users, health professionals, and managers	Focus groups; records of CGP meetings
Screening and access	Number of people screened and number who screen positive for symptoms of depression, anxiety, and insomnia	App assessment data

The secondary outcomes are clinical and are assessed at 12 weeks after baseline, with intermediate assessments at 2 and 4 weeks. They include changes in PHQ-9 and GAD-7 scores; remission of depression (PHQ-9 score <10) or anxiety (GAD-7 score <10) among participants who screened positive for the respective condition at baseline; and treatment response (a reduction of 50% or more in symptom scores). Changes in ISI, EQ-5D, and BADS scores are exploratory outcomes. Data on the use of health resources are summarized at baseline and at 12 weeks.

Participants receiving other psychological, psychiatric, or mental health treatments are not excluded from the study. Information on any concurrent treatments is collected to support a more comprehensive analysis; however, these treatments do not influence the treatment recommendations provided through CONEMO research team. The CONEMO intervention is designed to complement, rather than replace, participants' ongoing care.

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Data analysis plan

Data will be extracted from the CONEMO Firebase database and imported into Stata® for analysis. Consistent with the hybrid type III design, analyses will prioritize implementation outcomes. Descriptive statistics will summarize baseline characteristics, implementation indicators, including recruitment, app installation, retention, and engagement categories, overall and by municipality and UBS. Changes in clinical outcomes over time will be analyzed with linear mixed-effects models for continuous scores and mixed-effects logistic regression models for remission and response, with time included as a fixed effect and random intercepts for participants and UBS. Analyses will include participants with a baseline assessment and available outcome data at 1 or more follow-up time points. Exploratory analyses will examine associations between engagement patterns, baseline characteristics, and symptom trajectories, comparing outcomes across engagement groups to identify potential dose–response relationships. Clinical outcomes will be interpreted with caution given the absence of a control group.

Qualitative data from the focus groups will be transcribed and analysed using IRAMUTEQ software (Interface de R pour les Analyses Multidimensionnelles de Textes et de Questionnaires). IRAMUTEQ enables classic textual statistics, group specificity analysis, descending hierarchical classification, similarity analysis, and word clouds [48]. Qualitative findings will be integrated with the quantitative results, examining convergences, contradictions, and relationships between the findings to support a more comprehensive interpretation of the results.

Missing data will be assessed for frequency and patterns of occurrence. Mixed-effects models will use all available observations under the assumptions of the specified models. Sensitivity analyses will be conducted to assess the potential impact of missing data on study findings. Statistical significance will be set at $P<.05$. Where applicable, effect estimates and 95% confidence intervals will be reported alongside P values.

Ethical considerations

The study was approved by the Research Ethics Committee of the University of São Paulo Medical School (approval no. 7.780.012) on August 20, 2025. All participants provide electronic informed consent through the app before completing the baseline assessment. The study was registered on ClinicalTrials.gov (NCT06692842) and on the Open Science Framework (OSF; https://doi.org/10.17605/OSF.IO/NQPUE).

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The study is conducted in accordance with the ethical principles of the Declaration of Helsinki and the Brazilian National Health Council Resolution No. 466/2012. Participants do not receive financial compensation for participation.

The study collects sensitive personal and health data. Participants are informed through the consent form about the collection and use of these data. Access to identifiable data is restricted to the research team and health professionals at the participants' respective primary health care units (UBS). Data are deidentified before analysis, in accordance with the Brazilian General Data Protection Law (Law No. 13,709/2018).

Study findings will be disseminated through peer-reviewed publications, scientific conferences, and communication with participants and stakeholders. Dissemination activities will include feedback meetings, technical reports for health professionals and managers, and institutional communication channels. Data will be stored securely on institutional servers and preserved in accordance with institutional data governance policies.

RESULTS

The CONEMO study is evaluating the implementation of a self-guided digital cognitive behavioral therapy intervention across primary health care services in Brazil. Recruitment began in January 2026. As of October 2026, approximately 400 participants had been enrolled, and the intervention had been implemented in 21 primary health care units across 2 municipalities: all 18 units in Indaiatuba and 3 units in Jaguariúna. Recruitment is scheduled to continue until December 2026, with the final 12-week follow-up assessments expected by March 2027. The study will provide evidence on the implementation of digital mental health care in routine primary health care settings, including implementation outcomes, barriers and facilitators, and changes in depressive and anxiety symptoms. Data analysis and dissemination of the findings are planned following completion of data collection.

