A Chat-bot Based Version of the WHO-validated Intervention Self-Help+ for Stress Management in Pregnant Women: Protocol for a Pilot Feasibility Study

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Abstract

Background: Pregnancy is a multifaceted period marked by significant changes in a woman's life, influencing her physical, mental, and social dimensions. The way a woman navigates these transformations can significantly impact her overall well-being and psychological health. The existing literature underscores the prevalence of various psychological symptoms among pregnant women, with anxiety, stress, and depression being the most frequently reported. Prioritising a healthy lifestyle that specifically addresses a woman's psychological welfare is paramount. In this context, emerging digital solutions play a pivotal role in bolstering the psychological well-being of expectant mothers with no underlying psychological or psychiatric disorders. The development and implementation of such digital tools, such as a virtual coach integrated into a smartphone, have become increasingly evident as valuable resources to support the mental health of physiologically pregnant women.

Objective: Our objective was to assess the feasibility, acceptability, and utility of an ACT-based stress management mobile app. The primary objective of the present research is to explore the feasibility of using a virtual coach, ALBA, developed within the Trec Ricerca App to promote women's psychological well-being during pregnancy through five sessions based on ACT. Finally, through the delivery of this intervention, the level of psychological well-being will be explored as a secondary objective.

Methods: The current study serves as a proof-of-concept investigation, where a small sample size (N=50) is deemed adequate to fulfil the study's objectives. Participant recruitment will be conducted among pregnant women affiliated with the pregnancy care services of the Azienda Provinciale per i Servizi Sanitari di Trento, utilising a convenience sampling approach. ALBA will interact with the participating women for 6 weeks, starting from weeks 14 and 26 of pregnancy. Specifically, there will be one session per week, which the woman can choose, to allow more flexibility toward her needs, supplemented by ALBA-supported exercises to be performed between sessions.

Results: The psychoeducational approach aims to yield notable outcomes regarding the usability and engagement of women with ALBA. Furthermore, an anticipated enhancement in psychological well-being and quality of life is expected. The analysis of the data gathered in this study will primarily adopt a descriptive perspective, focused on evaluating the attainment of the study

objectives.

Conclusions: Existing literature indicates a preference among women in the perinatal period for online support, highlighting the potential of digital interventions to address barriers related to social stigma and seeking assistance. In this context, ALBA emerges as a valuable resource, providing consistent psychoeducational support for women throughout the course of pregnancy. Clinical Trial: This study was approved by the ethics committee of the APSS (Provincial Health Services Authority) under number 17241 (July 17, 2024)

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Introduction

Overview

The current scientific literature shows a growing need for psychological support from the general population, and this need increases even more when considering populations vulnerable to stressful situations [1, 2], including pregnancy.

The pregnancy period is characterised by essential transformations in the woman, with relevant impact on her physical, mental, and social well-being. How a woman adapts to these changes can affect her quality of life and psychological well-being. The literature highlights that various psychological symptoms can be commonly experienced during pregnancy, ranging from anxiety, stress, and/or depression [3-7]. To date, psychoeducational interventions that promote women's psychological well-being during pregnancy are scarce and tend to focus primarily on sub-groups of women with psychiatric symptomatology, such as perinatal depressive disorder [3,8].

Evidence of the effectiveness of psychological interventions targeting pregnant women is increasing [9], but access to support services still presents several challenges. A considerable proportion of women face geographic barriers, with specialised centres often far from their homes. In addition, a shortage of qualified staff, such as psychologists, further limits access to specialised care. The stigma associated with mental health problems can also prevent women from seeking psychological support in these circumstances.

The overall strategy adopted by the World Health Organization (WHO) for mental health promotion is based on principles of inclusiveness and scalability. Within this framework, special attention is paid to the potential role of digital technologies in promoting psychological well-being, as it can be an optimal solution; women can access it from anywhere and at any time, thus remaining flexible to their needs and reducing barriers related to service availability, social stigma, and seeking help [10].

The study described in this protocol is in line with WHO strategies and aims to assess the acceptability and feasibility of an intervention delivered through digital tools to promote psychological well-being. To our knowledge, the intervention, originally validated by WHO and named Self Help Plus (SH+), has never been used on this study's target population, pregnant women.

SH+ is a low-intensity intervention developed by a multidisciplinary and international working group [11-13]. This type of intervention is usually designed to be transdiagnostic, easily adaptable in different settings, deliverable by nonspecialists, and based on sound evidence-based psychological principles embedded in a self-help approach (guided or unguided).

This approach has already been validated on different target populations, with the purpose of promoting psychological well-being and clinical intervention, such as healthcare workers, migrants or refugees, showing general levels of acceptability and potential effectiveness [13]. A first attempt was made to make the protocol web-based within the RESPOND project, but the involvement of a human person, in the role of helper, was still necessary [14].

Cognitive Behavioural Therapy (CBT) techniques, and in particular those referring to third-generation therapy, are shown to be more suitable than other psychotherapeutic approaches to be transferred into low-intensity interventions delivered by nontraditional methods such as e-health applications. SH+ is based on the principles of Acceptance and Commitment Therapy (ACT), a third-

wave form of CBT [15,16], and is divided into five chapters that address five strategies for managing stress and promoting psychological well-being. The five chapters, later translated into sessions, are 1. Grounding (mindfulness); 2. Unhooking (defusion); 3. Acting on your values (values-based behavioural activation); 4. Being kind (gratitude); and 5. Making room (acceptance).
In conclusion, this study protocol aims to make the ALBA platform (described in the following paragraphs) available to women by evaluating the acceptability and feasibility of delivering SH+ through a virtual assistant created to deliver psychoeducational sessions through dialogues, video, audio and images (i.e., the five chapters of SH+), as well as representing a virtual coach who guides the user in carrying out assigned exercises and tasks to be done independently between sessions.

Goal of the Study and Research Questions

The present study is positioned within the design and development cycle of the Obesity-Related Behavioural Intervention Trials (ORBIT) model [17], specifically the Refine phase. It involves delivering material based on SH+ in text, audio, and video formats by a virtual coach (i.e., a digital assistant, identified as ALBA) implemented within the TreC Research application (App).
This intervention is embedded into the framework of behaviour change interventions [18], which aim to enable women to acquire adaptive strategies to improve or maintain their psychological well-being. It should be noted that the term intervention in this context is used to identify a tool (in this case, the virtual coach) that will periodically be offered in a predefined (i.e., rule-based), structured, and ordered manner, informational material structured and reviewed by psychological professionals.
This intervention has been developed and implemented for research purposes. The final goal is to validate a digital health intervention targeting women's psychological well-being during pregnancy by helping them manage stressful situations more effectively through modules based on the principles of ACT.

Primary Objective

The primary objectives of this proof-of-concept study described in this protocol paper are (1) to exploratively investigate user experience (UX) and user engagement (UE), that is, women's experience and engagement when interacting with the TreC Research App and the virtual coach, ALBA, and (2) to assess the women's UE with ALBA and the App through semi-structured interviews and investigate their feelings and overall experience during the intervention.

Secondary Objectives

The secondary objective is to assess the level of pre-post psychological well-being through administered self-report questionnaires at the beginning and the end of the intervention.

