

A Methodology for Adapting the WHO Evidence-Based Self-Help+ Intervention for Stress Management via Chatbot

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Abstract

Background: This research paper explores the use of digital technologies to expand mental health support, focusing on an evidence-based WHO low-intensity intervention called Self-Help Plus (SH+). The SH+ protocol has been integrated into a chatbot-guided mobile application called "ALBA."

Objective: The present study aims to describe the adaptation (porting) of this approach i) from a face-to-face/group delivered intervention to a tech-enabled intervention and ii) to an adapted intervention for women with breast cancer and for women who are pregnant.

Methods: The development process is based on multi-professional collaboration, and it embraces a user-centered design approach. It includes i) adapting the SH+ protocol to suit the chatbot-driven ALBA platform, ii) tailoring content to the target population, and iii) incorporating interactive features for improving engagement and potential efficacy.

Results: Preliminary outcomes are promising, whilst a structured pathway to assess the usability, efficacy and scalability of the intervention is presented. The discussion focuses on the potential of virtual coaching applications in mental health, emphasising how new technologies could further improve accessibility and personalisation of the interventions.

Conclusions: A final section explores future development scenarios, including real-world research and additional potential adaptations for different target groups and purposes, ranging from primary prevention to clinical practice.

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Original Manuscript

A Methodology for Adapting the WHO Evidence-Based Self-Help+ Intervention for Stress Management via Chatbot

Abstract

Background: This research paper investigates the adaptation of an evidence-based intervention for mental health, Self-Help Plus (SH+), to a digital platform, aiming to expand mental health support through innovative technological solutions. The SH+ intervention, designed by the World Health Organization (WHO), is a low-intensity, self-guided program aimed at improving mental well-being. The intervention has been integrated into a chatbot-driven mobile application called "ALBA" (Automated Well-Being Assistant).

Objectives: This study examines the transition (porting) from a traditional face-to-face, group-based approach to a tech-enabled model, tailored specifically for women with breast cancer and pregnant women. It aims to describe the adaptation of this approach, focusing on two key aspects: i) the shift from in-person delivery to a tech-enabled intervention, and ii) the customization of the intervention to address the unique needs of the selected target groups.

Methods: The development of the ALBA application involved a collaborative, multi-disciplinary approach, combining expertise in psychology, eHealth information technology, interaction design, and specific domain knowledge related to pregnancy and oncology. The development process followed two primary methodologies: user-centred design and service design. These approaches emphasize understanding user needs, promoting iterative improvements, and continuously incorporating user feedback. The development followed the Obesity-Related Behavioral Intervention Trials (ORBIT) model, which involves a cycle of literature review, stakeholder consultation, content development, software development, and evaluation. At the same time, specific attention has been dedicated in i) adapting the SH+ protocol to suit the chatbot-driven ALBA platform, ii) tailoring content to the target population, and iii) incorporating interactive features for improving engagement and potential efficacy.

Results: The manuscript outlines the key steps and processes involved in adapting the SH+ intervention into the ALBA digital platform. This includes an overview of the challenges and opportunities of translating a face-to-face, group-based intervention into a tech-enabled model, and provides insight into how customization for specific populations, such as women with breast cancer and pregnant women, was integrated into the design of the platform. This is in view of informing future studies on the development and adaptation of already validated protocols into m-health intervention in the field of mental health and mental well-being.

Conclusions: The digital adaptation of the SH+ intervention into the ALBA platform could represent a significant step forward in expanding the accessibility and personalization of mental health interventions in potentially different settings and target groups. The use of virtual coaching applications can play a central role in improving the availability and easy-to-access of psychological support, even in different and m-health formats. Future developments could include further testing in real-world settings, to expand i) adaptations for various target groups and ii) purpose of use ranging from primary prevention to more clinically focused interventions.

KEYWORDS

digital health; virtual coach; mobile application; breast cancer; pregnancy; stress management

Introduction

Theoretical Framework

Current scientific literature shows an increasing demand for psychological support within the general population, with even higher levels when considering vulnerable populations exposed to stressful situations [1]. The World Health Organization's (WHO) strategy for global mental health is based on principles of inclusivity and scalability, covering the entire arch of mental health promotion and prevention for citizens exposed to the risk of mental distress. The gap between the prevalence of mental health problems and the services available to those in need of specific interventions represents a current public health challenge, and WHO has further underlined this issue through the "mental health Global Action Program" (mhGAP) [2], where particular attention is also paid to the potential role of digital technologies in facilitating both availability of services and optimised delivery of the intervention [3]. Digital health is considered a pivotal strategy to promote equitable, affordable and universal access, reducing the gap between services and those who can benefit from receiving mental health interventions [4]. Indeed, an increasing body of literature confirms the potential of new technologies – including telemedicine, mobile health (m-health) initiatives and digital therapeutics (DTx) – in promoting a continuum of care from clinic to home and a stepped-care approach. In particular, low-intensity mental health interventions could be considered appropriate for implementation within digital health solutions [5]. They usually refer to specific programs where the active involvement of healthcare staff and specialists is not necessarily required. They are based on solid principles from evidence-based psychological interventions embedded into a self-help approach. Among them, WHO is promoting Self-Help Plus (SH+), a low-intensity intervention for stress management initially developed for hard-to-reach vulnerable population groups [6]. These types of interventions are usually designed to be transdiagnostic and easily adaptable in different contexts. Because of their general structure and purpose, low-intensity approaches can be easily used to increase access to viable and evidence-based psychological interventions to a broader target audience, reporting either limited or mild symptoms linked with mental distress and/or illness within a stepped-care approach [7]. The potential combination of evidence-based low-intensity interventions and m-health approaches could lead to an effective, sustainable and inclusive strategy for improving the scalability of mental health interventions both in terms of prevention and treatment [8].

Intervention characteristics

Self-Help Plus (SH+)

SH+ is a transdiagnostic intervention based on Acceptance and Commitment Therapy (ACT), a third-wave Cognitive-Behavioral Therapy (CBT), [9]. SH+ is structured into five sessions, comprising audio recordings featuring mindfulness practices and exercises, aiding participants in recognizing barriers and facilitators related to stress management. Several studies report positive effects of SH+, considering long-term efficacy in a target population of refugees and asylum seekers [10–15]. Other studies show a still debatable effect of SH+ when applied to healthcare professionals [16].

SH+ is particularly suitable for a digital version, considering that i) it is largely based on third-wave CBT techniques, usually more suitable than other psychotherapeutic approaches for transferring

into interventions delivered by mobile Apps [9]; ii) it includes self-help materials, like the illustrated Doing What Matters in times of stress (DWM) booklet [17] encompassing exercises designed to reduce stress and increase social support networks, adaptive coping mechanisms, and resilience. The latter has recently been converted into a web app for populations in war (RESPOND PROJECT), [18].