DISCUSSION

This study aims to provide evidence on the implementation of a self-guided digital intervention for common mental disorders (CMDs) in primary care settings in a low- and middle-income country (LMIC). Despite the high prevalence of CMDs and the efficacy of CBT interventions for depression and anxiety, access to adequate treatment remains limited. Fewer than

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6% of individuals in LMICs receive minimally adequate treatment for mental and substance use disorders [49]. Digital interventions may reduce costs and increase access to evidence-based mental health interventions in primary care settings.

Earlier versions of CONEMO, supported by nursing professionals, were tested in previous clinical trials for depressive symptoms [24,25] and showed promising results. However, integrating a digital intervention into routine primary care involves challenges beyond its clinical potential, including user engagement, acceptability, feasibility, and the capacity of health services to incorporate new workflows. The pilot of the self-guided version suggested that delivery through primary care was feasible but identified user engagement as a key challenge. We therefore expect the strategies introduced in the current study, including the WhatsApp chatbot, automated feedback to users, team training, and the monitoring dashboard, to address some of the barriers identified during the pilot and support the integration of CONEMO into routine care. Their contribution to implementation outcomes, including acceptability, feasibility, and engagement, will be examined using quantitative and qualitative data.

By combining implementation indicators with the perspectives of users, health professionals, and managers, this study will help characterize how a self-guided digital intervention is implemented under real-world primary care conditions. The mixed-methods approach will also allow quantitative findings to be interpreted in light of participants' experiences and the organizational context in which implementation takes place. In the longer term, as represented in the logic model, the integration of CONEMO into routine care may contribute to reducing costs to the health care system, waiting times, referrals to specialists, use of medication, and emergency care related to crises and suicide attempts; however, these potential effects are beyond the scope of the present study and will not be directly assessed. Furthermore, digitally delivered interventions may help reduce geographic barriers to accessing mental health support, although their contribution to reducing territorial inequalities will depend on implementation conditions and equitable access to digital technologies.

STRENGTHS AND LIMITATIONS

This study has limitations. It is not a controlled trial, which limits inferences about the effectiveness of CONEMO; however, the main objective is the evaluation of its implementation, rather than establishing its causal effect on clinical outcomes. Clinical outcomes are self-reported

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and collected through the app, which may introduce reporting bias. Attrition is expected to be high, as observed in the pilot, and follow-up is limited to 12 weeks restricting the assessment of longer-term outcomes and sustained engagement. Participation requires a smartphone and some digital literacy, which may exclude individuals facing barriers to digital access and limit the representativeness of the study population. Concurrent treatments are recorded but not controlled, which may complicate the interpretation of changes in depressive and anxiety symptoms. Finally, the study takes place in 2 municipalities in the State of São Paulo, which may limit the transferability of the findings to other regions and health care contexts in Brazil.

Among the study's strengths are the delivery of the intervention under routine primary care conditions, the use of mixed methods, and the planned implementation across up to 28 primary care units. The inclusion of different stakeholder perspectives and the assessment of implementation outcomes alongside clinical outcomes may provide a more comprehensive understanding of the factors that facilitate or hinder the integration of digital mental health interventions into public primary care services.

CONCLUSIONS

In conclusion, this protocol describes a hybrid type III implementation-effectiveness study evaluating the integration of a self-guided digital cognitive behavioral therapy intervention for CMDs into routine primary care in Brazil. The study will assess implementation outcomes, explore barriers and facilitators to implementation, and examine changes in depressive and anxiety symptoms over 12 weeks. By investigating implementation processes and clinical outcomes under real-world conditions, this study is expected to generate evidence to inform the implementation and potential scale-up of digital mental health interventions in Brazilian primary care and other LMIC settings.

ABBREVIATIONS

BADS: Behavioral Activation for Depression Scale

CBT: cognitive behavioral therapy

CGP: Research Management Committee (Comitê Gestor da Pesquisa)

CMD: common mental disorder

EQ-5D: EuroQol 5-Dimension

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GAD-7: Generalized Anxiety Disorder-7

iCBT: internet-delivered cognitive behavioral therapy

ISI: Insomnia Severity Index

LMIC: low- and middle-income country

PHQ-9: Patient Health Questionnaire-9

S-RAP: Suicide Risk Assessment Protocol

UBS: primary care unit (Unidade Básica de Saúde)

WHO: World Health Organization

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Research Ethics Committee of the University of São Paulo Medical School (approval no. 7.780.012) on August 20, 2025. All participants provide electronic informed consent through the app before completing the baseline assessment.