ALBA Intervention

The virtual coach, ALBA, will deliver an intervention based on ACT techniques to promote quality of life (QoL) and perceived psychological well-being and manage stressful situations by pregnant women. The module is self-administered and available for both Android and iOS devices. All the contents of the dialogues were developed by a group of researchers afferent to the Digital Health Research of the Bruno Kessler Foundation of Trento (Fondazione Bruno Kessler - Trento; FBK) and psychologists from the Istituto Pavoniano Artigianelli with specific communication skills, based on the SH+ manual [19]. Subsequently, materials have been revised by a psychologist from the

psychology operating unit of the Healthcare Trust of
the Autonomous Province of Trento (APSS). The dialogues, videos and audio tracks were developed using an educational approach, not an emergency management approach. In addition, the structuring of the material and delivery methods was supervised by professionals from the WHO Center for Research in Mental Health at the University of Verona, who have already carried out implementation and validation studies of SH+ nationally and internationally.

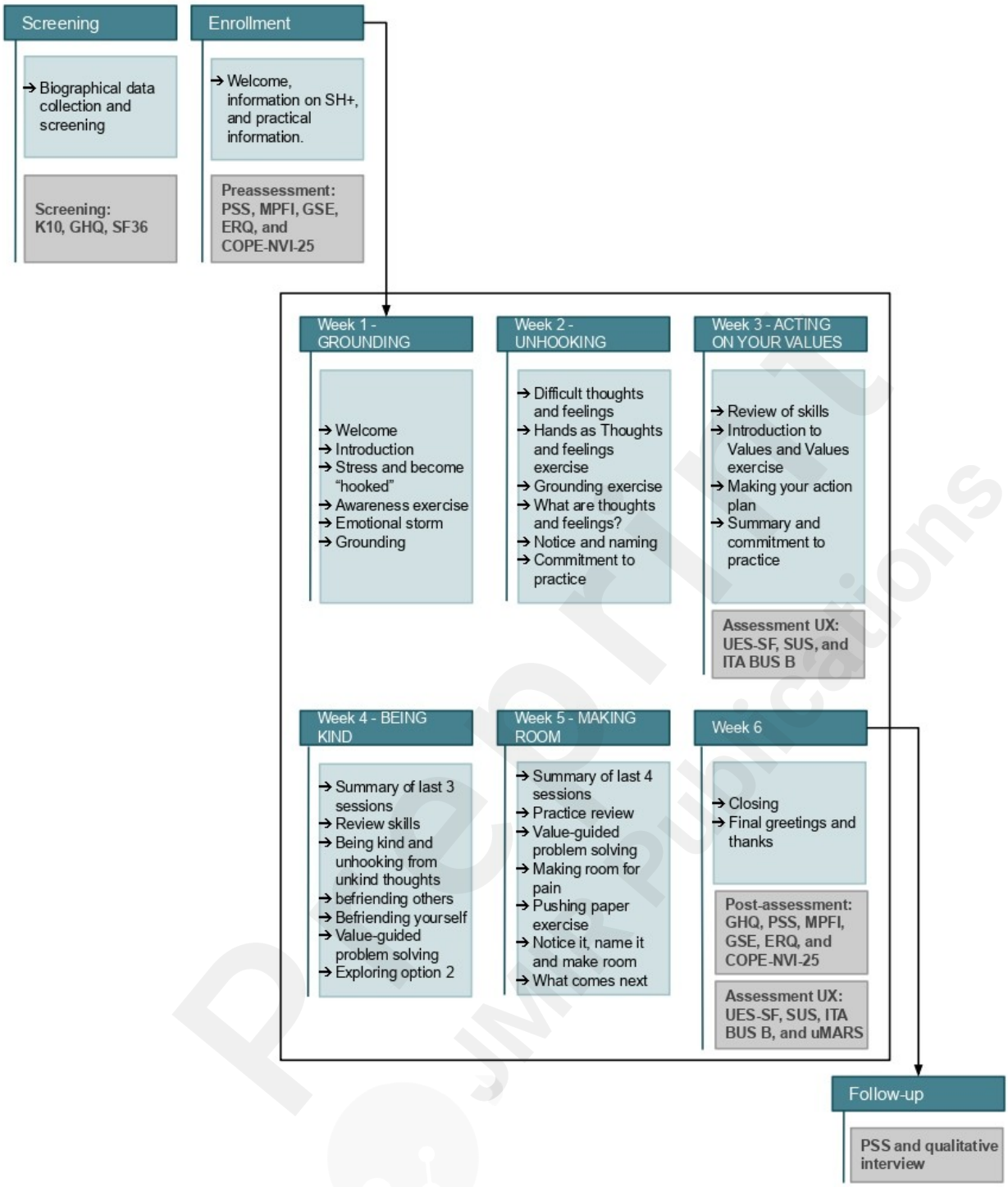
Technological tools

The technological component of the study is based on TreC. This platform allows citizens of the Autonomous Province of Trento (PAT) to access, manage and share information on their health and well-being [20]. TreC stands for *Cartella Clinica del Cittadino* (citizen's medical record) and is a reliable and well-tested platform designed to be a “system of systems” rather than a simple data hub. The central pillar of the TreC platform is the role of the citizen or patient as the manager of their health-related data, as in the case of a personal health record. TreC is designed with a flexible architecture, which enables the collection and management of heterogeneous data and allows the development and use of further subsystems to provide additional and specific functions.
This research project uses an additional module of the TreC platform, TreC Ricerca. The application can be downloaded via a specific link sent directly to participants. Authentication should be carried out via two-factor authentication (OTP code), which is secure and GDPR-compliant.

Self Help + Sessions

SH+ intervention lasts 6 weeks, with 1 session of approximately 40 minutes per week, which can be divided into two sub-sessions of 20 minutes each. Figure 1 shows a graphical representation of the conversational protocol delivered to women and its chronological structure.

Figure 1. Graphical representation of the conversational protocol delivered to women and its chronological structure. K10: Kessler Psychological Distress Scale; GHQ: General Health Questionnaire; SF36: Short Form Health Survey 36; UES-SF: User Engagement Scale-Short Form; SUS: System Usability Scale; ITA BUS B: Chatbot Usability Scale, version B; PSS: Perceived Stress Scale; MPFI: Multidimensional Psychological Flexibility Inventory; GSE: General Self-Efficacy Scale; ERQ: Emotion Regulation Questionnaire; COPE-NVI-25: Coping Orientation to the Problems Experienced; uMARS: User Mobile Application Rating Scale.



This intervention aims to enable women to acquire healthy coping strategies in stressful situations to promote psychological well-being during and after pregnancy.

The intervention was developed by referring to the SH+ program and adapting it to a psychoeducational course delivered via virtual coach. The contents are presented through a gradual path that will enable the woman to become aware of herself and the present moment, accept and normalise internal states, cope with stress, and perceive an increase in her psychological well-being. In addition, the woman will be asked to perform tasks independently and fill out her diary daily.

Methods

Design and study plan

ALBA is designed to interact with pregnant women for 6 weeks starting between weeks 14 and 26 of pregnancy. Weekly sessions are followed by the virtual coach instructions to independently perform some simple exercises and fill in the personal diary. The woman can choose the best day and time to interact with ALBA and doing exercises.

At the beginning of the pathway, ALBA will administer 6 self-report questionnaires, described in the Data Collection section, to establish a baseline for the examined psychological variables. After the data collection phase, the module will be administered, and its contents will be presented in different formats (i.e., text, images, audio, and video).

An additional round of questionnaire administration is foreseen at the end of the intervention to assess potential changes in terms of psychological well-being and QoL perceived by the women. Four questionnaires will be administered to assess usability. To ensure all the necessary data, reminders were scheduled to complete the questionnaires 24, 48, and 72 hours after the first request. However, at present, there are no reminders for session completion.