Target populations: public health issues and sustainability

The present adaptation model is designed to target two specific groups usually exposed to stress and potentially stigmatised when accessing mental health services: women with breast cancer and pregnant women.

Physical illnesses like breast cancer often coexist with psychological distress, including stress, anxiety, and depression [19]. Furthermore, chronic fatigue, sleep problems, body image disturbance, and diminished social interactions emerge as characteristic comorbidities. Additionally, women diagnosed with primary breast cancer continue to exhibit susceptibility to psychological ailments over an extended duration, underscoring the profound influence of this medical condition on patients' quality of life (QoL), [19]. It has been observed that a positive psychological attitude improves disease management and recovery, underscoring the significance of addressing mental health issues in addition to physical ones [20]. Numerous studies have highlighted the efficacy of CBT interventions in improving mental health and overall QoL for women with breast cancer [21,22].

A second target group for the present exercise are pregnant women. The transition to motherhood is an event that entails a significant change in a woman's life. Pregnancy is characterised by major transformations in the woman, with an impact on her physical, mental and social well-being. The literature shows that pregnant women experience various psychological symptoms, the most frequent being anxiety, stress, and/or depression [23]. Thus, women in the perinatal period may experience worries and the fear of being unable to manage the changes associated with the period and the baby/children yet to be born [24]. To date, psychoeducational interventions that promote women's psychological well-being during pregnancy are scarce and tend to focus mainly on samples of women with psychiatric symptoms (e.g., perinatal depression disorder), [25].

Despite the demonstrated effectiveness of psychological support interventions in alleviating stress in these target populations, only a negligible proportion of women belonging to these groups have access to psychological support. Indeed, the need for public resources and mental healthcare services is increasing due to the ageing population and the rising prevalence of cancer and diseases which accompany mental illness. However, there are several challenges to accessing mental care services. For example, only 17% and 28%, respectively, of Italian and German women with breast cancer benefit from psycho-oncological support [26,27]. On the other hand, in a Portuguese study, only from 13.6% up to 20.2% of women screened positive for possible depressive disorders sought help during pregnancy [28].

Many women face geographical barriers, with specialised centres often located far away and the qualified personnel are limited. Stigma and self-stigma can also prevent patients from seeking psychological support [29].

Opportunities from new technologies

The use of digital tools has been explored as a means of providing psychological support to face

mental health care accessibility and sustainability challenges. DTx has surfaced as a convenient and readily accessible alternative for individuals pursuing psychological support [30]. They offer evidence-based and clinically evaluated digital mental health interventions delivered through software, addressing various diseases and disorders by providing treatment, management, and preventive measures [31]. M-Health services could improve accessibility and standardisation of service delivery, as well as reduce costs and potential stigma associated with access to service through a stepped-care approach enabled by technologies [32]. m-Health and DTx might support a patient-centric approach, empowerment and self-care, despite the potential lack of human contact [33]. Using digital tools to promote psychological well-being can be an optimal solution specifically for pregnant women and those with breast cancer, considering the flexibility, adaptability to patients' needs characterising these tools, as well as reduced social stigma [34]. Literature reports promising results concerning the effectiveness of DTx based on CBT targeting psychological well-being for both our target groups [35–38].

Objectives

The primary aims of this paper are as follows:

1. To map a solid pathway to design and adapt SH+ protocol into a technology-enabled intervention, for implementation through a novel technological tool, the chatbot ALBA.
2. To emphasise the specific adaptations of a digitally-delivered low-intensity intervention when applied to sub-population particularly exposed to social-psychological stressors, such as women with breast cancer and pregnant women.

Methods

This section reports the development of a Virtual Coaching solution named "ALBA", an "Automated well-Being Assistant". Subsequently, the section clarifies the adaptation process of the SH+ protocol into a mobile application.

Process overview

The development of the intervention leveraged the integration of different expertise, including psychology, eHealth information technology (IT), interaction design and domain knowledge on pregnancy and oncology. A multidisciplinary team was created to account for the user's different needs, to accommodate for psychological consistency of the intervention and the proper adoption of IT requirements and user-design principles in the process, to ensure high quality in terms of adaptability of the proposed tools in the digital context .

The entire development of the intervention is based on two main methodologies: user-centered [39] and service design [40]. These approaches emphasise understanding and meeting user needs, promoting iteration and continuous improvement based on user feedback. SH+ will be developed iteratively, following the Obesity-Related Behavioral Intervention Trials (ORBIT) model [41], as illustrated in **Figure 1**. The development process included: literature review; exploration, incorporating input from user representatives, healthcare providers, and eHealth experts, including designers and developers; intervention content development, which was identified and adjusted from the SH+s intervention manual; iterative software development and formative evaluation; and finally, considerations regarding privacy, security, and organisational anchoring.

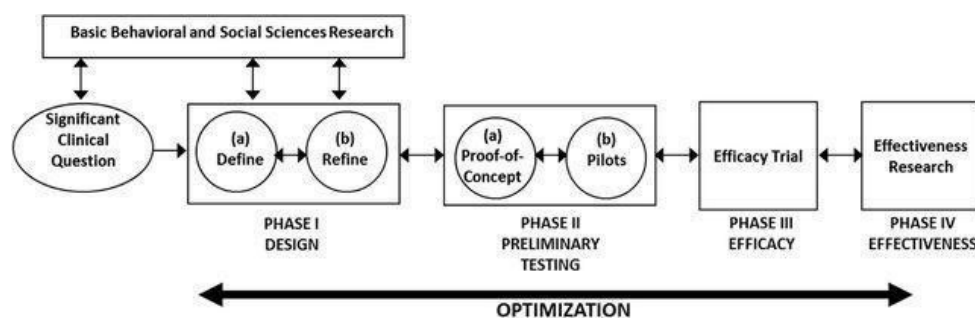


Figure 1. The ORBIT model [41].

After the preliminary phase of literature review and integration of the WHO protocol, we systematically carried out the subsequent steps to develop the ALBA chatbot prototype. Following the ORBIT development process ensures a scientifically step-by-step approach to recognised a standardised creation of digital behavioural change interventions. We then progressed to the initial stage of the ORBIT model, specifically Phase 1.a (Define). This phase is designed to establish a solid foundation for the intervention by clearly defining the clinical problem to be addressed, the targets, and ensuring that the intervention is conceptually sound and grounded in relevant theory and empirical evidence. In line with this, our goal was to adapt and refine the core components of SH+ prior to feasibility testing. Accordingly, this paper focuses on the initial adaptation methodology and the process is described in detail in the following sections and summarised in the supplementary table [see **Additional File 1**]. In contrast, real-world usage metrics, such as dropout rates, session completion, and participant feedback, will be addressed in later phases, including firstly preliminary testing (Proof of Concept and Pilots), and subsequently during efficacy and effectiveness trials. These results will be presented in future publications.