CONSENT FOR PUBLICATION

Not applicable.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

FUNDING

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AUTHORS' CONTRIBUTIONS

AnCMX and BHSA contributed equally to this work and share first authorship. Conceptualization: PRM, HGC. Methodology: PRM, HGC. Supervision: PRM, HGC. Project administration: PRM. Investigation: AnCMX, BHSA, PP, AlCMX. Writing – original draft: AnCMX, BHSA, AlCMX, RRF, LPG. Writing – review & editing: MAM, CBD, AH, VCCJ, PP, AC, HGC, PRM. All authors read and approved the final manuscript.

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FIGURES

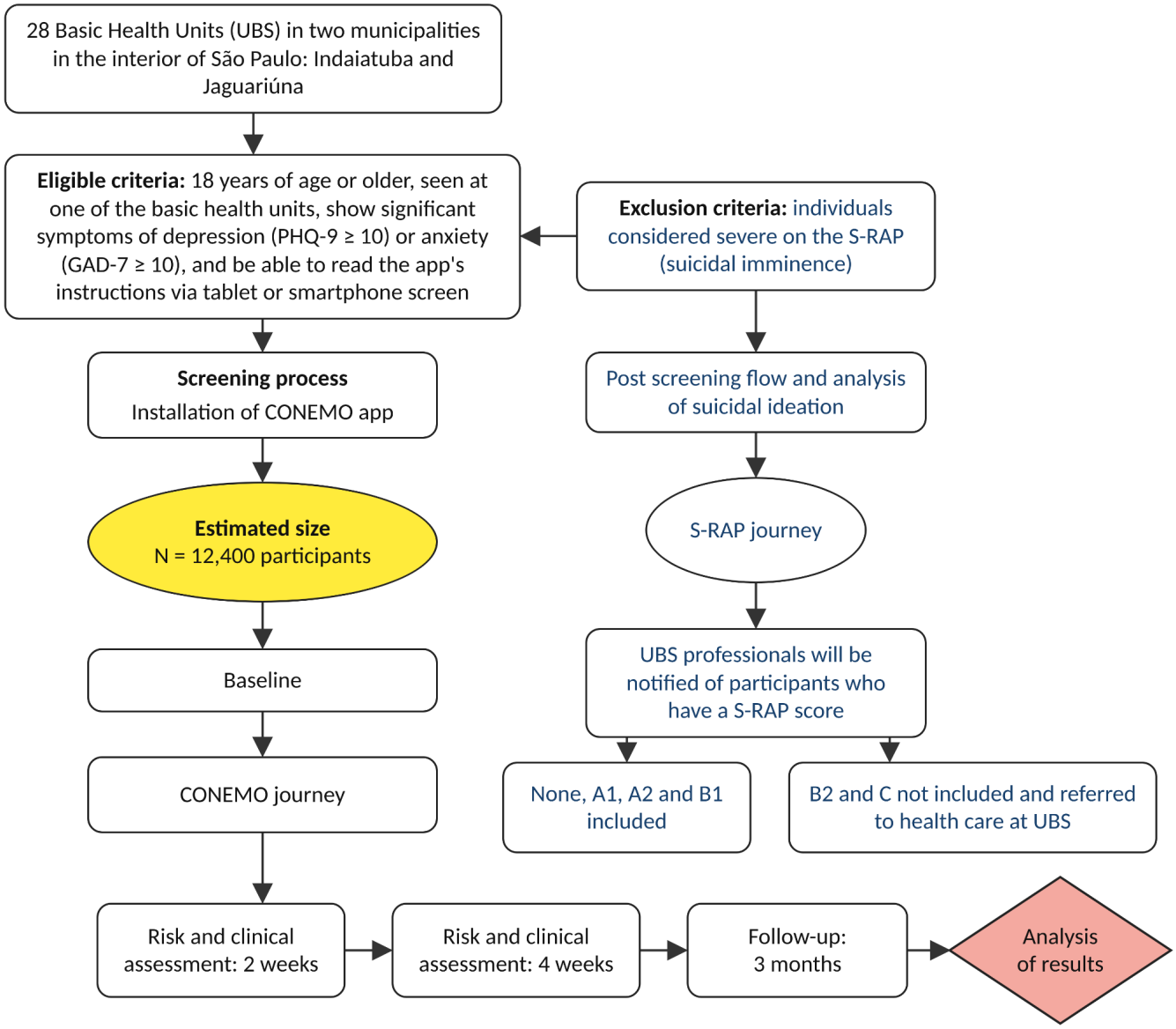


Figure 1: The flowchart describes the steps the participant will go through in the study. PQH-9: Patient Health Questionnaire; GAD-7: Generalized Anxiety Disorder-7; S-RAP: Suicidal Risk Assessment Protocol; iCBT: Internet Cognitive-behavioral therapy; RCT: Randomized clinical trial; TAU: Treatment as usual.

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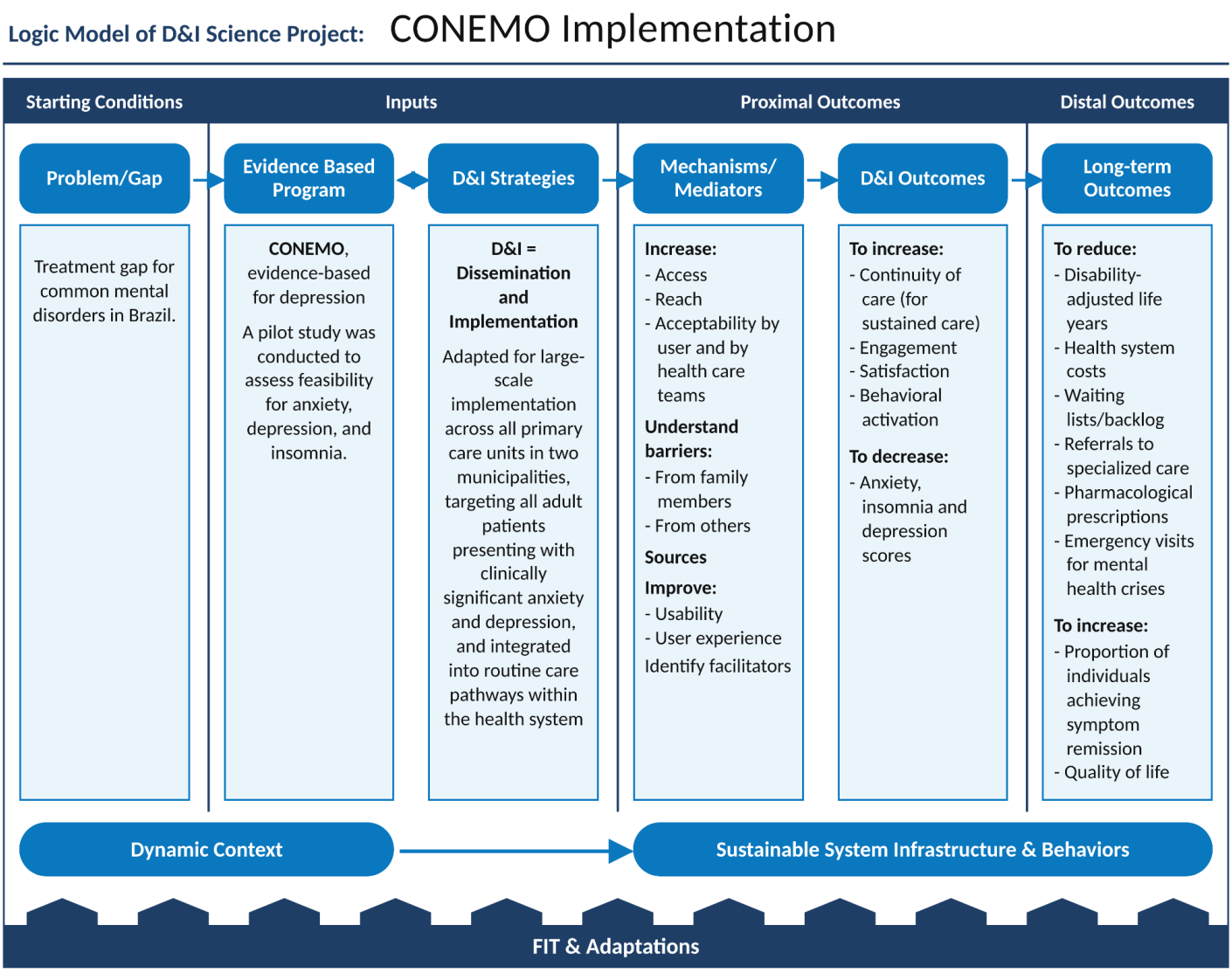


Figure 2: Logical model of CONEMO implementation in Indaiatuba and Jaguariúna, 2025. Adapted from Tabak 2012.