Two months after giving birth, women who have given their consent will be invited to a semistructured interview to investigate their experience using ALBA and the pp and to collect a more in-depth understanding of women's experiences during the psycho-educational process. The 2-month postpartum period was chosen for both organisational convenience and methodological considerations. The expert group identified this timeframe to find a balance between scientific appropriateness and practical arrangements of the interviews, avoiding a prolonged span after the end of the intervention whilst ensuring that interviews with patients did not occur too closely to the childbirth weeks. The underlying assumption is that the period immediately following childbirth may be a logistically and emotionally complex time for the family, with a particular focus on the mother's availability and experience.

Participant recruitment and withdrawal

Recruitment will occur within the group of pregnant women between the 14th and 26th weeks of gestation attending the Pregnancy Care Services of the APSS in Trentino.

Midwives from the APSS hospital and territorial service were involved in the study to identify women potentially eligible to participate.

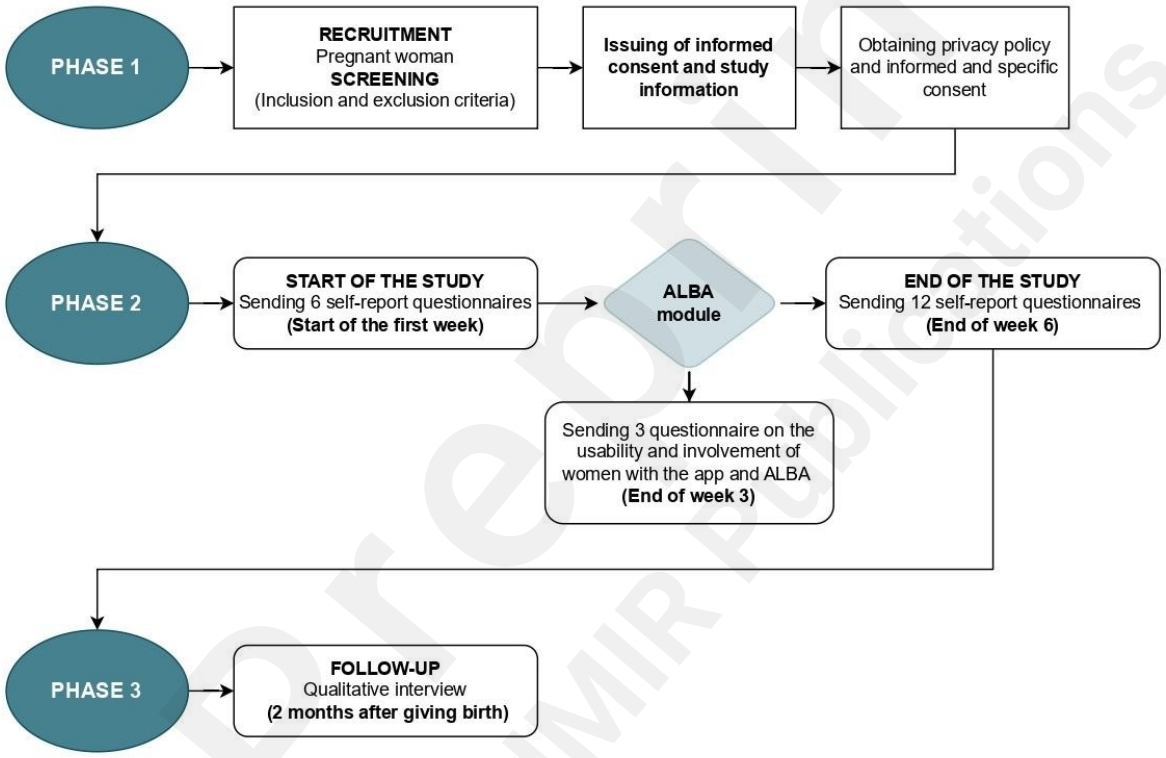
The inclusion criteria to participate in the study are as follows: (1) be pregnant; (2) be in a gestational state between the 14th and the 26th week; (3) be aged ≥ 18 years; (4) have a smartphone with internet access, be able to download the App, and be able to use it; (5) be a resident of the PAT; (6) know and understand the Italian language; (7) have a stress level score, as measured by the Kessler Psychological Distress Scale (K10), between 15. 9 and 29.9; (8) have a general well-being score, as measured by the General Health Questionnaire (GHQ), ≥ 3; (9) obtain a score on the Mental Health scale of the Short Form Health Survey 36 (SF-36) between 30 and 80.

The exclusion criteria are reported as follows: (1) patients unable to provide informed consent, which is a prerequisite for participation in the study; (2) inadequate understanding of the Italian language; (3) substance addiction or in recovery for <1 year; (4) suicidal tendencies; (5) depression or other psychiatric diagnoses; (6) women undergoing medically assisted procreation (due to the increased risk of anxiety and depression states, ascertained in the literature); (7) already being placed or followed or taken care of on a psychological or psychotherapeutic path at the time of recruitment.

Recruited women who meet the inclusion criteria and consent to participate will be enrolled in the research. All women who decide to take part in the study will be asked to sign an informed consent at the time of enrolment after a careful explanation of the project, its aims, how the data will be

collected, managed and processed, the level of involvement required; and the duration of the research, as well as any confidentiality issues. The woman will also be informed of the possibility of quitting the study at any time she wishes without any explanation and that this option would not impact the quality of care or interfere with her course of treatment.
The participant must provide written informed consent.
Participants will also receive a privacy policy statement regarding the processing of their personal data during the research. They should provide their explicit consent to the data processing.
Copies of the study's informed consent and privacy consent form will be provided to the participant. This information will also be available in a dedicated section of the App. Figure 2 shows a flowchart of the research project procedure.

Figure 2. Flowchart of the research project procedure.



Sample Size

This research project is designed as a proof-of-concept study, where a limited sample is sufficient to achieve the intended aims. It was calculated that if nonparametric statistics are conducted (assuming the distribution is not normal), the sample should consist of 24 pregnant women with Bonferroni correction (α=.025). The sample size and power for nonparametric tests (Kruskal-Wallis Test, Wilcoxon post-hoc test) were calculated according to Noether [21]. If parametric statistics are conducted (assuming the normal distribution), the sample should consist of 41 pregnant women with Bonferroni correction (α=.025). The sample calculation was further confirmed with the PASS and STATA programme, for which the resulting numerosity is N=41 subjects, assuming null hypothesis (Ho):d=d0, alternative hypothesis (Ha):d≠d0, and considering as study parameters α=.025; Mean of group 1 (ma1): 0.000; Power (power): 0.800; Mean of group 2 (ma2): 1.000; Delta (difference of means, delta): 0.500; Expected difference (da): 1.000; Standard deviation of difference (sd_d): 2.000. Thus, by a power level set at 0.80, a significance level of .025, and considering a 20% potential

dropout rate, 50 pregnant women were estimated to need to be recruited to conduct the study.

Study Outcomes

Primary Outcome

The primary outcomes are UX and UE. They will be assessed using 4 questionnaires, namely the User Engagement Scale Short-form (UES-SF) [22], the System Usability Scale (SUS) [23], the Italian version of the Chatbot Usability Scale (ITA BUS B) [24], and the User Mobile Application rating Scale (uMARS)[25], which will be administered at different time slots throughout the study, in particular at the end of the week 3 and the end of the study (i.e., week 6).

The endpoints that will be measured are the scores of the individual items of the questionnaires (USE-SF, SUS, ITA BUS B, and uMARS), the average score of the questionnaires, and the difference between the average score values of the individual questionnaires at different survey times.

The evaluation of the experience using the App and the virtual coach (ALBA) and the use of the intervention itself will also be assessed through the semistructured interviews conducted 2 months after childbirth. In this case, qualitative data will be collected to enrich the information related to the primary outcome.