Adaptation from SH+

Content

The SH+ package has three main components: a pre-recorded audio course, a facilitator manual, and the DWM booklet. All materials have been downloaded and translated (if necessary) from the WHO website [42]. The audio material imparts key information about stress management and guides participants through individual exercises and small group discussions. The innovation is that main intervention components are delivered as intended through the use of pre-recorded audio, without the burden of extensive training and supervision to target hard-to-reach populations. SH+ is structured into five sessions based on ACT for stress management, namely i) grounding, ii) unhooking, iii) acting on your values, iv) being kind, and v) making room. The initial phase involved carefully examining the guide manual and audio. A judicious assimilation of selected components from the DWM booklet complemented this endeavour. Emphasis was placed on augmenting the visual and illustrative facets, notably by incorporating cartoon- and comic-book-like elements.

The working group then ventured into adapting the group and in-person intervention to an individually delivered approach through a chatbot on an application. This transposition required various human and logistical factors to be changed or reconsidered to accommodate the new mode of psychological support delivery. ALBA is responsible for disseminating diverse content forms such as textual materials, auditory cues, video presentations, and graphical depictions (**Figure 2 (a)**). The

auditory components about SH+ exercises, alongside visual elements, are slated for comprehensive modification, tailored to suit an intervention delivered through mobile devices. Furthermore, the integration of psychoeducational elucidations of complex concepts is realised through videos or graphical representations. This strategic approach is conceived in response to the challenges posed by the transfer of substantial didactic information within the confines of a chatbot-mediated interaction.

Guide

The facilitator guide manual of SH+ helps trained non-specialist facilitators conduct the course using audio pre-recorded materials. The facilitators run the group, run discussions and answer any questions. They also make sure the group runs safely. They have a limited role in explaining content as this mostly comes from the audio. In the RESPOND interventions [18] the user also receives weekly support through a 15-minute telephone call from a "helper." The helper, as a trained individual, adheres to a predefined script and is responsible for initiating weekly telephonic interactions with the participant. These interactions serve the multiple purposes of supporting, encouraging, problem-solving and vigilantly tracking the participant's advancements along the trajectory of stress management.

The conventional role assumed by facilitators in the physical realm is supplanted within this context by ALBA. This automated agent guides participants throughout the sessions (**Figure 2 (b)**). ALBA utilizes pre-written scripts with the option to provide personalized responses based on user button choices and free text answers. While this approach may not offer the same level of customization as generative methods, it ensures SH+ protocol transposition standardisation and safeguards against potential issues such as hallucinations and biases commonly associated with generative artificial intelligence models [43]. The intervention was constructed in such a way that ALBA is always the first to interact with the user. It is currently not possible for the user to ask specific questions. Additionally, the chatbot functions in an interactive capacity, prompting moments of introspection and contemplation. It engages participants through a series of inquiries, encompassing both directed and open-ended questions, thereby soliciting feedback pertaining to the comprehensibility and lucidity of the disseminated subject matter. ALBA will also assume a role similar to that of the helper within the RESPOND protocol framework (**Figure 2 (c)**). Its operational function encompasses the supervision and oversight of exercise implementation, primarily bolstering participant engagement and fostering intervention adherence. Notably, integrating these roles constitutes an innovative and resource-efficient approach to orchestrating the participant's progression through the sessions. Moreover, this amalgamation inspires the participant with a consistent and reassuring sense of guidance.

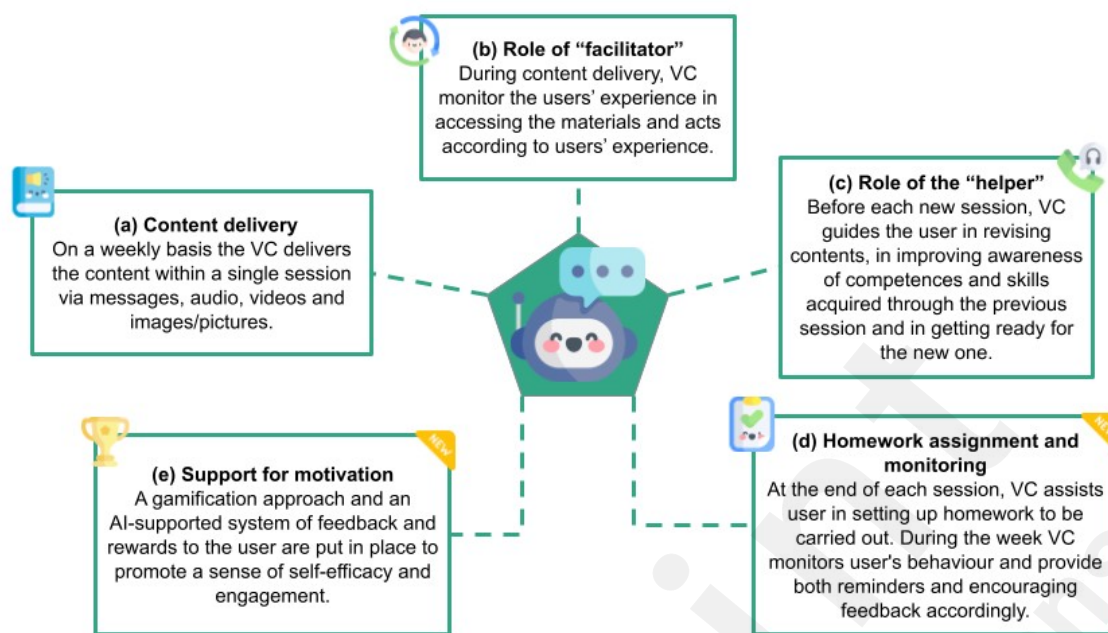


Figure 2. ALBA chatbot and its functionalities as Virtual Coach (VC).

Adaptation to the target populations

Participants

Participants recruitment will be conducted through word of mouth and direct acquaintance and by advertising the study within public healthcare settings. Only volunteers aged ≥ 18 years will be included. All data will be collected confidentially with participants' informed consent. For more details about co-design participants recruitment see our previous study [44].