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SUPPLEMENTARY MATERIAL

1. INSTRUMENTS

WEB FORM	
Name	
CPF (subject national ID)	
Consent form	
I accept	
I do not accept	
For your Journey	
Yes	
No	
Question/options	**Variable**
Date (dd/mm/yyyy) (automatic)	(prescreen)
Sex: 1. Female 2. Male	(sexgr)
PS2. What is your date of birth? If UNDER 18 YEARS OF AGE, end and thank the participant	PS2
Inclusion criteria	
PHQ – 9	
Over the last two weeks, how often have you been bothered by any of the following problems:	
PHQ9.1. Little interest or pleasure in doing things 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq1
PHQ9.2. Feeling "down", depressed, or hopeless 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq2
PHQ9.3. Trouble falling or staying asleep, or sleeping too much 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq3
PHQ9.4. Feeling tired or having little energy 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq4
PHQ9.5. Poor appetite or overeating 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq5
PHQ9.6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq6
PHQ9.7. Trouble concentrating on things, such as reading the newspaper or watching television 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq7
PHQ9.8. Moving or speaking so slowly that other people could have noticed; or the opposite - being so fidgety or restless that you have been moving around a lot more than usual 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq8

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PHQ9.9. Thoughts that you would be better off dead or of hurting yourself in some way 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day	phq9
SC2. Symptom level *(sum of PHQ9 questions 1-9 \= Total score)* 0. No depression ≤ 4 1. Mild symptoms 5 to 9 2. Moderate 10 to 14 3. Moderately severe 15-19 4. Severe 20 or more	SC2
SC3. Indicate how difficult these symptoms have made it for you to do your work, take care of things at home, or get along with other people 0. No difficulty 1. Some difficulty 2. Much difficulty 3. Extreme difficulty	SC3
SC4. Pre-S-RAP question (only asked if PHQ9-9 is level 1, 2, or 3)	
In the last two weeks, have you thought about ending your life (killing yourself)? 0. No 1. Yes If the participant answers YES, begin the Suicide Risk Assessment Procedure – S-RAP. If the participant answers NO, end the assessment.	SC4
SUICIDE RISK ASSESSMENT PROCEDURE (S-RAP)	
THOUGHTS SRAP1. Have you thought about how you would end your life? 0. No 1. Yes	srap1
If YES, how? (open answer)	srap1a
PLANS SRAP2. Do you have any current plan to end your life? 0. No 1. Yes	srap2
If YES, what plans? (open answer) If NO, end.	srap2a
MEANS SRAP3. Do you have the means to do this? 0. No 1. Yes	srap3
If YES, what means? (open answer) If NO, end.	srap3a
SRAP4. Are these means readily available to you? 0. No 1. Yes	srap4
If YES, please describe? (open answer) If NO, end.	srap4a
IMMINENCE - from SRAP5 onward, ask everyone at risk	
SRAP5. Have you decided when you will end your life? 0. No (go to question 7); 1. Yes	srap5
If YES, please describe. (open answer) (fill in the details below and go to question 6)	srap5a
SRAP6. When are you planning to do this? Will it be today or very soon? 1. Today; 2. Soon; 99. Don't know/not sure	srap6
If TODAY or SOON, please describe. (open answer) If DON'T KNOW/NOT SURE, end.	srap6a
RECENT ATTEMPT SRAP7. Have you recently attempted to end your own life? 0. No 1. Yes	srap7
If YES, please describe. (open answer) If NO, end.	srap7a
SRAP8. When was this? (dd/mm/yyyy)	srap8
SRAP9. What did you do? (open answer)	srap9
SRAPTa. Suicide risk (recorded but not shown, automatic) 0. No 1. Yes	srapt
SRAPTb. Suicide risk level: (recorded but not shown, automatic) Level A1 Level A2 Level B1 Level B2 Level C	level

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SRAPTc. Please describe your actions below. Remember that for safety reasons you must follow all required steps.	sraptc