Secondary Outcome

The variable expressing the “psychological well-being” outcome will be assessed by 6 administering self-report questionnaires at the beginning (i.e., week 0) and end (i.e., week 6) of the module (refer to Table 1 for a detailed overview of the questionnaire adopted). The endpoints that will be measured are as follows: a score of the individual items of the questionnaires; the average score of the questionnaires; and the difference between the average score values of the individual questionnaires in the 2 survey times.

Table 1. Summary of the questionnaires administered and their timing

Screening	At the beginning of the study (week 0)	At the end of week 3	At the end of the study (week 6)	Follow-up (2 months after birth)
K10[a]	N/A	N/A	N/A	N/A
GHQ[b]	N/A	N/A	GHQ	N/A
SF36[c]	N/A	N/A	N/A	N/A
N/A[d]	PSS[e]	N/A	PSS	PSS
N/A	MPFI[f]	N/A	MPFI	N/A
N/A	GSE[g]	N/A	GSE	N/A
N/A	ERQ[h]	N/A	ERQ	N/A
N/A	COPE-NVI-25[i]	N/A	COPE-NVI-25	N/A
N/A	N/A	UES-SF[l]	UES-SF*	N/A
N/A	N/A	SUS[m]	SUS*	N/A
N/A	N/A	ITA BUS B[n]	ITA BUS B*	N/A

N/A	N/A	N/A	uMARS[o]*	N/A
N/A	N/A	N/A	N/A	Qualitative interview

[a] K10 = Kessler Pyshological Distress Scale.
[b] GHQ = General Health Questionnaire.
[c] SF36 = Short Form Health Survey 36.
[d] N/A = not applicable.
[e] PSS = Perceived Stress Scale.
[f] MPFI = Multidimensional Psychological Flexibility Inventory.
[g] GSE= General Self-Efficacy Scale.
[h] ERQ = Emotion Regulation Questionnaire.
[i] COPE-NVI-25 = Coping Orientation to the Problems Experienced.
[l] UES-SF = User Engagement Scale-Short Form.
[m] SUS = System Usability Scale.
[n] ITA BUS B = Chatbot Usability Scale, version B.
[o] uMARS = User Mobile Application Rating Scale
* These usability questionnaires will be administered the following day, so as not to burden the participant during completion

Data Collection

Step 1. Data collection

The first phase of participant recruitment will take place in collaboration with midwives. In this first phase, the clinical figures will collect and send to the FBK researchers the sociodemographic data and email addresses of possible participants (i.e., those women who meet inclusion criteria (a) to (f) and have no exclusion criteria), after collecting informed consent and explaining the study and its purposes, as well as the need for verification of the characteristics required by inclusion criteria (g) to (i).
Midwives will collect socio-demographic data using a pre-structured form. Each woman will be assigned a unique alphanumeric code. The socio-demographic data collection form and the data collected during the study will be stored separately. In addition, data will be pseudonymized to ensure confidentiality.
The parameters requested from pregnant women will be (1) date of birth, (2) expected date of delivery, (3) educational level, (4) occupation, (5) marital status, (6) the number of pregnancies and deliveries, and (7) partner's occupation, if any.

Step 2. Screening

To fulfil the verification of inclusion criteria (g) to (i), the researchers will contact the participants via email and administer the screening questionnaires in Table 1 via the LimeSurvey platform. This platform complies with current data protection requirements and regulations. After the results of the screening questionnaires and the different socio-demographic inclusion criteria have been processed, the women will be contacted again. The following scenarios will open up.
(1) The participant does not meet the inclusion criteria by manifesting a markedly positive psychological well-being status (stress level as measured by the Kessler Psychological Distress Scale (K10)<15.9; a general well-being score as measured by the General Health Questionnaire (GHQ) < 3, a well-being level >80 on the "Mental Health" scale of the Short Form Health Survey 36 (SF-36). In this case, the woman may not be enrolled in the study, and the reasons for exclusion and the results obtained on the screening questionnaires will be returned by the research psychologists only upon the participant's request.
(2) The participant does not meet the inclusion criteria by manifesting a markedly negative

psychological well-being status (stress level measured by the Kessler Psychological Distress Scale (K10)>29.9; obtaining a well-being level <30 on the "Mental Health" scale of the Short Form Health Survey 36 (SF-36)). Even in the latter case, the woman may not be enrolled in the study, and the reasons for exclusion from the study and the results obtained on the screening questionnaires will be returned by the research psychologists only upon the participant's request. In addition, indications of territorial services to which to turn for problems that have arisen will be appropriately provided, again only at the participant's request. This is so that a structured and agreed system of possible access to a territorial service of qualified psychological support can be suggested to the woman concerned, who will provide intake when appropriate.
(3) The participant meets the inclusion criteria and is enrolled in the study.

Step 3. Participation

Women who meet the inclusion criteria and give their consent to participate in the study are enrolled in the study. All women who freely decide to take part in the study will be made to sign an informed consent after a careful explanation of the study, as described in the participant recruitment and withdrawal section.
The woman will also be asked if she would like to participate in a qualitative interview 2 months after delivery. In case of positive feedback, their telephone number will be collected to facilitate future contact and follow-up interviews. Women who provide consent to this interview will be sent (again via the App) a questionnaire one month after the expected date of delivery in which the following will be asked: (1) actual date of delivery, (2) type of delivery, (3) sex of baby, (4) name of baby, (5) mode of breastfeeding, and (6) date and time when the woman wishes to be contacted for the interview.
As shown in Table 1, the psychoeducational intervention involves completing self-report questionnaires delivered at the beginning, during, and at the end of the interaction with ALBA, in addition to the initial screening phase. Completing the instruments takes about 20 minutes. Specifically, 5 questionnaires will be administered at the beginning and 6 at the end of the intervention to investigate stress, self-efficacy, emotional regulation, psychological flexibility, coping strategies, and psychological well-being. None of these questionnaires have diagnostic purposes, so they will not be used to make diagnoses of psychopathology but only to collect descriptive data. Women with psychopathology will be excluded a priori from participation in the study (as defined in the Exclusion Criteria section). Four questionnaires will be delivered during the course to assess the usability and engagement of the woman with the App and ALBA. Specifically, usability questionnaires will be offered at the end of weeks 3 and 6 (i.e., the end of the study).
A detailed description of each instrument that will be administered is presented below.
The Coping Orientation to the Problems Experienced [26] is a shortened version of the COPE Inventory, designed to assess various coping strategies individuals use to deal with stress. This 25-item questionnaire explores strategies such as active coping, planning and acceptance, providing a complex picture of an individual's coping behaviour. It uses a Likert scale from 1 (never do it) to 4 (do it often), with a minimum score of 25 points and a maximum of 100. Foà et al. [27] translated and validated the questionnaire in Italian, showing good psychometric characteristics.
The Emotion Regulation Questionnaire [28] is a 10-item scale designed to measure the tendency to use two emotional regulation strategies as cognitive reappraisal and expressive suppression. Respondents answer each item on a 7-point Likert-type scale ranging from 1 (strongly disagree) to 7 (strongly agree). Balzarotti, John and Gross [29] translated and validated the questionnaire in Italian, showing good psychometric characteristics. In the present study, Cronbach's α was .81 for cognitive reappraisal and .84 for expressive suppression.
The General Health Questionnaire is a self-assessment instrument designed to identify mental health disorders and monitor general psychological well-being. Developed by David Goldberg [30], the

GHQ is widely used in clinical, research and public health settings. The 12 items of the questionnaire are formulated to investigate how the individual has been feeling recently, with reference to psychological symptoms (such as anxiety and depression), ability to cope with everyday situations, sleep disturbances, and somatic symptoms. The response is based on a 4-point Likert scale, ranging from "much better than usual" to "much worse than usual" with a maximum score of 36. Fontanesi et al. translated and validated the questionnaire in Italian, showing good psychometric characteristics [31].