A thorough evaluation of the psychological states of prospective female participants is undertaken before they engage in the intervention. This evaluative process encompasses an appraisal of key indicators of mental well-being, thereby facilitating the discernment of suitability for study inclusion. This procedural component serves as a crucial gatekeeping mechanism and furnishes a foundational benchmark against which the eventual intervention's effectiveness can be gauged. Implementing baseline and subsequent temporal administration of questionnaires yields a comprehensive and scientifically based view, thereby illuminating the trajectory and impact of the final intervention over time. Regarding materials they have been translated into Italian and culturally adapted for the target populations. Exemplary content designed for humanitarian emergencies is redrafted to suit the context of stressful events experienced by Italian women (e.g. typical familiar environment, medical conditions). The chatbot's functionality is attuned to the distinctive requirements of the designated populations. To elucidate, all pertinent materials is tailored to encompass a prototype generic Italian female user, incorporating requisite specific adaptations (e.g. Italian feminine adjectives and words' desinences). Throughout the whole design process, a careful assessment is directed toward the potential transmutation of exercises into a stress-inducing factor (e.g. focusing on body exercises for women diagnosed with breast cancer).

Session

Original SH+ intervention is organised in 2-hour sessions and groups of 20 to 30 people on an

established weekly schedule. ALBA releases dialogue sessions in this digital translation, but the intervention is literally in the end-user's hands, offering a self-help intervention wherever she wants. Moreover, the user can personalise sessions' day. The dialogue duration is fixed at 40 minutes. To support adherence, the session can be divided into two mini-sessions on two subsequent days, preventing user fatigue and improving the usability of both the chatbot and the app. After completing a session, participants receive supportive and motivational reminders and feedback (**Figure 3**). This facilitates the establishment of a routine increasing exercise completion in populations with different personal and time management needs, like pregnant women and women with breast cancer.

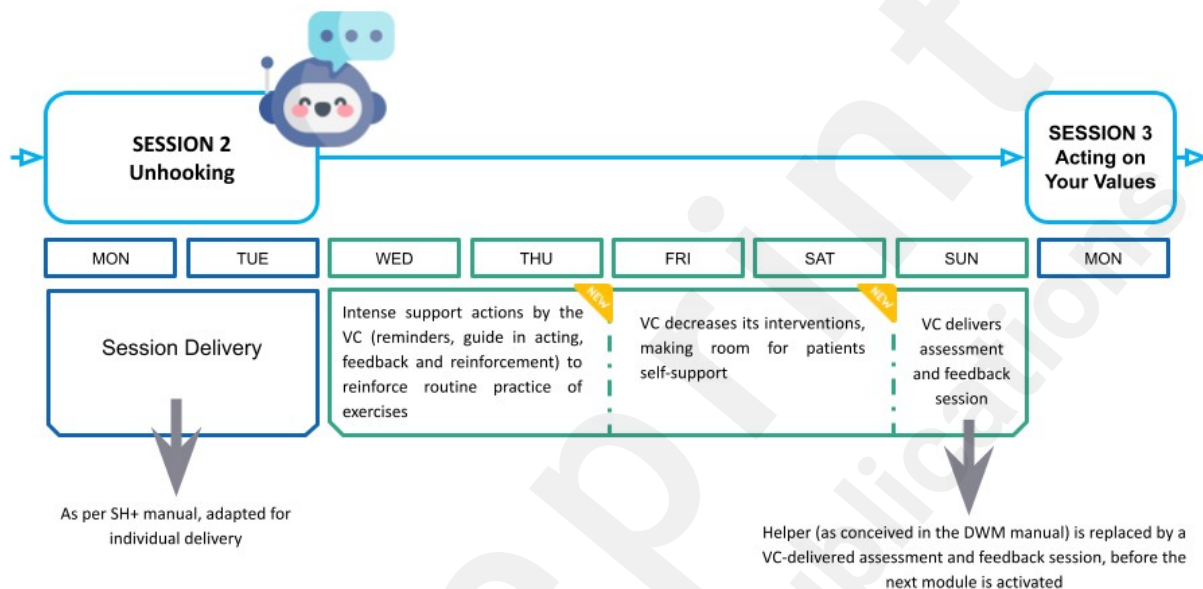


Figure 3. Representation of an exemplary week (Week 2: Session Unhooking) intervention's structure.

Key Points from chatbot and m-health literature

Homework

User interface design and feedback are essential for personalised behaviour change support systems. Incentives and reminders are useful strategies that facilitate adherence, learning, and safety during self-guided interventions [45,46].

ALBA will assign homework during the session delivery. This homework consists of exercises that should be carried out by the users before the following session, as per facilitator's instructions. The diary section will support self-monitoring of exercise progress and completeness of sessions (**Figure 2 (d)**). It is within this section that all reminder and feedback controls are created. Indeed, the novelty of this app is that the completion of exercises is monitored in the evenings before the next session, reinforcing engagement, which is different from standard SH+ in-person delivery. This will be achieved through the strategic incorporation of gamification elements (like badges), and timely feedback prompts interposed between sessions. This paper will not discuss all these sets of sophisticated IT rules and components.

Engagement

The design and deployment of conversational agents, such as chatbots, as virtual coaching solutions

allow for maintaining the intuitiveness and naturalness of dialogue-based interaction while exploiting the benefits of full automation [47,48]. Moreover, gamification in healthcare is a promising way to improve patient adherence. It can make interventions more fun and engaging, increase patient awareness and give patients ownership over their treatment [49].

Our app has a main page where users can dialogue with ALBA by selecting the toolbar button. It also includes other sections: the “Gallery”, featuring educational videos and intervention introductions; the “Diary”, strictly connected with the “Exercises” page with all available self-help exercises; the “Progress” section provides users with an overview of their “journey” towards increased well-being. Here users can see the sticker badges earned by practising exercises between sessions appearing on their suitcase illustration, serving as long-term positive rewards. Badges also have symbolic meanings for psychological instruments and techniques acquired during the intervention. Instead of human helpers, the avatar-like chatbot serves as the primary support system, giving feedback and rewards, promoting a sense of accomplishment and the app gains users’ motivation (**Figure 2 (e)**).

Ethical considerations

All future studies' data and our previous preliminary data [44] will/are confidentially collected in Italian and deidentified with participants' informed consent. Eventual confidential audio recordings of semistructured interviews are used for data analysis, and participants are identified only by numeric codes. At the studies' conclusion, participants can request the research outcomes from the research manager. Participants did not receive any compensation. A local Ethics Committee will approve all future studies, as our previous co-design study [44]. Privacy issues require strict adherence to informed consent protocols and secure data retention compliant with the General Data Protection Regulations (GDPR). Finally, the participants will then be informed of the study's results through the dissemination of articles.