Question/options
Generalized Anxiety Disorder - 7 - GAD-7
Over the last 2 weeks, how often have you been bothered by the problems below?
1. Feeling nervous, anxious, or on edge 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
2. Not being able to stop or control worrying 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
3. Worrying too much about different things 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
4. Trouble relaxing 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
5. Being so restless that it is hard to sit still 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
6. Becoming easily annoyed or irritable 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
7. Feeling afraid as if something awful might happen 0 Not at all; 1 Several days; 2 More than half the days; 3 Nearly every day
ISI - Insomnia Severity Index
1. Please rate the characteristics of your sleep (for example, over the last two weeks) with regard to:
a) Difficulty falling asleep 0. None; 1. Mild; 2. Moderate; 3. Severe; 4. Very severe
b) Difficulty staying asleep 0. None; 1. Mild; 2. Moderate; 3. Severe; 4. Very severe
c) Problem waking up too early 0. None; 1. Mild; 2. Moderate; 3. Severe; 4. Very severe
2. How satisfied or dissatisfied are you with your current sleep pattern? 0. Very satisfied; 1. Satisfied; 2. Neutral (indifferent); 3. Dissatisfied; 4. Very dissatisfied
3. To what extent do you consider that your sleep problem interferes with your daytime activities (e.g., daily fatigue, ability to work/perform daily activities, concentration, memory, mood, etc.)? 0. Does not interfere; 1. Interferes a little; 2. Interferes somewhat; 3. Interferes much; 4. Interferes extremely
4. How much do you think others notice that your sleep problem affects your quality of life? 0. Do not notice; 1. Notice a little; 2. Notice somewhat; 3. Notice much; 4. Notice extremely
5. How worried/stressed are you about your sleep problem? 0. Not at all worried; 1. A little worried; 2. Somewhat worried; 3. Very worried; 4. Extremely worried
CONEMO APP
IP8a1. Alternative phone 1 (open answer)
IP9*. CPF number
IP12. Enrollment date __/__/____ (automatic)
ENROLLMENT REGISTRATION – LOCATION INFORMATION IL1. Emergency contact IL1a. Name IL1b. Mobile phone

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Background
HL3. How do you classify your color or race? 1. Black 2. Brown (Parda) 3. White 4. Yellow (East Asian) 5. Indigenous 6. Other:_____ 99. DK/NA
HL4. What is the highest level of education you completed? Did not attend school (go to CC1) Elementary/Middle School (go to hl42) High School (go to hl43) Technical Education (go to hl44) Higher Education – Technologist degree (go to hl45) Higher Education – Bachelor's degree (go to hl46) Postgraduate (go to hl47)
HL4.2 Up to which year did you study? [Elementary/Middle School] __01 __02 __03 __04 __05 __06 __07__08 (go to CC1)
HL4.3 Up to which year did you study? [High School] __01__02 __03 (go to CC1)
HL4.4 Up to which year did you study? [Technical Education] __01 __02__03 __04 __05
HL4.5 Up to which year did you study? [Higher Education – Technologist] __01 __02 (go to CC1)
HL4.6 Up to which year did you study? [Higher Education – Bachelor's] __01 __02 __03 __04 __05__06 (go to CC1)
HL4.7 Up to which year did you study? [Postgraduate] __01 __02 __03 __04__05+ (go to CC1
CURRENT LIFE CIRCUMSTANCES
CC1. What is your marital status? 1. Married 2. Stable domestic partnership (informal / not registered) 3. Single 4. Separated or Divorced 5. Widowed 99. NA/DK
SOCIOECONOMIC CHARACTERISTICS
SE1. Which of the following best describes your main activity over the last 12 months (the activity you spend most of your time on)? Employed Self-employed Unemployed Student Homemaker Retired Other. Which? (open answer)
SE2. Total family income No income (R$ 0) Up to 1 minimum wage (From R$1.00 to R$ 1,412.00) Up to 2 minimum wages (Up to R$ 2,824.00) Up to 3 minimum wages (Up to R$ 4,236.00) Up to 4 minimum wages (Up to R$ 5,648.00) Up to 5 minimum wages (Up to R$ 7,060.00) Up to 6 minimum wages (Up to R$ 8,472.00) Up to 7 minimum wages (Up to R$ 9,884.00) Up to 8 minimum wages (Up to R$ 11,296.00 Up to 9 minimum wages (Up to R$ 12,708.00) Up to 10 minimum wages (Up to R$ 14,120.00) More than 10 minimum wages (More than R$ 14,120.00)
SOCIAL SUPPORT
SS1. About the people in your life, answer yes or no 1. I have someone to go out with and count on for leisure activities 0. No 1. Yes 2. I have someone to help and support me when I need it 0. No 1. Yes
MENTAL HEALTH SERVICES
MS1. Have you ever in your life received psychological and/or psychiatric treatment for emotional problems? 0. No; 1. Yes; 99. DK/NA
MS2. Have you ever undergone or do you currently undergo treatment for emotional or psychiatric problems (therapy, groups)? 0. No 1. Yes, less than 1 year ago 2. Yes, more than 1 year ago 99. DK/NA *(If NO, go to question MS4)*