The General Self-Efficacy Scale [32] is a psychometric instrument designed to assess an individual's general perception of self-efficacy, i.e., confidence in one's ability to organize and perform the actions necessary to handle potentially stressful or difficult situations. The GSE consists of 10 statements on which respondents must express their level of agreement on a Likert scale ranging from 1 (not true for me) to 4 (exactly true for me). Items on the scale explore various aspects of self-efficacy, such as problem-solving ability, overcoming obstacles and handling unexpected situations. The total score, obtained by summing the scores of all items, reflects the individual's overall perceived level of self-efficacy and can range from 10 to 40. The GSE scale was translated into 28 languages. Scholz et al. [33] examined the instrument's psychometric properties in 25 countries, concluding that the construct of perceived self-efficacy is international and that the GSE is an equivalent measure across different cultures. Cronbach's alphas ranged from .79 to .90. The Italian adaptation of the GSE scale was developed by Sibilia et al. [34].

The Kessler Pyshological Distress Scale is a widely used screening instrument to measure psychological distress. Developed by Kessler and colleagues [35], the K10 is a short questionnaire consisting of 10 items that investigate the frequency of psychological symptoms experienced by the individual in the past month, such as nervousness, sadness, fatigue and feelings of hopelessness. Each question is scored on a 5-point scale, ranging from "not at all" to "all the time." Total scores can range from a low of 10 to a high of 50, with higher scores indicating a higher level of psychological distress. The Transcultural Mental Helath Center also makes available the validated version in Italian [36].

The Multidimensional Psychological Flexibility Inventory [37] is an assessment tool that measures psychological flexibility on several dimensions. It investigates how people adapt their thoughts and behaviours in response to changing situations and challenges. The MPFI focuses on various aspects of psychological flexibility, including openness to experiences, present-moment awareness, and value-driven action. The 12 dimensions of flexibility and inflexibility (according to the Hexaflex model) are assessed through 60 Likert scale items from 1 to 6. The Italian adaptation of the MPFI scale was developed by Landi et al. [38].

The Perceived Stress Scale [39] is a self-report questionnaire used to measure perceived stress. Specifically, it aims to determine the degree to which situations are perceived as stressful in a person's daily life. Ten 5-point Likert scale questions investigate thoughts or feelings one has had in the past month about certain events, such as how often one has felt unable to control important things in one's life. The Italian translation of the PSS-10 by Fossati from the [40] was used.

The Short Form Health Survey 36 [41] is the most widely used instrument for measuring general health status. It includes 8 scales: physical functioning (10 items), limitations due to physical health (4 items), pain (2 items), perception of general health (5 items), energy and fatigue (4 items), social activities (2 items), limitations due to emotional problems (3 items) and emotional well-being (4 items). The 36th item differentially assesses the change in health status (1 item) from the previous year. For each dimension, question scores are coded, summed and transformed into a scale ranging from 0 (worst possible health status) to 100 (best possible health status). The SF36 has been used in large population studies and in many different clinical conditions, showing excellent psychometric properties. It has been translated and validated in several languages, including Italian [42].

The Italian Version of the Chatbot Usability Scale, version B [43], is designed to assess users' ease of use, effectiveness, and satisfaction in interacting with chatbots. This tool is structured around 11

items that cover various aspects of the user experience with chatbots, aiming to provide an in-depth, multidimensional assessment of their usability. The items involve responses on a 5-point Likert scale, where 1 equals "strongly disagree" and 5 equals "strongly agree" thus scoring from 11 to 55.
The System Usability Scale [44] is a quick and reliable tool for assessing system usability. It consists of 10 items with Likert-type responses from 1 to 5. The questionnaire, developed by Brooke, provides an overall score that reflects the ease of use and applicability of a system or product. This score can range from 10 to 50. A document with printable SUS questions is available online [45].
The User Engagement Scale Short-form [46] is a short self-report questionnaire to assess user engagement with a digital solution. This measure includes 12 items based on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The questionnaire consists of 4 factors: (1) focused attention, which indicates the feeling of being immersed in the interaction; (2) perceived usability, which is the negative effect experienced due to the interaction and the effort expended; (3) aesthetic attractiveness, which represents the graphical and visual appeal to a digital solution; (4) the reinforcement factor (reward). The latter is a single factor that includes duration, which evaluates the overall success of the interaction; novelty, which examines the general interest related to the interaction with a digital solution; and, finally, the perceived engagement factor, which evaluates the overall enjoyment of the interaction. This questionnaire was not translated into Italian and was, therefore, translated through the Back Translation procedure.
The User Mobile Application Rating Scale [47] is a tool for assessing the quality of mobile apps and its functionalities. It is characterised by a 20-item measure that includes 4 objective quality subscales (engagement, functionality, aesthetics, and information quality) and 1 subjective quality subscale rated on a 5-point Likert scale, ranging from 1 (poor) to 5 (excellent). The total and subscales scores have very high Cronbach alpha coefficients (.90 and .78-.80, respectively). The scale has been also validated in an Italian context [48].

Qualitative interview

A chartered psychologist from FBK will conduct the interviews. The interviews are structured with ad hoc items to purposively capture specific characteristics of the study and participants' experiences [49]. They will be carried out 2 months after the birth, last approximately 20 minutes, and, subject to the woman's consent, be audio-recorded to allow subsequent analysis.
The platform adopted for the intervention allows for recording activity logs, enabling proper mapping of patients' actions and experiences. This covers a range of logs, assessing whether the patient is appropriately exposed to the intervention protocol whilst recording usage patterns (e.g., session execution time, number of accesses, usage patterns of different features). Among the considered variables are any missed sessions or interruptions. These data will be correlated with acceptability scores during the analysis phase. In case a patient does not complete activities and fails to fill in specific questionnaires (leading to data missing), particular pieces of information on patients' experiences and platform usage will be collected during the scheduled post-intervention interview sessions.

Privacy and Data

As regards data protection, a privacy policy will be provided pursuant to Articles 13 and 14 of the Regulation EU 2016/679 of the General Data Protection Regulation, explaining the purposes and legal grounds of the data processing, how the personal data will be collected, their categories, how it will be managed, including the data retention period, the obligations of the data controllers and the rights of the data subjects. Personal data is processed for specific research purposes within the scope of public interest tasks of the data controllers. Informed, freely given, voluntary and explicit consent will be collected regarding the processing of particular categories of personal data (i.e., data

concerning health and data on self-reported behavioural habits in the area of lifestyle health). Moreover, specific consent will be requested regarding the possibility of contacting the data subject via telephone to conduct the research interviews.
All data collected will be kept confidential and managed by authorised persons. Data necessary for evaluating the study objectives will be pseudo-anonymised before processing. Therefore, data is pseudonymised and not anonymised.
Copies of the study information and the privacy policy will be issued to the woman and always available in a dedicated section of the App.
The study manager produces a research report and reports the data responsibly and consistently. Personal data will neither be disclosed nor disseminated except in anonymised or aggregated form for publishing purposes. The publication of data from this study will take place independently of the results obtained. The transmission or dissemination of the data, by means of scientific journals and/or presentations at congresses, conferences and seminars, will take place exclusively in anonymous form using only aggregated data that prevent any identification of the participants, even indirectly. This sharing is expected within one year after the conclusion of the study.