Expected Results

The preliminary outcomes derived from the initial adaptation phase show a promising development trajectory. Our previous co-design study validated the chatbot's dialogues for effective content delivery [44]. Positive feedback highlighted the app's structure, user-friendly design, and perceived credibility. Key innovations included interactive elements, gamification, and personalized feedback. Methodical selections for facilitating the transition from manual modality to the application domain are shown in prototypical mock-up representations in **Figure 4**. The application is poised to feature a subdued colour palette, coupled with cartoonish character renditions, strategically created to alleviate the emotional burden of embarking on such a path to manage stress [50]. Moreover, this stylish choice also aligns with the cartoonish characters of the DWM booklet.

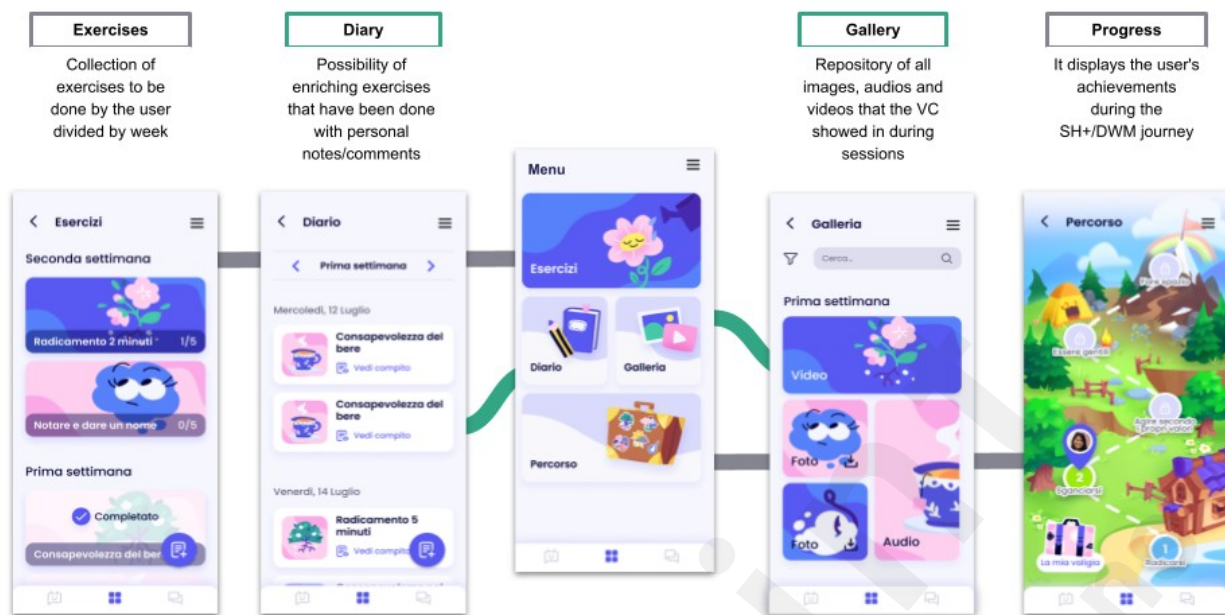


Figure 4. ALBA app mock-ups of different sections (Exercises, Diary, Principal Menu, Galley, and Progress).

The app is poised to be compartmentalised into discrete segments, the utility of which will undergo rigorous evaluative scrutiny in a methodologically standardised manner, as delineated in the co-design investigations pertaining to Phase I.b of the ORBIT model. Subsequently, a comprehensive evaluation of usability and acceptability will be undertaken during Phase II. These future phases will consist of a plan encompassing the scrutiny of the application's prototypes through successive stages of deployment. This sequential study will initially involve a limited cohort of stakeholders, followed by an equivalently small sample of volunteer women contending with breast cancer and gestational conditions.

The complete array of dialogues and transcripts constituting the ALBA virtual coach, originating from the SH+ manual and DWM booklet, has been fashioned utilising the methodologies expounded in the preceding sections. These textual compositions are presently undergoing the technical instantiation process. A selected mockup extracted from these dialogues is visually depicted in **Figure 5**, offering a glimpse into their compositional structure and stylistic attributes. Noteworthy features encompass a spectrum of question types, comprising both structured dialogue and open dialogue exchanges concurring to foster a heightened degree of interactivity and engagement within the communication exchange.



Figure 5. ALBA's dialogue section with open-ended questions and button-based responses (guided answers).

Discussion

Principal findings

New technologies can improve the sustainability of the healthcare system by providing round-the-clock support to patients and optimising the intervention of healthcare professionals [5]. Nevertheless, the innovations associated with developing and utilising new technologies for mental health remain a subject of ongoing discussion. Empirical studies on evidence-based digital interventions for mental health, including internet-based CBT, have shown that these interventions are effective, feasible, and acceptable to users [51–53]. However, some limitations have been found, mainly regarding users' low engagement and completion rates [51,54]. Integrating human coaching and support in digital mental health interventions can help improve adherence and behaviour change outcomes [55,56], although this may reduce the scalability of such solutions. In this optic, the use of chatbots for digital mental health interventions has attracted interest in the design community. A growing number of studies are reporting their acceptability and feasibility for users [57,58], as well as their effectiveness in reducing perceived stress [54], thereby improving symptoms of anxiety [59–61], depression [60,61], and insomnia [62]. A recent meta-analysis suggests that internet-delivered cognitive-behavioural therapy (ICBT) is likely as effective as conventional face-to-face CBT. However, there are still unanswered questions about treatment moderators and implementation strategies [63]. Another study highlights the importance of understanding and accommodating diverse patient preferences when implementing self-management applications in cancer care. It underscores the significance of patient engagement in self-help and suggests that digital interventions can empower individuals to control their well-being. However, participant experiences varied, with differing perceptions of added value. Recommendations include refinements for improved user-friendliness and tailoring content to individual preferences through continuous evaluation and collaboration with end-users to enhance intervention effectiveness and user experience [64].

In line with these new emerging technological tools to face socio-psychological demands, this paper

seeks to provide insights beyond the end-user interfaces, delving into the complexities of a m-health application for stress management development, ALBA. This ongoing research adapts the transdiagnostic SH+ package to a chatbot intervention for women with breast cancer and pregnant women in Italy. ALBA replaces human facilitators, delivering text, audio, video, and graphics content, guiding participants, initiating interactions, and ensuring exercise implementation. The adaptation process involved careful consideration of cultural nuances and the psychological states of the target populations. The adaptation process required evaluating psychological states, tailoring materials, and customising content for the specific needs. Moreover, the intervention was adapted to individual support: the chatbot-mediated approach aims to provide a resource-efficient and innovative way to help through digital translation, allowing flexible session delivery with personalised sessions and reminders to enhance adherence to stress-management path. The chatbot incorporates gamification elements, assigning homework, monitoring progress, and providing feedback through a diary section with badges as favourable reinforcement. Gamification principles enhance engagement and motivation, making the intervention more effective and enjoyable for end users.