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MS4. Have you used or do you use medication to treat emotional or psychiatric symptoms? 0. No 1. Yes, less than 1 year ago 2. Yes, more than 1 year ago99. DK/NA (*If NO, go to question MS5*)
MS5. How many times in your life have you needed hospitalization for emotional or mental health problems? _____Number of times 99. Don't know/ Not answered
MS6. Have you had contact with any of the following health services for psychiatric treatment in the last 3 months?
1. ER / Psychiatric emergency 0. No; 1. Yes; 99. DK/NA
If yes: 1. Public 2. Private or Health plan / Health insurance 3. Other 99. DK/NA
2. Outpatient psychiatric services such as CAPS, NAPS
If yes: 1. Public 2. Private 3. Health plan / Health insurance 4. Other 99. DK/NA
3. Outpatient services for alcohol and drug problems such as CAPSad
If yes: 1. Public 2. Private 3. Health plan / Health insurance 4. Other 99. DK/NA
4. Hospitalization in a mental health service
If yes: 1. Public 2. Private 3. Health plan / Health insurance 4. Other 99. DK/NA
ALCOHOL - AUDIT-C – short version
"Now we would like to ask about your alcohol use over the last year" ***Consider 1 (one) standard alcoholic drink to be:*** 150 ml of wine 40 ml of spirits (whisky, cachaça, vodka) 350 ml of beer 1 cocktail
AU1. How often did you drink alcoholic beverages over the last year? Never (go to question TO1) Once a month or less Two to four times a month Two to three times a week Four or more times a week
AU2. How many drinks did you have on a typical day over the last year? 0 drinks 1 or 2 drinks 3 or 4 drinks 5 or 6 drinks 7 to 9 drinks 10 or more
AU3. How often did you have six or more drinks on a single occasion over the last year?
TOBACCO
TO1. Do you currently smoke at least one cigarette a day? 0. No;1. Yes, ____ cigarettes a day. 99. DK/NA ***(If NO,** go to SL1**)***
CURRENT ACTIVITIES - BEHAVIORAL ACTIVATION SCALE ONLY FOR PEOPLE ON THE DEPRESSION JOURNEY
Please read each statement carefully and then select the number that best describes how true the statement was for you DURING THE PAST WEEK, INCLUDING TODAY.
CA1. There were certain things I needed to do that I didn't do. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA2. I am content with the amount and types of things I did. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA3. I engaged in many different activities. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA4. I made good decisions about the type of activities and/or situations I put myself in. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA5. I was an active person and accomplished all of the goals I set for myself. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA6. Most of what I did was to escape from or avoid something unpleasant.

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CA7. I spent a long time thinking over and over about my problems. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
CA9. I did things that were enjoyable. 0. Not at all; 1; 2. A little; 3.; 4. A lot; 5.; 6. Completely
QUALITY OF LIFE - EQ-5D
"Please indicate which statement best describes your health state today." (Read carefully and select only one option)
QL1. Mobility 0. I have no problems walking 1. I have some problems walking 2. I am confined to bed
QL2. Self-care 0. I have no problems with my self-care 1. I have some problems washing or dressing myself 2. I am unable to wash or dress myself
QL3. Usual activities (e.g., work, study, housework, family or leisure activities) 0. I have no problems performing my usual activities 1. I have some problems performing my usual activities 2. I am unable to perform my usual activities
QL4. Pain/discomfort 0. I have no pain or discomfort 1. I have moderate pain or discomfort 2. I have extreme pain or discomfort
QL5. Anxiety/Depression 0. I am not anxious or depressed 1. I am moderately anxious or depressed 2. I am extremely anxious or depressed

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