Data Analysis

Preliminary data analysis is scheduled for early October 2024, while final results will be available at the end of the study (second half of 2025). The results will be published within one year after the study's conclusion.

Quantitative analysis

Statistical data processing will be conducted using the software R (version 4.0.0; R Foundation for Statistical Computing), SPSS Statistics (IBM Corp), and Stata17 (StataCorp LLC).
Categorical variables will be summarised through absolute and percentage frequency distributions, and quantitative variables through appropriate centrality and variability indexes.
Descriptive analyses will be calculated for both psychological variables (stress level, anxiety level, depression level, emotional regulation, psychological flexibility, coping strategies, well-being, and QoL) and variables on usability (UX) and user engagement (UE). These analyses will be performed on the variables analysed at the beginning, during, and at the end of the interaction with ALBA.
The relationships between variables will be analyzed mainly through ad hoc statistical tests, such as the chi-square test, Fisher's exact test, 2-tailed *t* test for paired data, Wilcoxon nonparametric tests, and the sign test (based on assessment of compliance with assumptions), to understand the differences between the beginning and the end of the course in the same study sample with respect to the variables under investigation.
In addition, univariate logistic or multinomial regression models will be presented. Finally, to eliminate possible confounders, multiple regression models will be proposed in which the effects of the explanatory variables on the outcome variables will be adjusted for possible confounders. For each analysis, statistical significance will be found with a P value of $\leq .05$. It is also planned to use McNemar's test [50] and Cochran's Q [51] to evaluate paired qualitative data.

Qualitative analysis

For the analysis of the semi-structured interviews, a text mining approach [49] will be used to extract the responses that appear repeatedly in the interviews. The interviews will be conducted regarding the women's experience of using ALBA and how they felt throughout the process.

Ethical Considerations

This study was approved by the ethics committee of the APSS (17241; July 17, 2024). At the time of enrolment, all women who freely decide to take part in the study will be asked to sign an informed consent form after a careful explanation of the study, its aims, the level of involvement required and the duration of the research, as well as all ethical issues concerning confidentiality. The study will be explained partially by the midwives. Still, a video recorded by the research team explaining the study, the purpose, and the woman's involvement in simple, understandable words will also be available. The participants will be informed of the study's results through the App.

Results

The psychoeducational course delivered through a virtual coach, ALBA, integrated within the App, is expected to have significant results in terms of women's satisfaction and engagement with the use of the innovative digital solution. Women's psychological well-being, QoL, psychological flexibility, self-efficacy and emotional regulation skills, and functional coping strategies are also expected to increase between the pre-and post-intervention period.

Discussion

This study aims to investigate and evaluate women's experience and engagement with the TreC Ricerca App and the virtual coach dedicated to the stress intervention (ALBA) and assess the level of pre-post psychological well-being.
Firstly, we expect to collect relevant feedback and suggestions from the women in order to possibly improve the structure of the intervention, making it more engaging and improving the interaction. Furthermore, we contemplate to find differences in terms of improved pre-post psychological well-being. However, we are aware that this change may not be related to the intervention itself and that the evaluation of effectiveness will be carried out through a randomised clinical trial at a later stage.
All results will be reported and adequately discussed, including through a comparison with the relevant literature.

Limitations

This study is characterised by a series of limitations that should be considered and solved in the implementation of future studies. First, as mentioned above, it is crucial to consider that this study does not aim to evaluate the effectiveness of the intervention, which is why a control group is not planned. It will be crucial to involve a control group to assess the actual effectiveness in an RCT study. In addition, the present study involves a number of pregnant women from the Autonomous Province of Trento, in Italy. It would be interesting to extend the study to women from other Italian regions (and not only) as well.
It is important to emphasise that ALBA might be a valuable technological support in providing regular psycho-educational services for women during pregnancy. Moreover, literature has shown that women during the perinatal period indicated a preference for the support provided online, suggesting that the implementation of digital interventions can overcome barriers to social stigma and asking for help. Finally, it is crucial to remember that this technological support (ALBA and TreC Ricerca) is not a substitute for clinical and medical pathways and in-life medical support; instead, it is an additional element in promoting psychological well-being and healthy lifestyles during pregnancy.
If the results of this study are positive, we expect that, after evaluating its effectiveness, the

intervention could be made available as a tool to support the psychological well-being of pregnant women.

Conclusion

Existing literature indicates a preference among women in the perinatal period for online support, highlighting the potential of digital interventions to address barriers related to social stigma and seeking assistance. In this context, ALBA emerges as a possible valuable resource, providing consistent psychoeducational support for women throughout the course of pregnancy.

Data Availability

The data sets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Disclaimer

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Conflicts of Interest

None declared.

Abbreviations

ACT: Acceptance and Commitment Therapy
App: Application
APSS: Azienda Provinciale per i Servizi Sanitari di Trento
BDI-II: Beck Depression Inventory
CBT: Cognitive Behavioural Therapy
COPE-NVI-25: Coping Orientation to Problems Experienced
ERQ: Emotion Regulation Questionnaire
FBK: Fondazione Bruno Kessler (Trento)
GDPR: Regulation EU 2016/679
GHQ: General Health Questionnaire
GSE: General Self-Efficacy Scale
ITA BUS B: Chatbot Usability Scale - Italian version
K10: Kessler Psychological Distress Scale
MPFI: Multidimensional Psychological Flexibility Inventory
PAT: Autonomous Province of Trento
PSS: Perceived Stress Scale
SF-36: Health Survey Instrument
SH+: Self Help Plus
SUS: System Usability Scale
UE: User Engagement
UES-SF: User Engagement Scale Short-form

uMARS: User Mobile Application Rating Scale
UX: User Experience
WHO: World Health Organization
WHOQOL BREF: World Health Organization Quality of Life - short version

References

1. Saltzman LY, Hansel TC, Bordnick PS. Loneliness, isolation, and social support factors in post-COVID-19 mental health. *Psychological Trauma: Theory, Research, Practice, and Policy*. 2020;12(S1):S55-S57. doi:https://doi.org/10.1037/tra0000703
2. World Health Organization. *World Mental Health Report: Transforming Mental Health for All*.; 2022. https://www.who.int/publications/i/item/9789240049338
3. Goodman JH, Guarino A, Chenausky K, et al. CALM Pregnancy: results of a pilot study of mindfulness-based cognitive therapy for perinatal anxiety. *Archives of Women's Mental Health*. 2014;17(5):373-387. doi:https://doi.org/10.1007/s00737-013-0402-7
4. Zarenejad M, Yazdkhasti M, Rahimzadeh M, Mehdizadeh Tourzani Z, Esmaelzadeh-Saeieh S. The effect of mindfulness-based stress reduction on maternal anxiety and self-efficacy: A randomized controlled trial. *Brain and Behavior*. 2020;10(4). doi:https://doi.org/10.1002/brb3.1561
5. Woods SM, Melville JL, Guo Y, Fan MY, Gavin A. Psychosocial Stress during Pregnancy. *Obstetric Anesthesia Digest*. 2010;30(4):237. doi:https://doi.org/10.1097/01.aoa.0000389617.09252.47
6. Fonseca A, Gorayeb R, Canavarro MC. Women′s help-seeking behaviours for depressive symptoms during the perinatal period: Socio-demographic and clinical correlates and perceived barriers to seeking professional help. *Midwifery*. 2015;31(12):1177-1185. doi:https://doi.org/10.1016/j.midw.2015.09.002
7. Li H, Bowen A, Bowen R, Muhajarine N, Balbuena L. Mood instability, depression, and anxiety in pregnancy and adverse neonatal outcomes. *BMC Pregnancy and Childbirth*. 2021;21(1). doi:https://doi.org/10.1186/s12884-021-04021-y
8. Chen C, Wang X, Xu H, Li Y. Effectiveness of digital psychological interventions in reducing perinatal depression: a systematic review of meta-analyses. *Archives of women's mental health*. 2023;26(4):423-439. doi:https://doi.org/10.1007/s00737-023-01327-y
9. Trapani S, Caglioni M, Villa G, Duilio Fiorenzo Manara, Caruso R. Mindfulness-Based Interventions During Pregnancy and Long-Term Effects on Postpartum Depression and Maternal Mental Health: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Journal of integrative and complementary medicine*. 2023;30(2). doi:https://doi.org/10.1089/jicm.2023.0114
10. Barrera AZ, Wickham RE, Muñoz RF. Online prevention of postpartum depression for Spanish- and English-speaking pregnant women: A pilot randomized controlled trial. *Internet Interventions*. 2015;2(3):257-265. doi:https://doi.org/10.1016/j.invent.2015.06.002
11. Purgato M, Carswell K, Tedeschi F, et al. Effectiveness of Self-Help Plus in Preventing Mental Disorders in Refugees and Asylum Seekers in Western Europe: A Multinational Randomized Controlled Trial. *Psychotherapy and Psychosomatics*. Published online July 20, 2021:1-12. doi:https://doi.org/10.1159/000517504
12. Purgato M, Carswell K, Acarturk C, et al. Effectiveness and cost-effectiveness of Self-Help Plus (SH+) for preventing mental disorders in refugees and asylum seekers in Europe and Turkey: study protocols for two randomised controlled trials. *BMJ Open*.