This research underscores the inherent value of consistent daily engagement with virtual coaches, surpassing sporadic interactions with human specialists and thus mitigating constraints stemming from their limited availability [2,3]. Moreover, considering the link between costs and human interaction, the shift from group-based interventions to individualised approaches is explored. Although this shift may increase accessibility and affordability, it simultaneously triggers reflections on the communal synergy and interpersonal involvement integral to group interventions. Nevertheless, the chatbot offers a prospect to decipher the precise impact of virtual coaching interventions, not burdened by an array of confounding variables [16]. This study also contributes to understanding their potential within the mental health landscape by delineating the nuanced advantages and considerations surrounding virtual coaching applications.

Another aim is to draw clinical attention to new target populations' stress triggers and management through the delicate and underestimated design phases. In all the adaptation steps, the end-user viewpoint was considered. The research emphasises the importance of considering end-users and their perspectives in enhancing the accessibility of the intervention through a user-friendly chatbot-guided system. The commitment to tailoring the intervention for Italian women, is a comprehensive approach aimed at meeting the specific needs of the target demographic. Indeed, the need for support from these two populations is increasingly evident. The transposition of CBT techniques into digital tools is the most functional according to the literature both for pregnant women [65] and women with breast cancer diagnosis [35] decreasing anxiety and depression symptoms. The application of digital CBT therapies is still open to experimentation, and this digital intervention will be included in this panorama.

Challenges and limitations

The adaptation work for a digital stress management application has highlighted several practical challenges. One significant challenge is the need for intermediaries to guide during or between sessions, necessitating the anticipation and embedding of potential user queries or uncertainties within the application framework. To address difficulties such as comprehension issues, the application will offer feedback based on a manual and provide avenues for further assistance, including technical support or access to a psychologist.

Engagement maintenance during the transition from group to individual digital sessions is another key challenge addressed through gamification elements and interactive exercises with feedback and

reminders. Subsequent empirical investigations are needed to validate these strategies and assumptions.

Future research questions and challenges include participant recruitment and privacy concerns. While stress management's universal relevance aids recruitment prospects, obstacles may arise from stigmas and healthcare access barriers. Alternative recruitment channels such as voluntary participation and partnerships are being explored.

Further developments

ALBA will adhere to the successive stages of the ORBIT model. The initial emphasis will be on Phase I.b, followed by the comprehensive redefinition of components through standardised co-design investigations. Subsequent efforts will encompass the methodical assessment of prototype usability, in terms of app architecture, design iterations, and technical performance, and the evaluation of app efficacy after its revision in randomised control trials. These steps are needed to understand the user experience (UX) and acceptability of the app, proving its clinical efficacy and facilitating its possible successful implementation in real-world settings with these specific target populations. Every specification inherent to possible end-user app utilisation will be deeply considered and empirically validated.

An additional advancement involves examining the practical implications of utilising this application within real-world settings. This would encompass a comprehensive evaluation of the intervention's efficacy and efficiency in rendering support and facilitating progressive care for the designated populations. It could shed light on sustainability in terms of the resource allocation and human capital expenditures stemming from implementing this preventative and low-intensity support framework. From a broader perspective, the potential exists for the creation of analogous applications, exhibiting tailored cultural and linguistic adaptations to address the needs of diverse target demographics, encompassing women who have breast cancer as well as pregnant women from varying cultural backgrounds.

Conclusions

Introducing ALBA, a new mobile tool designed for some vulnerable female populations, enriches the m-health scientific literature. This innovation involves implementing SH+ validated intervention using a new delivery tool, incorporating the previously outlined and targeted modifications. Employing the SH+ protocol will shed light on the exploration in assessing the efficacy of the chatbot as an innovative intervention strategy, along with evaluating the impact of the evidence-based intervention on these specific groups. The commitment extends to comprehensive implementation research, delving into clinical outcomes and examining app implementation-related factors such as feasibility, fidelity, and accessibility.

List of abbreviations

WHO = World Health Organization

mhGAP = mental health Global Action Program

m-health = mobile health

DTx = digital therapeutics

ACT = Acceptance and Commitment Therapy
 CBT = Cognitive-Behavioral Therapy
 SH+ = Self-Help Plus
 DWM = Doing What Matters in times of stress
 QoL = quality of life
 ALBA = Automated well-Being Assistant
 IT = information technology
 ORBIT = Obesity-Related Behavioral Intervention Trials
 VC = Virtual Coach
 GDPR = General Data Protection Regulation
 UX = user experience

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Data Availability

The data generated and analyzed during the current study are available from the corresponding author upon reasonable request. Before disclosure, data is aggregated and anonymised.

Conflicts of Interest

None declared.

Appendix 1

Table 1. Description of the adaptation from SH+ to ALBA. The table's columns, starting from the conceptual Elements that make up the SH+ protocol, elucidate the modifications made in transitioning from the SH+ intervention to ALBA application. This is achieved by describing the overall Digital translation process and the significance of this adaptation step, referred to as Porting.

	Elements	SH+ →	→ Digital translation →	→ Porting →	→ A
Adaptation from SH+	Content	Manuals (SH+ and DWM) with figures and audios, pre-recorded sessions' materials	Mobile app with dialogues and multimedial resources	Sustainable and accessible DTx intervention [34,51–53,66–68]	Orig disp dial and reso diff app Exer

	Guide	Human guides: Two facilitators in-person (SH+ protocol); Helpers' phone calls (RESPOND project)	Chatbot intervention guided	No need of human resources, both for training of facilitators/helpers and the following guided sessions and supervision [66,67] Intuitiveness and naturalness of chatbot dialogue-based interaction [47,48]	The inte
Adaptation and needs of the target populations	Participant	Participant: person experiencing stressful situation (e.g., refugees), group member	Italian single participant experiencing stressful situation and app end-user	Individualization of the intervention with more attention to personalization No desirability or external pressures effects [69]	End pati indi fem
	Session	In presence 2-hours sessions on established weekly appointment	Chatbot dialogues to release sessions	Self-help at home, intervention in the end-user hands Possibility of personalization of sessions' day for dialogues delivery [33,66,69]	At h with Dial min the and sub
Key Points from chatbot and m-health literature	Homework	Participant are requested to do individual homeworks (no monitored in SH+; phone calls' monitoring in RESPOND)	Requested homeworks with monitoring reminders, feedbacks and a diary section.	The end user is monitored and assisted in doing her homeworks to give strength and continuity to the self-help intervention [45,46]	Che exer dial to c ALB add dial mon
	Engagement	Being part of a group and face to face intervention, strong inner motivation to participate and reach the sessions' location	Interactivity and gamification aspects of the chatbot dialogues and intersessions monitoring, inner motivation to participate	The interest in the intervention is kept alive during the dialogues with interactive answers modalities and during the intersession week through an adequate level of assistance and monitoring. Gamification aspects extrinsically encourage and motivate the user to going on in the intervention [45,46,49]	ALB thro ans (but ans ALB bad as j Mon feed

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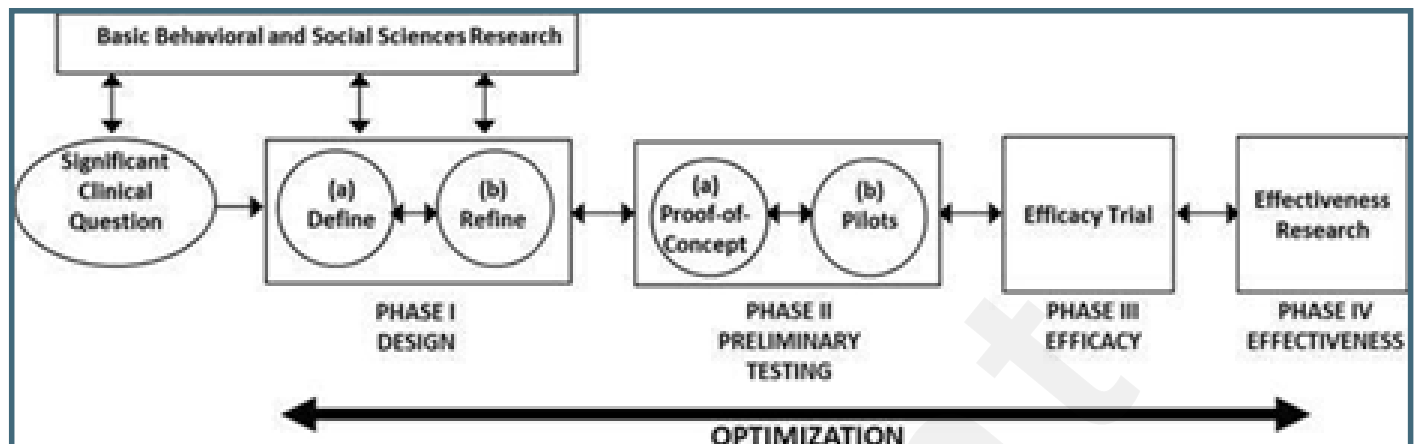
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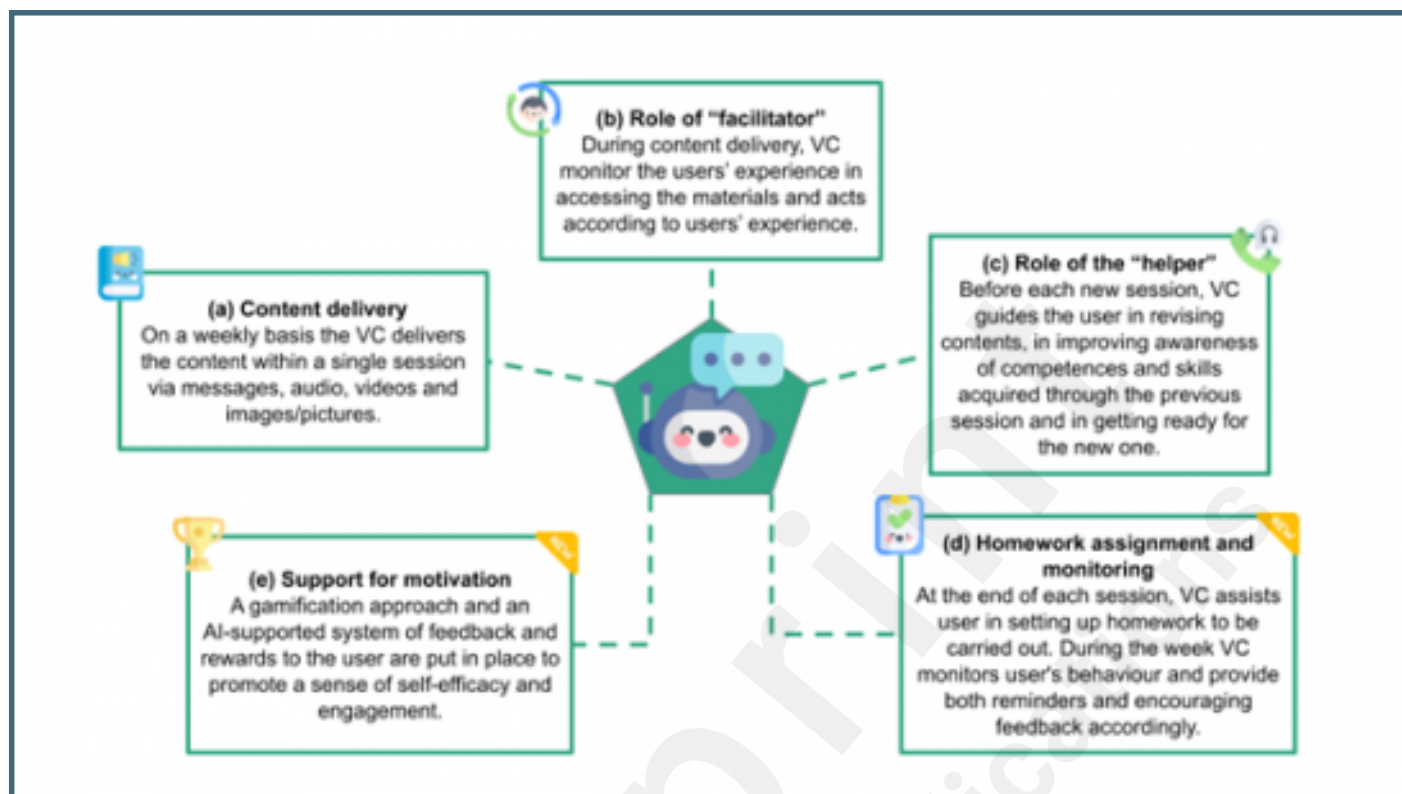
Supplementary Files