2019;9(5):e030259. doi:https://doi.org/10.1136/bmjopen-2019-030259
13. Lorenzo-Luaces L, Howard J, Robinson De Jesús-Romero, et al. Acceptability and Outcomes of Transdiagnostic Guided Self-help Bibliotherapy for Internalizing Disorder Symptoms in Adults: A Fully Remote Nationwide Open Trial. *Cognitive Therapy and Research*. 2022;47(2):195-208. doi:https://doi.org/10.1007/s10608-022-10338-5
14. Mediavilla R, McGreevy KR, Felez-Nobrega M, et al. Effectiveness of a stepped-care programme of internet-based psychological interventions for healthcare workers with psychological distress: Study protocol for the RESPOND healthcare workers randomised controlled trial. *Digital Health*. 2022;8:20552076221129084. doi:https://doi.org/10.1177/20552076221129084
15. Hayes SC, Strosahl KD, Wilson KG. *Acceptance and Commitment Therapy: The Process and Practice of Mindful Change*. 2nd ed. Guilford Press; 2012.
16. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and Commitment Therapy: Model, processes and outcomes. *Behaviour Research and Therapy*. 2006;44(1):1-25. doi:https://doi.org/10.1016/j.brat.2005.06.006
17. Czajkowski SM, Powell LH, Adler N, et al. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. *Health Psychology*. 2015;34(10):971-982. doi:https://doi.org/10.1037/hea0000161
18. Michie S, Johnston M. Theories and techniques of behaviour change: Developing a cumulative science of behaviour change. *Health Psychology Review*. 2012;6(1):1-6. doi:https://doi.org/10.1080/17437199.2012.654964
19. World Health Organization. SELF-HELP PLUS (SH+). www.who.int. Published September 23, 2021. https://www.who.int/publications/i/item/9789240035119
20. Eccher C, Gios L, Zanutto A, Bizzarri G, Conforti D, Forti S. TreC platform. An integrated and evolving care model for patients' empowerment and data repository. *Journal of Biomedical Informatics*. 2020;102:103359. doi:https://doi.org/10.1016/j.jbi.2019.103359
21. Noether GE. Sample Size Determination for Some Common Nonparametric Tests. *Journal of the American Statistical Association*. 1987;82(398):645-647. doi:https://doi.org/10.1080/01621459.1987.10478478
22. O'Brien HL, Cairns P, Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and new UES short form. *International Journal of Human-Computer Studies*. 2018;112:28-39. doi:https://doi.org/10.1016/j.ijhcs.2018.01.004
23. Brooke J. Sus: a "quick and dirty'usability. *Usability evaluation in industry*. 1996;189(3):189-194.
24. Borsci S, Prati E, Malizia A, Schmettow M, Chamberlain A, Federici S. Ciao AI: the Italian adaptation and validation of the Chatbot Usability Scale. *Personal and Ubiquitous Computing*. Published online June 1, 2023. doi:https://doi.org/10.1007/s00779-023-01731-2
25. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS). *JMIR mHealth and uHealth*. 2016;4(2):e72. doi:https://doi.org/10.2196/mhealth.5849
26. Carver CS, Scheier MF, Weintraub JK. Assessing coping strategies: A theoretically based approach. *Journal of Personality and Social Psychology*. 1989;56(2):267-283. doi:https://doi.org/10.1037/0022-3514.56.2.267
27. Foà C, Tonarelli A, Caricati L, Fruggeri L. COPENVI25: validazione italiana della versione ridotta della Coping Orientation to the Problems Experienced (COPENVI). *COPENVI25: validazione italiana della versione ridotta della Coping Orientation to the Problems Experienced (COPENVI)*. Published online 2015:123-140.
28. Gross JJ, John OP. Individual differences in two emotion regulation processes: Implications for affect, relationships, and well-being. *Journal of Personality and Social Psychology*. 2003;85(2):348-362. doi:https://doi.org/10.1037/0022-3514.85.2.348