Figures

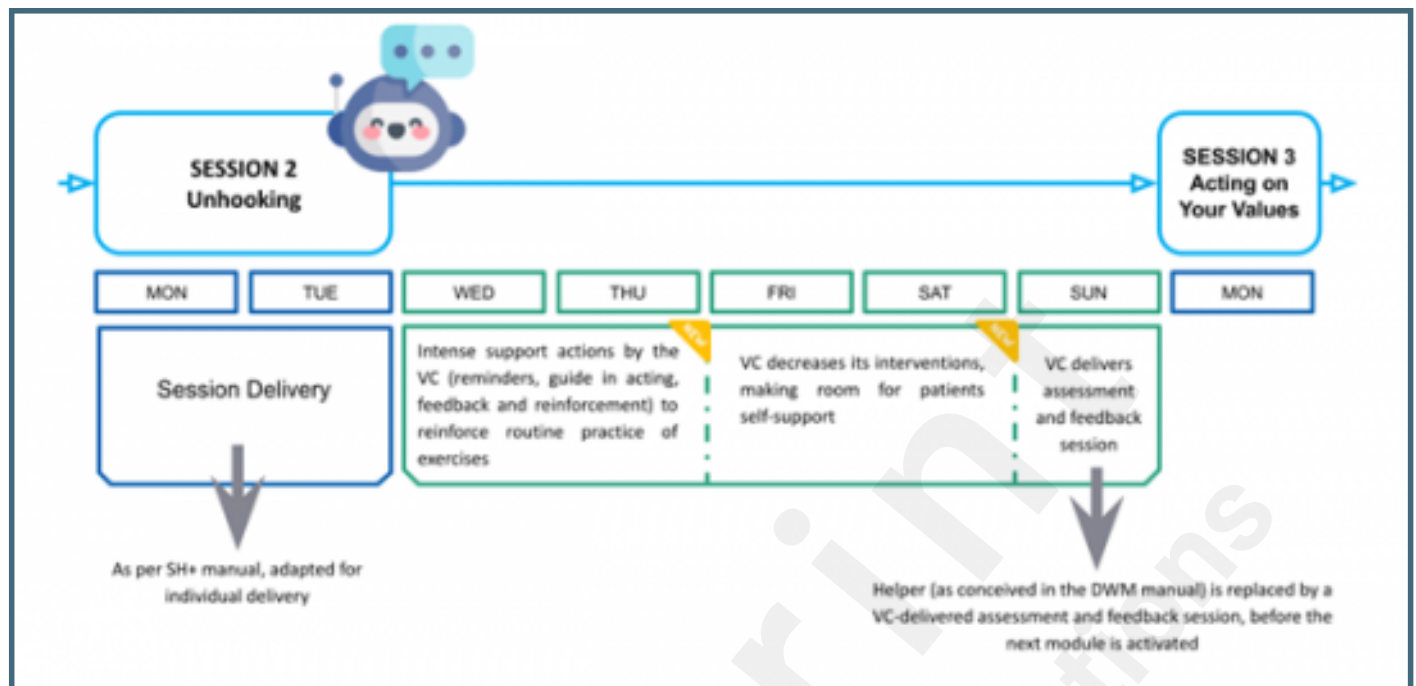
The ORBIT model [41].



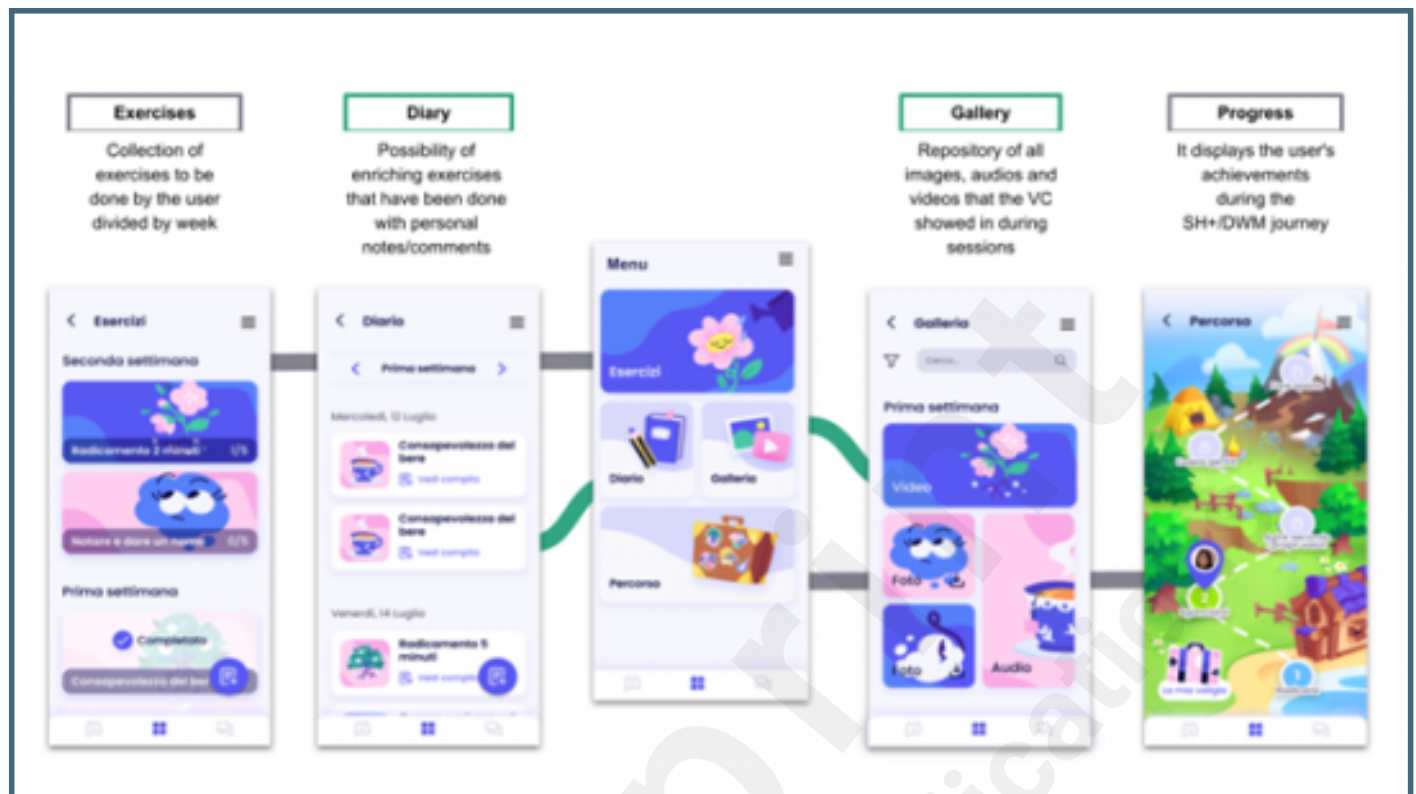
ALBA chatbot and its functionalities as Virtual Coach (VC).



Representation of an exemplary week intervention's structure.



ALBA app mock-ups.



ALBA's dialogue section.