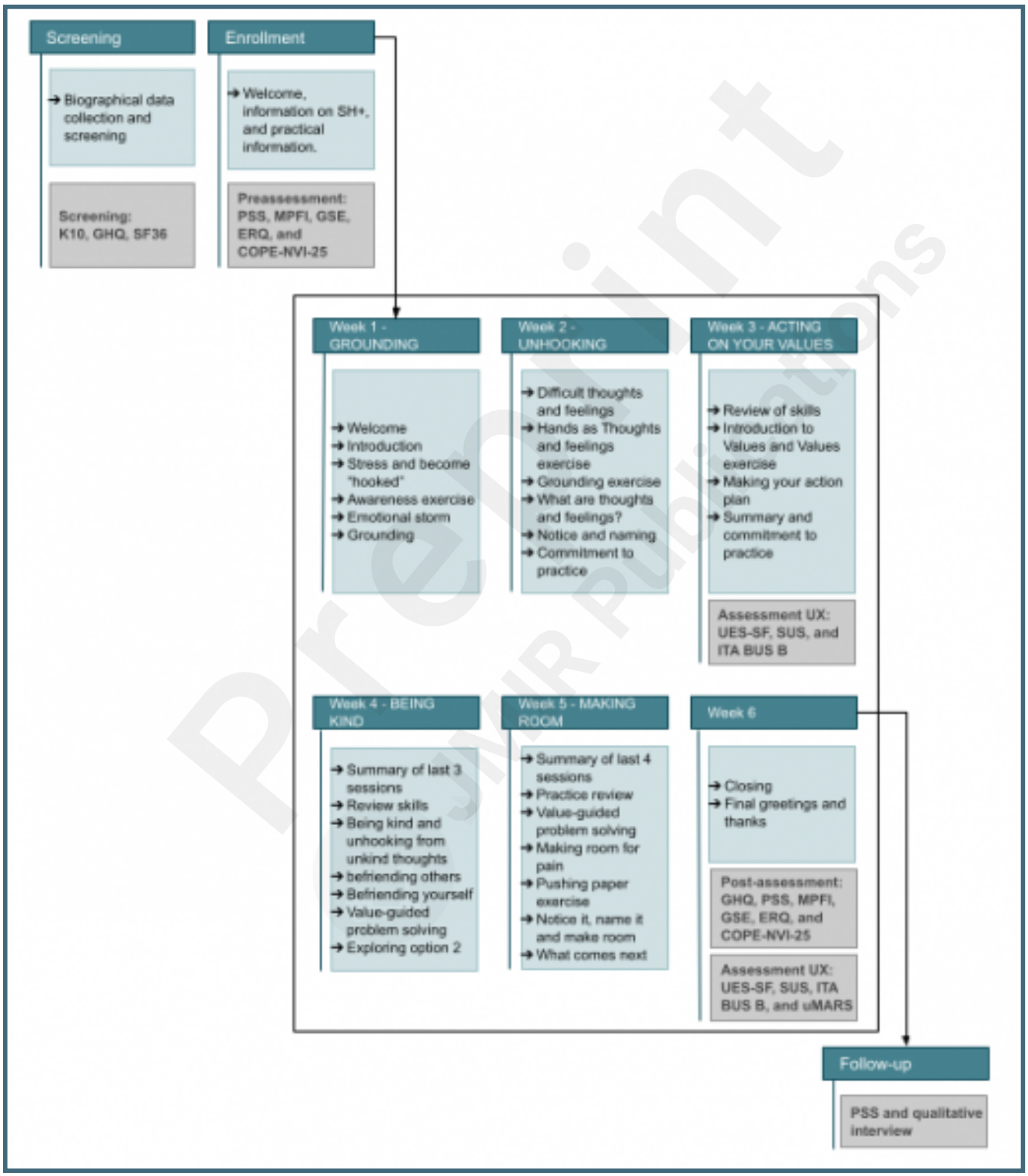
29. Balzarotti S, John OP, Gross JJ. An Italian Adaptation of the Emotion Regulation Questionnaire. *European Journal of Psychological Assessment*. 2010;26(1):61-67. doi:https://doi.org/10.1027/1015-5759/a000009
30. Goldberg DP, Blackwell B. Psychiatric Illness in General Practice: A Detailed Study Using a New Method of Case Identification. *BMJ*. 1970;2(5707):439-443. doi:https://doi.org/10.1136/bmj.2.5707.439
31. Fontanesi F, Gobetti C, Zimmermann-Tansella Ch, Tansella M. Validation of the Italian version of the GHQ in a general practice setting. *Psychological Medicine*. 1985;15(2):411-415. doi:https://doi.org/10.1017/s0033291700023710
32. Schwarzer R, Jerusalem M. General Self-Efficacy Scale. *PsycTESTS Dataset*. Published online 1995. doi:https://doi.org/10.1037/t00393-000
33. Scholz U, Gutiérrez Doña B, Sud S, Schwarzer R. Is general self-efficacy a universal construct? *European Journal of Psychological Assessment*. 2002;18(3):242-251. doi:https://doi.org/10.1027//1015-5759.18.3.242
34. Sibilia L, Schwarzer R, Jerusalem M. Italian adaptation of the General Self-Efficacy Scale: Self-Efficacy Generalizzata. userpage.fu-berlin.de. Published 1995. Accessed April 17, 2024. http://userpage.fu-berlin.de/~health/italian.htm
35. KESSLER RC, ANDREWS G, COLPE LJ, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological Medicine*. 2002;32(6):959-976. doi:https://doi.org/10.1017/s0033291702006074
36. Centre TMH. Kessler 10. www.dhi.health.nsw.gov.au. Accessed April 17, 2024. https://www.dhi.health.nsw.gov.au/transcultural-mental-health-centre-tmhc/resources/multilingual-resources-by-title/kessler-10
37. Rolffs JL, Rogge RD, Wilson KG. Disentangling Components of Flexibility via the Hexaflex Model: Development and Validation of the Multidimensional Psychological Flexibility Inventory (MPFI). *Assessment*. 2016;25(4):458-482. doi:https://doi.org/10.1177/1073191116645905
38. Landi G, Pakenham KI, Giovannetti AM, et al. Italian validation of the Italian multidimensional psychological flexibility inventory (MPFI). *Journal of Contextual Behavioral Science*. 2021;21:57-65. doi:https://doi.org/10.1016/j.jcbs.2021.05.007
39. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. *Journal of Health and Social Behavior*. 1983;24(4):385-396. doi:https://doi.org/10.2307/2136404
40. Carnegie Mellon University. Scales - Laboratory for the Study of Stress, Immunity, and Disease - Department of Psychology - Carnegie Mellon University. Cmu.edu. Published 2014. https://www.cmu.edu/dietrich/psychology/stress-immunity-disease-lab/scales/index.html
41. Ware JE, Cathy Donald Sherbourne. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *PubMed*. 1992;30(6):473-483.
42. Apolone G, Mosconi P. The Italian SF-36 Health Survey. *Journal of Clinical Epidemiology*. 1998;51(11):1025-1036. doi:https://doi.org/10.1016/s0895-4356(98)00094-8
43. Borsci S, Prati E, Malizia A, Schmettow M, Chamberlain A, Federici S. Ciao AI: the Italian adaptation and validation of the Chatbot Usability Scale. *Personal and Ubiquitous Computing*. Published online June 1, 2023. doi:https://doi.org/10.1007/s00779-023-01731-2
44. Peres SC, Pham T, Phillips R. Validation of the System Usability Scale (SUS). *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*. 2013;57(1):192-196. doi:https://doi.org/10.1177/1541931213571043
45. Gruppo di Lavoro per l'Usabilità (GLU). Ministro per la Pubblica Amministrazione. Published January 25, 2016. Accessed May 16, 2024. http://www.funzionepubblica.gov.it/glu
46. O'Brien HL, Cairns P, Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and new UES short form. *International Journal of*

Human-Computer Studies. 2018;112:28-39. doi:https://doi.org/10.1016/j.ijhcs.2018.01.004
47. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS). *JMIR mHealth and uHealth*. 2016;4(2):e72. doi:https://doi.org/10.2196/mhealth.5849
48. Morselli S, Sebastianelli A, Domnich A, et al. Translation and validation of the Italian version of the user version of the Mobile Application Rating Scale (uMARS). *Journal of Preventive Medicine and Hygiene*. 2021;62(1):E243-E248. doi:https://doi.org/10.15167/2421-4248/jpmh2021.62.1.1894
49. Marshall C, Rossman GB, Blanco GL. *Designing Qualitative Research*. Sage Publishing, Inc; 2022.
50. Sheskin D. *Handbook of Parametric and Nonparametric Statistical Procedures*. Taylor & Francis Group Chapman & Hall/Crc; 2011.
51. 51.COCHRAN WG. THE COMPARISON OF PERCENTAGES IN MATCHED SAMPLES. *Biometrika*. 1950;37(3-4):256-266. doi:https://doi.org/10.1093/biomet/37.3-4.256

Supplementary Files

Figures

Graphical representation of the conversational protocol delivered to women and its chronological structure. K10: Kessler Psychological Distress Scale; GHQ: General Health Questionnaire; SF36: Short Form Health Survey 36; UES-SF: User Engagement Scale-Short Form; SUS: System Usability Scale; ITA BUS B: Chatbot Usability Scale, version B; PSS: Perceived Stress Scale; MPFI: Multidimensional Psychological Flexibility Inventory; GSE: General Self-Efficacy Scale; ERQ: Emotion Regulation Questionnaire; COPE-NVI-25: Coping Orientation to the Problems Experienced; uMARS: User Mobile Application Rating Scale.



Flowchart of the research project procedure.